digene® HC2® System Software User Manual — Custom Assay Protocols

For use with *digene* HC2 System Software version 3.4
as part of *digene* HC2 System Suite 4.4

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9024232 Rev. 01

Sample to Insight

QIAGEN

Contents

1 Introduction

Thank you for choosing the *digene* Hybrid Capture® 2 (HC2) System Software. We are confident it will become an integral part of your laboratory.

Before using the *digene* HC2 System Software, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation.

1.1 About this manual

This user manual provides instructions on using the *digene* HC2 System Software to measure and analyze specimens in conjunction with a *digene* Microplate Luminometer (DML) instrument. Use this user manual along with the other user manuals provided as part of the *digene* HC2 System Suite.

1.1.1 References to custom assay protocols

Custom assay protocols are not applicable for IVD use of the *digene* HC2 System Software.

1.2 General information

1.2.1 Technical assistance

At QIAGEN we pride ourselves on the quality and availability of our technical support. If you have any questions or experience any difficulties, do not hesitate to contact us.

QIAGEN customers are a valuable source of information regarding our products. We encourage you to contact us if you have any suggestions or feedback concerning our products.

For technical assistance and more information, contact QIAGEN Technical Services or a local distributor.

1.2.2 Version management

This document is *digene* HC2 System Software User Manual — Custom Assay Protocols, 9024232, Rev. 01. This user manual is for use with *digene* HC2 System Software version 3.4 as part of *digene* HC2 System Suite 4.4.

1.2.3 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.2.4 Software license agreement

The license agreement for the software applies only to the software purchased with the *digene* HC2 System. This license agreement sets forth the terms and conditions of the license and the limited warranty for the *digene* HC2 System Software and the Microsoft® Windows® software provided as part of the *digene* HC2 System.

1.2.5 License grant

The customer does not receive title to the *digene* HC2 System Software. The customer is granted a nonexclusive license to use the *digene* HC2 System Software subject to the restrictions and terms set forth in the agreement. The *digene* HC2 System Software is installed on the HC2 System computer at the time of delivery to the customer.

1.2.6 Restrictions

An installed copy of the *digene* HC2 System Software may not be used on multiple computers through file serving, networking or communications packages. The *digene* HC2 System Software may not be rented, loaned or leased. The *digene* HC2 System Software or accompanying documentation may not be copied, except as specifically permitted in this license agreement. Proprietary notices, labels or marks on the *digene* HC2 System Software or accompanying documentation may not be removed or altered. The *digene* HC2 System Software or accompanying documentation may not be modified, translated, reverse engineered, disassembled or decompiled.

1.2.7 Termination and transfer

Any failure to comply with the terms and conditions of this agreement will result in automatic termination of this license. Upon termination of this license for any reason, the customer must destroy all copies of the *digene* HC2 System Software and accompanying documentation. The customer may not transfer the *digene* HC2 System Software without prior written agreement.

1.2.8 Communication of license agreement

The customer agrees to communicate the terms and restrictions contained in this license agreement to all persons under his or her employment, direction or control.

1.2.9 Unauthorized use and compliance

The customer will use all reasonable efforts to see that employees, agents, assignees or other persons under the direction and control of the customer abide by the terms and conditions of this license agreement.

1.2.10 Warranty and special provisions

QIAGEN warrants that the *digene* HC2 System Software will perform in accordance with the accompanying written materials for a period of 90 days from the date of receipt. Any implied warranties on the *digene* HC2 System Software are limited to 90 days. Some countries, states or jurisdictions do not allow limitations on duration of an implied warranty.

1.2.11 Limitation of liability

The Microsoft software programs are provided to the end user "as is" without warranty of any kind, either expressed or implied, including but not limited to, warranties of merchantability and fitness for a particular purpose. The entire risk of the quality and performance of the Microsoft software is with the recipient.

The foregoing warranties are exclusive and are given and accepted in lieu of any and all other warranties, expressed or implied, including without limitation, the implied warranty of merchantability and the implied warranty of fitness for a particular purpose. Neither party shall be liable to the other for any incidental, indirect, special, or consequential damages.

1.2.12 Requirements for users

The *digene* HC2 System Software is intended for professional use by qualified laboratory personnel trained in test procedures and protocols.

The table below shows the level of training and experience required for transportation, installation, use, maintenance and servicing of the instrument.

Type of task	Personnel	Training and experience
Transportation	Approved carrier	Appropriately trained, experienced and approved by QIAGEN
Installation	Laboratory technicians or equivalent	Appropriately trained, experienced, and familiar with the use of computers and automation in general
Routine use	Laboratory technicians or equivalent	Appropriately trained, experienced, and familiar with the use of computers and automation in general
Maintenance	Laboratory technicians or equivalent	Appropriately trained, experienced, and familiar with the use of computers and automation in general
Service	QIAGEN Field Service employees or personnel trained by QIAGEN	Trained, certified and authorized by QIAGEN

1.3   Operating software

The instructions in this user manual assume the use of the Windows operating system "Classic View" rather than "Category View". To set the HC2 System computer to "Classic View," see "Switching the control panel display to Classic View," page 23.

Users must be familiar with the use of computers to initiate instrument functions, such as to activate or halt automated functions and to retrieve stored data. The *digene* HC2 System Software is password protected to prevent modification.

The following terms are used when naming features of the software.

Term	Description
Box	An item in a dialog box which can be checked or unchecked.
Button	An item in a dialog box or toolbar, which the user clicks in order to execute something.
Dialog box	A box that appears temporarily and displays information or requires input from the user.
Dialog field	An item in a dialog box where the user can type in or select something. **Note**: Some fields are inactivated or simply display numerical or textual information.
Drop-down list	A list of items that appears when the user clicks a menu or the downward arrow appearing in some dialog fields.
Graphic	A picture displayed in the software to represent the instrument or a feature of the instrument.
Icon	A small graphic either on the desktop or in the file manager, which represents a file, application or folder.
Menu	An item in the menu bar which the user clicks to display a drop-down list. A menu is also a list of items which appears when the user right-clicks the mouse.
Panel	A clearly marked area of a window or dialog box containing a particular group of information.
Parameter	Something that is specified by the user. A parameter is specified by checking/unchecking boxes and entering/selecting information in dialog fields.
Radio button	A circle in a dialog box, which can be selected or deselected.
Scroll arrows	Up and down arrows that enable the user to view additional content or select a value.
Status bar	The area at the bottom of the window that displays messages concerning the status of the software.
Subpanel	A subdivision of a panel.
Tab	A feature in a window that resembles a file tab and contains a particular subset of information.

Term	Description
Taskbar	The long horizontal bar at the bottom of the screen. It has three main sections: the **Start** button which opens the **Start** menu, the middle section showing which programs and files are open, and the notification area, which includes a clock and icons communicating the status of certain programs and computer settings.
Window	A primary user interface of the software.
Wizard	A sequence of windows or dialog boxes, which guide the user through a procedure.

The following terms are used to describe the operation of the software.

Term	Description
Check	Move the pointer over a box and click the left mouse button to display a check mark.
Click	Move the pointer over a button or tab and click the left mouse button.
Click and drag	Move the pointer over an item, hold down the left mouse button, pull the pointer and item to a new location and release the mouse button.
Deselect	Move the pointer over a radio button and click the left mouse button to unselect the radio button.
Double-click	Move the pointer over an item and click the left mouse button twice in quick succession.
Highlight	Move the pointer over an item and click the left mouse button to highlight the item. **Note**: Multiple items are highlighted in the software by holding either the **Ctrl** or **Shift** keys on the keyboard and selecting the desired items.
Right-click	Move the pointer over an item and click the right mouse button.
Select	Move the pointer over an item in a drop-down list or over a radio button and click the left mouse button to make a selection.
Uncheck	Move the pointer over a box and click the left mouse button to remove the check mark.

2 Safety Information

This user manual contains information about warnings and cautions that users must follow to ensure safe operation of the software and to maintain the software in a safe condition.

The following types of safety information appear in this user manual.

WARNING

The term WARNING is used to inform you about situations that could result in **personal injury** to you or others.

Details about these circumstances are provided to avoid personal injury to you or other persons.

CAUTION

The term CAUTION is used to inform you about situations that could result in **damage to the instrument** or other equipment.

Details about these circumstances are provided to avoid damage to the instrument or other equipment.

Before using the software, it is essential to read this user manual carefully and to pay particular attention to any instructions it contains concerning hazards that may arise from the use of the software.

The guidance given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in your country.

2.1 Proper use

Never power OFF the DML instrument while the *digene* HC2 System is being operated as a loss of data may result.

Do not power OFF the HC2 System computer while any disk drive indicator light is illuminated; the drive may be damaged or the data contained on the disk may be corrupted.

Always perform an archive using the applicable *digene* HC2 System Software program and version prior to installing, reinstalling or upgrading the *digene* HC2 System Software or *digene* HC2 System assay protocols.

WARNING   **Incorrect test results**

Do not perform an archive during an RCS run. Performing an archive during the operation of the RCS could impact the timing of the test steps by slowing the RCS.

CAUTION   **Loss of data**

Always perform an archive prior to installing, restoring or upgrading the *digene* HC2 System Software or *digene* HC2 System assay protocols.

Data could be lost permanently if an archive is not performed.

CAUTION   **Loss of access**

Do not forget the password for an assay protocol as there is no way to retrieve a forgotten password.

Do not attempt to access the *digene* HC2 System Software data files. User manipulation of these files can result in a loss of data.

Data generated by the *digene* HC2 System are not encrypted during data export to a laboratory information system (LIS) or to a file.

2.2   Electrical safety

The *digene* HC2 System hardware components are equipped with alternating current (AC) power cords that, when connected to the applicable AC power outlet, ground the instruments. Do not operate any *digene* HC2 System component from an AC power outlet that has no ground connection.

Refer to the applicable user manual for additional safety information.

3 Functional Description

The following hardware and software components are required to use the *digene* HC2 System Suite:

- DML instrument
- HC2 System computer and computer peripherals (monitor, keyboard, mouse and printer)
- *digene* HC2 System Software
- *digene* HC2 System assay protocols
- LumiCheck Plate Software

The software components of the *digene* HC2 System Suite are provided on two CDs with the following content:

- the *digene* HC2 System software containing both the *digene* HC2 System Software and the LumiCheck Plate Software
- the *digene* HC2 System assay protocols

3.1   The *digene* HC2 System Software

The *digene* HC2 System Software is run using the Windows 7 operating system. The *digene* HC2 System Software provides data reduction and works in conjunction with the DML instrument.

The *digene* HC2 System Software has been tested in the environment of the supplied software applications. Installation of additional programs or connecting the HC2 System computer to the internet may adversely interact with the *digene* HC2 System Software and cause it to be inoperable. Accordingly, installation of programs not provided by QIAGEN on the HC2 System computer may result in conflicts that render the *digene* HC2 System Software inoperable. Installation of additional software or connecting the HC2 System computer to the internet voids all warranties.

4   Unpacking Procedures

4.1   Materials provided

The *digene* HC2 System will be shipped in separate cartons and will consist of the following hardware components:

- HC2 System computer and power cord
- Keyboard, mouse and Universal Serial Bus (USB)-to-Serial converter
- Monitor, power cord and cable
- Printer and power cord
- Printer cable
- DML instrument, power cord, power adapter and serial cables

4.2   Unpacking the *digene* HC2 System hardware

1. Open the cartons containing the *digene* HC2 System component.

   Refer to the respective user manual for instructions to unpack the instruments.
2. Remove the contents of the cartons.

   Save the packaging materials and shipping cartons.
3. Examine the packaging of each component to make sure that the associated power cord, power adapters and all other materials have been removed.
4. Inspect all hardware for damage.

   If any damage is observed, immediately contact QIAGEN Technical Services.

5   Installation

This section provides the procedures for installing the *digene* HC2 System hardware and software components.

The HC2 System computer must be dedicated to running only components provided by QIAGEN; do not add any additional software applications or components.

For the specifications and minimum requirements, including operating system requirements, of the *digene* HC2 System, see "Appendix A — Technical Data A Technical Data," page 235.

5.1   Connecting the *digene* HC2 System hardware components

Important: Do not plug any of the power cords into an outlet power source until instructed.

1. Connect the HC2 System computer, monitor, keyboard, mouse and printer according to the HC2 System computer manufacturer's installation instructions.
2. Set up and connect the DML instrument according to the instructions provided in the DML instrument user manual.
3. Plug the power cords of the hardware components into the applicable electrical outlets and power ON the *digene* HC2 System hardware components.

5.2   Installing the *digene* HC2 System Software

The HC2 System computer should arrive with the *digene* HC2 System Software installed; however, follow these instructions if the installation of the *digene* HC2 System Software is required for some other reason.

Installation of the *digene* HC2 System Software is performed by a wizard that is initiated when the CD containing the software is inserted in the CD-ROM drive of the HC2 System computer.

The following are the requirements for installation of the *digene* HC2 System Software:

- A minimum of 1.5 gigabytes (GB) of free hard disk space
- The user installing the *digene* HC2 System Software must have administrator rights in the Windows operating system

The wizard automatically installs the *digene* HC2 System Software to the working directory in **C:\Program Files\QIAGEN** and **C:\Users\Public\QIAGEN**.

Note: If data from previous versions of the software must be transferred to this version of the software, contact QIAGEN Technical Service for assistance.

1. Insert the CD containing the *digene* HC2 System Software into the CD-ROM drive of the HC2 System computer.

   A wizard will open.

   Note: If the wizard is not automatically initiated, navigate to the CD-ROM drive and double-click the executable file **HC2AppSetup.exe**.

2. Follow the wizard prompts to install the *digene* HC2 System Software and the LumiCheck Plate Software.

   The *digene* HC2 System Software and the LumiCheck Plate Software are installed once the wizard is complete. Shortcuts for the *digene* HC2 System Software and LumiCheck Plate Software will display on the desktop, and the software can be accessed using the Windows **Start** menu.

5.3   Installing the *digene* HC2 System assay protocols

The HC2 System computer will not arrive with the *digene* HC2 System assay protocols installed. The *digene* HC2 System Software must be installed before the *digene* HC2 System assay protocols are installed. A wizard automatically installs the *digene* HC2 System assay protocols to the working directory in **C:\Users\Public\QIAGEN\HC2 System Software\Protocol Library**.

1. Insert the CD containing the *digene* HC2 System assay protocols in the CD-ROM drive of the HC2 System computer.

   A wizard will open.

   Note: If the wizard is not automatically initiated, navigate to the CD-ROM drive and double-click the executable file **HC2ProtocolSetup.exe**.

2. Follow the wizard prompts to install the *digene* HC2 System assay protocols.

   The *digene* HC2 System assay protocols are installed once the wizard is complete.

5.4   Setting up the Windows operating system

The Windows operating software must be set up prior to using the *digene* HC2 System Software. The HC2 System computer should arrive with the setup of the Windows operating system complete, with the exception of specifying the printer paper size and setting the system time. Set the system time appropriate for your region before using the software. Do not change the system time once the software is put into use.

This section is included in case a setting requires modification.

5.4.1 Switching the control panel display to Classic View

Perform this procedure if the Windows operating system **Control Panel** window displays in Category View rather than in Classic View.

1. On the Windows taskbar, click the **Start** button and select **Control Panel** from the menu.
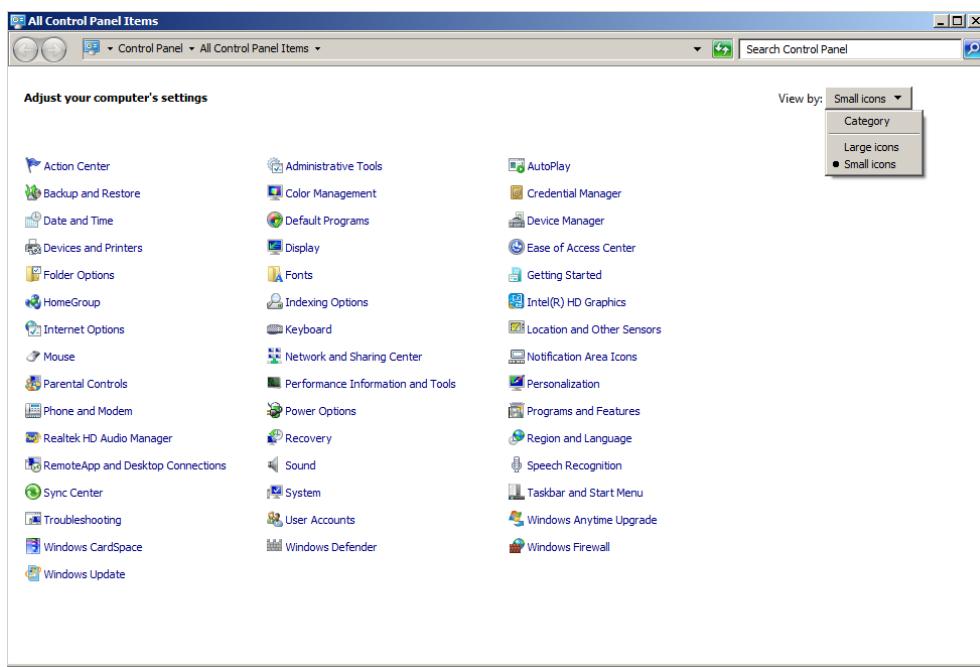
2. Select **Small icons** from the **View by:** drop-down list.
3. Select **Personalization**.
4. Scroll through **Themes** and select **Windows Classic**.

5.4.2 Specifying the printer paper size

1. On the Windows taskbar, click the **Start** button and select **Devices and Printers**.

   The **Devices and Printers** dialog box opens.

2. Right-click the icon of the printer supplied with the *digene* HC2 System.

   A menu displays.

3. Select **Properties** from the menu.

The printer **Properties** dialog box opens on the **General** tab.

Example:
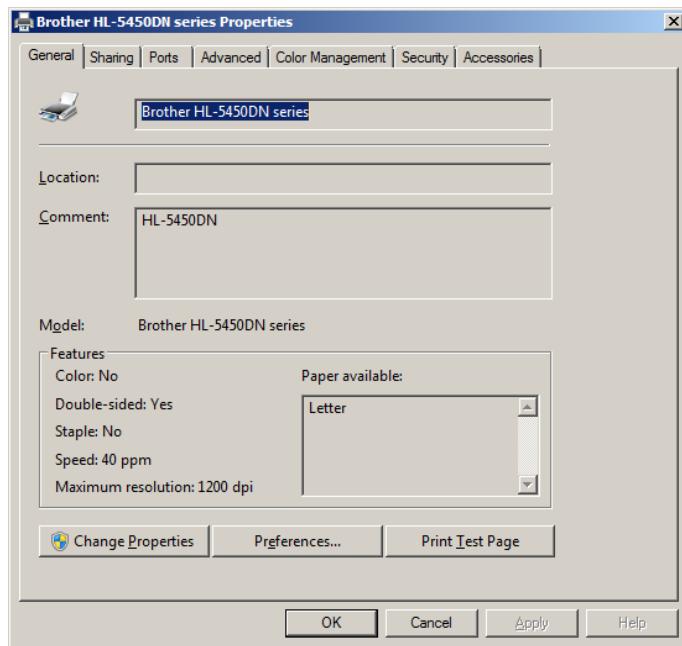
4. Click the **Preferences…** button.

The **Printing Preferences** dialog box opens.

Example:
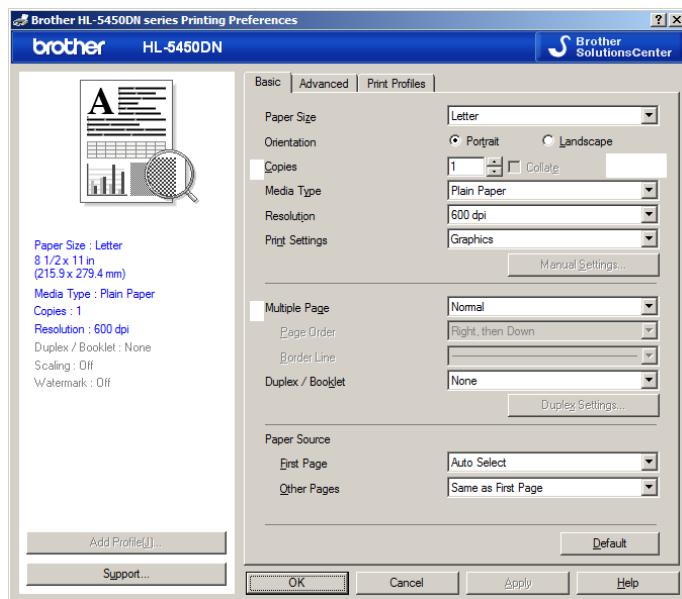
5. In the **Paper Size** drop-down list, select the applicable paper size.

6. Click the **OK** button to close the **Printing Preferences** dialog box.

7. Click the **OK** button to close the **Properties** dialog box.

8. Make sure the *digene* HC2 System printer is set as the default printer.

   Note: A checkmark displays next to the default printer.

   To set the default printer, right-click the applicable printer and select **Set as default printer** from the menu that displays.

9. Close the **Devices and Printers** dialog box.

5.4.3   Configuring the monitor screen resolution

Perform this procedure for every affected Windows user account.

1. On the Windows taskbar, click the **Start** button and select **Control Panel** from the menu.

2. In the **Control Panel** window, double-click the **Display** icon.

3. In the **Display** window, select **Adjust resolution**.

   The **Screen Resolution** window opens.

   Example:

4. In the **Resolution:** drop-down list, move the slider to a minimum of 1024 x 768.

5. Click the **Apply** button and then click **OK**.

5.4.4 Setting up page numbering

1. On the Windows taskbar, click the **Start** button, select **All Programs** and then select **Internet Explorer** from the menu.

   The Internet Explorer® browser opens.

   Note: If the **New Connection Wizard** displays, click the **Cancel** button to close the wizard and then select **Internet Explorer** from the **Start** menu again to open the browser.

2. Click the **Print** menu and select **Page setup**.

   The **Page Setup** dialog box opens.

3. In the **Headers and Footers** panel, select **Title** in the first **Header:** drop-down list. Select **Empty** in the second **Header:** drop-down list. Select **Page # of total pages** in the third **Header:** drop-down list.

4. In the **Headers and Footers** panel, select **Empty** for the **Footer** fields.

   Example:
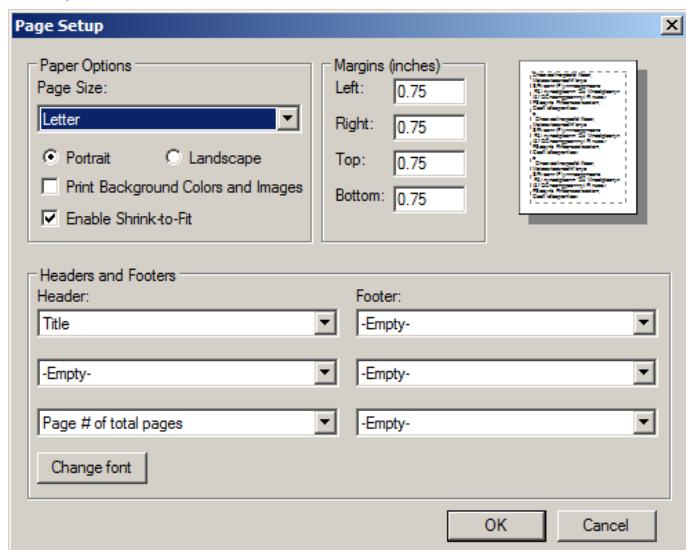
5. Click **OK**.

6. Close the Internet Explorer browser.

5.4.5 Configuring regional options

The *digene* HC2 System Software was validated using the **English** language setting.

Important: Do not modify the regional settings of the *digene* HC2 System Software. The setting must remain **English (United States)**.

Note: If you are using an English (United Kingdom) keyboard, you may change the default language for the keyboard to English (United Kingdom). Change the default keyboard input language as follows:

1. Click **Start**.
2. In the **Start** menu, select **Control Panel**. The **Control Panel** window opens.
3. In the **Control Panel** window, select **Region and Language**.
4. In the **Region and Language** dialog box, select the **Keyboards and Languages** tab and click the **Change Keyboards…** button.

   The **Text Services and Input Languages** dialog box opens.

   Example:

5. In the **Text Services and Input Languages** dialog box, click the **Add…** button.

   The **Add Input Language** dialog box opens.

   Example:
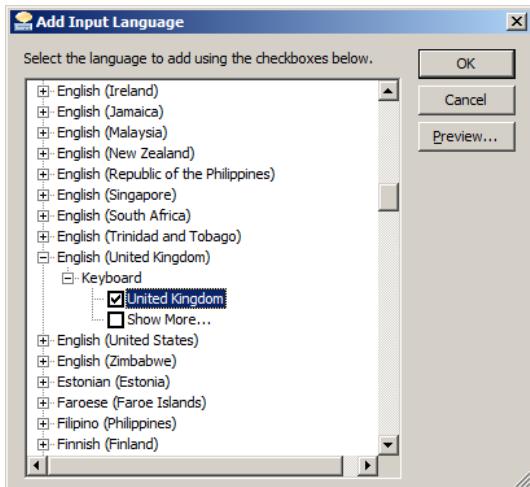
6. In the **Add Input Language** dialog box, click the **+** symbol beside **English (United Kingdom)**.
   Select the checkbox beside United Kingdom.

7. Click **OK**.

   The **Add Input Language** dialog box closes.

8. In the **Text Services and Input Languages** dialog box, click the **General** tab and select **English (United Kingdom)** in the **Default input language** panel.

   Example:
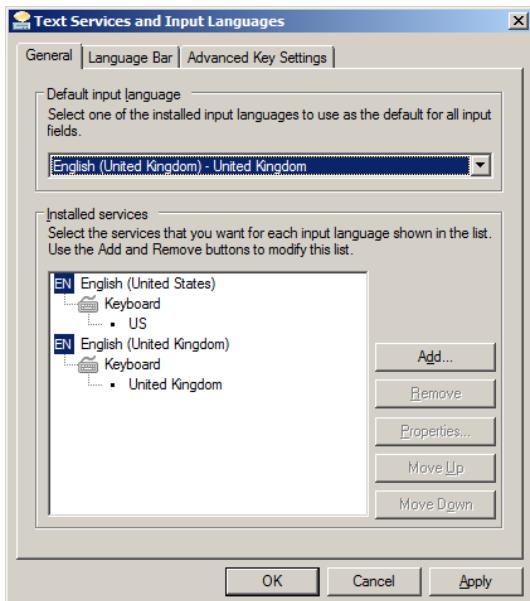
9. Click the **Apply** button and click **OK** to close the **Text Services and Input Languages** dialog box.

10.Click **OK** to close the **Region and Language** dialog box. Close the **Control Panel** window.

5.4.6   Setting up user accounts in the Windows operating system

The Windows operating system requires a user to log in with a user ID and password. The user ID indicates certain rights within the operating system.

The HC2 System computer is set up with two administrative user accounts and one standard user account. Use the following case-sensitive credentials for the Windows operating system.

Administrative user account:

● User ID: Administrator

● Password: digene

    You will be prompted to change the password the first time you log in to the administrator user account.

Standard user account:

● User ID: Welcome

● Password: welcome

The second administrative account is for use by QIAGEN service personnel.

5.5   Uninstalling the *digene* HC2 System Suite software

A wizard is used to uninstall the *digene* HC2 System Suite software, which uninstalls the *digene* HC2 System Software, the LumiCheck Plate Software and the *digene* HC2 assay protocols. The uninstall wizard is installed when the *digene* HC2 System Software is installed.

The data generated using the *digene* HC2 System Suite software are not removed or deleted. If the *digene* HC2 System Software is uninstalled and reinstalled, all prior data, including data archived to the hard disk, can be viewed.

To uninstall the *digene* HC2 System Suite software, click the **Start** button on the Windows taskbar, select **Programs** from the menu, select **HC2 System Software** and click **Uninstall HC2 Suite 4.4**. Follow the prompts to uninstall the software.

5.6 Virus scanners

We are aware of the threat that viruses cause to any computer that exchanges data with other computers. The *digene* HC2 System is intended to be installed in environments where local policies exist to minimize this threat and where the *digene* HC2 system is not exposed to the internet. Local policies usually require use of a particular antivirus tool. The *digene* HC2 System Software was tested on a computer using McAfee® Endpoint Protection Essential for SMB and on a computer using Windows Defender. Due to the sheer number of antivirus tools available, it is not possible for QIAGEN to predict the possible impact on the system if such a tool is active. The selection of an appropriate virus scanning tool is the customer's responsibility. QIAGEN has not validated the *digene* HC2 System Software for use with any virus scanning software.

The firewall on the HC2 System computer is configured to block all incoming connections. IT personnel must configure the firewall settings as required for use with an anti-virus solution.

The system administrator should ensure the following:

* QIAGEN directories are excluded from virus scanning. For the *digene* HC2 system Software, these directories are:
  * **C:\Users\Public\QIAGEN**
  * **C:\Program Files\QIAGEN**
* File access is not intercepted by a virus scanner when the *digene* HC2 System Software is in use
* Updates to the virus database are not performed when the *digene* HC2 System Software is in use
* File scans are not performed when the *digene* HC2 System Software is in use

We strongly recommend disabling virus scanner activity during laboratory working hours to prevent interference of the virus scan with the operation of the *digene* HC2 System Software. The virus scanner tasks described above can only be safely carried out when the *digene* HC2 System Software is not running, otherwise there is a risk of adverse impact on the performance of the system.

6 Software Features

The *digene* HC2 System Software contains a series of tabs that display across the top of the software window. The **Plates** tab is foremost when the *digene* HC2 System Software is started and when a user logs in. The footer of the window remains constant.

The window header provides the following functions:

Feature	Function
Current luminometer: dialog box	Displays the serial number of the DML instrument selected to perform measurement.
Current user: dialog box	Displays the user ID of the current user logged in to the *digene* HC2 System Software.
Help button	Opens the **QIAGEN HC2 System Software Help** dialog box. The information to contact QIAGEN Technical Services is displayed.
Change User… button	Opens the **User Login** dialog box. A new user must log in.
About… button	Opens the **About QIAGEN HC2 System Software** dialog box. The version and copyright information for the *digene* HC2 System Suite and the associated software is displayed.
Exit button	Opens the exit dialog box. Click **Yes** to exit the *digene* HC2 System Software or **No** to keep the *digene* HC2 System Software open.

6.1   Using the **Plates** tab

The **Plates** tab is used to:

- Create, modify and manage hybridization plates

- Associate capture plates with hybridization plates

- Generate reports for test results

- Accept test results

- Export data to an LIS or to file

Example of the **Plates** tab:

The **Unmeasured Hybridization Plates** panel lists the assay protocol type, hybridization plate ID and creation date of hybridization plates that have been created but not yet measured. When a hybridization plate is highlighted in the **Unmeasured Hybridization Plates** panel, the associated capture plate and assay protocols as well as the occupied wells on the plate are displayed in the lower subpanel.

The following table describes the actions that can be performed in the **Unmeasured Hybridization Plates** panel.

To...	Click or select...
create a new hybridization plate to be tested using a custom assay protocol	the **New Custom…** button. See "Creating a hybridization plate manually," page 162, for additional instructions.
modify the plate layout	the applicable hybridization plate and click the **Edit…** button. See "Modifying the plate," page 167, for additional instructions.
delete the hybridization plate	the applicable hybridization plate and click the **Delete** button. See "Deleting a plate ," page 170, for additional instructions.
create a hybridization plate using an Extensible Markup Language (XML)-formatted output file from a pre-analytical instrument	the **Plate Import…** button. See "Creating a hybridization plate from a pre-analytical instrument," page 158, for additional instructions.
associate a capture plate with a hybridization plate	the applicable hybridization plate and click the **Associate** button. See "Associating a capture plate ID manually," page 169, for additional instructions.

The **Measured Capture Plates** panel lists the assay protocol type, capture plate ID and measurement date of measured capture plates. When a capture plate is highlighted in the **Measured Capture Plates** panel, the associated hybridization plate, assay protocols and the plate status are displayed in the lower subpanel.

The following table describes the actions that can be performed in the **Measured Capture Plates** panel.

To...	Click or select...
re-measure the capture plate	the applicable capture plate and click the **Re-measure** button. See "Re-measuring a plate," page 197, for additional instructions.
accept the results for the measured capture plate	the applicable capture plate and click the **Accept Results** button. See "Accepting results," page 198, for additional instructions.
generate a full report	the applicable capture plate, select the **Full Report** radio button and click the **Show** button. See "Generating test reports," page 176, for additional instructions.
generate a raw data report	the applicable capture plate, select the **Raw data** radio button and click the **Show** button. See "Generating test reports," page 176, for additional instructions.
generate a plate report	the applicable capture plate, select the **Plate** radio button and click the **Show** button. See "Generating test reports," page 176, for additional instructions.

To...	Click or select...
generate a column report	the applicable capture plate, select the **Column** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.
generate an assay report	the applicable capture plate, select the **Assay** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.

The **Accepted Capture Plates** panel lists the assay protocol type, capture plate ID and LIS transmission status of accepted capture plates. When a capture plate is highlighted in the **Accepted Capture Plates** panel, the associated hybridization plate and assay protocols as well as the occupied wells on the plate are displayed in the lower subpanel.

The following table describes the actions that can be performed in the **Accepted Capture Plates** panel.

To...	Click or select...
export the plate data	the applicable capture plate and click the **Export** button.
	See "Exporting data," page 215, for additional instructions.
filter the list in the **Accepted Capture Plates** panel to display only plates with an LIS transmit status of not transmitted	the **Not Transmitted** radio button in the **Filter** subpanel.
filter the list in the **Accepted Capture Plates** panel to display all accepted capture plates	the **All** radio button in the **Filter** subpanel.
generate a full report	the applicable capture plate, select the **Full Report** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.

To...	Click or select...
generate a raw data report	the applicable capture plate, select the **Raw data** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.
generate a plate report	the applicable capture plate, select the **Plate** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.
generate a column report	the applicable capture plate, select the **Column** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.
generate an assay report	the applicable capture plate, select the **Assay** radio button and click the **Show** button.
	See "Generating test reports," page 176, for additional instructions.

6.1.1   Using the **Create/Edit Layout** window

The **Create/Edit Layout** window is used to create and modify plates. This window is accessed from the **Plates** tab by clicking **New Custom…** to create a new hybridization plate or **Edit…** to modify an existing hybridization plate. See "Creating a hybridization plate manually," page 162, for additional instructions on creating a hybridization plate.

Example of the **Create/Edit Layout** window:

The **Create/Edit Layout** window displays a graphical representation of a 96-well microplate, referred to as the plate layout grid. Each well of the microplate is represented on the plate layout grid as a cell. As assay protocols and specimens are added, the applicable information displays in the cells of the plate layout grid.

The following table describes the fields that are above the plate layout grid.

Field	Description
Hybridization Plate ID: dialog box	Displays the hybridization plate ID associated with the plate.
Capture Plate ID: dialog box	Displays the capture plate ID associated with the plate.
Creation Date: dialog box	Displays the date the plate was created.
Modified Date: dialog box	Displays the most recent date that the plate was modified.

Each cell of the plate layout grid is either empty or contains a calibrator, quality control or specimen. The cell displays information based on the content type. The following table describes the font colors used in the plate layout grid.

Color	Plate layout grid content type
Blue	Calibrator
Green	Quality control
Brown	Specimen

The information displayed in the cell depends on the content type. The following table describes the information provided in the cells of the plate layout grid.

Position in the cell	Description
Upper-left	ID of calibrator, quality control or specimen
Upper-right	Replicate number; if only one replicate, the position is blank
Lower-left for a quality control	Displays **V** when the quality control is used in assay validation; blank means the quality control is not required for validation of the assay.
Lower-left for a specimen	Specimen type
Lower-right for a specimen	Cutoff type; blank is primary; secondary is **2°**; tertiary is **3°**

The following table describes the actions that can be performed in the **Assays on layout** panel.

To...	Click or select...
add an assay protocol to the plate	the **Add New Assay…** button. See "Adding an assay protocol to a plate," page 163, for additional instructions.
highlight the calibrators, quality controls and specimens on the plate layout grid associated with an assay protocol	the assay protocol ID in the list. The associated items will have a red outline.
remove an assay protocol from the plate	the applicable assay protocol ID in the list and click the **Remove Assay** button. **Note**: The status of all associated specimens will be changed to unassigned.
modify the header information for an assay protocol on the plate layout grid	the applicable assay protocol ID in the list and click the **Edit Header…** button. See "Using the **Header Information** dialog box," page 43, for additional instructions.
view the parameters for an assay protocol on the plate layout grid	the applicable assay protocol ID in the list and click the **View Assay Protocol…** button. See "Using the **View Custom Assay Protocol** dialog box," page 71, for additional instructions.

The following table describes the actions that can be performed in the **Unassigned specimens** panel.

To...	Click or select...
sort the specimens in the list	either **Alphanumeric** or **Entry order** from the **Sort By:** drop-down list.
specify the number of replicates to add when a specimen is added to the plate layout grid	either the **1** or **2** radio button in the **Replicates** subpanel.

To...	Click or select...
add a specimen after the last occupied cell on the plate layout grid	the applicable specimen ID and click the **Add** button.
	This function can also be performed by double-clicking the applicable specimen ID in the list.
	Add multiple specimen IDs by highlighting the applicable specimen IDs in the list and clicking the **Add** button.
	See "Adding a specimen to a plate," page 165, for additional instructions.
add a specimen to a specific cell on the plate layout grid	the applicable specimen ID, select the cell location on the plate layout grid and click the **Add At** button.
	Add multiple specimen IDs by highlighting the applicable specimen IDs list and clicking the **Add At** button.
	See "Adding a specimen to a plate," page 165, for additional instructions.
create a new specimen	the **New Specimens…** button.
	The **New/Edit Specimens** dialog box opens.
	See "Creating specimens," page 135, for additional instructions.
modify a specimen	the **New Specimens…** button.
	The **New/Edit Specimens** dialog box opens.
	See "Modifying a single specimen using the **New/Edit Specimens** dialog box," page 143, for additional instructions.
delete a specimen	the applicable specimen ID and click the **Delete** button.
	Delete multiple specimen IDs by highlighting the applicable specimen IDs and clicking the **Delete** button.
	See "Deleting a specimen using the **Create/Edit Layout** window," page 149, for additional instructions.
print or save the list of specimens in the list	the **Print…** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

The following table describes the actions that can be performed in the **Quality controls** panel.

To...	Click or select...
specify the number of replicates to add when a quality control is added to the plate layout grid	either the **1** or **2** radio button in the **Replicates** subpanel. See "Adding a quality control to a plate," page 164, for additional instructions.
add a quality control after the last occupied cell on the plate layout grid	the applicable quality control ID and click the **Add** button. This function can also be performed by double-clicking the applicable quality control ID in the list. Add multiple quality controls by highlighting the applicable quality control IDs in the list and clicking the **Add** button. See "Adding a quality control to a plate," page 164, for additional instructions.
add a quality control to a specific cell on the plate layout grid	the applicable quality control ID, select the cell location on the plate layout grid, and click the **Add At** button. Add multiple quality controls by highlighting the applicable quality control IDs in the list and clicking the **Add At** button. See "Adding a quality control to a plate," page 164, for additional instructions.
manage the quality controls associated with an assay protocol	the **Manage QCs…** button. The **Quality Control List** dialog box opens. See "Managing quality controls," page 154, for additional instructions.
apply updated quality control information to the quality controls on the plate layout grid	the **Update QCs…** button. See "Modifying a quality control," page 156, for additional instructions.
print or save the list of quality controls	the **Print…** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

Note: The **No. of required QCs** dialog field displays the number of quality controls that are required as defined by the assay protocol parameters. An equivalent number of quality controls

with the **Automatically set for use in validation when added to a plate layout** box checked are required on the plate before plate measurement can occur.

The following table describes the actions that can be performed in the **Actions on plate** panel.

To...	Click or select...
remove a specimen or quality control from the plate layout grid	the applicable specimen ID or quality control ID on the plate layout grid and click the **Remove** button.
	Note: When removing a specimen, the status of the specimen is changed to unassigned and is returned to the list in the **Unassigned specimens** panel.
modify or view the information associated with a specimen	the applicable specimen ID on the plate layout grid and click the **Edit Specimen…** button.
	See "Modifying a single specimen using the **Edit Specimen** dialog box," page 141, for additional instructions.
restore a removed specimen or quality control to the plate layout grid	the applicable removed specimen ID or quality control ID on the plate layout grid and click the **Restore** button.
	Note: This function is only applicable to a specimen ID or quality control ID created from an output file of a pre-analytical instrument.
	See "Modifying a hybridization plate created from a pre-analytical instrument," page 161, for additional instructions.
remove all empty cells between the first and last occupied cell on the plate layout grid	the **Reallocate** button.
	See "Modifying the plate," page 167, for additional instructions.
specify that an added assay protocol to the plate layout grid is added at the beginning of the next column	the **Add/Reallocate assay on new column** box.
	Uncheck this box for assay protocols added to the plate layout grid to be added after the last occupied cell on the plate layout grid.
	See "Modifying the plate," page 167, for additional instructions.

The following table describes the actions that can be performed in the **Create/Edit Layout** window.

To...	Click or select...
print or save the plate layout	the **Print...** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.
save the plate and close the **Create/Edit Layout** window	the **Save** button.

6.1.2 Using the **Header Information** dialog box

Each plate has a header that contains information relevant to the plate and is displayed on reports. The **Header Information** dialog box is used to modify header information.

The **Header Information** dialog box opens automatically when an assay protocol is added to a plate. See "Adding an assay protocol to a plate" page 163, for additional instructions.

Example of the **Header Information** dialog box:
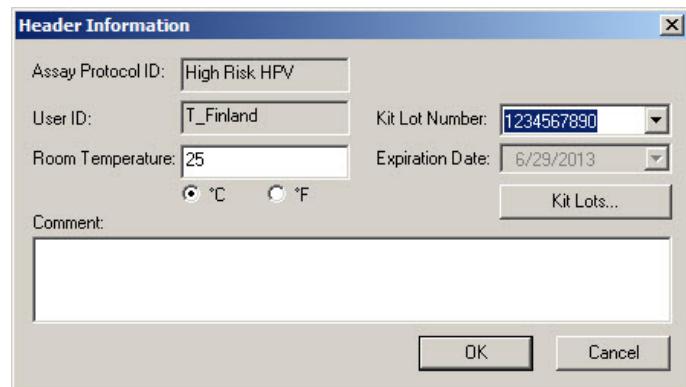
The following table describes the features that are available in the **Header Information** dialog box.

Feature	Function
Assay Protocol ID: dialog field	Displays the assay protocol ID added to the plate.
User ID: dialog field	Displays the user ID that added the assay protocol to the plate.
Room Temperature: dialog field	Parameter specifying the room temperature of the laboratory at the time of plate measurement.
℃ and **℉** radio buttons	Parameter specifying either **℃** for degrees Celsius or **℉** for degrees Fahrenheit for the unit of measure for the room temperature of the laboratory at the time of plate measurement.
Kit Lot Number: drop-down list	Parameter specifying the kit lot used for testing with the applicable assay protocol.
Expiration Date: dialog field	Displays the expiration date of the kit lot displayed in the **Kit Lot Number:** dialog field.
Kit Lots… button	Opens the **Kit Lot Number Entry** dialog box. See "Managing kit lots," page 152, for additional instructions.
Comment: dialog field	Parameter specifying any information applicable to the assay protocol on the plate. **Note**: The maximum length is 100 characters.

Feature	Function
OK button	Accepts the information displayed and closes the **Header Information** dialog box.
	Note: If the **OK** button is clicked during the addition of an assay protocol to a plate layout grid, the **Header Information** dialog box closes, and the assay protocol is added to the plate layout grid.
Cancel button	Closes the **Header Information** dialog box without making any changes.
	Note: If the **Cancel** button is clicked during the addition of an assay protocol to a plate layout grid, the **Header Information** dialog box closes and the assay protocol is not added to the plate layout grid.

6.1.3   Using the **New/Edit Specimens** dialog box

The **New/Edit Specimens** dialog box is used to create or modify specimens. The **New/Edit Specimens** dialog box is accessed from the **Create/Edit Layout** window or the **Specimen List** window. Access the **Create/Edit Layout** window from the **Plates** tab by clicking **New Custom...** to create a new hybridization plate or **Edit...** to modify an existing hybridization plate. Access the **Specimen List** window on the **Assay Protocols** tab by highlighting the applicable assay protocol ID and clicking the **Specimens** button.

To create a specimen, see "Creating a specimen individually," page 136. To modify a specimen or specimens, see "Modifying a single specimen using the **New/Edit Specimens** dialog box," page 143, or "Modifying multiple specimens using the **New/Edit Specimens** dialog box," page 144, for additional instructions.

The **Single ID**, **Series of IDs** and **Import IDs** tabs are used to create or modify specimens. Click the respective tab to perform the desired action.

Example of the **New/Edit Specimens** dialog box:
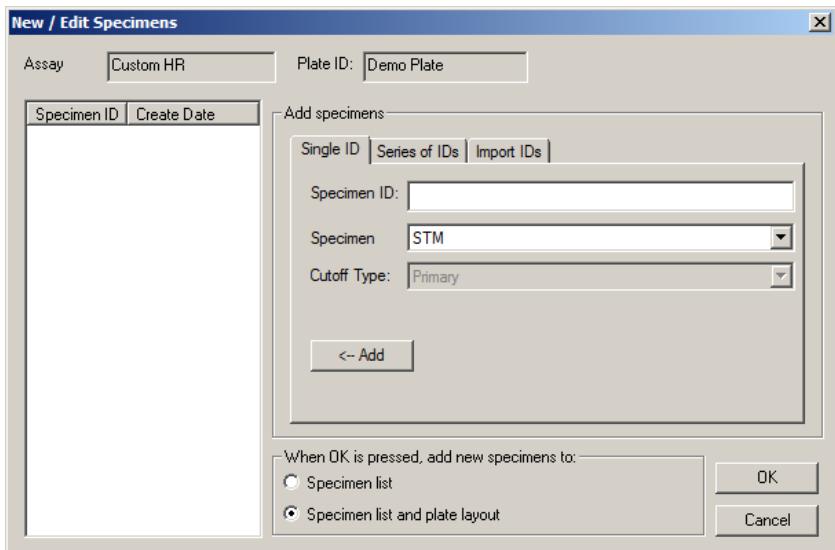
The following table describes the functions that are available in the **New/Edit Specimens** dialog box.

Feature	Function
Assay dialog field	Displays the assay protocol ID.
Plate ID: dialog field	Displays the plate ID.
Specimen ID list	Displays the specimen IDs created or modified while the **New/Edit Specimens** dialog box is open.

The **Single ID** tab is used to create or modify one specimen at a time. Multiple specimens may be created or modified by repeating the creation or modification procedures. The specimens created or modified during the procedure are displayed in the list. See "Creating a specimen individually," page 136, and "Modifying a single specimen using the **New/Edit Specimens** dialog box," page 143, for additional instructions.

Example of the **Single ID** tab:
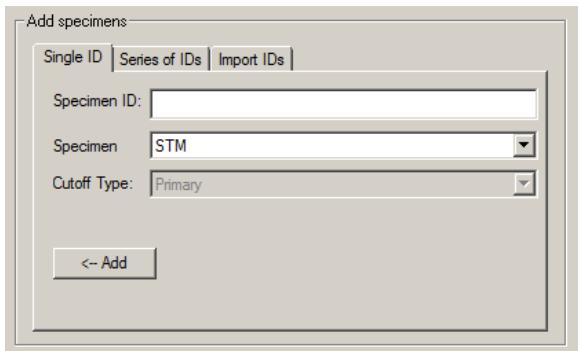
The following table describes the actions that can be performed in the **Single ID** tab.

To...	Click or select...
create a new specimen or specify a specimen for modification	the **Specimen ID:** dialog field and enter the specimen ID. **Notes**: ● The maximum length of a specimen ID is 30 characters. ● A hand-held bar code reader may be used to enter the specimen ID. The bar code reader must be programmed to include a return for continuous entry.
specify a specimen type for the specimen	a specimen type from the **Specimen** drop-down list.
specify a cutoff type for the specimen	a cutoff type from the **Cutoff Type:** drop-down list. **Note**: The **Cutoff Type:** drop-down list will be grayed-out if creating a specimen for a consensus assay protocol.
add the created or modified specimen to the list of specimens created or modified	the **<-- Add** button. The specimen will display in the list.
add the created or modified specimens to the specimen list when **OK** is clicked	select the **Specimen list** radio button in the **When OK is pressed, add new specimens to:** panel. **Note**: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window.

To...	Click or select...
add the created or modified specimens to the specimen list and plate layout grid when **OK** is clicked	select the **Specimen list and plate layout** radio button in the **When OK is pressed, add new specimens to:** panel.

Note: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window. |
| create or modify the specimens in the list | the **OK** button.

The **New/Edit Specimens** dialog box closes, and the specimens are created or modified. |
| cancel the creation or modification of the specimens in the list | the **Cancel** button.

The **New/Edit Specimens** dialog box closes. |

The **Series of IDs** tab is used to create or modify multiple specimens that have the same starting identifier to the specimen ID. The specimens created or modified during the procedure are displayed in the list. See "Creating a series of specimens," page 137, and "Modifying multiple specimens using the **New/Edit Specimens** dialog box," page 144, for additional instructions.

Example of the **Series of IDs** tab:
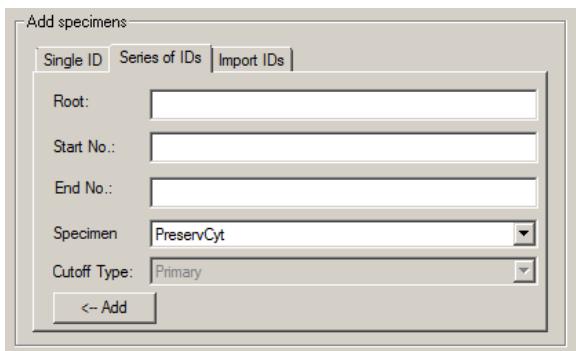
The following table describes the actions that can be performed in the **Series of IDs** tab.

To...	Click or select...
specify a root name that is at the beginning of each specimen ID in the series	the **Root:** dialog field and enter the root for the series of specimen IDs. **Note**: The maximum length of a specimen ID is 30 characters. The combination of the root and the sequential numbers must not exceed 30 characters.
specify a start number for the series that will be appended to the root	the **Start No.:** dialog field and enter the start number for the series of specimen IDs.
specify an end number for the series that will be appended to the root	the **End No.:** dialog field and enter the end number for the series of specimen IDs. **Notes**: ● The ending number must be greater than the start number. ● If the number begins with a zero, the zero is ignored during the creation of the specimen ID.
specify a specimen type for the series of specimens	a specimen type from the **Specimen** drop-down list.
specify the cutoff type for the series of specimens	the cutoff type from the **Cutoff Type:** drop-down list. **Note**: The **Cutoff Type:** drop-down list will be grayed-out if creating a specimen for a consensus assay protocol.
add the created or modified specimens to the list of specimens created or modified	the **<-- Add** button. The specimens will display in the list.
add the created or modified specimens to the specimen list when **OK** is clicked	select the **Specimen list** radio button in the **When OK is pressed, add new specimens to:** panel. **Note**: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window.

To...	Click or select...
add the created or modified specimens to the specimen list and plate layout grid when **OK** is clicked	select the **Specimen list and plate layout** radio button in the **When OK is pressed, add new specimens to:** panel. **Note**: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window.
create or modify the specimens in the list	the **OK** button. The **New/Edit Specimens** dialog box closes, and the specimens are created or modified.
cancel the creation or modification of the specimens in the list	the **Cancel** button. The **New/Edit Specimens** dialog box closes.

The **Import IDs** tab is used to import multiple specimens from a text file. See "Creating specimens from a text file," page 137, for additional instructions.

Example of the **Import IDs** tab:
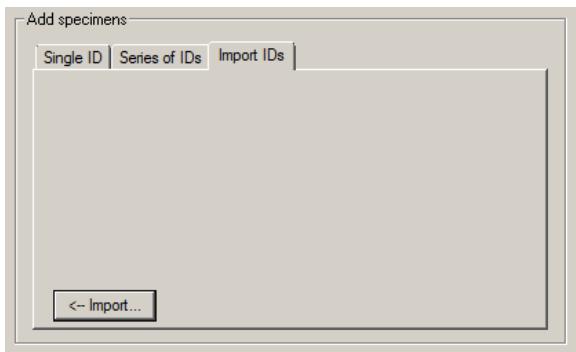
The following table describes the actions that can be performed in the **Import IDs** tab.

To...	Click or select...
import specimens using a text file	the **<-- Import…** button. A directory dialog box opens. See "Creating specimens from a text file," page 137, for additional instructions.
add the created specimens to the specimen list when **OK** is clicked	select the **Specimen list** radio button in the **When OK is pressed, add new specimens to:** panel. **Note**: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window.
add the created specimens to the specimen list when **OK** is clicked	select the **Specimen list and plate layout** radio button in the **When OK is pressed, add new specimens to:** panel. **Note**: This option is only available if the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window.
create the specimens in the list	the **OK** button. The **New/Edit Specimens** dialog box closes, and the specimens are created.
cancel the creation of the specimens in the list	the **Cancel** button. The **New/Edit Specimens** dialog box closes.

6.1.4   Using the **Edit Specimen** and **Edit Multiple Specimens** dialog boxes

The **Edit Specimen** and **Edit Multiple Specimens** dialog boxes are used to modify the information associated with a specimen or multiple specimens, as applicable. See "Modifying specimen information," page 140, for additional instructions.

Example of the **Edit Specimen** dialog box:
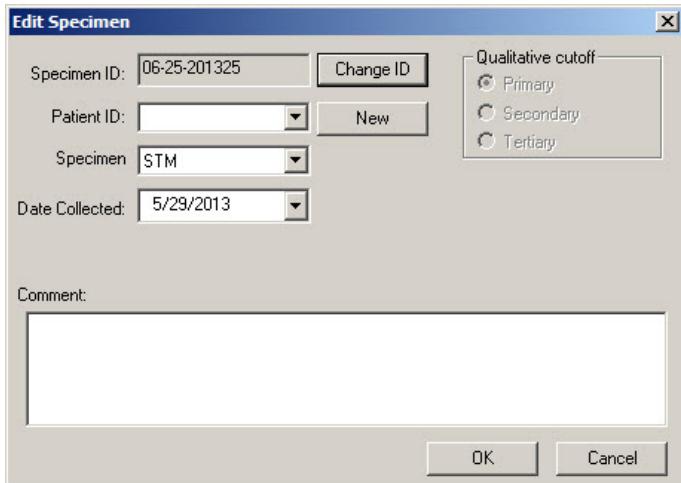
Example of the **Edit Multiple Specimens** dialog box:
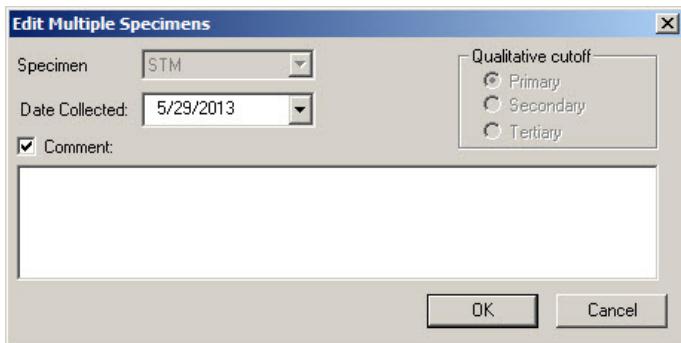
The following table describes the actions that can be performed in the **Edit Specimen** and **Edit Multiple Specimens** dialog boxes.

To...	Click or select...
modify the specimen ID	the **Change ID** button.
	The **Edit Specimen ID** dialog box opens.
	Modify the information in the **Specimen ID:** dialog field and click **OK**.
	See "Modifying specimen information," page 140, for additional instructions.
	Note: This function is only available if modifying a single specimen.

To...	Click or select...
associate an existing patient ID with the specimen	the applicable patient ID from the **Patient ID** drop-down list. **Note**: This function is only available if modifying a single specimen.
create a new patient	the **New** button. See "Creating a patient," page 150, for additional instructions. **Note**: This function is only available if modifying a single specimen.
remove a patient ID associated with a specimen	**<Not Assigned>** from the **Patient ID:** drop-down list. **Note**: This function is only available if modifying a single specimen.
modify the specimen type	the applicable specimen type from the **Specimen** drop-down list.
enter or modify the specimen collection date	the applicable date in the **Date Collected** dialog field.
modify the cutoff type for the specimen	the applicable radio button in the **Qualitative cutoff** panel. **Note**: This function is only available for non-consensus assay protocols.
enter a comment about the specimen that will be included on reports	the **Comment:** dialog field and enter the comment. If modifying multiple specimens, check the **Comment:** box and enter the comment in the **Comment:** dialog field. **Note**: The maximum length is 100 characters.
save the specimen with the modifications	the **OK** button.
close the dialog box without making modifications to the specimen	the **Cancel** button.

6.2   Using the **Measure** tab

The **Measure** tab is used to measure plates and to perform raw data measurements.

Example of the **Measure** tab:
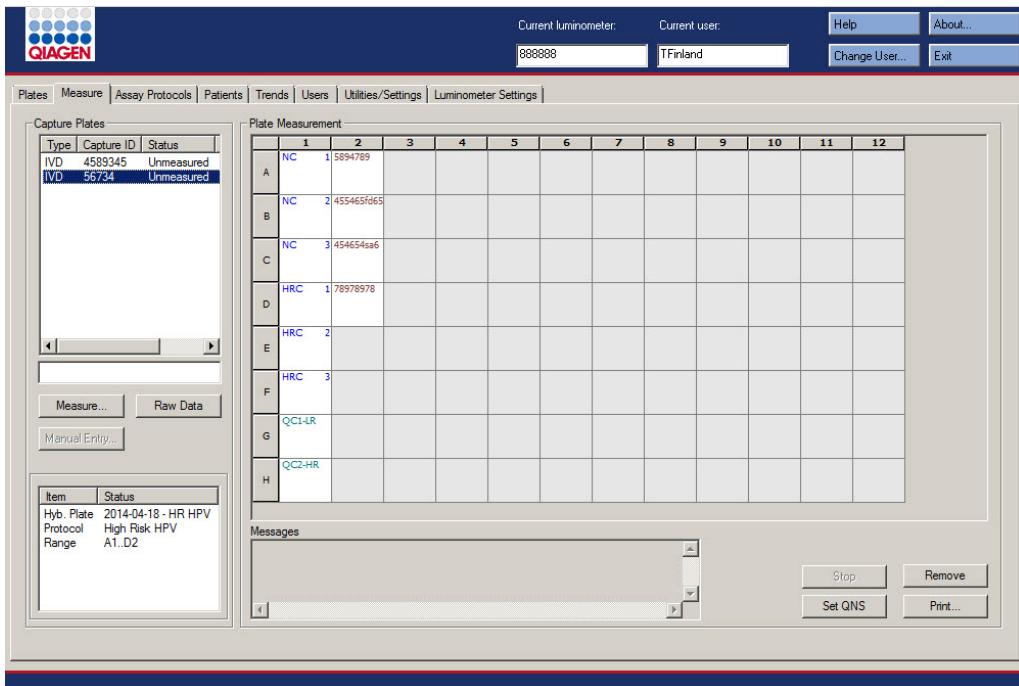
The following table describes the actions that can be performed in the **Capture Plates** panel.

To...	Click or select...
select a capture plate for measurement	the applicable capture plate in the list. The layout for the capture plate selected displays in the **Plate Measurement** panel. Select multiple capture plates by highlighting the applicable capture plates in the list.

To...	Click or select...
use a bar code reader to start capture plate measurement	scan the bar code of the applicable capture plate. The capture plate ID displays in the dialog box above the **Measure…** button. **Notes**: ● This function only works if the capture plate is available in the **Capture Plates** panel. ● The capture plate ID will not display in the dialog box above the **Measure…** button if other functions are selected on the **Measure** tab. Click on the dialog box to display the capture plate ID.
measure a capture plate	the applicable capture plate from the list and click the **Measure…** button. See "Measuring a plate," page 170, for additional instructions.
measure a capture plate as raw data	the **Raw Data** button. See "Measuring a plate as raw data," page 173, for additional instructions.
enter RLU values manually for a capture plate	the applicable capture plate from the list and click the **Manual Entry…** button. See "Entering RLU values manually," page 174, for additional instructions.

The subpanel of the **Capture Plates** panel displays the associated hybridization plate and assay protocols as well as the occupied wells of the highlighted capture plate.

The following table describes the actions that can be performed in the **Plate Measurement** panel.

To...	Click or select...
stop the measurement of a capture plate	the **Stop** button. See "Canceling plate measurement," page 173, for additional instructions.

To...	Click or select...
remove a specimen from the plate layout grid	the applicable specimen ID on the plate layout grid and click the **Remove** button.
	Multiple specimen IDs can be removed by highlighting multiple specimen IDs in the plate layout grid and clicking the **Remove** button.
	The cell of the removed specimen is empty and is grayed-out.
	See "Measuring a plate," page 170, for additional instructions.
set the final result of a specimen as quantity not sufficient	the applicable specimen ID on the plate layout grid and click the **Set QNS** button. A dialog box opens to confirm setting the status of the specimen to quantity not sufficient. Click the **Yes** button.
	Multiple specimen IDs can be set to quantity not sufficient by highlighting multiple specimen IDs in the plate layout grid and clicking the **Set QNS** button.
	The cell of the specimen set to quantity not sufficient is empty and grayed-out.
	Note: A calibrator or quality control as well as specimen with a status of unclear or invalid cannot be set to quantity not sufficient.
	See "Measuring a plate," page 170, for additional instructions.
print or save the plate	the **Print...** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

The **Messages** dialog field displays information relevant to the measurement of the plate. If using a DML 2000, the **Background** dialog box will display if the **Show plate background in measure window** box is checked on the **Luminometer Settings** tab. The **Background** dialog box displays the value of the plate background (10) performed immediately before plate measurement. See "Understanding the plate background (10) reading," page 124, for additional instructions.

6.3   Using the **Assay Protocols** tab

The **Assay Protocols** tab is used to manage assay protocols and to access other functions used to manage specimen, quality control and kit lot information.

The **Custom Assay Protocols** panel lists assay protocol IDs created by the user and are not validated by QIAGEN. The **Specimens not bound to a protocol** panel lists specimens that are not assigned to an assay protocol.

Example of the **Assay Protocols** tab:
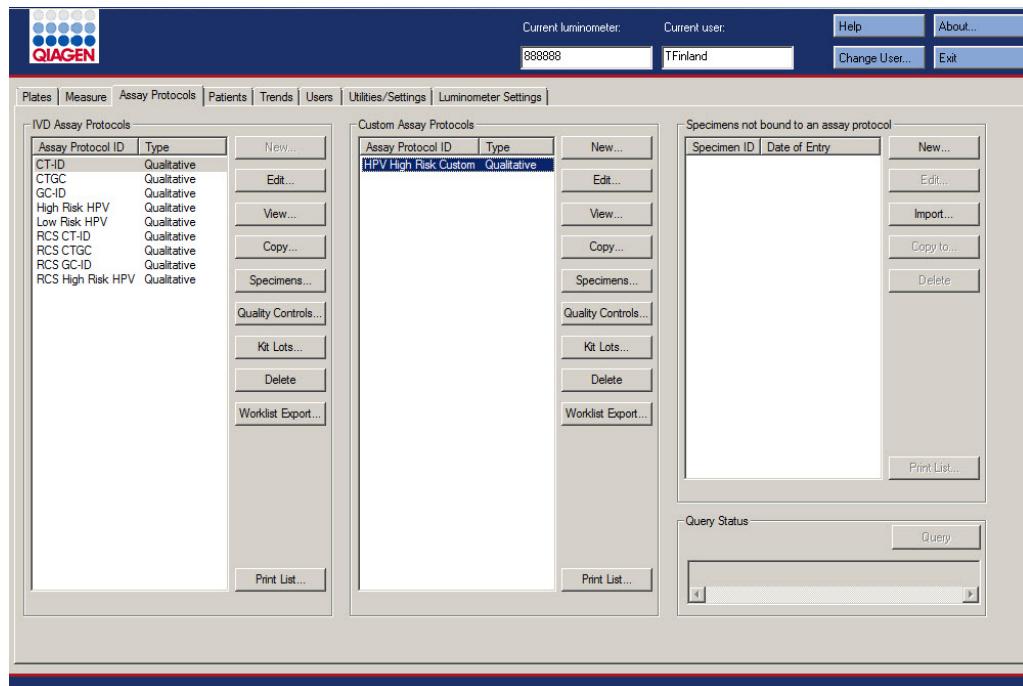
The following table describes the actions that can be performed in the **Custom Assay Protocols** panel.

To...	Click or select...
create a new custom assay protocol	the **New…** button. See "Creating custom assay protocols," page 127, for additional instructions.
modify the parameters of an assay protocol	the applicable assay protocol ID and click the **Edit…** button. The **Edit Custom Assay Protocol** dialog box opens. See "Modifying assay protocols," page 128, for additional instructions.
view the parameters of the assay protocol	the applicable assay protocol ID and click the **View…** button. The **View Custom Assay Protocol** dialog box opens. See "Viewing assay protocol information," page 126, for additional instructions.
create a new custom assay protocol by copying a currently available assay protocol	the applicable assay protocol ID and click the **Copy…** button. See "Creating a custom assay protocol by copying an existing assay protocol," page 127, for additional instructions.
view the specimen list for an assay protocol	the applicable assay protocol ID and click the **Specimens…** button. The **Specimen List** dialog box opens. See "Using the **Specimen List** window," page 74, for additional instructions.
manage the quality controls associated with an assay protocol	the applicable assay protocol ID and click the **Quality Controls…** button. The **Quality Control List** dialog box opens. See "Using the **Quality Control List** dialog box," page 72, for additional instructions.
manage the kit lots associated with an assay protocol	the applicable assay protocol ID and click the **Kit Lots…** button. The **Kit Lot Number Entry** dialog box opens. See "Managing kit lots," page 152, for additional instructions.

To...	Click or select...
delete an assay protocol	the applicable assay protocol ID and click the **Delete** button.
	See "Deleting an assay protocol," page 128, for additional instructions.
	Note: If the assay protocol is associated with any specimens, including specimens with a status of unassigned, the assay protocol cannot be deleted.
export a list of unassigned specimens for an assay protocol	the applicable assay protocol ID and click the **Worklist Export...** button. The **Worklist Export** dialog box opens.
	See "Exporting unassigned specimens," page 147, for additional instructions.
print or save the list of assay protocols	the **Print List...** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

The following table describes the actions that can be performed in the **Specimens not bound to an assay protocol** panel.

To...	Click or select...
create a specimen	the **New...** button. The **New/Edit Specimens** dialog box opens.
	See "Creating specimens," page 135, for additional instructions.
modify the information associated with a specimen	the specimen ID in the list and click the **Edit...** button. The **Edit Unbound Specimen** dialog box opens.
	Edit multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Edit...** button.
	See "Modifying a single specimen or multiple specimens using the **Edit Unbound Specimen** dialog box," page 143, for additional instructions.
import specimens from a text file	the **Import...** button.
	See "Creating specimens from a text file," page 137, for additional instructions.

To...	Click or select...
copy a specimen to an assay protocol	the specimen ID and click the **Copy to...** button.
	Copy multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Copy to...** button.
	See "Copying unbound specimens to an assay protocol," page 139, for additional instructions.
delete the specimen	the specimen ID and click the **Delete** button.
	Delete multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Delete** button.
	See "Deleting an unbound specimen," page 148, for additional instructions.
print or save the list of unbound specimens	the **Print List...** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

The **Query** button in the **Query Status** panel is used to manually query for test orders. Bidirectional communication with the LIS must be configured before a test order can be received in the *digene* HC2 System Software. See "Managing the data export settings," page 116, for additional instructions.

The dialog field in the **Query Status** panel contains information about the last query for test orders. If the query was successful, the date and time of last query as well as the number of specimens received from the LIS is displayed; if the query was unsuccessful, the error description is displayed. The following are examples of the information displayed in the dialog field in the **Query Status** panel:

- 20131108 07:45:53 - 1 Test Order(s) received.
- 20141201 12:12:24 - Query cannot be performed when no order mappings are defined.

6.3.1 Using the **Edit Custom Assay Protocol** dialog box

The **Edit Custom Assay Protocol** dialog box is used to modify the parameters of an assay protocol. Access the applicable dialog box on the **Assay Protocols** tab by highlighting the assay protocol in the **Custom Assay Protocols** panel and clicking the **Edit…** button.

Parameters that may not be modified are grayed-out. Parameters may not be edited based on access level. To modify the parameters of the assay protocol, see "Creating custom assay protocols," page 127, for additional instructions.

Example of the **Edit Custom Assay Protocol** dialog box:
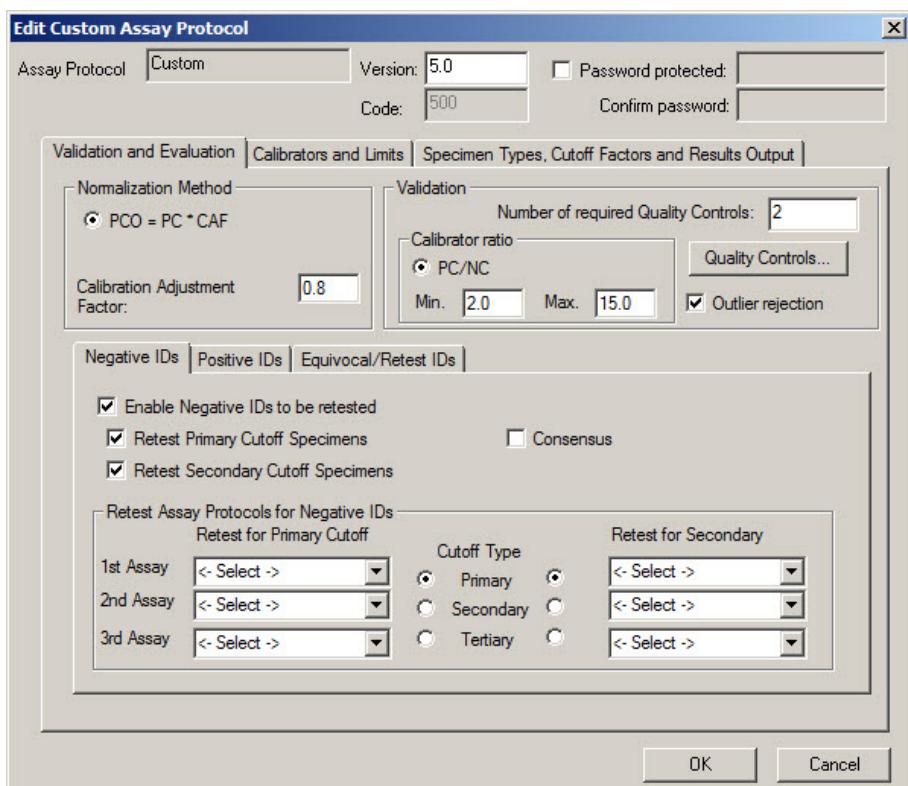
The following table describes the functions that are available in the **Edit Custom Assay Protocol** dialog box.

Feature	Function
Assay Protocol dialog field	Displays the assay protocol ID.
Version: dialog field	Displays the current version of the *digene* HC2 System assay protocol.
Code: dialog field	Displays the assay protocol code to be transmitted to an LIS.

CAUTION   **Loss of access**

Do not forget the password for an assay protocol as there is no way to retrieve a forgotten password.

Password protected: box	Indicates if a password is required for editing the assay protocol parameters. Check the box to require a password.
	Note: A user with supervisor access level can modify this dialog field.
Password protected: dialog field	Available for modification if the **Password protected:** box is checked. Enter a password to protect the assay protocol.
	If the **Password protected:** box is not checked, the dialog field is grayed-out.
Confirm password: dialog field	Available for modification if the **Password protected:** box is checked. Enter a password to protect the assay protocol.
	If the **Password protected:** box is not checked, the dialog field is grayed-out.

The **Validation and Evaluation** tab contains the **Normalization Method** panel, the **Validation** panel and the tabs that determine the retesting parameters for non-consensus assay protocols.

Example of the **Validation and Evaluation** tab :
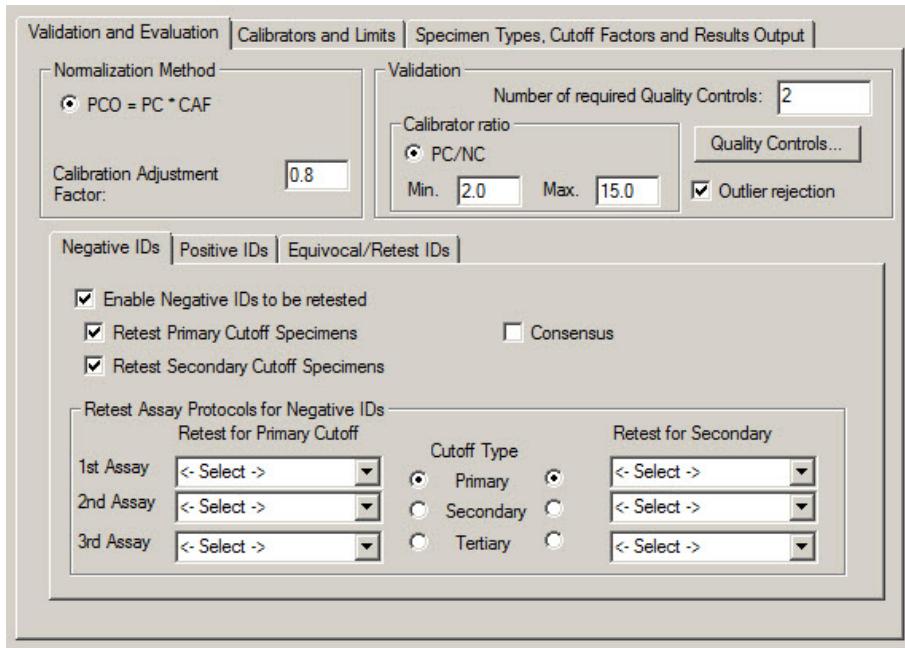
The following table describes the functions that are available in the **Normalization Method** panel.

Feature	Function
PCO = PC * CAF radio button	Specifies the method for determining the positive assay cutoff (PCO) of the assay protocol.
	The positive assay cutoff is determined by multiplying the average of the positive calibrators (PC) by the calibration adjustment factor (CAF).
Calibration Adjustment Factor: dialog field	Specifies the CAF that is used to calculate the positive assay cutoff for each assay.

The **Validation** panel contains the settings for the number of quality controls required for validation and the calibrator ratio. The following table describes the functions that are available in the **Validation** panel.

Feature	Function
Number of required Quality Controls: dialog box	Specifies the number of quality controls that are required to validate the plate. An equivalent number of quality controls with the **Automatically set for use in validation when added to a plate layout** box checked are required on the plate before plate measurement can occur.
PC/NC radio button in the **Calibrator ratio** subpanel	Specifies the method for determining the calibrator ratio of the assay validation. The calibrator ratio is determined by dividing the average of the positive calibrators (PC) by the average of the negative calibrators (NC).
Min. dialog field in the **Calibrator ratio** subpanel	Specifies the minimum value of the calibrator ratio required for validation of the assay protocol.
Max. dialog field in the **Calibrator ratio** subpanel	Specifies the maximum value of the calibrator ratio required for a validation of the assay protocol.
Outlier rejection box	Specifies if the assay protocol is permitted to reject one of the calibrator results as an outlier when calculating the average. If the box is checked, the value furthest from the calibrator average will be rejected as an outlier if the coefficient of variation (CV) for the calibrators is not within specification. The average of the calibrator results and the CV is calculated with the remaining calibrator results.
Quality Controls… button	Opens the **Quality Control List** dialog box. See "Using the **Quality Control List** dialog box," page 72, for additional instructions.

The **Negative IDs**, **Positive IDs** and **Equivocal/Retest IDs** tabs contain the retest parameters for a non-consensus assay protocol. Each tab has the same functionality for the respective type of ID. The following table describes the functions that are available in the tabs.

Feature	Function
Consensus box	Activates the assay protocol as a consensus assay protocol.
	Note: If the box is checked, no other features of the **Negative IDs**, **Positive IDs** and **Equivocal/Retest IDs** tabs are available.
	If the box is not checked, the assay protocol is defined as a non-consensus assay protocol.
Enable Negative IDs to be retested box	Enables or disables the application of retest parameters based on the applicable specimen result.
Enable Positive IDs to be retested box	
Enable Equivocal/Retest IDs to be retested box	
Retest Primary Cutoff Specimens box	Implements retest parameters for specimens according to the primary cutoff factor parameters as defined on the **Specimen Types, Cutoff Factors and Results Output** tab.
	If this box is checked, the **Retest for Primary Cutoff** dialog fields are active in the panel below. If the box is not checked, the dialog fields are grayed-out.
Retest Secondary Cutoff Specimens box	Implements retest parameters for specimens according to the secondary cutoff factor parameters as defined on the **Specimens Types, Cutoff Factors and Results Output** tab.
	If this box is checked, the **Retest for Secondary** dialog fields are active in the panel below. If the box is not checked, the dialog fields are grayed-out.
Retest Assay Protocols for Negative IDs panel	Displays retest parameters for the assay protocol.
Retest Assay Protocols for Positive IDs panel	
Retest Assay Protocols for Equivocal/Retest IDs panel	

Feature	Function
1st Assay drop-down list	Defines the assay protocol for the retest of specimens.
2nd Assay drop-down list	
3rd Assay drop-down list	
Cutoff Type radio buttons	Defines the cutoff factor type for the retest of specimens.

The **Calibrators and Limits** tab specifies the parameters for the calibrators associated with the assay protocol. If the box beside a parameter is checked, the parameter is activated for the assay protocol.

Example of the **Calibrators and Limits** tab:

The following table describes the functions that are available on the **Calibrators and Limits** tab.

Feature	Function
Neg Cal: row	Parameters for the negative calibrator associated with the assay protocol.
Pos Cal: row	Parameters for the positive calibrator associated with the assay protocol.
Unknown: row	Parameters for the specimens associated with the assay protocol.
Replicates column	Specifies the number of replicates required for the respective calibrator. Regarding the **Unknown:** row, the specification determines the number of specimen replicates that is added by default to a plate associated with the assay protocol.
Min RLU column	Specifies the minimum RLU for the respective calibrator required to validate the assay protocol.
Max RLU column	Specifies the maximum RLU for the respective calibrator required to validate the assay protocol.
Max %CV column	Specifies the maximum CV for the respective calibrator required to validate the assay protocol.
Printing Abbreviation column	Specifies the printing abbreviation for the respective calibrator.
Min: dialog field in the **Room Temperature** panel	Specifies the minimum temperature required at the time of plate measurement for the assay protocol.
Max: dialog field in the **Room Temperature** panel	Specifies the maximum temperature required at the time of plate measurement for the assay protocol.
°C and **°F** radio buttons in the **Room Temperature** panel	Specifies either **°C** for degrees Celsius or **°F** for degrees Fahrenheit for the unit of measure for the temperature at the time of plate measurement.

The **Specimen Types, Cutoff Factors and Results Output** tab defines the specimen types, cutoff factors and the result designations for the assay protocol.

Example of the **Specimen Types, Cutoff Factors and Results Output** tab:

The following table describes the functions that are available in the **Specimen Types, Cutoff Factors and Results Output** panel.

Feature	Function
Type ID column	Displays the specimen type IDs associated with the assay protocol.
Correction Factor column	Displays the correction factors for the specimen types associated with the assay protocol.
Results Final column	Displays if the retest algorithm is applicable to the specimen type. If **Yes**, the final result for the specimen type is determined based on the primary test. If **No**, the final result of a specimen is determined using the retest algorithm, as applicable. **Note**: The **Results Final** column only displays if the **Consensus** box is checked on the **Validation and Evaluation** tab.

Feature	Function
Box beside each specimen type ID	The checked box specifies the default specimen type for the assay protocol.
	See "Changing the default specimen type of an assay protocol," page 132, for additional instructions.
Add Type button	Opens the **Add Specimen Type** dialog box to add a specimen type associated with the assay protocol.
	See "Adding a new specimen type to an assay protocol," page 131, for additional instructions.
Rename Type button	Opens the **Rename Specimen Type ([specimen type name])** dialog box for the highlighted specimen type.
	To change the specimen type ID, modify the type ID and click **OK**.
	The **Rename Specimen Type ([specimen type name])** dialog box closes and the type ID is updated in the list.
Remove Type button	Opens a dialog box to confirm the removal of the highlighted specimen type. Click the applicable response to remove the specimen type from the assay protocol.
	Specimens with the deleted specimen type will not be deleted. Those specimens are given the default specimen type.
For Research Use Only and **Validated by <lab name>** radio buttons	The parameters available for the information displayed on reports for the assay protocol.
Default specimen type can be determined by user box	Specifies if a user with operator access level can select the default specimen type for the assay protocol. If the box is checked, a user with operator access level can select the default specimen type.
	Note: A user with operator status can check or uncheck this box.

The information displayed in the **Cutoff Factors: < [specimen type] >** and **Result Designations: < [specimen type] >** panels is specific to the specimen type highlighted in the **Specimen Types** panel.

The following table describes the functions that are available in the **Cutoff Factors: < [specimen type] >** panel.

Feature	Function
Negative row	Specifies the cutoff factor parameters for determining a negative result. Any result that is less than the specified parameter is considered negative. **Note**: If the **Negative** cutoff does not equal the **Positive** cutoff and the result falls between the cutoffs, the result is considered equivocal/retest.
Positive row	Specifies the cutoff factor parameters for determining a positive result. Any result that is equal to or greater than the specified parameter is considered positive. **Note**: If the **Negative** cutoff does not equal the **Positive** cutoff and the result falls between the cutoffs, the result is considered equivocal/retest.
Primary column	Specifies the parameters of the primary cutoff factors for a specimen.
Secondary column	Specifies the parameters of the secondary cutoff factors for a specimen.
Tertiary column	Specifies the parameters of the tertiary cutoff factors for a specimen.

The following table describes the functions that are available in the **Results Designations < [specimen type] >** panel.

Feature	Function
Negative row	Specifies the result displayed for a negative result.
Positive row	Specifies the result displayed for a positive result.
Equivocal/Retest row	Specifies the result displayed for an equivocal or retest result.
SPLIT row	Specifies the result displayed for a split result.
Preliminary column	Specifies the result displayed for a preliminary result.
	Note: The **Preliminary** column does not display when the **Consensus** box is checked on the **Validation and Evaluation** tab or when the **Results Final** column is **Yes** in the **Specimen Types** panel.
Final column	Specifies the result displayed for a final result.

6.3.2   Using the **View Custom Assay Protocol** dialog box

The **View Custom Assay Protocol** dialog box displays the parameters of the assay protocol. Information displayed cannot be modified with the exception of the **Quality Control** button. To access the dialog box, highlight the applicable assay protocol in the **Custom Assay Protocols** panel on the **Assay Protocols** tab and click the **View…** button.

Click the **Validation and Evaluation**, **Calibrators and Limits** or **Specimen Types, Cutoff Factors and Results Output** tabs to view the desired information.

6.3.3 Using the **Quality Control List** dialog box

The **Quality Control List** dialog box is used to manage quality controls. The **Quality Control List** dialog box can be accessed using one of the following methods:

- On the **Plates** tab in the **Unmeasured Hybridization Plates** panel, click the **New Custom…** button or select a hybridization plate ID from the list and click the **Edit…** button. The **Create/Edit Layout** window opens. Click the **Manage QCs…** button in the **Quality controls** panel.

- On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Quality Controls…** button.

- On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Edit…** button. The **Edit Custom Assay Protocol** dialog box opens. On the **Validation and Evaluation** tab, click the **Quality Controls…** button.

- On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **View…** button. The **View Custom Assay Protocol** dialog box opens. On the **Validation and Evaluation** tab, click the **Quality Controls…** button.

Example of the **Quality Control List** dialog box:

The following table describes the features that are available in the **Quality Control List** dialog box.

Feature	Function
Assay dialog field	Specifies the assay protocol ID that is associated with the quality controls displayed.
Quality Control ID list	Specifies the quality control IDs associated with the specified assay protocol.
	If the box beside the quality control ID is checked, the **Automatically set for use in validation when added to a plate layout** box is checked for the quality control. If the quality control is added to the plate, the quality control must meet the defined specifications of the quality control for the assay to be valid.

The following table describes actions that can be performed in the **Quality Control List** dialog box.

To...	Click or select...
add a new quality control	the **New…** button. The **QC ID Entry** dialog box opens.
	See "Creating a quality control," page 155, for additional instructions.
modify the information for a quality control	the applicable quality control ID and click the **Edit…** button. The **Edit Quality Control** dialog box opens.
	See "Modifying a quality control," page 156, for additional instructions.
delete a quality control	the applicable quality control ID and click the **Delete** button.
	See "Deleting a quality control," page 156, for additional instructions.
view the list of quality controls associated with an assay protocol	the **Print List…** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.
close the **Quality Control List** dialog box	the **Close** button.

6.3.4 Using the **Specimen List** window

Use the **Specimen List** window to view specimen information and to manage specimens. Access this window on the **Assay Protocols** tab by highlighting the applicable assay protocol ID and clicking the **Specimens** button.

Example of the **Specimen List** window:
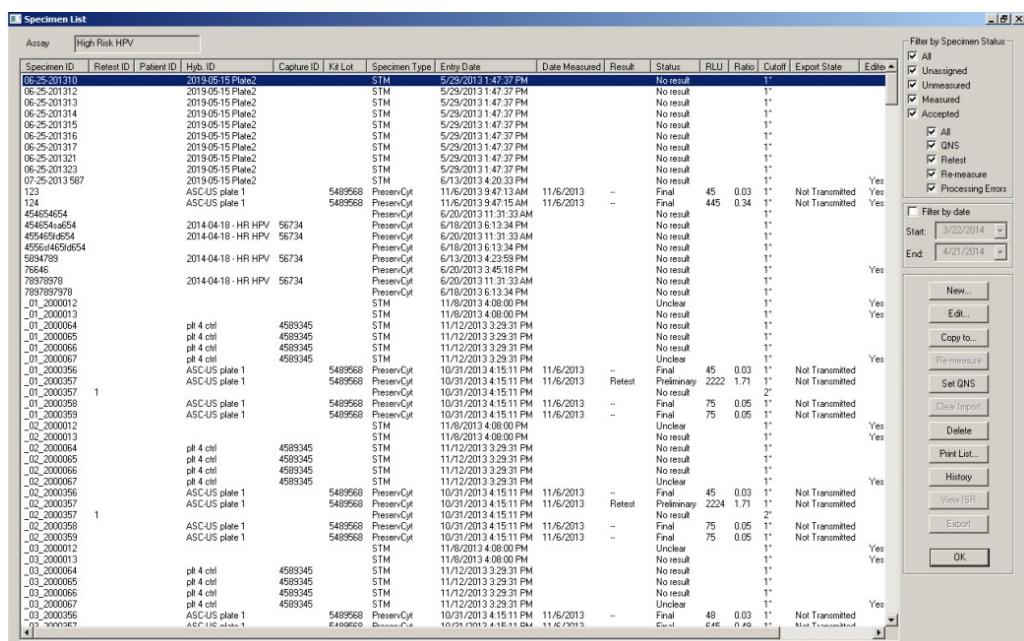
The assay protocol ID is displayed in the **Assay** dialog field at the top of the window.

The following table describes the actions that can be performed in the **Specimen List** window.

To...	Click or select...
sort the specimen list by a particular parameter	the applicable column header. **Note**: Each click of the column alternates between ascending and descending sort order.
include in the specimen list all specimens associated with the assay protocol	the **All** box in the **Filter by Specimen Status** panel. **Note**: This box acts as a toggle to select or unselect all other specimen status filters.

To...	Click or select...
include in the specimen list all specimens with a status of unassigned	the **Unassigned** box in the **Filter by Specimen Status** panel. Uncheck this box to remove from the specimen list those specimens with a status of unassigned.
include in the specimen list those specimens with a status of unmeasured	the **Unmeasured** box in the **Filter by Specimen Status** panel. Uncheck this box to remove from the specimen list those specimens with a status of unmeasured.
include in the specimen list those specimens with a status of measured	the **Measured** box in the **Filter by Specimen Status** panel. Uncheck this box to remove from the specimen list those specimens with a status of measured.
include in the specimen list those specimens with a status of accepted	the **Accepted** box in the **Filter by Specimen Status** panel. Uncheck this box to remove from the specimen list those specimens with a status of accepted.
include in the specimen list all specimens selected using the boxes in the first column of the **Filter by Specimen Status** panel	the **All** box in the second column of the **Filter by Specimen Status** panel. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.
include in the specimen list those specimens with a result of quantity not sufficient	the **QNS** box in the second column of the **Filter by Specimen Status** panel. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.
include in the specimen list those specimens with a result of retest	the **Retest** box in the second column of the **Filter by Specimen Status** panel. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.
include in the specimen list those specimens set to be re-measured	the **Re-measure** box in the second column of the **Filter by Specimen Status** panel. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.

To...	Click or select...
include in the specimen list those specimens with a status of unclear and invalid	the **Processing Errors** box in the second column of the **Filter by Specimen Status** panel. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.
refine the specimen list using a date range for the date of plate measurement	the **Filter by date** box and select the parameters in the **Start:** and **End:** drop-down lists. **Note**: A box must be checked in the first column of the **Filter by Specimen Status** panel.
create a specimen	the **New…** button. The **New/Edit Specimens** dialog box opens. See "Creating specimens," page 135, for additional instructions.
modify the information associated with a specimen	the specimen ID in the list and click the **Edit…** button. Alternatively, double-click a specimen ID in the list. The **Edit Specimen** dialog box opens. See "Modifying a single specimen using the **Edit Specimen** dialog box," page 141, for additional instructions. To modify multiple specimens, see "Modifying multiple specimens using the **Edit Multiple Specimens** ," page 142, for additional instructions.
copy a specimen to an assay protocol	the specimen ID in the list and click the **Copy to…** button. Copy multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Copy to…** button. See "Copying specimens from one assay protocol to another assay protocol," page 139, for additional instructions.
set a specimen to be re-measured	the specimen ID in the list and click the **Re-measure** button. See "Re-measuring a specimen," page 198, for additional instructions. **Note**: Only users with supervisor access level are able to use this function; the **Re-measure** button is grayed-out if the function is not available.

To...	Click or select...
set the final result of a specimen as quantity not sufficient	the applicable specimen ID in the list and click the **Set QNS** button. A dialog box opens to confirm setting the status of the specimen to quantity not sufficient. Click the **Yes** button. Multiple specimen IDs can be set to quantity not sufficient by highlighting multiple specimen IDs in the list and clicking the **Set QNS** button. **Notes**: ● A calibrator or quality control as well as specimen with a status of unclear or invalid cannot be set to quantity not sufficient. ● The **Set QNS** button is grayed-out if none of the specimens selected can be set to quantity not sufficient.
clear the status of a specimen with an unclear or invalid status	the specimen ID in the list and click the **Clear Import** button. See "Clearing the status of a specimen," page 196, for additional information. **Note**: The **Clear Import** button is grayed-out if the function is not available.
delete an unmeasured specimen	the applicable specimen ID in the list and click the **Delete** button. A dialog box opens to confirm the deletion of the specimen. Click the **Yes** button. Multiple specimen IDs can be deleted by highlighting multiple specimen IDs in the list and clicking the **Delete** button. **Notes**: ● Unmeasured specimens with a status of retest cannot be deleted. ● The **Delete** button is grayed-out if none of the specimens selected can be deleted.
print or save the specimen list for an assay protocol	the **Print List...** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

To...	Click or select...
view a specimen history report	the specimen ID in the list and click the **History** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions. See "Understanding the specimen history report," page 193, for additional information.
view an individual specimen report	the specimen ID in the list and click the **View ISR** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions. See "Understanding the individual specimen report," page 191, for additional information. **Note**: The **View ISR** button is grayed-out if the function is not available.
export the test results of a specimen with the status of quantity not sufficient	the specimen ID in the list and click the **Export** button. Multiple specimen IDs with a status of quantity not sufficient can be exported by highlighting the applicable specimen IDs in the list and clicking the **Export** button. **Note**: Only a specimen with a status of quantity not sufficient can be exported from the **Specimen List** window; the **Export** button is grayed-out if the function is not available.
close the **Specimen List** window	the **OK** button.

6.4 Using the **Patients** tab

The **Patients** tab is used to view and manage patient information.

Example of the **Patients** tab:
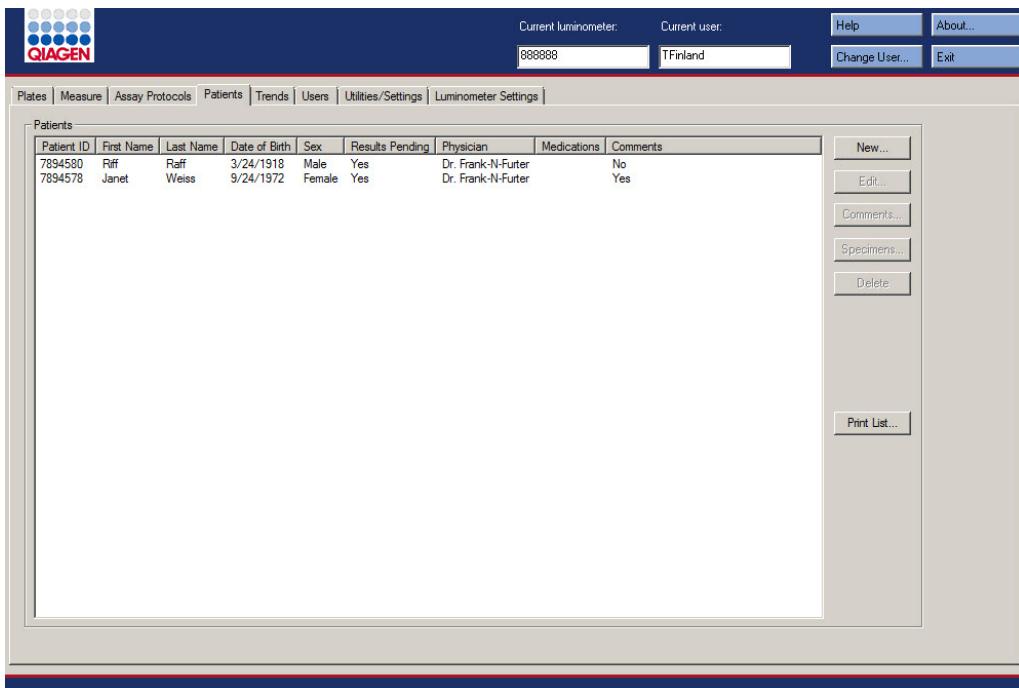
The following table describes the actions that can be performed on the **Patients** tab.

To...	Click or select...
sort the patient list by a particular parameter	the applicable column header. **Note**: Each click of the column alternates between ascending and descending sort order.
add a new patient	the **New…** button. The **Patient ID Entry** dialog box opens. See "Creating a patient," page 150, for additional instructions.
modify the information for a patient	the applicable patient ID and click the **Edit…** button. The **Edit Patient** dialog box opens. See "Modifying patient information," page 150, for additional instructions.

To...	Click or select...
view, modify or delete the comments associated with a patient	the applicable patient ID and click the **Comments…** button. The **Patient Comments** dialog box opens. See "Creating a patient comment," page 151, "Modifying a patient comment," page 151, and "Deleting a patient comment," page 152, for additional instructions.
view the specimen information associated with a patient	the applicable patient ID and click the **Specimens…** button. The **Specimens** dialog box opens. See "Viewing patient information," page 150, for additional information.
delete a patient	the applicable patient ID and click the **Delete** button. A dialog box opens to confirm the deletion of the patient. Click the applicable response. Multiple patient IDs can be deleted by highlighting the applicable patient IDs in the list and clicking the **Delete** button. A dialog box opens for each patient ID to confirm the deletion of the patient. Click the applicable response. See "Deleting a patient ID," page 152, for additional instructions.
print or save the patient list	the **Print List…** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

6.5   Using the **Trends** tab

The **Trends** tab is used to view trending reports based on the database maintained by the *digene* HC2 System Software.

To generate trend reports for patients, quality controls, calibrators, specimens and background measurements, see "Generating trending reports," page 200, for additional instructions. The trend reports for background measurements are only available for the DML 2000.

Example of the **Trends** tab with a DML 3000 selected as the DML instrument:
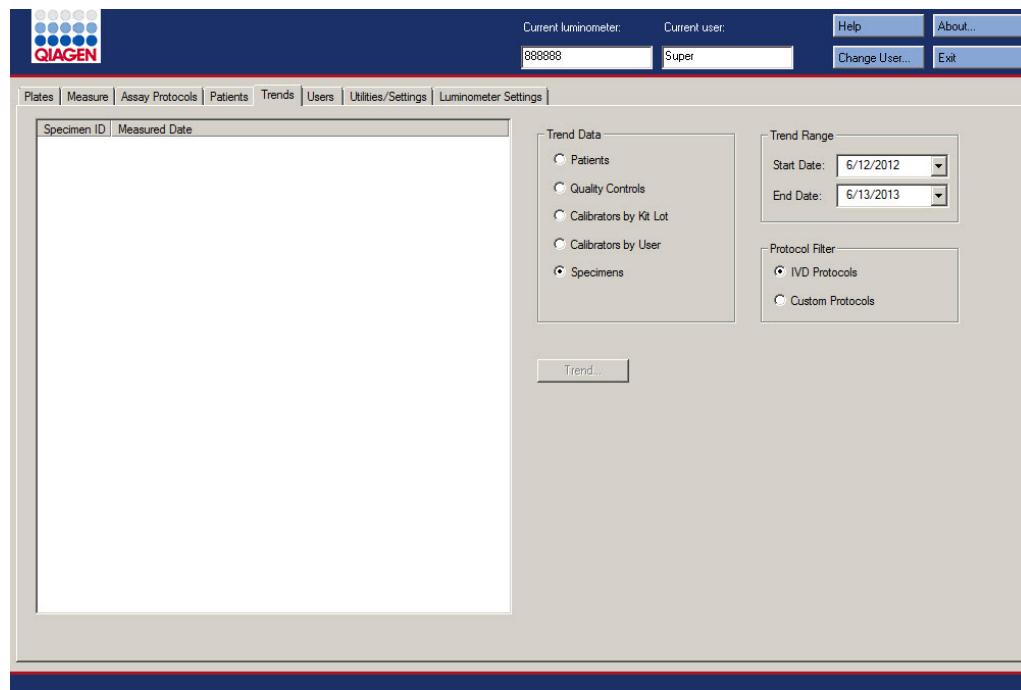
Example of the **Trends** tab with a DML 2000 selected as the DML instrument:
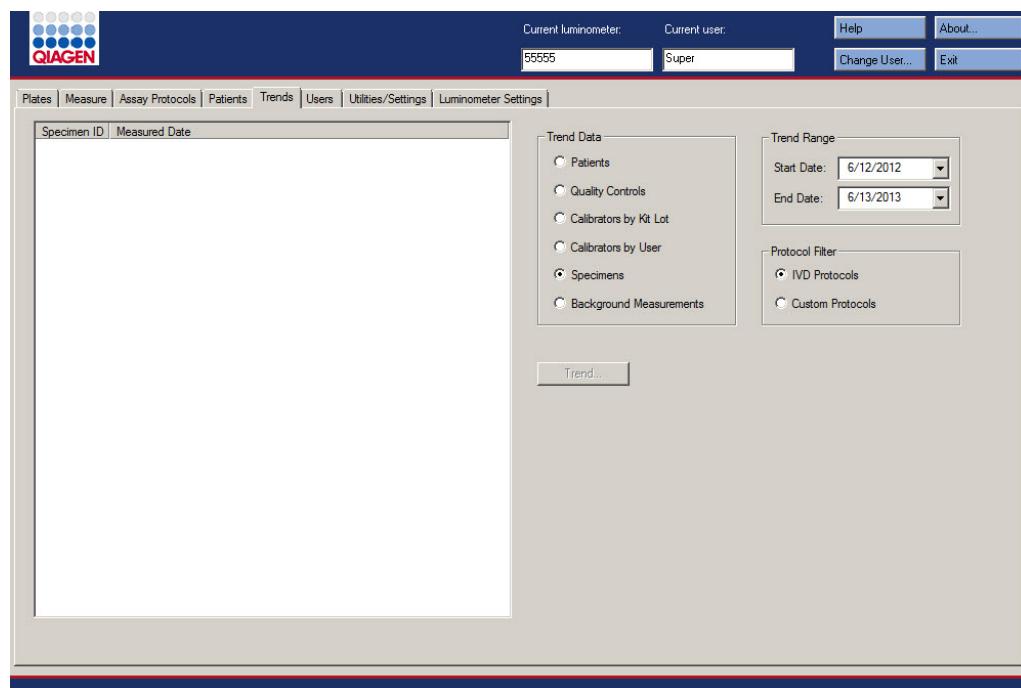
The following actions can be performed on the **Trends** tab.

To...	Click or select...
specify the type of data for the trend report	the applicable radio button in the **Trend Data** panel.
specify a date range for the trend report	the applicable parameters in the **Start Date:** and **End Date:** dialog fields in the **Trend Range** panel.
specify the type of assay protocol for the trend report	the **Custom Protocols** radio button in the **Protocol Filter** panel. **Note**: One of the radio buttons is selected at all times and only one radio button may be selected at a time.
specify the serial number of the DML instrument for the trend report	the serial number of the DML instrument from the drop-down list in the **Serial Number for Trend** panel. **Note**: The **Serial Number for Trend** panel is available only when a DML 2000 is selected as the current DML instrument.
generate a trending report with the parameters selected	the **Trend...** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

6.6 Using the **Users** tab

The **Users** tab is used to create and manage user accounts. The **Users** tab only displays if a user has supervisor access level. See "Managing users," page 107, for additional instructions.

Example of the **Users** tab:
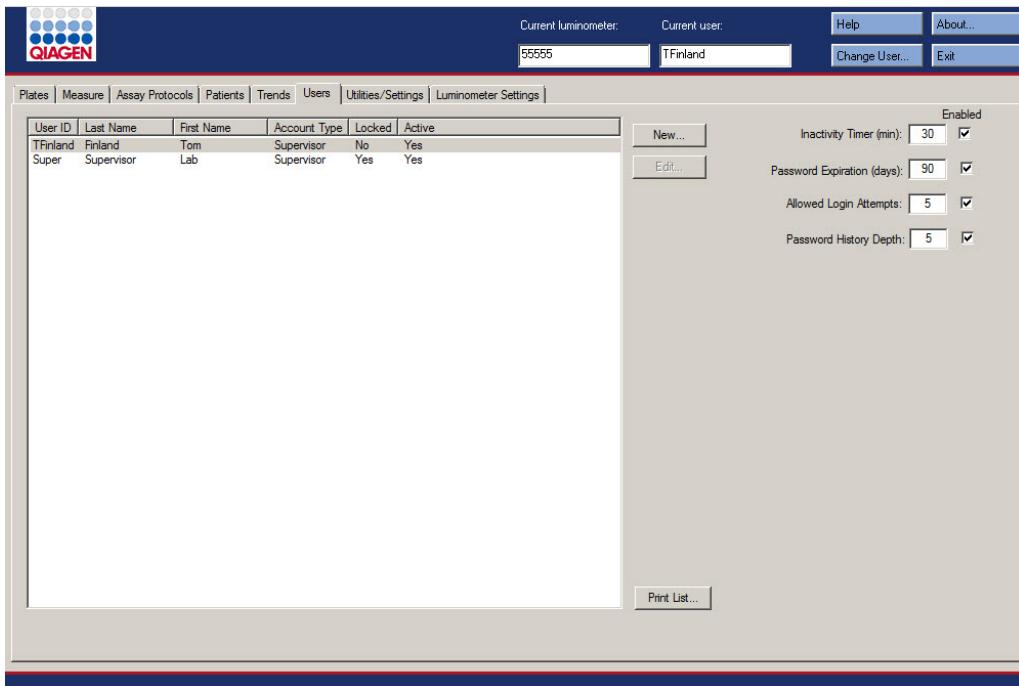
The following table describes the actions that can be performed on the **Users** tab.

To...	Click or select...
sort the user list by a particular parameter	the applicable column header. **Note**: Each click of the column header alternates between ascending and descending sort order.
add a user	the **New...** button. The **User ID Entry** dialog box opens. See "Creating a user," page 108, for additional instructions.
modify the login password or access level of a user	the user ID from the list and click the **Edit...** button. The **Edit User** dialog box opens. See "Modifying a user," page 109, for additional instructions.

To...	Click or select...
modify the inactivity timer setting	the **Inactivity Time (min):** dialog field and enter the number of minutes of user inactivity that will result in the inactivation of the *digene* HC2 System Software. See "Setting the inactivity timer," page 111, for additional instructions.
inactivate the inactivity timer setting	the **Inactivity Time (min):** box. The **Inactivity Time (min):** dialog field will be grayed-out. See "Setting the inactivity timer," page 111, for additional instructions.
modify the password expiration setting	the **Password Expiration (days):** dialog field and enter the number of days after which the user is prompted to change their login or eSign password. See "Setting the password expiration," page 111, for additional instructions.
inactivate the password expiration setting	the **Password Expiration (days):** box. The **Password Expiration (days):** dialog field will be grayed-out. See "Setting the password expiration," page 111, for additional instructions.
modify the allowed login attempts setting	the **Allowed Login Attempts:** dialog field and enter the number of times a user may attempt to log in before the user is locked out of the *digene* HC2 System Software. See "Setting the allowed login attempts," page 112, for additional instructions.
inactivate the allowed login attempts setting	the **Allowed Login Attempts:** box. The **Allowed Login Attempts:** dialog field will be grayed-out. See "Setting the allowed login attempts," page 112, for additional instructions.
modify the password history depth setting	the **Password History Depth:** dialog field and enter the number of past passwords that may not be used by the user when creating a new password. See "Setting the password history depth," page 112, for additional instructions.

To...	Click or select...
inactivate the password history depth setting	the **Password History Depth:** box. The **Password History Depth:** dialog field will be grayed-out.
	See "Setting the password history depth," page 112, for additional instructions.
print or save the user list	the **Print List...** button. The **QIAGEN Report Viewer** window opens.
	See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.
	Note: Passwords do not print.

6.7 Using the **Utilities/Settings** tab

The **Utilities/Settings** tab is used to:

- Modify the laboratory name and header information
- Archive data
- Modify the *digene* HC2 System Software settings
- Install assay protocols
- View the audit log
- Configure the data interface for the export of test results
- Schedule queries for bidirectional communication between the *digene* HC2 System Software and the LIS

Example of the **Utilities/Settings** tab:
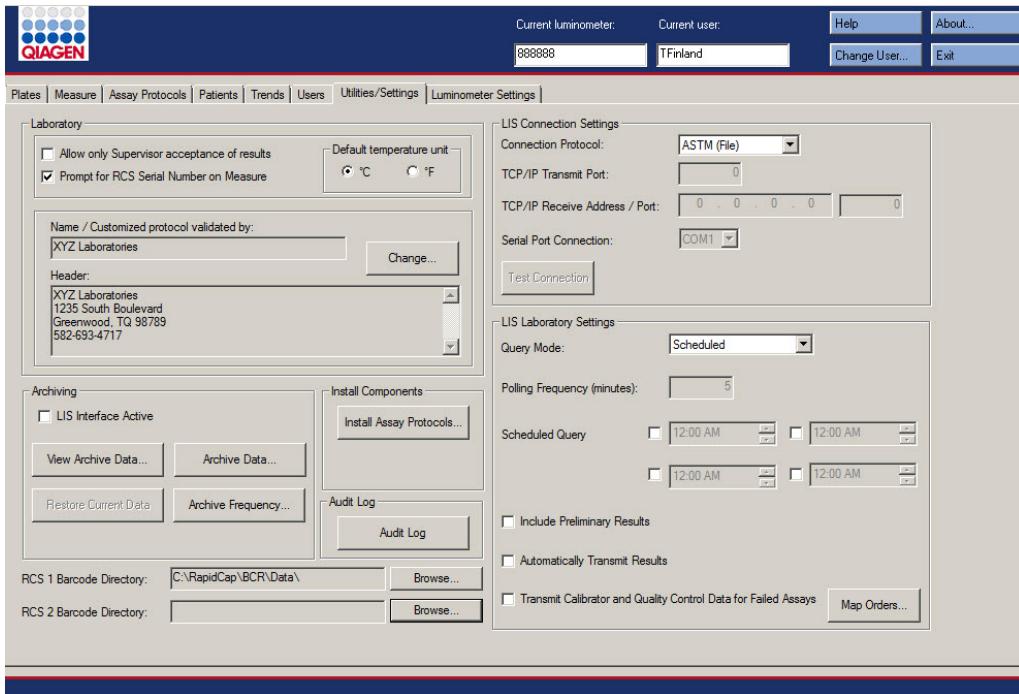
The following table describes the actions that can be performed on the **Utilities/Settings** tab.

To...	Click or select...
prohibit a user with operator access level from accepting results	the **Allow only Supervisor acceptance of results** box. If the box is not checked, a user with operator access level can accept plates. See "Determining the access level required to accept results," page 112, for additional instructions. **Note**: Only users with supervisor access level can modify this function.
activate the **RCS Serial Number:** dialog field in the dialog box that opens immediately prior to plate measurement	the **Prompt for RCS Serial Number on Measure** box. See "Modifying the prompt during plate measurement," page 113, for additional instructions.

To...	Click or select...
specify the unit of measure for the temperature used on reports	either the **°C**, for Celsius, or **°F**, for Fahrenheit, radio button in the **Default temperature unit** panel. **Note**: Only users with supervisor access level can modify this function.
modify the laboratory and header information	the **Change…** button. The **Edit Laboratory Information** dialog box opens. See "Modifying the laboratory information," page 113, for additional instructions. **Note**: Only users with supervisor access level can modify this function.
only archive plates that have an export status of transmitted	the **LIS Interface Active** box in the **Archiving** panel. See "Managing the archive settings," page 114, for additional instructions. **Note**: Only users with supervisor access level may modify this function.
view an archive	the **View Archive Data…** button in the **Archiving** panel. The **View Archive Data** dialog box opens. See "Viewing an archive," page 217, for additional instructions.
end the viewing of an archive and restore the current data	the **Restore Current Data** button in the **Archiving** panel. See "Viewing an archive," page 217, for additional instructions.
perform an archive	the **Archive Data…** button in the **Archiving** panel. The **Archive Data** dialog box opens. See "Creating an archive," page 216, for additional instructions.
set the frequency of archive reminder	the **Archive Frequency…** button in the **Archiving** panel. The **Archive Frequency** dialog box opens. See "Managing the archive settings," page 114, for additional instructions. **Note**: Only users with supervisor access level may modify this function.

To...	Click or select...
restore assay protocols	the **Install Assay Protocols…** button in the **Install Components** panel. See "Restoring *digene* HC2 System assay protocols," page 129, for additional information. **Note**: Only users with supervisor access level may modify this function.
view the audit log	the **Audit Log** button in the **Audit Log** panel. The **Audit Log** window opens. See "Using the **Audit Log** window," page 91, and "Viewing the audit log," page 219, for additional instructions.
specify the directory containing the import mapping files for automatic capture plate ID association	the **Browse…** button beside the **RCS 1 Barcode Directory:** dialog field or the **RCS 2 Barcode Directory:** dialog field. See "Setting up the RCS Bar Code Reader directory," page 115, for additional instructions. **Note**: Only users with supervisor access level may modify this function.
select the type of connection for exporting results	the applicable parameter from the **Connection Protocol:** drop-down list in the **LIS Connection Settings** panel. See "Managing the data export settings," page 116, for additional instructions. **Note**: Only users with supervisor access level may modify this function.
enter the transmission control protocol/internet protocol (TCP/IP) transmit port through which the HC2 System computer is connected to an LIS	the **TCP/IP Transmit Port:** dialog box in the **LIS Connection Settings** panel and enter the applicable parameter. See "Setting up data export using the HL7 standards," page 117, for additional instructions. **Notes**: ● The **TCP/IP Transmit Port:** dialog box is grayed-out unless **HL7 (Ethernet)** is selected in the **Connection Protocol:** drop-down list. ● Only users with supervisor access level may modify this function.

To...	Click or select...
enter the TCP/IP receive address/port through which the HC2 System computer is connected to an LIS	the **TCP/IP Receive Address/Port:** dialog boxes in the **LIS Connection Settings** panel and enter the applicable parameters. See "Setting up data export using the HL7 standards," page 117, for additional instructions. **Notes**: ● The **TCP/IP Receive Address/Port:** dialog boxes are grayed-out unless **HL7 (Ethernet)** is selected in the **Connection Protocol:** drop-down list. ● Only users with supervisor access level may modify this function.
select the serial port through which the HC2 System computer is connected to an LIS	the applicable COM port from the **Serial Port Connection:** drop-down list in the **LIS Export Settings** panel. See "Setting up data export using the CLSI standards," page 116, for additional instructions. **Notes**: ● The **Serial Port Connection:** drop-down list is grayed-out unless **ASTM (Serial)** is selected in the **Connection Protocol:** drop-down list. ● Only users with supervisor access level may modify this function.
test the connection of the HC2 System computer to the LIS	the **Test Connection** button. See "Managing the data export settings," page 116, for additional instructions. **Notes**: ● The **Test Connection** button is grayed-out unless **ASTM (Serial)** or **HL7 (Ethernet)** is selected in the **Connection Protocol:** drop-down list. ● Only users with supervisor access level may modify this function.
select query mode for requesting test orders from the LIS	the applicable parameter from the **Query Mode:** drop-down list in the **LIS Laboratory Settings** panel. See "Setting up bidirectional communication," page 117, for additional instructions. **Note**: Only users with supervisor access level may modify this function.

To...	Click or select...
specify the frequency of polling for test orders from the LIS	the **Polling Frequency (minutes):** dialog box and enter the applicable parameter. See "Setting up bidirectional communication," page 117, for additional instructions. **Notes**: ● The **Polling Frequency (minutes):** dialog box is grayed-out unless **Polling** is selected in the **Query Mode:** drop-down list. ● Only users with supervisor access level may modify this function.
schedule the time(s) for test order query to occur	the **Schedule Query** box and modify the time in the dialog field using the arrows. See "Setting up bidirectional communication," page 117, for additional instructions. **Notes**: ● The **Schedule Query** dialog boxes are grayed-out unless **Scheduled** is selected in the **Query Mode:** drop-down list. ● Only users with supervisor access level may modify this function.
include preliminary results when exporting results	the **Include Preliminary Results** box in the **LIS Laboratory Settings** panel. If the box is not checked, preliminary results will not be exported. See "Determining if preliminary results are exported," page 118, for additional instructions. **Note**: Only users with supervisor access level may modify this function.
automatically transmit results at the time the results are accepted	the **Automatically Transmit Results** box in the **LIS Laboratory Settings** panel. If the box is not checked, accepted results will not transmit until manually exported. See "Determining if accepted results are automatically exported," page 119, for additional instructions. **Note**: Only users with supervisor access level may modify this function.

To...	Click or select...
include calibrator and quality control data when exporting results for invalid assays	the **Transmit Calibrator and Quality Control Data for Failed Assays** box in the **LIS Laboratory Settings** panel.
	If the box is not checked, the information for an invalid assay will not be exported.
	See "Determining if calibrator and quality control results are exported for failed assays," page 119, for additional instructions.
	Note: Only users with supervisor access level may modify this function.
map the assay protocols according to the parameters specified in the LIS	the **Map Orders…** button. The **LIS Assay Protocol Map** dialog box opens.
	See "Setting up bidirectional communication," page 117, for additional instructions.
	Note: Only users with supervisor access level may modify this function.

6.7.1 Using the **Audit Log** window

The *digene* HC2 System Software includes an audit log of certain events to track changes and to make troubleshooting easier. Open the **Audit Log** window by clicking the **Audit Log** button in the **Audit Log** panel on the **Utilities/Settings** tab. The information displayed in the **Audit Log** window can be filtered to refine the information displayed. Actions that are tracked as part of specimen history are not included in the audit log.

The following events are included in the audit log:

- Assay protocol parameter modified
- Assay protocol deleted
- Assay protocol removed from a plate
- Patient deleted
- Kit lot deleted
- Quality control parameters modified
- Quality control moved on a plate
- Quality control removed from a plate
- Quality control deleted

- Specimen information changed

- Specimen moved on a plate

- Specimen removed from a plate

- Specimen re-measured

- Specimen deleted

- Plate re-measured

- Plate deleted

- User account locked

See "Viewing the audit log," page 219, for additional instructions.

Example of the **Audit Log** window:
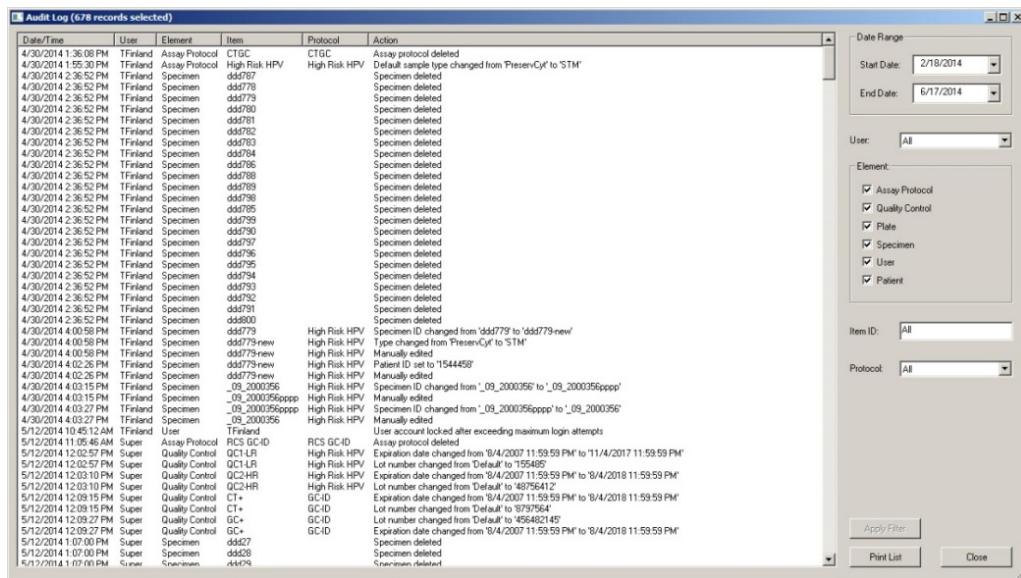
The following table describes the actions that can be performed in the **Audit Log** window.

To...	Click or select...
select a specific date range for the audit log	the applicable parameters in the **Start Date:** and **End Date:** dialog fields in the **Date Range** panel.
select a specific user for the audit log	the applicable user in the **User:** drop-down list. **Note**: The default setting is **All**.

To...	Click or select...
include in the audit log the actions applicable to assay protocols	the **Assay Protocol** box in the **Element:** panel.
include in the audit log the actions applicable to quality controls	the **Quality Control** box in the **Element:** panel.
include in the audit log the actions applicable to plates	the **Plate** box in the **Element:** panel.
include in the audit log the actions applicable to specimens	the **Specimen** box in the **Element:** panel.
include in the audit log the actions applicable to users	the **User** box in the **Element:** panel.
include in the audit log the actions applicable to patients	the **Patient** box in the **Element:** panel.
enter a specific parameter for the audit log	the applicable parameter in the **Item ID:** dialog field. **Note**: The default setting is **All**; leaving the dialog field blank is equal to having **All** in the dialog field.
select a specific assay protocol for the audit log	the applicable assay protocol in the **Protocol:** drop-down list. **Note**: The default setting is **All**.
apply the filters specified for the audit log	the **Apply Filter** button.
print the displayed audit log	the **Print List** button. The **QIAGEN Report Viewer** window displays the list. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.
close the **Audit Log** window	the **Close** button.

6.8   Using the **Luminometer Settings** tab

The **Luminometer Settings** tab is used to:

- Manage the settings for the DML instruments
- Perform DML instrument diagnostic tests
- Test the connection between the HC2 System computer and the DML instrument

Only users with supervisor access level can perform the functions available on the **Luminometer Settings** tab. See "Managing the DML instrument," page 119, for additional instructions.

6.8.1   Using the **Luminometer Settings** tab with a DML 3000

Example of the **Luminometer Settings** tab for the DML 3000:

The following table describes the actions that can be performed on the **Luminometer Settings** tab for the DML 3000.

To...	Click or select...
change the current DML instrument used to measure a plate	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel.
add a new DML instrument	the **Add Luminometer** button in the **Luminometer Selection** panel. The **Luminometer Settings** dialog box opens. See "Adding a DML instrument," page 120, for additional instructions.
delete a DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Remove Luminometer** button. See "Deleting a DML instrument," page 125, for additional instructions.
set the *digene* HC2 System Software to perform a mechanical test of the DML instrument automatically when a user logs in or the user is changed	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and check the **Perform mechanical test on startup box** in the **Mechanical Test Settings** panel. See "Performing a mechanical test," page 122, for additional instructions.
display the results of the mechanical test immediately after the mechanical test is complete	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and check the **Display mechanical report after completion box** in the **Mechanical Test Settings** panel. See "Performing a mechanical test," page 122, for additional instructions.
modify the settings of a DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Settings…** button. The **Luminometer Settings** dialog box opens. See "Modifying the settings of a DML instrument," page 121, for additional instructions.

To...	Click or select...
perform a mechanical test	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Perform Mechanical Test** button in the **Luminometer Actions** panel.
	See "Performing a mechanical test," page 122, for additional instructions.
manually control the DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Luminometer Controls…** button in the **Luminometer Actions** panel.
	See "Controlling the DML instrument manually," page 125, for additional instructions.

6.8.2   Using the **Luminometer Controls** dialog box with a DML 3000

The DML 3000 can be manually controlled to determine if the instrument is functioning correctly. The DML 3000 is controlled using the **Luminometer Controls** dialog box. The **Luminometer Controls** dialog box is accessed on the **Luminometer Settings** tab by selecting the DML instrument from the **Luminometer Selection** drop-down list and clicking the **Luminometer Controls…** button. Only users with supervisor access level can perform the functions available using the **Luminometer Controls** dialog box.

Example of the **Luminometer Controls** dialog box for the DML 3000:

The following table describes the actions that can be performed in the **Luminometer Controls** dialog box for the DML 3000.

To...	Click or select...
get the status of the DML instrument	the **Get Status** button. The information in the **Luminometer Controls** dialog window will update on the current status of the DML instrument.
move the plate carrier to the home position	the **Move Home** button.
measure a specific well location	the specific location on the plate using the drop-down lists in the **Functions** panel and click the **Read Well** button. The RLU result displays in the dialog field below the drop-down lists.
turn off the stepper motor for the plate carrier	the **Motor Off** button.
close the **Luminometer Controls** dialog box	the **Close** button.

The following table describes the features that are available in the **Luminometer Controls** dialog box for the DML 3000.

Feature	Function
Door Closed box	If this box is checked, the door was closed during the last status check of the DML instrument. If the box is not checked, the door was open during the last status check of the DML instrument.
Communicating box	If this box is checked, the DML instrument is currently communicating with the HC2 System computer. If the box is not checked, the DML instrument is currently not communicating with the HC2 System computer.

6.8.3 Using the **Luminometer Settings** tab with a DML 2000

Example of the **Luminometer Settings** tab for the DML 2000:

The following table describes the actions that can be performed on the **Luminometer Settings** tab for the DML 2000.

To...	Click or select...
change the current DML instrument used to measure a plate	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel.
add a new DML instrument	the **Add Luminometer** button in the **Luminometer Selection** panel. The **Luminometer Settings** dialog box opens. See "Adding a DML instrument," page 120, for additional instructions.
delete a DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Remove Luminometer** button. See "Deleting a DML instrument," page 125, for additional instructions.

To...	Click or select...
set the *digene* HC2 System Software to perform a mechanical test of the DML instrument automatically when a user either logs in or is changed	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and check the **Perform mechanical test on startup** box in the **Mechanical Test Settings** panel. See "Performing a mechanical test," page 122, for additional instructions.
display the results of the mechanical test immediately after the mechanical test is complete	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and check the **Display mechanical report after completion box** in the **Mechanical Test Settings** panel. See "Performing a mechanical test," page 122, for additional instructions.
display the results of the plate background (10) reading during plate measurement	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and check the **Show plate background in measure window** box in the **Luminometer Background** panel. See "Understanding the plate background (10) reading," page 124, for additional instructions.
specify a minimum RLU value that will cause the DML instrument to re-measure a well	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and enter an RLU value in the **Re-measure Minimum:** dialog field of the **Background Baseline** subpanel. Any well measured with an RLU value less than the specified parameter will be measured three times and the average reported as the RLU.
modify the background offset	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and enter an RLU value in the **Background Offset:** dialog field in the **Background Offset** subpanel. See "Understanding the background baseline (100) reading," page 122, for additional instructions.

To...	Click or select...
modify the settings of a DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Settings...** button. The **Luminometer Settings** dialog box opens. See "Modifying the settings of a DML instrument," page 121, for additional instructions.
perform a mechanical test	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Perform Mechanical Test** button in the **Luminometer Actions** panel. See "Performing a mechanical test," page 122, for additional instructions.
perform the background baseline (100) reading	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Set Background Baseline (100)** button. See "Performing a background baseline (100) reading," page 123.
set the frequency of background baseline (100) reading reminders	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Background Baseline Reminder Frequency...** button. The **Baseline Background Frequency** dialog box opens. See "Setting the frequency of background baseline (100) reading reminders," page 123, for additional instructions.
manually control the DML instrument	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Luminometer Controls...** button in the **Luminometer Actions** panel. The **Luminometer Controls** dialog box opens. See "Controlling the DML instrument manually," page 125, for additional instructions.

The following table describes the features that are available on the **Luminometer Settings** tab for the DML 2000.

Feature	Function
Last plate background (10): and **RLUs taken on** dialog fields in the **Background Baseline** subpanel	Displays the result and date of the last plate background (10) reading for the DML instrument selected in the **Luminometer Selection** panel.
Last Background Baseline (100): and **RLUs taken on** dialog fields in the **Background Baseline** subpanel	Displays the result and date of the last background baseline (100) reading for the DML instrument selected in the **Luminometer Selection** panel.
Background Max: dialog field in the **Background Offset** subpanel	Displays the maximum RLU for the plate background (10) reading result. See "Understanding the plate background (10) reading," page 124, for additional instructions.
Background Min: dialog field in the **Background Offset** subpanel	Displays the minimum RLU for the plate background (10) reading result. See "Understanding the plate background (10) reading," page 124, for additional instructions.

6.8.4   Using the **Luminometer Controls** dialog box with a DML 2000

The DML 2000 can be manually controlled to determine if the instrument is functioning correctly. The DML 2000 is controlled using the **Luminometer Controls** dialog box. The **Luminometer Controls** dialog box is accessed on the **Luminometer Settings** tab by selecting the DML instrument from the **Luminometer Selection** drop-down list and clicking the **Luminometer Controls…** button. Only users with supervisor access level can perform the functions available using the **Luminometer Controls** dialog box.

Example of the **Luminometer Controls** dialog box for the DML 2000:

The following table describes the actions that can be performed in the **Luminometer Controls** dialog window for the DML 2000.
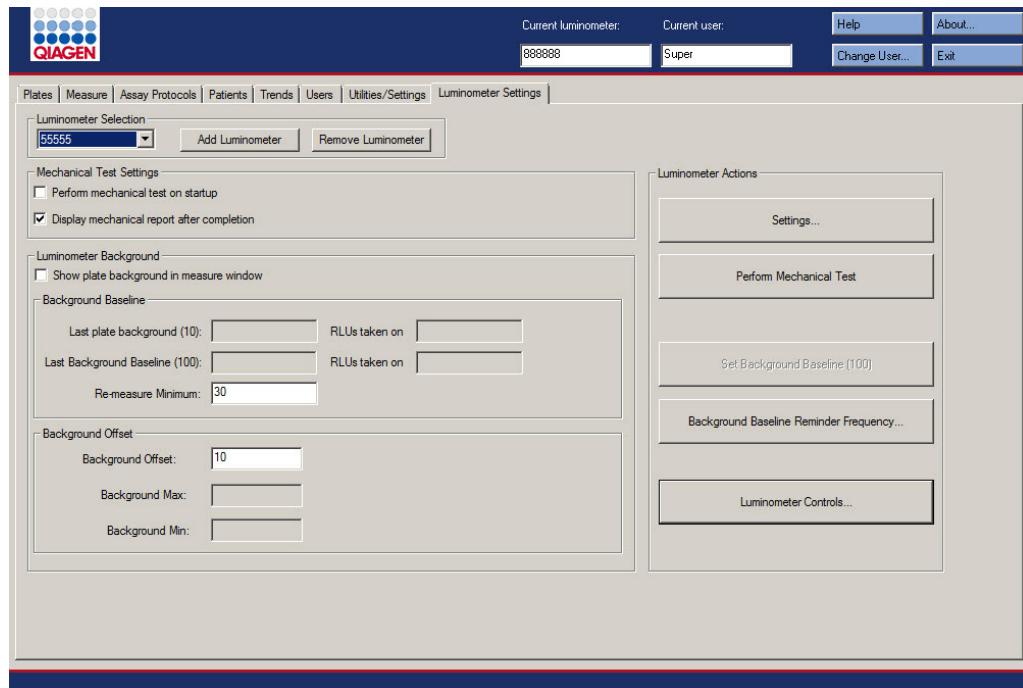
To...	Click or select...
get the status of the DML instrument	the **Get Status** button in the **Status** panel. The information in the **Luminometer Controls** dialog window will update with the current status of the DML instrument.
move the plate carrier to the home position	the **Move Home** button in the **Movement** panel.
move the plate carrier to a specified location	the specific location on the plate using the drop-down lists in the **Movement** panel and click the **Move To** button.
determine the location of the plate carrier	the **Get Position** button in the **Movement** panel. The position of the plate carrier is displayed in the dialog field below the **Get Position** button. **Note**: **RR** is the home position.
measure the well at the current location of the plate carrier	the **Get Value** button in the **Functions** panel. The RLU result displays in the dialog field below the **Get Value** button.
turn off the stepper motor for the plate carrier	the **Motor Off** button in the **Functions** panel.
open the iris	the **Open Iris** button in the **Functions** panel.

To...	Click or select...
close the iris	the **Close Iris** button in the **Functions** panel.
close the **Luminometer Controls** dialog box	the **Close** button.

The following table describes the features that are available in the **Luminometer Controls** dialog box for the DML 2000.

Feature	Function
Door Closed box	If this box is checked, the door was closed during the last status check of the DML instrument. If the box is not checked, the door was open during the last status check of the DML instrument.
Iris Closed box	If this box is checked, the iris was closed during the last status check of the DML instrument. If the box is not checked, the iris was open during the last status check of the DML instrument.
X at Home box	If this box is checked, the plate carrier was in the home position for the X-axis during the last status check of the DML instrument. If the box is not checked, the plate carrier was not in the home position for the X-axis during the last status check of the DML instrument.
Y at Home box	If this box is checked, the plate carrier was in the home position for the Y-axis during the last status check of the DML instrument. If the box is not checked, the plate carrier was not in the home position for the Y-axis during the last status check of the DML instrument.
Communicating box	If this box is checked, the DML instrument is currently communicating with the HC2 System computer. If the box is not checked, the DML instrument is currently not communicating with the HC2 System computer.

6.9   Using the **QIAGEN Report Viewer** window

The **QIAGEN Report Viewer** window displays reports.

Modifying the default settings of the report may truncate information. Do not change the size of the report as information will not be truncated if the default settings are used.

An example of the menu bar that opens at the top of the **QIAGEN Report Viewer** window:
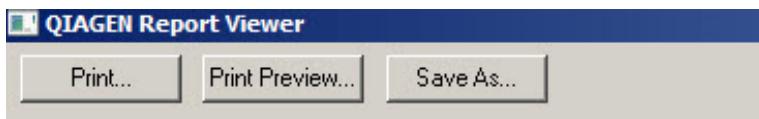
The following table describes the actions that can be performed using the **QIAGEN Report Viewer** window.

To...	Click or select...
print the displayed report to the default printer	the **Print…** button.
preview the displayed report in print format	the **Print Preview…** button. The **Print Preview** window opens displaying the report. Use the icons in the menu bar to modify the parameters for printing the report.
save the displayed report as a *.csv file	the **Save As…** button. The **Save File As** dialog box opens. Select the directory to which the file will be saved and enter the file name in the **File name:** dialog field. Click the **Save** button. A dialog box opens confirming the file was saved. Click **OK**.
exit the **QIAGEN Report Viewer** window	click the **Close** button.

7 General Operation

The *digene* HC2 System Software works with a DML instrument to measure a capture plate. In the absence of the DML instrument, the *digene* HC2 System Software can still perform all functions that do not require a DML instrument.

Performing a test using the *digene* HC2 System Software involves the following tasks:

- Creating a hybridization plate in the *digene* HC2 System Software
- Associating a capture plate with a hybridization plate
- Measuring the capture plate using the DML instrument
- Generating reports to view the test results
- Accepting the results of testing
- Transmitting the data to an LIS or to file

7.1 Starting the *digene* HC2 System

Starting the *digene* HC2 System involves powering ON the HC2 System computer and components and logging into the *digene* HC2 System Software.

When started, the *digene* HC2 System Software analyzes the available space on the hard disk on which it is installed, typically the **C:** drive. If less than 20% of the hard disk space is available, a dialog box opens that defines the current available free space and suggests removing data. The performance of the *digene* HC2 System Software may suffer if less than 20% of the hard disk space is available. To remove data, the archives containing the data must be removed using the operating system. See "Creating an archive," page 216, and "Backing up data," page 214, for additional instructions.

The *digene* HC2 System Software installs with one user that has supervisor access level. Use the following case-sensitive credentials to log in to the *digene* HC2 System Software the first time:

- User ID: Super
- Login password: Super1234

Once logged in the first time, the *digene* HC2 System Software will prompt to enter a new login password for the "Super" user ID.

1. Power ON the *digene* HC2 System hardware components.

   Refer to the respective user manuals for additional instructions.

2. Log in to the Windows operating system.

   Note: If logging into the Windows operating system for the first time, see "Setting up the Windows operating system," page 22, for additional instructions.

3. Start the *digene* HC2 System Software by double-clicking the *digene* HC2 System Software icon on the Windows desktop.

   Note: The *digene* HC2 System Software can also be started by clicking the Windows **Start** menu, selecting **All Programs**, selecting **HC2 System Software** and selecting **HC2 System Software v3.4**.

4. In the **User Login** dialog box, enter the user ID and login password in the applicable dialog fields and select the applicable serial number of the DML instrument from the **Luminometer Serial Number:** drop-down list.

   Notes:

   - If a DML instrument cannot be selected, see "Adding a DML instrument," page 120, for additional instructions to add a DML instrument once logged in.
   - The login password for the user ID can be changed from the **User Login** dialog box by checking the **Change Password** box. The **Old Password:**, **New Password:** and **Confirm Password:** dialog fields appear. Enter the applicable information.

5. Click **OK**.

   The *digene* HC2 System Software opens with the **Plates** tab at the forefront.

7.2   Shutting down the *digene* HC2 System

Shutting down the *digene* HC2 System hardware is optional; the *digene* HC2 System hardware components may be left powered ON without adverse effect.

Recommendation: Leave the *digene* HC2 System Software powered ON to maintain optimal performance.

1. Click the **Exit** button in the *digene* HC2 System Software window. Alternatively, click the **X** button in the upper-right corner of the window.

   A dialog box opens to confirm the exit of the *digene* HC2 System Software.

2. Select the applicable response to close the *digene* HC2 System Software.

3. Power OFF the DML instrument and printer and shut down the HC2 System computer.

7.3 Managing users

A user ID and login password are required to use the *digene* HC2 System Software. User IDs have an associated access level, either operator or supervisor, that determines the software functions the user can perform. Using individual user IDs with the *digene* HC2 System Software provides control over software functions based on the access level of the user. The *digene* HC2 System Software requires at least one user have the access level of supervisor.

Once a user is created, the user cannot be deleted from the *digene* HC2 System Software; however, a user can be inactivated.

Users with operator access level can perform the following functions:

● View assay protocol parameters
● Manage specimens
● Export a list of unmeasured specimens
● Manage patients
● Create and manage plates
● Import a plate
● Associate capture and hybridization plates
● Create and manage quality controls and test kit lots
● Delete unmeasured plates
● Measure capture plates
● Perform raw data measurements
● Generate reports
● Accept results, based on the setting
● Transmit accepted results to an LIS or to file
● View trend reports
● View the audit log
● Archive data and view archived data

Users with supervisor access level can perform all operator access level functions along with the following functions:

● Manage users
● Manage the settings of the *digene* HC2 System Software
● Specify the default specimen type for an assay protocol

- Delete assay protocols
- Set capture plates to re-measure
- Set specimens to re-measure
- Accept results
- Manage the DML instruments
- Manage the export settings of results

7.3.1 Creating a user

Recommendation: Reserve the user ID and login password combination of the "Super" user ID for QIAGEN Technical Services. Do not use this user ID to perform testing.

Only users with supervisor access level can perform the following procedure.

1. On the **Users** tab, click the **New…** button.

   The **User ID Entry** dialog box opens.

2. Enter the new user ID in the **Enter new User ID:** dialog box.

   Note: The user ID must consist of alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens with a minimum of 5 characters and a maximum of 25 characters.

3. Click **OK**.

   The **Create User** dialog box opens.

4. Enter the login password for the user in the **Password:** and **Confirm password:** dialog boxes.

   Notes:

   - The login password is case-sensitive and must consist of at least 8 alphanumeric characters or special symbols [~ ! @ # $ % ^ & * ( ) _ + = - ` : ; , .] as well as one uppercase character, one lowercase character and one numerical character.
   - The maximum length of the login password is 16 characters.

5. Using the **User Type:** drop-down list, select either the **Operator** or **Supervisor** access level.

6. Enter the first name and last name for the user in the **First Name:** and the **Last Name:** dialog boxes.

7. Enter the eSign password for the user in the **eSign Password:** and **eSign Confirm password:** dialog boxes.

   Notes:

   - The eSign password is case-sensitive and must consist of at least 8 alphanumeric characters or special symbols [~ ! @ # $ % ^ & * ( ) _ + = - ` : ; , .] as well as one uppercase character, one lowercase character and one numerical character.
   - The maximum length of the eSign password is 16 characters.
   - The eSign password must differ from the login password.

8. Make sure the **Account Active** box is checked to allow the user to perform actions in the *digene* HC2 System Software.

9. Click **OK**.

   The **Users** tab displays the user ID in the list.

   Note: As a different user created the login password, the newly created user will be required to change the login password upon logging in to the *digene* HC2 System Software for the first time.

7.3.2   Modifying a user

Once created, a user cannot be deleted from the *digene* HC2 System Software; however, a user can be deactivated. A deactivated user will not display in the **User ID:** drop-down list of the **User Login** dialog box and cannot log in to the *digene* HC2 System Software.

Based on the allowed login attempts setting, a user can lock the account by using an incorrect password. The user can only be activated if another user with supervisor access level logs in to the *digene* HC2 System Software and unlocks the account. If another user with supervisor access level is not available, contact QIAGEN Technical Services for assistance.

Only users with supervisor access level can perform the following procedure. The user logged in to the *digene* HC2 System Software cannot modify their own user account.

1. On the **Users** tab, highlight the user ID to modify and click the **Edit…** button.

   The **Edit User** dialog box opens.

2. Edit the login password using the **Password:** and **Confirm password:** dialog boxes, as applicable.

   Notes:

   - Based on the password history depth setting, the login password cannot be any of the defined number of previous login passwords.
   - The login password is case-sensitive and must consist of at least 8 alphanumeric characters or special symbols [~ ! @ # $ % ^ & * ( ) _ + = - ` : ; , .] as well as one uppercase character, one lowercase character and one numerical character.
   - The maximum length of the login password is 16 characters.
   - As a different user modified the login password, the modified user will be required to change the login password at the next log in to the *digene* HC2 System Software.

3. Edit the user access level by selecting the applicable access level from the **User Type:** drop-down list, as applicable.

4. Edit the eSign password using the **eSign Password:** and **eSign Confirm password:** dialog boxes, as applicable.

   Notes:

   - Based on the password history depth setting, the eSign password cannot be any of the defined number of previous eSign passwords.
   - The eSign password is case-sensitive and must consist of at least 8 alphanumeric characters or special symbols [~ ! @ # $ % ^ & * ( ) _ + = - ` : ; , .] as well as one uppercase character, one lowercase character and one numerical character.
   - The maximum length of the eSign password is 16 characters.
   - The eSign password must differ from the login password.
   - As a different user modified the eSign password, the modified user will be required to change the eSign password at the next use of the eSign password.

5. If the user is locked, uncheck the **Account Locked** box, as applicable.

6. Activate or deactivate the user by check or unchecking the **Account Active** box, as applicable.

   Note: If deactivated, the user ID will not display in the **User Login** dialog box and cannot log in to the *digene* HC2 System Software.

7. Click **OK**.

   The *digene* HC2 System Software returns to the **Users** tab.

7.4 Setting the security parameters

The *digene* HC2 System Software is equipped with multiple optional security features. The security features are found on the **Users** tab. Only users with supervisor access level can modify the security parameters.

7.4.1 Setting the inactivity timer

The inactivity timer logs a user out of the *digene* HC2 System Software after the specified time of inactivity has occurred. The *digene* HC2 System Software remains at the function that was being performed when the inactivity timer reached the maximum. The inactivity timer feature is suspended during plate measurement.

Once inactivated, the **User Login** dialog box opens, and any user may log in to the *digene* HC2 System Software; the same user is not required to log in to the *digene* HC2 System Software. The *digene* HC2 System Software cannot be exited while inactivated; a user must log in to exit the *digene* HC2 System Software. If a different user logs in with an access level that is unable to perform the unsaved function, the modification that was started will not be saved.

Important: Do not leave the *digene* HC2 System Software open with unsaved modifications to avoid loss of changes.

The default setting for the inactivity time is 30 minutes. The allowed parameter for the inactivity timer is from 1 to 60 minutes. Modify the inactivity timer using the **Inactivity Timer (min):** dialog field on the **Users** tab. Deactivate the inactivity timer by unchecking the **Inactivity Timer (min):** box.

7.4.2 Setting the password expiration

The password expiration setting defines the number of days before a user must change their password. Once the password has expired, the user will be prompted to change the applicable password at the next use of the password. The password expiration setting applies to both the login and eSign passwords; however, the setting for each of the passwords is tracked separately.

The default setting for the password expiration is 90 days. The allowed parameter for the password expiration is from 15 to 120 days. Modify the password expiration setting using the **Password Expiration (days):** dialog field on the **Users** tab. Deactivate the password expiration by unchecking the **Password Expiration (days):** box.

7.4.3   Setting the allowed login attempts

The allowed login attempts setting defines the number of times a user can incorrectly attempt to log in using an incorrect password before the user account is locked. The allowed login attempts setting applies to both the login and eSign passwords, and the setting for each of the passwords is tracked separately. Once a user account is locked, a user with supervisor access level must log in and unlock the account. See "Modifying a user," page 109, for additional instructions.

The default setting for the allowed login attempts is 5. The allowed parameter for the login attempts is from 1 to 10. Modify the allowed login attempts setting using the **Allowed Login Attempts:** dialog field on the **Users** tab. Deactivate the allowed login attempts by unchecking the **Allowed Login Attempts:** box.

7.4.4   Setting the password history depth

The password history depth setting defines the number of previous passwords that may not be used when changing a password. The setting applies to both the login and eSign passwords. The user will be prompted to change the password if using one of the previous passwords. The default setting for the password history depth is 5. The allowed parameter for the password history depth is from 5 to 15. Modify the password history depth setting using the **Password History Depth:** dialog field on the **Users** tab. Deactivate the password history depth by unchecking the **Password History Depth:** box.

7.5   Setting up the *digene* HC2 System Software

A user with supervisor access level should configure the *digene* HC2 System Software according to laboratory requirements. The various settings should be reviewed and modified, as applicable, before using the *digene* HC2 System Software. Pay special attention to the parameters on the **Utilities/Settings** tab. See "Using the **Utilities/Settings** tab," page 85, for additional information.

7.5.1   Determining the access level required to accept results

Accepting results means an authorized user has determined that the results associated with a capture plate are acceptable to be reported as test results. Once the results are accepted, the test results cannot be modified, and the results are automatically added to the database for trending. See "Accepting results," page 198, for additional instructions. Only users with supervisor access level can determine the access level required to accept results. A user with supervisor access level can always accept results. To restrict accepting results to only users with supervisor access level, check the **Allow only Supervisor acceptance of results** box on the **Utilities/Settings** tab. If the

Allow only Supervisor acceptance of results box is not checked, users with operator access level are able to accept results.

7.5.2 Modifying the prompt during plate measurement

At the start of plate measurement, the **Insert Plate for Measurement** dialog box opens which includes the **RCS Serial Number:** dialog field. If RCS-automated testing was performed with the capture plate being measured, the Rapid Capture® System (RCS) serial number should be included as part of the information for the capture plate; however, if RCS-automated testing was not performed, no RCS serial number is available.

Users with operator or supervisor access level can modify the setting for the RCS serial number. To activate the **RCS Serial Number:** dialog field, check the **Prompt for RCS Serial Number on Measure** box on the **Utilities/Settings** tab; to inactivate the **RCS Serial Number:** dialog field, uncheck the **Prompt for RCS Serial Number on Measure** box on the **Utilities/Settings** tab.

After an RCS serial number is entered, the **RCS Serial Number:** dialog field will default to the entered RCS serial number for consecutive plate measurements.

7.5.3 Modifying the laboratory information

The laboratory information displays on the header of all reports. The *digene* HC2 System Software uses the specified laboratory name as the validator on custom assay protocols and reports listing the assay protocol. Only users with supervisor access level can modify the laboratory information.

1. On the **Utilities/Settings** tab, click the **Change…** button.

   The **Edit Laboratory Information** dialog box opens.
2. Enter the applicable laboratory name in the **Name/Customized Assay Protocol** dialog field.

   Important: Do not use "QIAGEN" in the name.

   Note: Limit the name to a maximum of 20 characters to make sure the name fits in the printing area of the report.
3. In the **Header:** dialog field, type the information that is desired to display on all reports, such as the laboratory's name, address, phone number and fax number.

   Note: Limit the header information to 4 lines of 50 alphanumeric characters.
4. Click **OK**.

   The *digene* HC2 System Software returns to the **Utilities/Settings** tab, and the information displays in the respective dialog fields.

7.5.4 Managing the archive settings

Creating an archive removes accepted plates from the current data displayed in the *digene* HC2 System Software. During the creation of an archive, all accepted plates are copied to the archive and any plates that do not require further actions are removed from the current data.

The **LIS Interface Active** box on the **Utilities/Settings** tab determines if plates that have not been exported can be removed from the current data. If the **LIS Interface Active** box is checked, only plates that have been exported will be removed from the current data displayed in the *digene* HC2 System Software. If the **LIS Interface Active** box is not checked, all accepted plates that do not require further action will be removed from the current data displayed in the *digene* HC2 System Software.

An archive reminder can display upon opening the *digene* HC2 System Software if the archive frequency limit has been reached. It is recommended that an archive is performed when the archive reminder opens, but it is optional. A large amount of data may slow the *digene* HC2 System Software.

The available settings for the archive reminder frequency are:

- Never
- Monthly
- Quarterly
- Every **X** plates

The default archive reminder frequency is every 100 plates.

Recommendation: Set the archive reminder frequency to every 100 plates.

Only users with supervisor access level can perform the following procedure.

1. On the **Utilities/Settings** tab, click the **Archive Frequency…** button in the **Archiving** panel.

   The **Archive Frequency** dialog box opens.
2. Select the applicable radio button in the **Reminder Frequency** panel.

   Note: The every **X** plates option counts the number of accepted plates.
3. Click **OK**.

   The *digene* HC2 System Software returns to the **Utilities/Settings** tab.

7.5.5 Setting up the RCS Bar Code Reader directory

The RCS can be modified to include an RCS Bar Code Reader that automatically associates the plate IDs of the hybridization and capture plates processed on the RCS. For more information about the RCS Bar Code Reader, see "Associating a capture plate automatically," page 168, for additional instructions.

Only a QIAGEN representative can install the RCS Bar Code Reader Upgrade Package. Do not attempt to install the hardware components, the RCS scripts or the software application. Contact QIAGEN Technical Services for assistance.

For plate association to occur, the directory containing the import mapping files must be specified. The *digene* HC2 System Software is capable of monitoring 2 different directories. During the installation of the RCS Bar Code Reader Upgrade Package, a QIAGEN representative will set up the correct directory in the *digene* HC2 System Software. The following instructions are included in case the directory must be changed.

Only users with supervisor access level can perform the following procedure.

1. On the **Utilities/Settings** tab, click the **Browse…** button beside either the **RCS1 Barcode Directory:** or **RCS2 Barcode Directory:** dialog fields.

    The **Select Path** dialog box opens.

2. Click the **Browse** button.

    The **Browse for Folder** dialog box opens.

3. Using the directory, navigate to the folder that will contain the import mapping files.

    Note: The import mapping files have an *.imf file extension.

4. Click **OK**.

    The **Browse for Folder** dialog box closes.

5. In the **Select Path** dialog box, click **OK**.

    The **Select Path** dialog box closes, and the mapping of the folder is displayed in the dialog field.

7.6 Managing the data export settings

To export results to an LIS, the data interface between the *digene* HC2 System Software and an LIS must be programmed so that the data transmitted by the *digene* HC2 System Software can be parsed into reportable results by the testing laboratory.

Contact your laboratory's Information Technology (IT) department to set up the connection between the HC2 System computer and an LIS. Refer to digene *HC2 System Software Data Interface Guide* for more information.

Note: The firewall on the HC2 System computer has been configured to block all incoming connections. When configuring the connection to an LIS, IT personnel must configure the firewall settings appropriately.

Once the data interface is set up, the LIS connection settings and the LIS laboratory settings must be configured in the *digene* HC2 System Software. Only users with supervisor access level can manage the LIS connection for data export.

The **LIS Connection Settings** panel on the **Utilities/Settings** tab is used to configure the data export settings. The *digene* HC2 System Software can be configured to export data in accordance with the following standards:

● Clinical and Laboratory Standards Institute® (CLSI) standards LIS01-A2 and LIS2-A2

● Health Level 7 (HL7) and the Minimal Low Layer Protocol (MLLP) standards

7.6.1 Setting up data export using the CLSI standards

The applicable CLSI standards are referenced in the *digene* HC2 System Software and in this user manual as "ASTM" and "E 1394-97" as the standards previously used and referenced were ASTM E1394-97 and ASTM E1381.

Export data using the following methods:

● To export to file, select **ASTM (File)** from the **Connection Protocol:** drop-down list.

   Note: The exported data are saved in a file named after the hybridization plate ID and not the capture plate ID.

● To export using a serial port connection, select **ASTM (Serial)** from the **Connection Protocol:** drop-down list. Using the **Serial Port Connection:** drop-down list, select the applicable serial port connection. Click the **Test Connection** button to determine if the connection is functioning

properly. If functioning properly, a dialog box opens stating the connection with the LIS host has been established.

7.6.2 Setting up data export using the HL7 standards

Export data using the following methods:

- To export to file, select **HL7 (File)** from the **Connection Protocol:** drop-down list.

  Note: The exported data are saved in a file named after the hybridization plate ID and not the capture plate ID.

- To export using an Ethernet connection, select **HL7 (Ethernet)** from the **Connection Protocol:** drop-down list. Enter the applicable information in the **TCP/IP Transmit Port** and **TCP/IP Receive Address/Port** dialog boxes. Click the **Test Connection** button to determine if the connection is functioning properly. If functioning properly, a dialog box opens stating the connection with the LIS host has been established.

7.6.3 Setting up bidirectional communication

The *digene* HC2 System Software can use the data interface to query the LIS for test orders. The *digene* HC2 System Software will only receive test orders of specimens along with the associated patient and assay protocol information; a plate layout cannot be received. The **LIS Laboratory Settings** panel on the **Utilities/Settings** tab is used to configure the query settings.

Important: Specimens received as a result of a query from the LIS are given the default specimen type associated with the applicable assay protocol. Make sure specimens transmitted from the LIS are associated with the correct specimen type.

The *digene* HC2 System Software must query the LIS for information; the transmission of unsolicited information is not accepted. The query will request test orders for the previous 7 days. The setting for the query mode has the following options:

- Manually —clicking the **Query** button in the **Query Status** panel on the **Assay Protocols** tab
- Polling—query after an interval of time has passed
- Scheduled—query at up to 4 specified times

In addition to determining the query mode, the assay protocols must be mapped according to the parameters specified in the LIS for the query to occur. If a requested test order is not mapped, the test order is rejected.

1. Using the **Query Mode:** drop-down list in the **LIS Laboratory Settings** panel on the **Utilities/Settings** tab, select the query mode of **OFF (Transmit Only)**, **Manual**, **Polling** or **Scheduled**.

   Note: No further action is required if **OFF (Transmit Only)** is selected. No information will be received from the LIS.

2. If the **Polling** mode was selected, enter the applicable parameter in the **Polling Frequency (minutes):** dialog field.

   Note: The parameter must be between 5 and 60 minutes.

3. If the **Scheduled** mode was selected, check the applicable boxes and enter the times for the query to occur.

4. Click the **Map Orders…** button.

   The **LIS Assay Protocol Map** dialog box opens.

5. Select the assay protocol in the list and click the **Edit…** button.

   The **Edit Assay Protocol Map** dialog box opens.

6. Enter the applicable LIS name for the assay protocol in the **Order Mapping:** dialog field.

   Note: The LIS name for the assay protocol must appear in the order being received. The LIS name may be the same as the assay protocol ID in the *digene* HC2 System Software or defined by the laboratory.

7. Click **OK**.

   The **Edit Assay Protocol Map** dialog box closes.

8. Repeat steps 5 through 7 for each assay protocol that will receive test orders from the LIS.

9. Click **OK**.

   The **LIS Assay Protocol Map** dialog box closes. The *digene* HC2 System Software is now capable of bidirectional communication with the LIS.

7.6.4   Determining if preliminary results are exported

The exporting of preliminary results is configurable using the **Include Preliminary Results** box. To include preliminary results when exporting data, check the **Include Preliminary Results** box; to exclude preliminary results when exporting data, uncheck the **Include Preliminary Results** box. For more information about preliminary specimens, see "Understanding the retest algorithm," page 133, for additional information.

7.6.5 Determining if accepted results are automatically exported

The automatic exporting of accepted results is configurable using the **Automatically Transmit Results** box. To automatically transmit accepted results, check the **Automatically Transmit Results** box; to transmit accepted results manually, uncheck the **Automatically Transmit Results** box. For more information about accepting results, see "Accepting results," page 198, for additional information.

7.6.6 Determining if calibrator and quality control results are exported for failed assays

The inclusion of calibrator and quality control results during the data export of a failed assay is configurable using the **Transmit Calibrator and Quality Control Data for Failed Assays** box. To include the calibrator and quality control results, check the **Transmit Calibrator and Quality Control Data for Failed Assays** box; to exclude the calibrator and quality control results, uncheck the **Transmit Calibrator and Quality Control Data for Failed Assays** box. If the **Transmit Calibrator and Quality Control Data for Failed Assays** box is not checked, no information for a failed assay will be exported.

7.7 Using a hand-held bar code reader

QIAGEN recommends that either a PS/2- or USB-connected CCD bar code reader be used with the *digene* HC2 System Software. Check the HC2 System computer ports to determine the type of bar code reader needed and make sure that the selected bar code reader supports the bar code symbologies used in the laboratory.

Follow the installation instructions supplied by the manufacturer of the bar code reader. To function properly with the *digene* HC2 System Software, configure the bar code reader to automatically add a carriage return/line feed to the end of any scanned bar code.

7.8 Managing the DML instrument

The DML instrument measures the RLU of samples contained in a capture microplate placed in the instrument. The photomultiplier tube (PMT) is the component of the DML instrument used to detect light emitted by chemiluminescence.

The user cannot adjust the PMT or DML instrument as the PMT does not have a traceable standard for calibration. The assay acceptance criteria of the *digene* HC2 System is used to determine if

the DML instrument is performing within specification; therefore, if the results of a test meet the assay acceptance criteria, the DML instrument is functioning properly.

The LumiCheck Plate provides trend information of the DML instrument. On days of testing, perform a periodic check using the LumiCheck Plate prior to measuring the first microplate. Refer to *LumiCheck Plate and Software User Manual* for additional instructions.

The DML instrument is managed using the **Luminometer Settings** tab. See "Using the **Luminometer Settings** tab," page 94, for additional information.

7.8.1 Adding a DML instrument

The *digene* HC2 System Software can maintain the data for multiple DML instruments; however, only one DML instrument should be connected to the HC2 System computer at a time.

If adding a DML 2000, the following settings are specified during the manufacturing of the DML instrument and the user cannot modify these settings:

- **Settle Time:** — indicates the time to pause between the movement of the plate carrier and plate measurement
- **RLU Factor:** — the scale of the RLU reported by the DML instrument

1. On the **Luminometers Settings** tab, click the **Add Luminometer** button.

   The **Luminometer Settings** dialog box opens.
2. In the **COM Port:** drop-down list, select the communications port that connects the DML instrument to the HC2 System computer. Refer to the applicable DML instrument user manual to determine the COM port to select.
3. In the **Serial Number:** dialog field, enter the serial number of the DML instrument.

   Note: The serial number of the DML instrument is located on the back of the DML instrument.
4. In the **Instrument Type:** drop-down list, select the type of DML instrument.

   Important: Selecting the incorrect type will result in *digene* HC2 System Software or DML instrument errors.
5. If a DML 2000 is being added, enter the iris factor into the **Iris Factor:** dialog box.

   Note: The iris factor is a value specific to the DML instrument and is supplied on the Iris Factor Correction Sheet supplied with the DML instrument.
6. Click **OK**.

   The **Luminometer Settings** dialog box closes.

7. A dialog box will open to prompt for the performance of a mechanical test. See "Performing a mechanical test," page 122, for additional instructions.

   If a DML 2000 was added, a dialog box will open to prompt for the performance of a background baseline (100) reading. See "Understanding the background baseline (100) reading," page 122, for additional instructions.

   The DML instrument will be available for use with the *digene* HC2 System Software.

8. On the **Luminometer Settings** tab, click the **Luminometer Controls...** button in the **Luminometer Actions** panel.

   The **Luminometer Controls** dialog box opens.

   The communication of the *digene* HC2 System Software with the DML instrument is checked to make sure the DML instrument settings are correct.

9. For a DML 3000, select **H** and **12** from the drop-down lists in the **Functions** panel.

   For a DML 2000, select **H** and **12** from the drop-down lists in the **Movement** panel.

10. For a DML 3000, click the **Read Well** button in the **Functions** panel.

   For a DML 2000, click the **Move To** button in the **Movement** panel.

   If the DML instrument does not initialize, make sure the DML instrument settings are correct and check the connections between the HC2 System computer and the DML instrument.

   If the *digene* HC2 System Software communicates with the DML instrument, the DML instrument executes the command. The DML instrument is ready for use.

7.8.2   Modifying the settings of a DML instrument

The settings of a DML instrument are modified using the **Luminometer Settings** dialog box. Depending upon the DML instrument in use, See "Using the **Luminometer Settings** tab with a DML 3000," page 94, or "Using the **Luminometer Settings** tab with a DML 2000," page 98, for additional instructions.

1. On the **Luminometers Settings** tab, click the **Settings...** button in the **Luminometer Actions** panel.
   The **Luminometer Settings** dialog box opens.

2. Modify the parameters of the DML instrument and click **OK**.

   Note: Only the **COM Port:** dialog field may be modified for the DML 3000. The **COM Port:** and **Iris Factor:** dialog fields may be modified for the DML 2000.

3. Click the **OK** button.

   The **Luminometer Settings** dialog box closes.

7.8.3 Performing a mechanical test

A mechanical test for the DML instrument selected must have been completed and valid before a plate can be measured. During a mechanical test, the *digene* HC2 System Software:

- Checks the connection between the HC2 System computer and the DML instrument
- Moves the DML instrument plate carrier to the home position
- Opens and closes the iris of the DML instrument (DML 2000 only)

During the mechanical test, error messages will display if a problem is detected. For information about errors experienced during the mechanical test, refer to the applicable DML instrument user manual for additional information.

A mechanical test may be prompted when a user logs into the *digene* HC2 System Software if the **Perform mechanical test on startup** box is checked in the **Luminometer Settings** tab. See "Using the **Luminometer Settings** tab," page 94, for additional information.

A mechanical test can be performed at any time using the **Perform Mechanical Test** button on the **Luminometer Settings** tab. See "Using the **Luminometer Settings** tab," page 94, for additional information.

If the **Display mechanical test report after completion** box is checked on the **Luminometer Settings** tab, the **QIAGEN Report Viewer** window displays the mechanical test report after the mechanical test is completed. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.8.4 Understanding the background baseline (100) reading

The background baseline (100) reading only applies to the DML 2000. A background baseline (100) reading is a series of one hundred measurements that are averaged. The minimum, maximum and average measurements are reported and stored. Each time a new background baseline (100) reading is measured, the plate background (10) data are cleared.

Background baseline (100) readings are performed to establish the background offset parameters. The background maximum is determined by adding the background offset parameter to the average of the background baseline (100) readings; the background minimum is determined by subtracting the background offset parameter from the average of the background baseline (100) readings. The background offset parameter can be modified by the user; the

background maximum and background minimum parameters are automatically calculated based on the background offset parameter.

Recommendation: Do not exceed 20 for the background offset parameter.

The background maximum and minimum parameters are displayed in the **Background Offset** panel on the **Luminometer Settings** tab. The result and date of the most recent background baseline (100) reading is displayed in the **Background Baseline** panel on the **Luminometer Settings** tab. See "Using the **Luminometer Settings** tab with a DML 2000," page 98, for additional instructions.

The background offset parameters determine if the plate background (10) reading is within specification. See "Understanding the plate background (10) reading," page 124, for additional information.

7.8.5 Performing a background baseline (100) reading

Perform a background baseline (100) reading of the DML 2000 before using the instrument for the first time.

Note: A mechanical test must have been performed before a background baseline (100) reading can occur. See "Performing a mechanical test," page 122, for additional instructions.

1. On the **Luminometers Settings** tab, click the **Set Background Baseline (100)** button.

   After all background measurements are complete, the **QIAGEN Report Viewer** window opens with the background baseline (100) report. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

2. Make sure that the average background measurement is 80–500 RLU and the difference between the minimum and maximum measurements does not exceed 20 RLU.

   If the specified parameters are not met, contact QIAGEN Technical Services.

7.8.6 Setting the frequency of background baseline (100) reading reminders

A background baseline (100) reading reminder will display if the frequency limit has been reached. It is recommended that the background baseline (100) reading is performed when the reminder displays, but it is optional.

The available settings for the background baseline (100) reminder frequency are:

- 3 months
- Biannual
- Every **X** plates measured

The default setting is biannual.

The every **X** plates measured reminder is only reset after the reminder displays. Performing a background baseline (100) reading does not reset the reminder frequency. For example, if the setting is specified to display a reminder after every 50 plates are measured and a background baseline (100) reading is performed after 45 plates, the reminder to perform a background baseline (100) reading will display after 5 more plates are measured.

1. On the **Luminometer Settings** tab, click the **Background Baseline Reminder Frequency…** button in the **Luminometer Actions** panel.

   The **Baseline Background Frequency** dialog box opens.
2. Select the applicable radio button in the **Reminder Frequency** panel.
3. Click **OK**.

   The *digene* HC2 System Software returns to the **Luminometer Settings** tab.

7.8.7 Understanding the plate background (10) reading

The plate background (10) reading only applies to the DML 2000. The plate background (10) reading is a series of ten measurements that is performed immediately prior to capture plate measurement. The results of the reading are averaged and compared to the parameters displayed on the **Luminometer Settings** tab. For information about how the parameters are determined, see "Understanding the background baseline (100) reading," page 122, for additional instructions.

There are two possible outcomes of the plate background (10) reading:

- If the plate background (10) reading is within specification, the average RLU of the plate background (10) reading is subtracted from all subsequent RLU results of the plate measurement. The mean, maximum and minimum RLU values of the ten measurements are recorded in the trend database.
- If the plate background (10) RLU is not within specification, the *digene* HC2 System Software displays a message stating the plate background (10) is out of specification. The plate measurement may either be continued or canceled. If the plate measurement is continued, the average RLU of the plate background (10) reading is subtracted from all subsequent RLU results of the plate measurement. A statement that the plate background (10) is out of

specification displays on the assay report. See "Plate background errors," page 229, for additional instructions to troubleshoot plate background problems.

7.8.8 Controlling the DML instrument manually

The DML instrument can be manually controlled to determine if the instrument is functioning correctly. The DML instrument is controlled using the **Luminometer Controls** dialog box. Depending on the type of DML instrument, see "Using the **Luminometer Controls** dialog box with a DML 3000," page 96, or "Using the **Luminometer Controls** dialog box with a DML 2000," page 101, for additional instructions.

If the DML 3000 is not powered ON or is not connected to the HC2 System computer, a dialog box opens stating an error occurred during the initialization of the DML instrument.

7.8.9 Deleting a DML instrument

1. On the **Luminometer Settings** tab, select the applicable DML instrument serial number from the drop-down list in the **Luminometer Selection** panel.
2. Click the **Remove Luminometer** button.

   A dialog box opens to confirm the deletion of the DML instrument.
3. Select the applicable response to confirm the deletion of the DML instrument.

   The dialog box closes and the DML instrument serial number is deleted from the **Luminometer Selection** drop-down list.

7.9 Understanding assay protocols

The *digene* HC2 System uses assay protocols to maintain specific parameters and settings by which specimens are measured, analyzed and validated. Custom assay protocols are not validated or provided by QIAGEN.

All parameters of a custom assay protocol can be edited. The plate and column reports for a plate using a custom assay protocol have either **For Research Use Only** or **Validated by <Laboratory name>** in the header. The assay protocol ID is a unique identifier for an assay protocol.

The two types of assay protocols are non-consensus and consensus. A non-consensus assay protocol does not have a retest zone and all results are reported with a status of final.

A consensus assay protocol always has constituent tests and has a retest zone with a retest algorithm that is automatically tracked, as required, in the *digene* HC2 System Software.

7.9.1 Viewing assay protocol information

In addition to the instructions described below, assay protocol information can also be viewed from the **Create/Edit Layout** window by clicking the **View Assay Protocol…** button.

1. On the **Assay Protocols** tab, select an assay protocol ID in the **Custom Assay Protocols** panel and click the applicable **View…** button.

   The **View Custom Assay Protocol** dialog box opens displaying the settings for the selected assay protocol.

   Note: The displayed information cannot be modified. To modify the assay protocol, see "Modifying assay protocols," page 128, for additional instructions.

2. Click the various tabs to view the current settings.

   See "Using the **View Custom Assay Protocol** dialog box," page 71, for additional instructions.

3. Click the **Close** button.

   The **View Custom Assay Protocol** dialog box closes.

7.9.2 Printing and saving assay protocol information

1. On the **Assay Protocols** tab, select an assay protocol ID in the **Custom Assay Protocols** panel and click the applicable **View…** button.

   The **View Custom Assay Protocol** dialog box opens displaying the settings for the selected protocol.

   Note: The displayed information cannot be modified. To modify the assay protocol, see "Modifying assay protocols," page 128, for additional instructions.

2. Open the Windows Paint program.

3. Make the *digene* HC2 System Software the top window and simultaneously press **Alt** and **Print Screen** on the keyboard to capture the screenshot.

4. Paste the image into the Windows Paint program.

5. Print or save the image using the Windows Paint program.

6. Close the Windows Paint program.

7. In the *digene* HC2 System Software, click **Close** to return to the **Assay Protocols** tab.

7.10 Creating custom assay protocols

Create a custom assay protocol by either creating a new assay protocol ID and defining all the parameters of the assay protocol or by copying and renaming an existing assay protocol. Copying an assay protocol copies the parameters of the copied assay protocol.

7.10.1 Creating a custom assay protocol

1. On the **Assay Protocols** tab in the **Custom Assay Protocols** panel, click the **New…** button.

   The **Assay Protocol Type Selection** dialog box opens.

2. Click **OK**.

   The **Assay Protocol ID Entry** dialog box opens.

3. Enter a unique assay protocol ID in the **Enter new Assay Protocol ID:** dialog field and click **OK**.

   The **Edit Custom Assay Protocol** dialog box opens.

   Notes:

   - If the assay protocol ID is already in use, the *digene* HC2 System Software will prompt for a different assay protocol ID.
   - The assay protocol ID can be a maximum of 20 alphanumeric characters.

4. Modify the applicable parameters of the assay protocol.

   See "Using the **Edit Custom Assay Protocol** dialog box" dialog box," page 61, for additional instructions.

5. Click **OK**.

   The *digene* HC2 System Software returns to the **Assay Protocols** tab and the created assay protocol displays in the **Custom Assay Protocols** panel.

7.10.2 Creating a custom assay protocol by copying an existing assay protocol

1. On the **Assay Protocols** tab, select the assay protocol ID to be copied in either the **IVD Assay Protocols** or **Custom Assay Protocols** panels and click the **Copy…** button.

   The **Assay Protocol ID Entry** dialog box opens.

2. Enter a unique assay protocol ID in the **Enter new Assay Protocol ID:** dialog field and click **OK**.

   Notes:

   - If the assay protocol ID is already in use, the *digene* HC2 System Software will prompt for a different assay protocol ID.
   - The assay protocol ID can be a maximum of 20 alphanumeric characters.

3. If applicable, a dialog box opens regarding whether to copy the quality controls to the new assay protocol. Click the applicable selection on whether to copy the quality controls.

   The **Edit Custom Assay Protocol** dialog box opens.

4. Modify the applicable parameters of the assay protocols.

   See "Using the **Edit Custom Assay Protocol** dialog box," page 61, for additional instructions.

5. Click **OK**.

   The *digene* HC2 System Software returns to the **Assay Protocols** tab, and the created assay protocol displays in the **Custom Assay Protocols** panel.

7.11   Modifying assay protocols

The parameters of an assay protocol are modified using the **Edit Custom Assay Protocol** dialog box. The ability to modify a parameter of an assay protocol may be based on the access level of a user. See "Using the **Edit Custom Assay Protocol** dialog box," page 61, for additional instructions.

7.12   Deleting an assay protocol

Assay protocols can be deleted from the *digene* HC2 System Software. If an assay protocol is associated with any specimens, including specimens with a status of unassigned, the assay protocol cannot be deleted.

Users with operator or supervisor access level can perform the following procedure for custom assay protocols, however, a custom assay protocol can require a password if the assay protocol is password protected. Also, once deleted, a custom assay protocol cannot be restored.

1. On the **Assay Protocols** tab, select the assay protocol ID to be deleted from the **Custom Assay Protocols** panel.

2. Click the **Delete** button in the applicable panel.

   A dialog box opens to confirm the deletion.

3. Click the applicable button to delete the assay protocol.

   Note: If a *digene* HC2 System assay protocol is deleted, the assay protocol is retained in the assay protocol library directory and can be restored. See "Restoring *digene* HC2 System assay protocols," page 129, for additional instructions.

7.13   Restoring *digene* HC2 System assay protocols

If a *digene* HC2 System assay protocol is inadvertently deleted, install the *digene* HC2 System assay protocol from the assay protocol library using the following procedure. A custom assay protocol cannot be restored.

This function is only available to users with supervisor access level.

CAUTION	Loss of data
⚠	Always perform an archive prior to installing, restoring, or upgrading the *digene* HC2 System Software or *digene* HC2 System assay protocols.
	Data could be lost permanently if an archive is not performed.

1. Perform an archive of the data. See "Creating an archive," page 216, for additional instructions.
2. On the **Utilities/Settings** tab, click the **Install Assay Protocols…** button.

   The **Select Path** dialog box opens with **C:\Users\Public\QIAGEN\HC2 System Software\Protocol Library** in the **Select path for imported assay protocols** dialog box.
3. Click **OK**.

   The **Install Assay Protocols** dialog box opens.
4. Select the applicable assay protocols to install or click **Select All** to select the entire list of assay protocols.
5. Check or uncheck the **Install related Quality Control:** box, as applicable.
6. Click **Install**.

   The *digene* HC2 System Software installs the selected assay protocol and closes the **Install Assay Protocols** dialog box.

7.14 Understanding specimens

Each specimen is given a unique identifier called a specimen ID. A specimen ID must be unique in the specimen list of an assay protocol. Specimen IDs cannot exceed 30 characters and must consist of alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens. A specimen ID cannot start with a space or a hyphen.

Once a specimen ID is archived, the same unique identifier can be used again as a specimen ID.

Specimen IDs are created using one of the following methods:

● Entered manually using the **New/Edit Specimens** dialog box

● Scanned from bar code labels using the **New/Edit Specimens** dialog box

● Imported as part of a query order from the LIS

● Imported from an external text file

● Imported from an output file originating from a pre-analytical instrument

7.14.1 Understanding specimen types

A specimen type is created in association with an assay protocol. A specimen type ID must be unique for the associated assay protocol; however, different assay protocols may have the same specimen type IDs. Each assay protocol is required to have at least one specimen type. The information for a specimen type is found on the **View Custom Assay Protocol** dialog box. See "Using the **View Custom Assay Protocol** dialog box," page 71, for additional information.

Each specimen type has a correction factor that is defined when the specimen type is created. The correction factor is multiplied by the assay CO to normalize the specimen type, as applicable. A correction factor of **1.000** does not normalize the specimen type.

Each specimen type will have primary, secondary and tertiary cutoffs for negative and positive results. The primary, secondary and tertiary refer to the number of tests performed for the specimen. If the first test of the specimen, the primary cutoff factor is applied; if the second test of the specimen, the secondary cutoff factor is applied; if the third test of the specimen, the tertiary cutoff factor is applied.

For consensus assay protocols, the creation of the specimen type includes an **All specimens are Final** box that defines if the specimen type will have a retest algorithm. If the box is checked, all results are final based on the first test of the specimen and the primary cutoff factor. If the box is not checked, a retest zone can be created by having a difference between the negative and

positive cutoff factors. Specimens with a result in the retest zone will be given a status of preliminary. For example, if the negative primary cutoff factor is "1.00" and the positive primary cutoff factor is "2.50", the retest zone will be from 1.00 to 2.49. Specimens with test results in the retest zone will be given a status of preliminary and will require further testing. See "Understanding the retest algorithm," page 133, for additional information.

Non-consensus assay protocols will not have the **All results are Final** box during the creation of a specimen type. Requirements for retesting specimens are defined in the **Validation and Evaluation** tab when editing the assay protocol parameters. See "Using the **Edit Custom Assay Protocol** dialog box," page 61, for additional instructions.

7.14.2 Adding a new specimen type to an assay protocol

1. On the **Assay Protocols** tab, select the applicable assay protocol ID in the **Custom Assay Protocols** panel and click the applicable **Edit…** button.

   The **Edit Custom Assay Protocol** dialog box opens.
2. Click the **Specimen Types, Cutoff Factors and Results Output** tab.
3. Click the **Add Type** button.

   The **Add Specimen Type** dialog box opens.
4. In the **Specimen Type:** dialog field, enter the type ID for the specimen type.
5. In the **Correction Factor:** dialog field, enter the correction factor for the specimen type.

   Note: The correction factor is multiplied by the average positive cutoff to normalize the specimen type, if applicable. A correction factor of **1.000** does not normalize the specimen type.
6. Either check or uncheck the **All Results are Final** box.

   Note: If the box is checked, the first result is final, and no retest algorithm occurs. See "Understanding the retest algorithm," page 133, for additional information.
7. Click **OK**.

   The **Add Specimen Type** dialog box closes, and the specimen type displays in the list.

7.14.3 Changing the default specimen type of an assay protocol

Assay protocols can have multiple specimen types, but one specimen type is set as the default specimen type. The default specimen type is determined as one of the parameters of the assay protocol.

Important: The default specimen type of the assay protocol is applied to the specimen if an unbound specimen is copied to an assay protocol or the specimen is imported from an LIS order.

Note: Changing the default specimen type of the assay protocol will not change the specimen type of specimens previously associated with an assay protocol.

The default specimen type for an assay protocol can be modified by a user with operator access level depending on the parameters of the assay protocol. If the **Default specimen type can be determined by user** box is checked, users with operator access level can change the default specimen type. The **Default specimen type can be determined by user** box is on the **Specimen Types, Cutoff Factors and Results Output** tab in the **Edit Custom Assay Protocol** dialog box. See "Using the **Edit Custom Assay Protocol** dialog box," page 61, for additional instructions.

1. On the **Assay Protocols** tab, select the applicable assay protocol ID in the **Custom Assay Protocols** panel and click the **Edit…** button.

   A dialog opens with a notification that the changes to the assay protocol will not apply to plates currently associated with the assay protocol.

2. Click **OK**.

   The **Edit Custom Assay Protocol** dialog box opens.

3. Click the **Specimen Types, Cutoff Factors and Results Output** tab.

4. In the **Specimen Types** panel and using the left mouse button, check the box next to the applicable specimen type in the list to set the specimen type as the default.

   Important: Make sure to use the left mouse button to select the default specimen type. If using the right mouse button, then multiple boxes can be checked and it is unclear which specimen type is the default.

5. Click **OK**.

7.14.4 Understanding specimen status

A specimen always has a status within the *digene* HC2 System Software.

The following table describes the possible statuses for a specimen.

Specimen status	Description
Unbound	An unbound specimen is not associated with an assay protocol and cannot be tested until associated with an assay protocol and a plate. Unbound specimens are listed in the **Specimens not bound to an assay protocol** panel on the **Assay Protocols** tab.
Unassigned	An unassigned specimen is associated with an assay protocol but cannot be tested until associated with a plate. Unassigned specimens are listed in the **Specimen List** window of an assay protocol.
Unmeasured	An unmeasured specimen is associated with an assay protocol and an unmeasured plate.
Measured	A measured specimen is associated with plate that has been measured.

7.14.5 Understanding the retest algorithm

A consensus assay protocol always has constituent tests and has a retest zone with a retest algorithm that is automatically tracked, as required, in the *digene* HC2 System Software. The result of a consensus assay protocol is defined as either non-derived or derived. Non-derived consensus assay protocol results do not require retesting, meaning the final result is obtained from the initial constituent test and the retest algorithm is not required. All non-derived consensus assay protocol results are reported with a status of final.

Derived consensus assay protocol results require retesting, meaning the retest algorithm is required and the specimen is tracked to a final result in the *digene* HC2 System Software. Two further constituent tests may be required to derive a final result. Until a final result is derived, the *digene* HC2 System Software assigns the individual constituent test result a status of preliminary.

The retest algorithm is fully automated for the *digene* HC2 System assay protocols. Cutoff factors, test result statuses of preliminary or final and final results are determined according to the *digene* HC2 System assay protocol and specimen type.

The measured capture plate containing a specimen that requires additional testing must be accepted before the specimen can be associated with a new hybridization plate. When a capture plate containing a specimen that requires additional testing is accepted, the *digene* HC2 System Software automatically:

● Adds the specimen to the unassigned specimen list of the applicable assay protocol

● Assigns a **1** or **2** under the **Retest ID** column heading in the **Create/Edit Layout** and **Specimen List** windows. A **1** indicates the first retest of the specimen and a **2** indicates the second retest of the specimen

● Associates the applicable cutoff factor

The automatically generated retest specimen may then be added to a new hybridization plate for retesting. If the hybridization plate will be created from the output file of a pre-analytical instrument, the specimen ID of the output file must be identical to the automatically generated retest specimen ID. If the specimen IDs are not identical, then the *digene* HC2 System Software will not associate the two results and will treat both specimens as independent test results.

7.14.6 Retesting a specimen using replicates

If a specimen is being retested, two samples of the same specimen can be run on the same plate as replicates. This allows the second and third test to be run concurrently and will derive a final result from one assay. If both results of the replicates are positive, then both results are flagged with a result status of final. Likewise, if both results of the replicates are negative, then both results are flagged with a result status of final.

If, however, one sample is positive and the other is negative, then the final derived consensus assay protocol result is positive. The positive result is flagged with a final status and the negative result is flagged with a preliminary status.

7.15 Creating specimens

The method used to create the specimen will determine if the status of the created specimen is unbound or unassigned.

To create an unbound specimen, access the **New/Edit Specimens** dialog box by clicking the **New…** button in the **Specimens not bound to an assay protocol** panel on the **Assay Protocols** tab.

To create an unassigned specimen, access the **New/Edit Specimens** dialog box using one of the following options:

- On the **Plates** tab, click the **New Custom…** button to create a new plate or select the applicable assay protocol ID and click the **Edit…** button. The **Create/Edit Layout** window opens. Click the **New Specimens**… button.
- On the **Assay Protocols** tab, select the applicable assay protocol ID from the list and click the applicable **Specimens…** button. The **Specimen List** window opens. Click the **New…** button.

7.15.1 Creating a specimen from a test order from the LIS

The *digene* HC2 System Software can receive test orders for the testing of specimens from the LIS. Bidirectional communication with the LIS must be configured before a specimen can be created in the *digene* HC2 System Software. See "Managing the data export settings," page 116, for additional instructions.

The *digene* HC2 System Software will only receive test orders of specimens along with the associated patient and assay protocol information; a plate layout cannot be received. The query will request test orders for the previous 7 days. The setting for the query mode has the following options:

- Manually —clicking the **Query** button in the **Query Status** panel on the **Assay Protocols** tab
- Polling—query after an interval of time has passed
- Scheduled—query at up to 4 specified times

If the polling or scheduled option is configured, the specimen in the test orders will automatically populate in the *digene* HC2 System Software. If the manual option is configured, the user must click the **Query** button in the **Query Status** panel on the **Assay Protocols** tab for the *digene* HC2 System Software to query for test orders. If the *digene* HC2 System Software is configured for polling or scheduled query messages, a user can use the **Query** button in the **Query Status** panel on the **Assay Protocols** tab to manually send a query message.

Once a test order is received, the *digene* HC2 System Software verifies that the specimen ID does not already exist in the *digene* HC2 System Software.

If the specimen ID does not exist, the specimen ID is created in the *digene* HC2 System Software, and the specimen is given the status of unmeasured and is associated with the default specimen type for the assay protocol.

If the specimen ID exists in the *digene* HC2 System Software, the patient information associated with the specimen and contained in the test order is updated. See "Creating a patient from a test order from the LIS," page 149, for additional instructions.

7.15.2 Creating a specimen individually

1. Click the **Single ID** tab in the **Add specimens** panel.
2. Enter the specimen ID in the **Specimen ID:** dialog box.

   Notes:
   - The maximum length of a specimen ID is 30 characters.
   - A hand-held bar code reader may be used to enter the specimen ID. The bar code reader must be programmed to include a return for continuous entry.

3. Select the specimen type from the **Specimen** drop-down list.

   Note: This function is not available if creating a specimen with a status of unbound.

4. For a non-consensus assay protocol, select the cutoff type from the **Cutoff Type:** drop-down list.

   Note: The **Cutoff Type:** drop-down list will be grayed-out if creating a specimen with an unassigned status for a consensus assay protocol or if creating a specimen with a status of unbound.

5. Click the **<-- Add** button.

   The specimen will display in the list. Additional specimens may be added to the list by repeating the steps.

6. If the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window, select the applicable radio button in the **When OK is pressed, add new specimens to:** panel.

7. Click **OK**.

   If the **Specimens list and plate layout** radio button was selected, the **Replicates** dialog box opens. Select the applicable radio button for the desired number of replicates and click **OK**.

7.15.3 Creating a series of specimens

1. Click the **Series of IDs** tab in the **Add specimens** panel.

2. In the **Root:** dialog field, enter a root name that is at the beginning of each specimen ID in the series.

   Note: The maximum length of a specimen ID is 30 characters. The combination of the root and the sequential numbers must not exceed 30 characters.

3. In the **Start No.:** dialog field, enter a start number for the series that will be appended to the root.

4. In the **End No.:** dialog field, enter an end number for the series that will be appended to the root.

   Notes:

   - The ending number must be greater than the start number.
   - If the number begins with a zero, the zero is ignored during the creation of the specimen ID.

5. Select the specimen type from the **Specimen** drop-down list.

   Note: This function is not available if creating a specimen with a status of unbound.

6. For a non-consensus assay protocol, select the cutoff type from the **Cutoff Type:** drop-down list.

   Note: The **Cutoff Type:** drop-down list will be grayed-out if creating a specimen with an unassigned status for a consensus assay protocol or if creating a specimen with a status of unbound.

7. Click the **<-- Add** button.

   The specimens will display in the list. Additional specimens may be added to the list by repeating the steps.

8. If the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window, select the applicable radio button in the **When OK is pressed, add new specimens to:** panel.

9. Click **OK**.

   If the **Specimens list and plate layout** radio button was selected, the **Replicates** dialog box opens. Select the applicable radio button for the desired number of replicates and click **OK**.

7.15.4 Creating specimens from a text file

Multiple specimens can be imported from a text file. If importing specimens with a status of unassigned, the specimen type is the default for the applicable assay protocol and the cutoff type is primary. See "Changing the default specimen type of an assay protocol," page 132, for additional instructions.

In addition to using the **New/Edit Specimens** dialog box, the **Import…** button in the **Specimens not bound to an assay protocol** panel on the **Assay Protocols** tab can be used to import unbound specimens.

Requirements of the text file:

- Specimen IDs cannot exceed 30 characters and must consist of alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens.

  Note: The *digene* HC2 System Software will not import a specimen ID that is greater in length than 30 characters or contains an invalid character; however, all other specimen IDs contained in the file with the correct number of characters will be imported. A dialog box will display stating to only enter alphanumeric characters, hyphens, underscores and spaces.

- If importing a *.txt file, the encoding of the file must be **Unicode**. If using Notepad, the setting for the encoding is modified during the save process by using the **Encoding:** drop-down list beside the **Save** button. If using Windows Excel® program, select **Unicode Text (*.txt)** from the **Save as type:** drop-down list during the save process.

1. Create a file using a text editor program such as Windows Notepad program or a spreadsheet program such as Windows Excel program.
2. Enter one specimen ID per line and press the **Enter** key on the keyboard to move the next line.
3. Continue entering the specimen IDs until the list is complete.
4. Save the file with a *.txt extension and Unicode® text formatting.
5. In the **New/Edit specimens** dialog box, click the **Import IDs** tab and click the **<-Import…** button.

   Alternatively, on the **Assay Protocols** tab in the **Specimens not bound to an assay protocol** panel, click the **Import…** button.

   A directory dialog box opens.
6. Using the directory, locate the file to be imported and click the **Open** button.

   The specimens will display in the list. Additional specimens may be added to the list by repeating the steps.
7. If adding specimens using the **New/Edit Specimens** dialog box that was accessed from the **Create/Edit Layout** window, select the applicable radio button in the **When OK is pressed, add new specimens to:** panel.
8. Click **OK**.

   If the **Specimens list and plate layout** radio button was selected, the **Replicates** dialog box opens. Select the applicable radio button for the desired number of replicates and click **OK**.

7.15.5 Copying unbound specimens to an assay protocol

Unbound specimens display on the **Assay Protocols** tab in the **Specimens not bound to an assay protocol** panel. An unbound specimen can be copied to an assay protocol. An unbound specimen does not have a specimen type defined. When the specimen is copied to the assay protocol, the specimen will be set to the default specimen type as defined by the parameters of the assay protocol.

1. On the **Assay Protocols** tab, select a specimen ID from the **Specimens not bound to an assay protocol** panel and click the **Copy to…** button.

   The **Select Assay Protocol** dialog box opens.

   Note: Copy multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Copy to…** button.

2. Select the applicable radio button in the **Protocol Filter** panel and then select the applicable assay protocol ID.

3. Click **OK**.

   Click the applicable response if a dialog box opens.

   The selected specimens are copied to the selected assay protocol and display in the in the unassigned specimen list of the assay protocol.

7.15.6 Copying specimens from one assay protocol to another assay protocol

A specimen can be copied from one assay protocol to another assay protocol. If the specimen type is not defined for the specimen or the defined specimen type is not available for the assay protocol, the copied specimen will be set to the default specimen type as defined by the parameters of the assay protocol.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the specimens displayed.

   See "Using the **Specimen List** window," page 74, for additional instructions.

3. Select a specimen ID in the list and click the **Copy to…** button.

   The **Select Assay Protocol** dialog box opens.

   Note: Copy multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Copy to…** button.

4. Select the applicable radio button in the **Protocol Filter** panel and then select the applicable assay protocol ID.

5. Click **OK**.

   Click the applicable response if a dialog box opens.

   The selected specimens are copied to the selected assay protocol and display in the unassigned specimen list of the assay protocol.

6. Click **OK** to close the **Specimen List** window.

7.16   Viewing specimen information

Specimen information can be viewed for an assay protocol in the **Specimen List** window.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the specimens displayed.

   See "Using the **Specimen List** window," page 74, for additional instructions.

3. Click **OK** to close the **Specimen List** window.

7.17   Modifying specimen information

Specimen information may be modified using the **Edit Specimen** dialog box, the **Edit Multiple Specimens** dialog box, the **New/Edit Specimens** dialog box or the **Edit Unbound Specimen** dialog box. Modifications to a specimen are tracked and viewable in the specimen history report. The modification of specimen information is limited based on the type of assay protocol and the status of the specimen.

7.17.1 Modifying a single specimen using the **Edit Specimen** dialog box

The **Edit Specimen** dialog box may be accessed from the **Create/Edit Layout** window or the **Specimen List** window. To access the **Create/Edit Layout** window, see "Using the **Create/Edit Layout** window," page 36, for additional instructions. To access the **Specimen List** window, see "Using the **Specimen List** window," page 74, for additional instructions. The following table details the fields that may be modified for a single specimen using the **Edit Specimen** dialog box.

Assay protocol type	Specimen status	Fields that may be modified
Not applicable	Unbound	**Patient ID:**, **Date Collected** and **Comment:**
Consensus	Unassigned or unmeasured	**Specimen ID**, **Patient ID:**, **Specimen**, **Date Collected** and **Comment:**
Consensus	Measured	**Patient ID:**, **Date Collected** and **Comment:**
Consensus	Retest	**Patient ID**, **Date Collected** and **Comment:**
Non-consensus	Unassigned or unmeasured	**Specimen ID**, **Patient ID:**, **Specimen**, **Date Collected**, **Comment:** and **Qualitative cutoff**
Non-consensus	Measured	**Patient ID:**, **Date Collected** and **Comment:**

1. If accessing using the **Create/Edit Layout** window, select the applicable cell on the plate layout grid containing the specimen and click the **Edit Specimen…** button in the **Actions on plate** panel.

   If accessing using the **Specimen List** window, select the applicable specimen in the specimen list and click the **Edit…** button; alternatively, double-click a specimen ID in the list.

   The **Edit Specimen** dialog box opens.

2. In the **Edit Specimen** dialog box, modify the applicable parameters.

   See "Using the **Edit Specimen** and **Edit Multiple Specimens** dialog boxes," page 51, for additional instructions.

3. Click **OK**.

   The **Edit Specimen** dialog box closes.

   Note: Modifications are applied to both replicates of a specimen .

7.17.2 Modifying multiple specimens using the **Edit Multiple Specimens** dialog box

The **Edit Multiple Specimens** dialog box may be accessed from the **Specimen List** window. See "Using the **Specimen List** window," page 74, for additional information. The following table details the fields that may be modified for multiple specimens using the **Edit Multiple Specimens** dialog box.

Assay protocol type	Specimen status	Fields that may be modified
Not applicable	Unbound	**Comment:**
Consensus	Unassigned or unmeasured	**Specimen**, **Date Collected** and **Comment:**
Consensus	Measured	**Patient ID:**, **Date Collected** and **Comment:**
Consensus	Retest	**Date Collected** and **Comment:**
Non-consensus	Unassigned or unmeasured	**Specimen**, **Date Collected**, **Comment:** and **Qualitative cutoff**
Non-consensus	Measured	**Date Collected** and **Comment:**

1. On the **Assay Protocols** tab, select the applicable assay protocol ID in the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the list of specimens displayed.

   See "Using the **Specimen List** window," page 74, for additional instructions.

3. In the list of specimens, select the specimens to modify and click the **Edit…** button.

   The **Edit Multiple Specimens** dialog box opens.

4. Modify the applicable parameters.

   See "Using the **Edit Specimen** and **Edit Multiple Specimens** dialog boxes," page 51, for additional instructions.

5. Click **OK**.

   The **Edit Multiple Specimens** dialog box closes.

6. Click **OK** to close the **Specimen List** window.

7.17.3 Modifying a single specimen or multiple specimens using the **Edit Unbound Specimen** dialog box

If using the **Edit Unbound Specimen** dialog box to modify specimens, the **Patient ID:**, **Date Collected** and **Comment:** fields may be modified.

1. On the **Assay Protocols** tab, select the applicable specimen ID(s) in the **Specimens not bound to an assay protocol** panel and click the **Edit…** button.

   The **Edit Unbound Specimen** dialog box opens.

2. Modify the applicable parameters.

3. Click **OK**.

   The **Edit Unbound Specimen** dialog box closes.

7.17.4 Modifying a single specimen using the **New/Edit Specimens** dialog box

Access the **New/Edit Specimens** dialog box from the **Create/Edit Layout** window or the **Specimen List** window. To access the **Create/Edit Layout** window, see "Using the **Create/Edit Layout** window," page 36, for additional instructions. To access the **Specimen List** window, see "Using the **Specimen List** window," page 74, for additional instructions.

The following table details the fields that may be modified for a single specimen using the **New/Edit Specimens** dialog box. If a specimen is not eligible for editing using the **New/Edit Specimens** dialog box, then an error message will display.

Assay protocol type	Specimen status	Fields that may be modified
Not applicable	Unbound	None
Consensus	Unassigned	**Specimen**
Consensus	Unmeasured or measured	None
Consensus	Retest	None

Assay protocol type	Specimen status	Fields that may be modified
Non-consensus	Unassigned	**Specimen** and **Cutoff Type:**
Non-consensus	Unmeasured or measured	None
Consensus or non-consensus	Invalid or unclear	None

1. Click the **Single ID** tab in the **Add specimens** panel.
2. Enter the specimen ID in the **Specimen ID:** dialog field.

   Notes:
   - The maximum length of a specimen ID is 30 characters.
   - A hand-held bar code reader may be used to enter the specimen ID. The bar code reader must be programmed to include a return for continuous entry.

3. Select the specimen type from the **Specimen** drop-down list.
4. For a non-consensus assay protocol, select the cutoff type from the **Cutoff Type:** drop-down list.

   Note: The **Cutoff Type:** drop-down list will be grayed-out if editing a specimen with an unassigned status for a consensus assay protocol or if editing a specimen with a status of unbound.

5. Click the **<-- Add** button.

   The specimen will display in the list. Additional specimens may be edited by repeating the steps.

6. If the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window, select the applicable radio button in the **When OK is pressed, add new specimens to:** panel.

7. Click **OK**.

   If the **Specimens list and plate layout** radio button was selected, the **Replicates** dialog box opens. Select the applicable radio button for the desired number of replicates and click **OK**.

7.17.5 Modifying multiple specimens using the **New/Edit Specimens** dialog box

Access the **New/Edit Specimens** dialog box from the **Create/Edit Layout** window or the **Specimen List** window. To access the **Create/Edit Layout** window, see "Using the **Create/Edit Layout** window," page 36, for additional instructions. To access the **Specimen List** window, see "Using the **Specimen List** window," page 74, for additional instructions.

The following table details the fields that may be modified for multiple specimens using the **New/Edit Specimens** dialog box. If a specimen is not eligible for editing using the **New/Edit Specimens** dialog box, then an error message will display.

Assay protocol type	Specimen status	Fields that may be modified
Not applicable	Unbound	None
Consensus	Unassigned	**Specimen**
Consensus	Unmeasured or measured	None
Consensus	Retest	None
Non-consensus	Unassigned	**Specimen** and **Cutoff Type:**
Non-consensus	Unmeasured or measured	None
Consensus or non-consensus	Invalid or unclear	None

1. Click the **Series of IDs** tab in the **Add specimens** panel.
2. In the **Root:** dialog field, enter the root name that is at the beginning of each specimen ID in the series.
3. In the **Start No.:** dialog field, enter the start number for the series.
4. In the **End No.:** dialog field, enter the end number for the series.
5. Select the specimen type from the **Specimen** drop-down list.

   Note: This function is not available if editing a specimen with a status of unbound.
6. For a non-consensus assay protocol, select the cutoff type from the **Cutoff Type:** drop-down list.

   Note: The **Cutoff Type:** drop-down list will be grayed-out if editing a specimen with an unassigned status for a consensus assay protocol or if editing a specimen with a status of unbound.

7. Click the **<-- Add** button.

The specimens will display in the list. Additional specimens may be edited by repeating the steps.

If the **New/Edit Specimens** dialog box was accessed from the **Create/Edit Layout** window, select the applicable radio button in the **When OK is pressed, add new specimens to:** panel.

8. Click **OK**.

If the **Specimens list and plate layout** radio button was selected, the **Replicates** dialog box opens. Select the applicable radio button for the desired number of replicates and click **OK**.

7.18 Printing or saving a list of specimens

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the list of specimens displayed.

See "Using the **Specimen List** window," page 74, for additional instructions.

3. Click the **Print List…** button.

The **QIAGEN Report Viewer** window displays the list. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.18.1 Printing a list of unassigned specimens

A list of unassigned specimens associated with an assay protocol can be printed. The list can contain unassigned primary specimens (specimens that have not been tested), retest specimens (specimens that require additional testing to reach a final result) or both primary and retest specimens.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Worklist Export…** button.

The **Worklist Export** dialog box opens.

2. Using the **Start Date:** and **End Date:** dialog fields, enter the applicable time period.

3. Select the **Primary Only, by entry date**, **Retest Only, by measured date** or **Primary and Retest Combined** radio button to define the specimens that will be included.

4. Click the **Print** button.

The **QIAGEN Report Viewer** window displays the list. See "Using the **QIAGEN Report Viewer** window" window," page 104, for additional instructions.

7.19 Exporting unassigned specimens

Unassigned specimens associated with an assay protocol can be exported to an *.xml file. The exported file can contain unassigned primary specimens (specimens that have not been tested), retest specimens (specimens that require additional testing to reach a final result) or both primary and retest specimens.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Worklist Export…** button.

   The **Worklist Export** dialog box opens.

2. Using the **Start Date:** and **End Date:** dialog fields, enter the applicable time period.

3. Select the **Primary Only, by entry date**, **Retest Only, by measured date** or **Primary and Retest Combined** radio button to define the specimens that will be included in the file.

4. Click **OK**.

   The **Save File As** directory dialog box opens.

5. Using the directory, navigate to the location to which the file will be saved.

6. Modify the file name in the **File Name:** dialog field, as applicable.

   Note: The default file name format is a combination of the assay protocol and the specified date range.

7. Click the **Save** button.

   The file is saved and a dialog box opens providing information about the number of specimens that were exported.

8. Click **OK**.

7.20 Deleting specimens

A specimen with a status of unbound, unassigned or unmeasured can be deleted. The *digene* HC2 System Software prohibits users from deleting specimens with a status of measured or a specimen created as part of the retest algorithm.

7.20.1 Deleting an unbound specimen

Deleting unbound specimens does not delete the unassigned specimens that have been created using the unbound specimen.

1. On the **Assay Protocols** tab, highlight the applicable specimen ID in the **Specimens not bound to an assay protocol panel** and click the **Delete** button.

   Note: Delete multiple specimen IDs by highlighting the applicable specimen IDs in the list and clicking the **Delete** button.

   A dialog box opens to confirm the deletion of the specimen(s).

2. Select the applicable response to confirm the deletion of the specimen(s).

   The dialog box closes and the specimen is deleted from the list.

7.20.2 Deleting a specimen using the **Specimen List** window

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the list of specimens displayed.

   See "Using the **Specimen List** window," page 74, for additional instructions.

3. In the list of specimens, select the specimen ID to delete and click the **Delete** button.

   Note: Delete multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Delete** button.

   A dialog box opens to confirm the deletion of the specimen(s).

4. In the dialog box that opens, select the applicable response to confirm deletion of the specimen(s).

   The **Delete Specimen?** dialog box opens.

5. Enter an optional comment and click **OK**.

   Note: The comment and all information regarding the specimen are deleted and cannot be retrieved or viewed.

   The dialog box closes and the specimen is deleted from the list.

6. Click **OK** to close the **Specimen List** window.

7.20.3 Deleting a specimen using the **Create/Edit Layout** window

To access the **Create/Edit Layout** window, see "Using the **Create/Edit Layout** window," page 36, for additional instructions.

1. In the **Create/Edit Layout** window, select the applicable specimen ID in the **Unassigned specimens** panel.

   Note: Delete multiple specimens by highlighting the applicable specimen IDs in the list.

2. Click the **Delete** button.

   A dialog box opens to confirm the deletion of the specimen(s).

3. Click the applicable response to confirm deletion of the specimen(s).

   The dialog box closes and the specimen is deleted from the list.

4. Click the **Save** button to close the **Create/Edit Layout** window.

7.21 Managing patients

Patient information is maintained according to a patient ID. Patient results are used for trending reports, as applicable. The number of comments associated with a patient ID is unlimited, and the comments are stored by date. Patients are managed on the **Patients** tab. See "Using the **Patients** tab," page 79, for additional information.

7.21.1 Creating a patient from a test order from the LIS

The *digene* HC2 System Software can receive test orders for the testing of specimens from the LIS. Patient information can be transmitted as part of the test order, and the patient information will associate with the specimen ID. Patient information cannot be transmitted independently of a specimen. See "Creating a specimen from a test order from the LIS," page 135, for additional information.

If a patient is associated with a specimen from a test order, the *digene* HC2 System Software verifies that the patient ID does not already exist in the *digene* HC2 System Software. If the patient exists, the information sent in the test order replaces any current information associated with the patient with the exception of the patient ID. If a field is not included in the test order, the information associated with the patient is not changed; if a double quote (**""**) is contained in any field, the information associated with the patient is deleted.

If the patient did not exist, a new patient is created in the *digene* HC2 System Software with the information sent in the test order.

Once the patient information is updated or created, the patient is automatically associated with the applicable specimen contained in the test order.

7.21.2 Creating a patient

1. On the **Patients** tab, click the **New…** button.

   The **Patient ID Entry** dialog box opens.
2. Enter the patient ID in the **Enter new Patient ID:** dialog box and click **OK**.

   Note: The maximum length allowed for the patient ID is 20 characters.

   The **Edit Patient** dialog box opens.
3. Enter the applicable information for the parameters in the dialog fields.

   Note: The maximum length allowed for the **First name:**, **Last name:** and **Physician Name** dialog fields is 20 characters. The maximum length allowed for the **Medications:** dialog field is 100 characters.
4. Click **OK**.

   The **Edit Patient** dialog box closes and the patient ID displays in the list on the **Patients** tab.

7.21.3 Viewing patient information

The **Specimens** dialog box accessed on the **Patients** tab allows a user to see the specimens associated with a patient. To view patient information, click the **Specimens…** button, view the information and click **OK** to close the **Specimens** dialog box.

7.21.4 Modifying patient information

1. On the **Patients** tab, select the applicable patient ID in the list and click the **Edit…** button.

   The **Edit Patient** dialog box opens.
2. Modify the applicable parameters in the dialog fields.
3. Click **OK**.

   The **Edit Patient** dialog box closes and the patient information is updated.

7.21.5 Creating a patient comment

1. On the **Patients** tab, select the applicable patient ID in the list and click the **Comments…** button.

   The **Patient Comments** dialog box opens.

2. Click the **New…** button.

   The **Edit Patient Comment** dialog box opens.

3. In the **Date:** dialog field, enter the applicable date for the comment.

4. In the **Comment:** dialog field, enter the comment.

   Note: The length of the comment cannot exceed 100 characters.

5. Click **OK**.

   The **Edit Patient Comment** dialog box closes and the comment displays in the list of the **Patient Comment** dialog box.

6. Click the **Close** button.

   The **Patient Comments** dialog box closes.

7.21.6 Modifying a patient comment

1. On the **Patients** tab, select the applicable patient ID in the list and click the **Comments…** button.

   The **Patient Comments** dialog box opens.

2. Select the applicable date of the comment in the list and click the **Edit…** button.

   The **Edit Patient Comment** dialog box opens.

3. Modify the parameters of the comment.

   Note: The length of the comment cannot exceed 100 characters.

4. Click **OK**.

   The **Edit Patient Comment** dialog box closes and the comment is updated in the list of the **Patient Comment** dialog box.

5. Click the **Close** button.

   The **Patient Comments** dialog box closes.

7.21.7 Deleting a patient comment

1. On the **Patients** tab, select the applicable patient ID in the list and click the **Comments…** button.

   The **Patient Comments** dialog box opens.

2. Select the applicable date of the comment in the list and click the **Delete** button.

   A dialog box opens to confirm the deletion of the comment.

3. Click **Yes**.

   The dialog box closes and the comment is deleted from the comment list in the **Patient Comment** dialog box.

4. Click the **Close** button.

   The **Patient Comments** dialog box closes.

7.21.8 Deleting a patient ID

Deleting a patient ID does not affect the results of any specimens associated with patient ID.

1. On the **Patients** tab, select the applicable patient ID in the list and click the **Delete** button.

   A dialog box opens to confirm the deletion of the comment.

2. Click **Yes**.

   The dialog box closes and the patient ID is deleted from the list on the **Patients** tab.

7.22 Managing kit lots

Each test kit has a lot number that is a unique identifier that provides traceability of the test kit. A kit lot and expiration date must be associated with a plate before plate measurement can occur.

The *digene* HC2 System Software will display a warning dialog box if the kit lot has expired. A warning dialog box is also displayed when a kit lot is added to a plate if the kit lot is within 2 days of expiring. Although a warning may display, the user can choose to measure a plate with an expired kit lot.

Kit lots are managed using the **Kit Lot Number Entry** dialog box. The **Kit Lot Number Entry** dialog box can be accessed in the following ways:

- Selecting an assay protocol ID from the **Custom Assay Protocols** panel on the **Assay Protocols** tab and clicking the **Kit Lots…** button.

- Using the **Header Information** dialog box that appears when an assay protocol is associated with a plate and clicking the **Kit Lots…** button. To access the **Header Information** dialog box, see "Using the **Header Information** dialog box," page 43, for additional instructions.

7.22.1 Creating a kit lot

1. In the **Kit Lot Number Entry** dialog box, click the **New…** button.

   The **Create Kit Lot** dialog box opens.

2. Enter the kit lot number for the new kit in the **Kit Lot Number:** dialog field.

   Note: The maximum length for the **Kit Lot Number:** dialog field is 10 characters.

3. Enter the expiration date for the new kit in the **Expiration Date:** dialog field.

   Note: The format of the **Expiration Date** dialog box is MM/DD/YYYY. The *digene* HC2 System Software sets the expiration date of a kit lot at 00:00 (12:00 a.m.) of the day following the date entered. For example, a kit lot with an expiration date of 03/29/2007 will expire at 00:00 (12:00 a.m.) on 03/30/2007.

4. Click **OK**.

   The new kit lot displays in the list.

5. Click the **Close** button.

7.22.2 Modifying kit lot parameters

Once created, the information for a kit lot cannot be modified. To modify the parameters of a kit lot, delete the kit lot and add the kit lot with the correct parameters.

7.22.3 Deleting a kit lot

Deleting a kit lot removes the kit lot number from the list of kit lots associated with an assay protocol. Once deleted, the kit lot cannot be added to a plate; however, plates previously created that contain the deleted kit lot number are not affected. The deleted kit lot number remains as part of the information for the plate.

To remove a deleted kit lot from a plate previously created, click the **Edit Header…** button in the **Create/Edit Layout** window and use the **Kit Lot Number:** drop-down list to select a different kit lot. See "Using the **Header Information** dialog box," page 43, for additional instructions.

1. In the **Kit Lot Number Entry** dialog box, select the kit lot number to delete and click the **Delete** button.

    A dialog box opens to confirm the deletion of the kit lot.

2. Click the applicable response to confirm deletion of the kit lot.

    The dialog box closes and the kit lot is deleted from the list.

3. Click the **Close** button.

7.22.4 Printing or saving kit lot information

In the **Kit Lot Number Entry** dialog box, click the **Print List…** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.23 Managing quality controls

A quality control is always associated with an assay protocol. The quality control ID must be unique for the associated assay protocol; however, different assay protocols may have the same quality control IDs.

Quality controls can be created for custom assay protocols. The quality controls can be modified or deleted.

The parameters of the assay protocol define the number of quality controls that are required on the plate before plate measurement can occur. In the **View Custom Assay Protocol** dialog box, the **No. of required QCs** dialog field displays the number of quality controls that are required for the assay protocol.

An equivalent number of quality controls with the **Automatically set for use in validation when added to a plate layout** box checked are required. See "Viewing assay protocol information," page 126, for additional instructions.

Quality controls have an expiration date, and the *digene* HC2 System Software will display a warning dialog box if the quality control has expired. A warning dialog box is also displayed when a quality control is added to a plate if the quality control is within 2 days of expiring. Although a warning may display, the user can choose to measure a plate with expired quality controls.

Quality controls are managed using the **Quality Control List** dialog box. See "Using the **Quality Control List** dialog box," page 72, for additional information.

7.23.1 Creating a quality control

1. In the **Quality Control List** dialog box, click the **New...** button.

   The **QC ID Entry** dialog box opens.
2. Type a unique quality control ID in the **Enter new QC ID:** dialog field.

   Note: The maximum allowed length is 20 characters.
3. Click **OK**.

   The **Create Quality Control** dialog box opens.
4. Enter the desired parameters in the **Lot Number:**, **Minimum RLU/CO:**, **Maximum RLU/CO:** and **Maximum %CV:** dialog fields.

   Note: The maximum length for the **Lot Number:** field is 10 characters.
5. Select the expiration date from the drop-down list in the **Expiration Date:** field.

   Note: The format of the **Expiration Date:** field is MM/DD/YYYY.
6. To include the quality control as part of assay validation when added to the plate, check the **Automatically set for use in validation when added to a plate layout** box.

   Note: When the **Automatically set for use in validation when added to a plate layout** box is checked, the quality control will have **V** displayed in the cell of the plate layout grid when added to a plate.
7. Click **OK**.

   The created quality control appears in the list of the **Quality Control List** dialog box.
8. Click the **Close** button to exit the **Quality Control List** dialog box.

7.23.2 Modifying a quality control

Modifying the parameters of a quality control does not modify the parameters for the quality controls previously associated with a plate.

To apply the modifications made to a quality control to the quality controls previously associated with a plate, click the **Update QCs…** button in the **Quality Controls** panel of the **Create/Edit Layout** window for the plate. Click the applicable button to confirm the update.

1. In the **Quality Control List** dialog box, select the quality control ID to modify and click the **Edit…** button. Alternatively, double-click the quality control ID.

   A dialog box opens stating that changes made to the quality control will not affect quality controls already associated with a plate.

2. Click **OK**.

   The **Edit Quality Control** dialog box opens.

3. Modify the parameters of the quality control and click **OK**.

   Note: Only the **Lot Number:** and **Expiration Date:** dialog fields may be modified for quality controls required for a *digene* HC2 System assay protocol.

4. Click the **Close** button to exit the **Quality Control List** dialog box.

7.23.3 Deleting a quality control

Deleting a quality control removes the quality control from the list of quality controls associated with an assay protocol. Once deleted, the quality control cannot be added to a plate; however, plates previously created that contain the deleted quality control are not affected. The deleted quality control remains on the plate layout grid, even if the **Update QCs…** button is clicked.

To remove a deleted quality control from a plate previously created, select the quality control in the plate layout grid and click the **Remove** button.

1. In the **Quality Control List** dialog box, select a quality control ID.

2. Click the **Delete** button.

   A dialog box opens to confirm the deletion of the quality control.

3. Click **Yes**.

   The quality control is removed from the list in the **Quality Control List** dialog box.

4. Click the **Close** button.

7.23.4 Printing or saving a list of quality controls

In the **Quality Control List** dialog box, click the **Print List…** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.24 Understanding plates

A test requires two plates to perform an assay. The first plate, the hybridization plate, contains the samples and is used to perform the hybridization step of the assay. During hybridization, samples containing the target DNA hybridize with a specific HPV RNA probe. All samples are then transferred from the hybridization plate to the second plate, the capture plate. The RNA–DNA hybrids are captured onto the surface of the capture microplate wells that are coated with antibodies specific for RNA–DNA hybrids. The assay continues in the capture plate through to measurement of RLU by a DML instrument. The intensity of the light emitted denotes the presence or absence of target DNA in the specimen.

To measure a plate using the *digene* HC2 System Software, a plate must be created in the software reflecting the physical plates used during the performance of the testing. A plate in the *digene* HC2 System Software is a combination of the hybridization plate ID and the capture plate ID. First a hybridization plate ID is created and then a capture plate ID is associated with the hybridization plate. The association of the hybridization and capture plate IDs must occur before plate measurement can occur.

Important: Always create a hybridization plate ID and the associated plate layout in the *digene* HC2 System Software prior to starting either manual or RCS-automated testing.

A hybridization plate may be created using an output file from a pre-analytical instrument or manually. When creating a custom plate, only custom assay protocols can be added to the plate. See "Creating a hybridization plate from a pre-analytical instrument," page 158, or "Creating a hybridization plate manually," page 162, for additional instructions.

The association of the hybridization and capture plate IDs can be performed manually. If the RCS Bar Code Reader and the associated RCS scripts are installed on the RCS, the capture plate ID will automatically associate with the hybridization plate created in the *digene* HC2 System Software when RCS-automated testing is complete. See "Associating a capture plate with a hybridization plate," page 168, for additional instructions.

A plate will have one of the following three statuses:

Plate status	Description
Unmeasured	The hybridization plate has been created and the plate may be modified, if applicable.
Measured	The capture plate has been measured and the results are available for review.
Accepted	The results from the plate have been acknowledged as reportable by an authorized user.

7.25 Creating a hybridization plate from a pre-analytical instrument

Creating a hybridization plate from an output file of a pre-analytical instrument allows the electronic transfer of data from a pre-analytical instrument to the *digene* HC2 System Software. The plate is automatically created in the *digene* HC2 System Software with a unique hybridization plate ID and unique specimen IDs.

If a specimen ID or hybridization plate ID begins or ends with a space, the *digene* HC2 System Software will truncate the spaces of the specimen ID. The *digene* HC2 System Software will not notify the user if the specimen ID has been truncated.

During the import of the output file, the *digene* HC2 System Software will prompt to change the hybridization plate ID or cancel the creation of the plate if any of the following conditions exist:

- The hybridization plate ID is already in use within the *digene* HC2 System Software

  Note: Hybridization plate IDs in the *digene* HC2 System Software are not case-sensitive

- The hybridization plate ID is greater than 20 characters
- The hybridization plate ID contains invalid characters
- The hybridization plate ID begins with a hyphen

If the hybridization plate ID is changed, the hybridization plate ID from the output file will display in the header of the assay report for the plate.

During the import of the output file, the *digene* HC2 System Software will prompt to change a specimen ID or cancel the creation of the plate if any of the following conditions exist:

- The specimen ID is already in use within the *digene* HC2 System Software and associated with the applicable assay protocol

    Note: Specimen IDs in the *digene* HC2 System Software are not case-sensitive

- The specimen ID is greater than 30 characters
- The specimen ID contains invalid characters
- The specimen ID begins with a hyphen

If the specimen ID is changed, the specimen ID from the output file will display as a comment in the column and specimen history reports.

Review the output file from the pre-analytical instrument for errors prior to creating a plate.

1. In the pre-analytical instrument software, save the output file on a USB storage device.

    Refer to the applicable pre-analytical instrument user manual for instructions on saving the output file.

    Important: The file extension must be either *.zip or *.xml.

2. Insert the USB storage device into the USB port of the HC2 System computer.

3. On the **Plates** tab, click the **Plate Import…** button.

    A directory dialog box opens.

4. Using the directory, locate the output file from the pre-analytical instrument to be imported and click the **Open** button.

    The **Select Assay Protocol** dialog box opens.

5. Select the applicable assay protocol type from the **Protocol Filter** panel.

    The available assay protocols display in the **Assay Protocol** dialog box.

6. In the **Assay Protocol** dialog box, select the applicable assay protocol.

    The available specimen types display in the **Sample Type** dialog box.

7. In the **Sample Type** dialog box, select the applicable specimen type.

8. Click **OK**.

    The **Header Information** dialog box displays. See "Using the **Header Information** dialog box," page 43, for additional information.

9. As applicable, modify the information in the **Header Information** dialog box and click **OK**.

If the hybridization plate ID or a specimen ID is not compliant with the *digene* HC2 System Software, a dialog box opens prompting for a different name for the hybridization plate or specimen. Enter the new information, as applicable.

If the plate was created successfully without errors, the hybridization plate ID will display in the **Unmeasured Hybridization Plates** panel on the **Plates** tab.

If the hybridization plate was created successfully but contains unclear or invalid specimens, the **Import Complete** dialog box displays with the relevant information regarding the creation of the plate. The hybridization plate ID will display in the **Unmeasured Hybridization Plates** panel on the **Plates** tab. See "Understanding unclear and invalid specimens," page 160, for additional instructions.

If the hybridization plate was not created successfully due to some error, the **Import Complete** dialog box displays with **Plate Aborted**. See "Failure creating a hybridization plate from a pre-analytical instrument," page 230, for additional instructions.

7.25.1 Understanding quality controls on a plate created from a pre-analytical instrument

If a sample ID matches a quality control ID as defined in the *digene* HC2 System Software during the creation of a hybridization plate from a pre-analytical instrument, the quality control is recognized and associated as a quality control on the plate.

If the **Automatically set for use in validation when added to a plate layout** box is checked and the quality control is unclear or invalid, the results for the specimens on the plate will be invalid. The same applies if the quality control does not meet the parameters specified for the quality control; the plate and the specimen results are invalid.

If the **Automatically set for use in validation when added to a plate layout** box is not checked and the quality control is unclear or invalid, the results for the specimens on the plate are not affected by the status of the quality control. The plate can be valid if the parameters of the assay protocol are met. The same applies if the quality control does not meet the parameters specified for the quality control; the plate and specimen results are not affected.

7.25.2 Understanding unclear and invalid specimens

Specimens imported from an output file from a pre-analytical instrument may have a result status of unclear or invalid. The result status is associated during the import into the *digene* HC2 System Software. The unclear or invalid result status is caused by an error that occurred during the

sample preparation of the specimen. Refer to the output file from the pre-analytical instrument for additional information on the cause of the error.

If an unclear specimen is measured, the result will be an RLU value and the result status of unclear; if an invalid specimen is measured, the result will have the result status of invalid without an RLU value. The status of an unclear or invalid specimen can be cleared in order to add the specimen to another plate. The status cannot be cleared after the plate containing the specimen has been accepted. See "Clearing the status of a specimen," page 196, for additional instructions.

7.26 Modifying a hybridization plate created from a pre-analytical instrument

If a hybridization plate is created from an output file, the location of the calibrators, quality controls and specimens cannot be modified on the plate.

A user can manually add additional assay protocols, specimens and quality controls to the empty cells on the plate layout grid of a plate created from a pre-analytical instrument. See "Adding an assay protocol to a plate," page 163, "Adding a specimen to a plate," page 165, or "Adding a quality control to a plate," page 164, for additional instructions.

7.26.1 Modifying the quality controls on a plate created from a pre-analytical instrument

Quality controls can be removed from a plate using the **Remove** button in the **Actions on plate** panel. Select the applicable response to the dialog box that opens confirming the removal of the quality control. The plate layout grid displays the quality control ID and **Removed** in the vacated cell. The vacated cell will not be measured during plate measurement. A different quality control ID or specimen ID cannot be added to the vacated cell.

If a quality control is removed from the plate layout grid, the quality control can be returned to the plate layout grid at the same location. Select the applicable removed quality control and click the **Restore** button in the **Actions on plate** panel. The quality control is returned to the plate layout grid and will be measured during plate measurement.

7.26.2 Modifying the specimens on a plate created from a pre-analytical instrument

The specimens on the plate layout grid can be modified. See "Modifying a single specimen using the **Edit Specimen** dialog box," page 141, for additional instructions.

A specimen can be removed from a plate by selecting the specimen on the plate layout grid and clicking the **Remove** button in the **Actions on plate** panel. Select the applicable response to the dialog box that opens confirming the removal of the specimen. Once removed from the plate layout grid, the specimen is added to the list in the **Unassigned specimens** panel. The plate layout grid displays the specimen ID and **Removed** in the vacated cell. The vacated cell will not be measured during plate measurement. A different specimen ID or quality control ID cannot be added to the vacated cell.

If a specimen is removed from the plate layout grid, the specimen can be returned to the plate layout grid at the same location. Select the applicable removed specimen on the plate layout grid or in the **Unassigned specimens** panel and click the **Restore** button in the **Actions on plate** panel. The specimen is returned to the plate layout grid and will be measured during plate measurement.

7.27 Creating a hybridization plate manually

Manually creating a hybridization plate requires the creation of a hybridization plate ID. Once a hybridization plate ID is created, the assay protocols, kit lots, quality controls and specimens are added to the plate layout grid. Once added to the plate layout grid, the assay protocols, kit lots and quality controls are saved and remain set as at the time they were added to the plate layout grid – even if the information for the assay protocols, kit lots and quality controls is changed at a later time.

Plates are created and managed using the **Create/Edit Layout** window. See "Using the **Create/Edit Layout** window," page 36, for additional information.

7.27.1 Creating a hybridization plate ID

A hybridization plate ID is a unique identifier for a hybridization plate in the *digene* HC2 System Software. Hybridization plate IDs cannot exceed 20 characters and must consist of alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens. A hybridization plate ID cannot start with a space or a hyphen.

1. On the **Plates** tab, click the **New Custom…** button.

   The **Plate ID Entry** dialog box opens and displays a list of previously created hybridization plate IDs, including accepted plates.

2. Enter a new, unique hybridization plate ID in the **Enter new Plate ID:** dialog field.

   Notes:

   - Hybridization plate IDs cannot exceed 20 characters and must consist of alphanumeric characters and underscores as well as non-leading or non-trailing spaces and hyphens.
   - The maximum length for the **Enter new Plate ID:** field is 20 characters.
   - A hand-held bar code reader can be used to enter the hybridization plate ID.

3. Click **OK**.

   The *digene* HC2 System Software creates the hybridization plate ID, sets the creation date and opens the **Create/Edit Layout** window.

7.27.2 Adding an assay protocol to a plate

An assay protocol must be associated with a plate to complete testing. See "Understanding assay protocols," page 125, for additional information about assay protocols.

When a custom assay protocol is added to a plate, the calibrators are automatically added to the plate layout grid. More than one assay protocol can be added to a plate as long as sufficient cells remain on the plate layout grid.

1. In the **Create/Edit Layout** window of the applicable plate, click the **Add New Assay…** button in the **Assays on layout** panel.

   The **Select Assay Protocol** dialog box opens and displays the available assay protocols. To sort the list of assay protocols, click a column header.

2. Select the applicable assay protocol ID and click **OK**. Alternatively, double-click the assay protocol ID to select the assay protocol.

   The **Header Information** dialog box opens. See "Using the **Header Information** dialog box," page 43, for additional information.

3. In the **Room Temperature:** dialog field, enter the current room temperature of the laboratory and select the applicable radio button for the temperature unit.

   Notes:

   - The room temperature can be updated before plate measurement to reflect the temperature during the signal amplification step of the test.
   - As applicable, the *digene* HC2 System Software will convert the temperature specified to the applicable unit of measure as specified by the parameters of the assay protocol.

4. In the **Kit Lot Number:** drop-down list, select the applicable kit lot.

    If the kit lot is not available in the drop-down list, click the **Kit Lots…** button. The **Kit Lot Number Entry** dialog box opens, which can be used to add the applicable kit lot. See "Managing kit lots," page 152, for additional instructions.

5. In the **Comment** dialog box, enter any information applicable to the plate.

    Note: The maximum length of the comment is 100 characters.

6. Click **OK**.

    The calibrators and quality controls specified by the assay protocol are added to the plate layout grid. All unassigned specimens and the quality controls associated with the assay protocol display in the **Create/Edit Layout** window.

    Note: If the assay protocol is not the first assay protocol added to the plate, the placement of the calibrators and quality controls is determined by the **Add/Reallocate assay on new column** box.

7.27.3 Adding a quality control to a plate

All quality controls associated with an assay protocol are displayed in the **Quality controls** panel in the **Create/Edit Layout** window. Quality controls from this list can be added to the plate if empty cells are available.

When 2 replicates of a quality control are added to a plate, the replicates are linked. If the parameters of the quality control are set to include the quality control as part of assay validation, both quality control replicates must pass the specified assay protocol parameters for the assay to be valid.

Quality controls can be created and modified using the **Manage QCs…** button. See "Managing quality controls," page 154, for additional instructions.

1. In the **Create/Edit Layout** window, select a quality control ID from the **Quality controls** panel.
    Note: To add multiple quality controls, highlight the quality control IDs in the list.

2. In the **Replicates:** subpanel, select the applicable radio button for number of replicates of the quality control(s) to add to the plate.

3. Click the **Add** button to add the selected quality control(s) after the last occupied cell on the plate layout grid. Alternatively, select a cell on the plate layout grid and click the **Add At** button to add the quality control(s) to the selected cell location.

   Notes:

   - If using the **Add At** button to add multiple quality controls to a plate, the *digene* HC2 System Software will reverse the order of the quality controls as listed in the **Quality controls** panel.

   - If an occupied cell is selected on the plate layout grid, the specimen or optional quality control that occupied the cell and all subsequent occupied cells will shift on the plate. The specimen added to the plate will occupy the vacated cell. If the move causes the displaced cells to shift beyond a column, the displaced cells will shift to the top of the column to the right.

   - If the number of specimens selected is greater than the number of available cells on the plate layout grid, a dialog box opens. Click **OK**. The available cells on the plate layout grid are occupied, and the excess specimens will remain in the **Unassigned specimens** panel.

   The plate layout grid displays the added quality control.

7.27.4 Adding a specimen to a plate

Only specimens with an unassigned status may be added to a plate. Unassigned specimens associated with the applicable assay protocol display in the **Unassigned specimens** panel of the **Create/Edit Layout** window.

Use the **Sort By:** drop-down list to sort the specimens in the **Unassigned specimens** panel based on either **Alphanumeric** order or **Entry order**.

Unbound specimens will not display in the **Unassigned specimens** panel. The unbound specimens must be copied to the assay protocol. See "Copying unbound specimens to an assay protocol," page 139, for additional instructions.

1. In the **Unassigned specimens** panel, select the specimen ID to be added.

   Notes:

   - To add multiple specimens, highlight the specimen IDs in the list.
   - If a specimen ID is not listed in the **Unassigned specimens** panel, the **New Specimens…** button can be used to add the specimen ID. See "Creating specimens," page 135, for additional instructions.
   - During modification of a specimen, specimens may be added to a plate. See "Modifying a single specimen using the **New/Edit Specimens** dialog box," page 143, or "Modifying multiple specimens using the **New/Edit Specimens** dialog box," page 144, for additional instructions.

2. In the **Replicates:** subpanel, select the applicable radio button for either **1** or **2** replicates of the specimen(s).

3. Add the specimen to the plate using one of the following options:

   - Click the **Add** button to add the selected specimen(s) after the last occupied cell on the plate layout grid.
   - Double-click the specimen in the **Unassigned specimens** panel to add the selected specimen(s) after the last occupied cell on the plate layout grid.
   - Select a cell on the plate layout grid and click the **Add At** button to add the specimen(s) to the selected cell location.

   The plate layout grid populates with the specimens.

   Notes:

   - If an occupied cell is selected on the plate layout grid, the specimen or optional quality control that occupied the cell and all subsequent occupied cells will shift on the plate. The specimen added to the plate will occupy the vacated cell. If the move causes the displaced cells to shift beyond a column, the displaced cells will shift to the top of the column to the right.
   - If the number of specimens selected is greater than the number of available cells on the plate layout grid, a dialog box opens. Click **OK**. The available cells on the plate layout grid are occupied, and the excess specimens will remain in the **Unassigned specimens** panel.
   - If the unassigned specimen is a retest specimen originally created on a hybridization plate from a pre-analytical system, the **Add** and **Add At** buttons will be grayed out when the specimen is selected. Double-click the specimen ID in the **Unassigned specimens** panel to add the specimen to the plate.

4. Click the **Save** button to close the **Create/Edit Layout** window.

7.28 Modifying the plate

The location of assay protocols, specimens and quality controls on the plate can be modified. Plates are created and managed using the **Create/Edit Layout** window. See "Using the **Create/Edit Layout** window," page 36, for additional information.

The reallocate function removes all empty cells on the plate layout grid. To consolidate the plate, click the **Reallocate** button in the **Action on plate** panel of the **Create/Edit Layout** window.

The **Add/Reallocate assay on new column** box further refines the reallocate function. Uncheck this box to add a new assay after the last occupied cell on the plate layout grid, even if it is not at the start of a new column.

If a hybridization plate is created from an output file, the location of the calibrators, quality controls and specimens cannot be modified on the plate. See "Modifying a hybridization plate created from a pre-analytical instrument," page 161, for additional instructions.

7.28.1 Moving an assay protocol on the plate layout grid

All cells associated with an assay protocol can be moved by clicking the cell containing a required calibrator and dragging the cells to a different cell on the plate layout grid. If a required calibrator cell is selected, all cells associated with the assay protocol outline in red. Once the cells associated with an assay protocol are dragged, the resulting location of the moved cells is displayed with blue cells on the plate layout grid. Even if the first cell of the assay protocol is not selected, the first blue cell displays the location that the first cell associated with the assay protocol will be located. Once the desired location is displayed, release the mouse button to move the cells to the specified location.

The cells associated with an assay protocol cannot move past another assay protocol. Although all the cells associated with an assay protocol may fit in the space remaining, the cells cannot move past another assay protocol to the empty cells.

7.28.2 Moving a specimen or quality control on the plate layout grid

A specimen or quality control added to the plate layout grid can be moved by clicking the applicable cell and dragging the cell to a different cell on the plate layout grid. Selecting a cell outlines the cell in red. While the cell is being dragged, the resulting location is displayed as a blue cell. Once the desired location for the specimen is displayed, release the mouse button to move the cell to the specified location.

If a cell is moved to a cell occupied by another specimen or quality control, the specimen or quality control that occupied the cell and all subsequent occupied cells will shift on the plate. The moved cell will occupy the vacated cell. If the move causes the displaced cells to shift beyond a column, the displaced cells will shift to the top of the column to the right. If no cells are available for the displaced cells, a dialog box will open stating the problem and the move will be canceled.

Replicate pairs of a specimen or quality control are always consecutive on a plate and cannot be split. Moving one of the cells of a replicate pair will move both cells. If attempting to split a replicate pair, a dialog box will open stating the problem and the move will be canceled.

A specimen or quality control cannot move past another assay protocol. If attempting to move a specimen or quality control past another assay protocol, a dialog box will open stating the problem and the move will be canceled.

7.29   Associating a capture plate with a hybridization plate

Before a plate measurement can occur, the hybridization plate must be associated with a capture plate. The plate will not appear in the **Measure** tab for plate measurement until a capture plate ID is associated with the plate.

7.29.1 Associating a capture plate automatically

The hybridization and capture microplates supplied by QIAGEN now include human-readable bar codes that can be read by the RCS Bar Code Reader. The bar codes allow easier management of plates and alleviate the requirement of physically labeling the plates. The RCS Bar Code Reader Upgrade Package uses the bar codes on the plate to associate the plate IDs of the hybridization and capture plates processed on the RCS. The capture plate ID is then automatically associated when the corresponding hybridization plate ID is created in the *digene* HC2 System Software for seamless plate and sample management. The *digene* HC2 System Suite 4.4 has been developed for use with the RCS Bar Code Reader.

Automated scanning of the hybridization and capture microplates on the RCS occurs after the test script has started. Updated RCS scripts are required for testing using the RCS Bar Code Reader as well as the bar code reader software application that associates the plate IDs. The bar code reader software application installed on the HC2 System computer automatically captures the plate IDs that are scanned by the RCS Bar Code Reader. The bar code scans are retained as import mapping files in a specified directory.

Before plate measurement can occur, a capture plate ID must be associated with a hybridization microplate ID. When initiated and during operation, the *digene* HC2 System Software checks the specified directory for import mapping files. When the hybridization plate is created, the applicable capture plate ID automatically associates with the hybridization plate ID. The hybridization plate ID in the *digene* HC2 System Software must match the human-readable ID on the hybridization plate. The combination of creating a hybridization plate from a pre-analytical instrument and the RCS Bar Code Reader automatically creates a plate that is ready for measurement.

Automatically associated plate IDs cannot be modified by the user. If the hybridization plate ID and capture plate ID were automatically associated, the **Associate** button on the **Plates** tab will be grayed-out.

Only a QIAGEN representative can install the RCS Bar Code Reader Upgrade Package. Do not attempt to install the hardware components, the RCS scripts or the software application. Contact QIAGEN Technical Services for assistance.

7.29.2 Associating a capture plate ID manually

Important: Make sure the correct information for the capture plate ID is entered when associating a capture plate ID manually. Once the capture plate ID is associated with a hybridization plate ID, the capture plate ID cannot be modified.

1. On the **Plates** tab, select the applicable hybridization plate ID in the list of the **Unmeasured Hybridization Plates** panel.

2. Click the **Associate** button in the **Unmeasured Hybridization Plates** panel.

   The **Plate Association** dialog box opens.

3. Enter the capture plate ID in the **Capture Plate** field using one of the following methods:
   - Use the keyboard to enter the capture plate ID
   - Select the capture plate ID from the drop-down list
   - Use a bar code reader to enter the capture plate ID

4. Click **OK**.

   The **Plate Association** dialog box closes and the capture plate ID appears in the lower subpanel of the **Unmeasured Hybridization Plates** panel. The plate can now be measured.

7.30 Printing a plate

In the **Create/Edit Layout** window, click the **Print…** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.31 Deleting a plate

Only unmeasured hybridization plates can be deleted. When a plate is deleted, the specimens associated with the plate are given the status of unassigned.

1. On the **Plates** tab, select the applicable hybridization plate ID in the list of the **Unmeasured Hybridization Plates** panel.
2. Click the **Delete** button in the **Unmeasured Hybridization Plates** panel.

   A dialog box opens to confirm the deletion of the plate .
3. Click the applicable button to delete the plate .

   Important: The plate is permanently deleted.

   The dialog box closes and the plate is removed from the **Unmeasured Hybridization Plates** panel.

7.32 Measuring a plate

Plate measurement occurs once a plate is created and the applicable calibrators, quality controls and specimens are added to the plate as well as the hybridization and capture plate IDs are associated. Plate measurement is performed using the **Measure** tab. See "Using the **Measure** tab," page 54, for additional instructions.

The *digene* HC2 System Software will display a warning dialog box if the quality controls or the kit lot associated with a plate have expired or if the materials are within 2 days of expiring. Although a warning dialog box may display, the user can choose to measure a plate with expired materials.

The room temperature that was entered in the **Header Information** dialog box during plate creation is compared to the temperature range specified for the assay protocol parameters. If the entered temperature is outside of the specified parameter, a dialog box displays and the variation in temperature will display on the assay report. The temperature parameter is not a requirement for the validation of the assay.

Plate measurement will not occur until the plate contains the following minimum requirements:

- At least one assay protocol is associated with the plate
- A kit lot has been associated with the plate
- The required quality controls, as specified by the assay protocol parameters, have been added to the plate
- At least one specimen has been added to the plate for each assay protocol
- The capture plate ID has been associated with the hybridization plate ID

1. On the **Measure** tab, select the applicable capture plate ID in the **Capture Plates** panel.

   The plate layout grid for the plate selected displays in the **Plate Measurement** panel.

   Note: Multiple capture plates can be selected for measurement by highlighting the capture plate IDs. The plate layout grid for the first capture plate in the **Capture Plates** panel that is highlighted displays in the **Plate Measurement** panel.

2. As applicable, remove a specimen from measurement by selecting the cell in the plate layout grid and clicking the **Remove** button.

   A dialog box opens to confirm the removal. Click the applicable button to remove the specimen. The specimen is removed from the plate and an empty gray box displays in the cell.

   Note: Multiple specimens can be removed by highlighting multiple cells in the plate layout grid and clicking the **Remove** button. A dialog box will open to confirm the removal of each specimen.

3. As applicable, change the status of a specimen to quantity not sufficient by selecting the cell in the plate layout grid and clicking the **Set QNS** button.

   A dialog box opens to confirm the status change. Click the applicable button to change the status of the specimen. The specimen is removed from the plate and an empty blue box displays in the cell.

   Note: The status of multiple specimens can be set to quantity not sufficient by highlighting multiple cells in the plate layout grid and clicking the **Set QNS** button. A dialog box will open to confirm the status change of each specimen.

   Important: Changing the status of a specimen to quantity not sufficient cannot be undone.

4. Click the **Measure…** button in the **Capture Plates** panel.

   Alternatively, scan the bar code on the capture plate using a hand-held bar code reader. The capture plate ID of the scanned capture plate momentarily displays in the dialog field in the **Plates** panel.

   If the plate is missing a requirement for measurement, a dialog box will display. The plate cannot be measured until the requirements are met.

If a mechanical test of the DML instrument is required, the *digene* HC2 System Software prompts to perform the test. Click the applicable button to start the reading. See "Performing a mechanical test", page 122, for additional instructions.

If using a DML 2000 and a background baseline (100) reading of the DML instrument is required, a dialog box opens to perform the reading. Click the applicable button to start the reading. See "Understanding the background baseline (100) reading", page 122, for additional instructions.

The **Insert Plate for Measurement** dialog box opens.

5. Insert the capture microplate into the DML instrument corresponding to the capture plate ID displayed in the **Insert Plate for Measurement** dialog box.

   Refer to the applicable DML instrument user manual for additional instructions on operating the instrument.

6. As applicable, enter the serial number of the RCS in the **Insert Plate for Measurement** dialog box.

   Note: The setting for the entry of the RCS serial number is modified on the **Utilities/Settings** tab. See "Using the **Utilities/Settings** tab," page 85, for additional instructions.

7. Click **OK**.

   The *digene* HC2 System will display a dialog box if a material is expired and if a kit lot is not associated with the plate. Click the applicable button to close the dialog box.

   The **Header Information** dialog box opens.

8. Make sure the displayed information is applicable. See "Using the **Header Information** dialog box," page 43, for additional instructions.

9. Click **OK**.

   If the DML instrument is a DML 2000, the *digene* HC2 System Software performs a plate background (10) reading. If an error message displays during the reading, see "Understanding the plate background (10) reading," page 124, for additional instructions.

   Plate measurement begins, and each capture microplate well containing a calibrator, quality control or specimen is measured. The status of the plate changes to measured, and the capture plate ID displays in the **Measured Capture Plates** panel on the **Plates** tab.

   If measuring multiple plates, the *digene* HC2 System Software prompts for the next capture plate to be inserted into the DML instrument. Repeat the applicable instructions to measure the additional capture plates.

7.32.1 Canceling plate measurement

Plate measurement can be canceled at any time. When plate measurement is canceled, no results are stored for the plate, and the status of the plate is unmeasured. Once canceled, plate measurement cannot be continued, and plate measurement must be started again from the beginning.

To cancel plate measurement, click the **Stop** button on the **Measure** tab. A dialog box opens to confirm the cancelation of the plate measurement. Click the applicable button to cancel plate measurement.

7.33 Measuring a plate as raw data

Plate measurements using the raw data function are not associated with an assay protocol, and only RLU values are reported. All of the capture microplate wells are measured during a raw data plate measurement. Measuring a capture plate using the raw data function can be used to troubleshoot background uniformity issues.

Important: After the raw data measurement is complete, a user may view the results. The data associated with the raw data plate measurement are not saved or retained by the *digene* HC2 System Software. As soon as the user clicks on another capture plate, the data are lost. Make sure to print or save the report, as the data cannot be retrieved.

1. Insert the capture microplate into the DML instrument.

    Refer to the applicable DML instrument user manual for additional instructions on operating the instrument.

2. Click the **Raw Data** button in the **Capture Plates** panel.

    If a mechanical test of the DML instrument is required, the *digene* HC2 System Software prompts to perform the test. Click the applicable button to start the reading. See "Performing a mechanical test", page 122, for additional instructions.

    If using a DML 2000 and a background baseline (100) reading of the DML instrument is required, a dialog box opens to perform the reading. Click the applicable button to start the reading. See "Understanding the background baseline (100) reading", page 122, for additional instructions.

If the DML instrument is a DML 2000, the *digene* HC2 System Software performs a plate background (10) check. If an error message displays during the measurement, see "Understanding the plate background (10) reading," page 124. If an error message indicates that the measured background is out of the allowed range, contact QIAGEN Technical Services.

Plate measurement begins and each capture microplate well is measured.

3. Click the **Print…** button in the **Plate Measurement** panel. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

   Important: Make sure to print or save the data, as applicable, as the *digene* HC2 System Software does not retain data from a raw data plate measurement. Once the **QIAGEN Report Viewer** window is closed and another capture plate is measured, the data are lost.

7.34   Entering RLU values manually

Plates using a custom assay protocol can have results manually entered. Results manually entered will report results according to the applicable assay protocol; however, the results will be identified as edited on reports and as manually entered when exported.

1. On the **Measure** tab, select the applicable capture plate ID in the **Capture Plates** panel.

   The plate layout grid for the selected plate displays in the **Plate Measurement** panel.

2. As applicable, remove a specimen from measurement by selecting the cell in the plate layout grid and clicking the **Remove** button.

   A dialog box opens to confirm the removal. Click the applicable button to remove the specimen. The specimen is removed from the plate and an empty blue box displays in the cell.

   Note: Multiple specimens can be removed by highlighting multiple cells in the plate layout grid and clicking the **Remove** button. A dialog box will open to confirm the removal of each specimen.

3. As applicable, change the status of a specimen to quantity not sufficient by selecting the cell in the plate layout grid and clicking the **Set QNS** button.

   A dialog box opens to confirm the status change. Click the applicable button to change the status of the specimen. The specimen is removed from the plate and an empty blue box displays in the cell.

   Note: The status of multiple specimens can be set to quantity not sufficient by highlighting multiple cells in the plate layout grid and clicking the **Set QNS** button. A dialog box will open to confirm the status change of each specimen.

   Important: Changing the status of a specimen to quantity not sufficient cannot be undone.

4. Click the **Manual Entry…** button in the **Capture Plates** panel.

    If the plate is missing a requirement for measurement, a dialog box will display. The plate cannot be measured until the requirements are met.

    The **Insert Plate for Measurement** dialog box opens.

    Note: Do not insert a plate into the DML instrument.

5. As applicable, enter the serial number of the RCS in the **Insert Plate for Measurement** dialog box.

    Note: The setting for the entry of the RCS serial number is modified on the **Utilities/Settings** tab. See "Using the **Utilities/Settings** tab," page 85, for additional instructions.

6. Click **OK**.

    The *digene* HC2 System will display a dialog box if a material is expired and if a kit lot is not associated with the plate layout. Click the applicable button to close the dialog box.

    The **Header Information** dialog box opens.

7. Make sure the displayed information is applicable. See "Using the **Header Information** dialog box," page 43, for additional instructions.

8. Click **OK**.

    The first cell in the plate layout grid outlines in red, and the **RLU:** dialog field displays in the **Plate Measurement** panel.

9. Enter an RLU value for the cell in the **RLU:** dialog field.

10. Move to the next well by pressing the **Enter** key on the keyboard or pressing the down arrow on the keyboard. Move to any well by clicking the well with the mouse.

11. Enter an RLU value for all of the cells on the plate layout grid.

    Notes:

    - If an RLU value needs to be changed, select the cell using the mouse or the arrow keys on the keyboard and enter the RLU value in the **RLU:** dialog field.
    - The calibrators, quality controls and specimens are evaluated for validity and results according to the parameters of the assay protocol. The **Messages** subpanel displays messages about the validity of the assay results.

12. Make sure that all the applicable cells have RLU values entered and click the **Commit RLUs** button.

    The plate ID status changes to measured.

7.35 Generating test reports

After measuring a plate, reports can be generated to view the assay validation data and test results. A full, raw data, plate, column or assay report may be generated.

The full report includes both the plate report and the assay report. See "Understanding the plate report," page 179, and "Understanding the assay report," page 185, for additional descriptions.

All reports include the following information:

- Laboratory header information including the name of the laboratory and the address
  See "Modifying the laboratory information," page 113, for instructions to change the laboratory header information.
- The *digene* HC2 System Software version used to measure the plate
- Serial number of the DML instrument used to measure the plate
- Serial number of the RCS used to perform the test, as applicable

If the plate has been accepted, the following information will display on the plate and assay reports:

- Name and user ID of the user that accepted the plate
- Date the plate was accepted
- Time the plate was accepted

The raw data report does not display the plate acceptance information because no results are displayed on the report; the column report does not display the plate acceptance information because the report can be modified at any time to add or remove a patient.

Note: If multiple specimen IDs on a plate use the maximum character length, it is possible that a report that is printed will not display all of the information. This does not affect the display of the information on the HC2 System computer or the data saved in the *digene* HC2 System Software.

1. On the **Plates** tab, select a capture plate ID in the **Measured Capture Plates** panel or the **Accepted Capture Plates** panel.

2. Click the applicable radio button of the desired report and click the **Show** button in the applicable panel.

   The **QIAGEN Report Viewer** window displays the report. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

   If a full report was generated, click the tabs to view the different reports.

3. Click the **Close** button to return to the **Plates** tab.

7.35.1 Understanding the raw data plate report

The raw data plate report displays specimen IDs and RLU values. This report does not show specimen results.

Example of the raw data report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Capture Plate ID: Plate05H
Hybridization Plate ID: Plate05H

Status: Measured
Measured: 3/19/2015 3:08:01 PM

Test Name	Area	Operator	Kit Lot #	Validated By		Edited
CopyCt-ID	A1..E2	CooperA	newkit	For Research Use Only		Yes

		1	2	3	4	5	6	7	8	9	10	11	12
A	ID	NC	aaa12										
	RLU	10	150										
	Status												
B	ID	NC	aaa13										
	RLU	12	160										
	Status												
C	ID	NC	aaa14										
	RLU	15	500										
	Status												
D	ID	PC CT	aaa15										
	RLU	101	50										
	Status												
E	ID	PC CT	aaa16										
	RLU	105	701										
	Status												
F	ID	PC CT											
	RLU	108											
	Status												
G	ID	CT+ - V											
	RLU	400											
	Status												
H	ID	GC+ - V											
	RLU	50											
	Status												

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Luminometer Serial #: 2000   RCS Serial #:

The following table describes the fields in the header of the raw data report.

Field	Description
Capture Plate ID:	Capture plate ID in the *digene* HC2 System Software
Hybridization Plate ID:	Hybridization plate ID in the *digene* HC2 System Software
Status:	Plate status as **Measured** or **Accepted**
Measured:	Date and time of the plate measurement
Test name	Assay protocol ID
Area	Locations on the plate occupied by each individual assay protocol
Operator	User ID logged into the *digene* HC2 System Software during plate measurement
Kit lot #	Kit lot number
Validated by	Assay protocol validator
Edited	**Yes** or **No** indicates if the data were manually entered

The following table describes the fields in the well locations of the raw data report.

Field	Description
ID	Calibrator ID, quality control ID or specimen ID tested in the respective well
RLU	RLU result for the calibrator, quality control or specimen tested in the microplate well
Outlier	Displays in any well containing a calibrator that was determined to be an outlier

7.35.2 Understanding the plate report

The plate report displays information in a plate layout grid format. Generate a plate report when a shorter report with an overview of the results is desired.

The information displayed in a plate report depends on the following criteria:

- If the assay is valid, the results for each specimen are displayed
- If the assay is invalid, only RLU results are displayed for each specimen
- If the status of a specimen is unclear, only the RLU result is displayed
- If the status of a specimen is invalid, only the specimen ID is displayed

Example of the plate report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Capture Plate ID: Plate05H
Hybridization Plate ID: Plate05H

Status: Measured
Measured: 3/19/2015 3:08:01 PM

Test Name	Area	Operator	Kit Lot #	Valid Run	Validated By	Pos Cal Avg	Edited
CopyCt-ID 5.0	A1..E2	CooperA	newkit	Yes	For Research Use Only	104.67	Yes

	1	2	3	4	5	6	7	8	9	10	11	12
A — ID / RLU / Ratio / Result	NC / 10 / /	aaa12 / 150 / 1.43 / Equiv/Final										
B — ID / RLU / Ratio / Result	NC / 12 / /	aaa13 / 160 / 1.52 / Equiv/Final										
C — ID / RLU / Ratio / Result	NC / 15 / /	aaa14 / 500 / 4.77 / CT-ID+/Final										
D — ID / RLU / Ratio / Result	PC CT / 101 / /	aaa15 / 50 / 0.47 / --/Final										
E — ID / RLU / Ratio / Result	PC CT / 105 / /	aaa16 / 701 / 6.69 / CT-ID+/Final										
F — ID / RLU / Ratio / Result	PC CT / 108 / /											
G — ID / RLU / Ratio / Result	CT+ - V / 400 / 3.82 / Valid											
H — ID / RLU / Ratio / Result	GC+ - V / 50 / 0.47 / Valid											

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Luminometer Serial #: 2000   RCS Serial #:

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The following table describes the fields in the header of the plate report.

Field	Description
Capture Plate ID:	Capture plate ID in the *digene* HC2 System Software
Hybridization Plate ID:	Hybridization plate ID in the *digene* HC2 System Software
Status:	Plate status as **Measured** or **Accepted**
Measured:	Date and time of the plate measurement
Test name	Assay protocol ID
Area	Locations on the plate occupied by each individual assay protocol
Operator	User ID logged into the *digene* HC2 System Software during plate measurement
Kit lot #	Kit lot number
Valid Run	**Yes** means the assay is valid, and **No** means the assay is invalid
Validated by	Assay protocol validator
Pos Cal Average	The average of the positive calibrators for the assay protocol multiplied by the CAF
Edited	**Yes** or **No** indicates if the data were manually entered

The following table describes the fields in the well locations of the plate report.

Field	Description
ID	Calibrator ID, quality control ID or specimen ID tested in the respective well

Field	Description
RLU	RLU result for the calibrator, quality control or specimen tested in the respective well
Ratio	Ratio result of the RLU to the CO for the assay for the quality control or specimen tested in the respective well
Result	Result and result status of testing for the quality control or specimen tested in the respective well
	If ** is appended to the result, the result is preliminary, and the specimen requires further testing to achieve a final result; see "Understanding the retest algorithm," page 133, for additional instructions
Outlier	Displays in any well containing a calibrator that was determined to be an outlier

7.35.3 Understanding the column report

The column report provides information about a plate in a columnar format.

Example of the column report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Capture Plate ID: Plate05H　　　　　　**Status: Measured**　　　　　　**Measured: 3/19/2015 3:08:01 PM**
Hybridization Plate ID: Plate05H

Test Name	Area	Operator	Kit Lot #	Valid Run	Validated By	Pos Cal Avg	Edited
CopyCt-ID 5.0	A1..E2	CooperA	newkit	Yes	For Research Use Only	104.67	Yes

Loc.	Cnt	Specimen ID	Retest ID	Result	Result Status	Type	Cutoff	Patient ID	RLU	Mean RLU	% CV	RLU/CO	F/O
A1		NC							10	12	20.40	0.11	
B1		NC							12	12	20.40	0.11	
C1		NC							15	12	20.40	0.11	
D1		PC CT							101	104	3.36	1.00	
E1		PC CT							105	104	3.36	1.00	
F1		PC CT							108	104	3.36	1.00	
G1		CT+ (ctqx)		Valid					400			3.82	
H1		GC+ (gcqc)		Valid					50			0.47	
A2	1	aaa12		*Equiv*	Final	STM	1°		150			1.43	
B2	2	aaa13		*Equiv*	Final	STM	1°		160			1.52	
C2	3	aaa14		**CT-ID+**	Final	STM	1°		500			4.77	
D2	4	aaa15		--	Final	STM	1°		50			0.47	
E2	5	aaa16		**CT-ID+**	Final	STM	1°		701			6.69	

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Luminometer Serial #: 2000　　**RCS Serial #:**

The following table describes the fields in the header of the column report.

Field	Description
Capture Plate ID:	Capture plate ID in the *digene* HC2 System Software
Hybridization Plate ID:	Hybridization plate ID in the *digene* HC2 System Software
Imported Plate ID:	Plate ID from the output file **Note**: This field only displays if the plate ID is changed during the creation of the plate from the output file.
Status:	Plate status as **Measured** or **Accepted**
Measured:	Date and time of the plate measurement
Test name	Assay protocol ID
Area	Locations on the plate occupied by each individual assay protocol
Operator	User ID logged into the *digene* HC2 System Software during plate measurement
Kit lot #	Kit lot number
Valid Run	**Yes** means the assay is valid, and **No** means the assay is invalid
Validated by	Assay protocol validator
Pos Cal Average	The average of the positive calibrators for the assay protocol multiplied by the CAF
Edited	**Yes** or **No** indicates if the data were manually entered

The following table describes the fields in the results section of the column report.

Field	Description
Loc.	Microplate well location
Cnt	Specimen count
Specimen ID	Calibrator ID, quality control ID or specimen ID tested
Retest ID	Displays the status of the retest algorithm; the field is blank if the specimen is not being retested **1** indicates the first retest (or second assay) of the specimen; **2** indicates the second retest (or third assay) of the specimen See "Understanding the retest algorithm," page 133, for additional instructions.
Result	Test result for the quality control or specimen If ****** is appended to the result, the result is preliminary, and the specimen requires further testing to achieve a final result; see "Understanding the retest algorithm," page 133, for additional instructions
Result Status	Status of the test result of the specimen
Type	Specimen type of the specimen
Cutoff	Specimen cutoff type of the specimen
Patient ID	Patient ID associated with the specimen
RLU	RLU result for the calibrator, quality control or specimen tested in the microplate well
Mean RLU	Mean of the RLU results for replicates
% CV	CV of results for replicates

Field	Description
RLU/CO	Ratio of the RLU for the specimen tested in the microplate well to the RLU of the test cutoff
	If replicates are tested, the displayed value is the average of the ratios if the replicates have the same result status; the displayed value is for each result if the replicates have a split result status.
F/C	Displays whether a flag or comment is associated with the calibrator, quality control or specimen; the value will either be blank, meaning no comments, or **Y** with the comment displayed in the comments section of the report

If the calibrators, quality controls or specimens have comments associated, the information is displayed in another set of columns located below the last row of the result data.

The following table describes the fields of the comments section of the column report.

Field	Description
Specimen ID	Calibrator ID, quality control ID or specimen ID tested
Type	Type of comment that is associated with the calibrator, quality control or specimen
Flags/Comments	Comment associated with the calibrator, quality control or specimen

7.35.4 Understanding the assay report

The assay report displays assay validation information in a tabular format.

Example of the assay report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

HC2 Protocol: CopyCt-ID v5.0		Capture Plate ID: Plate05H	Assay is: Valid	
Date / Time:	3/19/2015 3:08:01 PM		Operator:	CooperA
Kit Lot #:	newkit		Expiration Date:	3/9/2016
Capture Plate ID:	Plate05H		Room Temp:	25° C
Hybridization Plate ID:	Plate05H		Status:	Measured
Edited:	Yes			
Validated By:	For Research Use Only			
Comments:				

Assay Verification Summary

	Protocol Parameters		Assay Values	Initial	Final	Status
	Discard Outliers	Yes				
RLU Ranges	NC	10-150	Mean NC	12.33	12.33	Pass
	PC CT	...	Mean PC CT	104.67	104.67	Pass
	Temperature	20-25 C°	Temperature		25° C	Pass
Max %CV	NC	25%	NC %CV	20.40	20.40	Pass
	PC CT	20%	PC CT %CV	3.36	3.36	Pass
Ratio	Pos/NC	2.0-20.0	Pos/NC		8.48	Pass
Correction Factors	STM	1.00	**Warnings:**			
	CTT	0.80				

Calibrator Replicates

Calibrator	RLU	Valid Reps	Calibrator	RLU	Valid Reps
NC	10	10	PC CT	101	101
NC	12	12	PC CT	105	105
NC	15	15	PC CT	108	108

Cutoff / Calculations

Specimen	Primary		Secondary		Tertiary	
	Positive	Negative	Positive	Negative	Positive	Negative
STM	>=261.68	<104.67	>=104.67	<104.67	>=104.67	<104.67
CTT	>=104.67	<104.67	>=131.88	<129.79	>=131.88	<131.88

Specimen Summary

Total # Specimens:	5	Positive Count	2

Ratios of Quality Controls

Quality Control	Kit Lot	Exp. Date	Range	Max %CV	%CV	RLU	Ratio	Status	Set for Validation
CT+	ctqx	8/4/2017	1.00-20.00	20	0.00	400	3.82	Valid	Yes
GC+	gcqc	8/4/2016	0.00-0.99	20	0.00	50	0.47	Valid	Yes

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The following table describes the fields in the header of the assay report.

Field	Description
HC2 Protocol	Assay protocol ID and version number
Capture Plate ID	Capture plate ID in the *digene* HC2 System Software
Assay is:	Validation status of the assay
Date/Time:	Date and time of the plate measurement
Kit lot #:	Kit lot number
Capture Plate ID:	Capture plate ID in the *digene* HC2 System Software
Hybridization Plate ID:	Hybridization plate ID in the *digene* HC2 System Software
Imported Plate ID:	Plate ID from the output file **Note**: This field only displays if the plate ID is changed during the creation of the plate from the output file.
Edited:	**Yes** or **No** indicates if the data were manually entered
Validated by	Assay protocol validator
Comments:	Displays any comments entered in the **Header Information** dialog box for the plate See "Using the **Header Information** dialog box," page 43, for additional instructions.
Operator	User ID logged into the *digene* HC2 System Software during plate measurement
Expiration Date:	Expiration date of the kit
Room temperature:	Room temperature at the time of plate measurement The room temperature is entered by the user.
Status:	Plate status as **Measured** or **Accepted**

The **Assay Verification Summary** panel of the assay report is broken into two subpanels of information. The **Protocol Parameters** subpanel on the left side of the **Assay Verification Summary** panel describes the parameters for the assay protocol. The **Assay Values** subpanel on the right side of the **Assay Verification Summary** panel describes the results of the assay.

The following table describes the fields in the **Protocol Parameters** subpanel of the **Assay Verification Summary** panel.

Field	Description
Discard Outliers	Specifies if outliers can be discarded from test results **Note**: This does not indicate that outliers were actually discarded from the test results of the report.
RLU Ranges	Specifies the RLU and temperature parameters of the calibrators associated with the assay protocol
Max %CV	Specifies the CV parameters of the calibrators associated with the assay protocol
Ratio	Specifies the ratio parameter associated with the assay protocol; the ratio is the average RLU of the positive calibrator to the average RLU of the negative calibrator
Correction Factors	Specifies the correction factor for each specimen type associated with the assay protocol

The following table describes the fields in the **Assay Values** subpanel of the **Assay Verification Summary** panel.

Field	Description
Assay Values	Column containing the assay protocol parameters that are required for validation of the assay
Initial	Column containing the results without outliers excluded
Final	Column containing the results with outliers excluded

Field	Description
Status	Column containing the status of the results as either **Pass** or **Fail** in relation to the information presented in the **Protocol Parameters** subpanel
Warnings:	Warning messages display in this field, as applicable **Note**: The **Warnings:** field is limited to 255 characters.

The **Calibrator Replicates** panel of the assay report presents information about the calibrators associated with the assay protocol.

The following table describes the fields in the **Calibrator Replicates** panel.

Field	Description
Calibrator ID	Column containing the calibrator ID
RLU	Column containing the RLU result for the specified calibrator
Valid Reps	Column containing the RLU result if the specified calibrator was used to calculate the calibrator mean; if it is blank, the RLU result was discarded

The following table describes the fields in the **Cutoff/Calculations** panel of the assay.

Field	Description
Specimen	Column containing specimen types associated with the assay protocol
Primary	Column containing the positive and negative RLU values for the primary cutoff factor
Secondary	Column containing the positive and negative RLU values for the secondary cutoff factor
Tertiary	Column containing the positive and negative RLU values for the tertiary cutoff factor

The following table describes the fields in the **Specimen Summary** panel of the assay report.

Field	Description
Total # Specimens:	Specifies the total number of specimens tested
Positive Count	Specifies the total number of specimens with an RLU above the CO for the assay*

* The positive count is not based on the result status of the specimen. The number includes unclear and invalid specimens that are above CO for the assay that do have a final result status.

The following table describes the columns in the **Ratios of Quality Controls** panel.

Column	Description
Quality control	Column containing the quality control IDs tested
Kit Lot	Column containing the kit lot associated with the specified quality control
Exp. Date	Column containing the expiration dates of the specified quality controls
Range	Column containing the RLU/CO range specification of the specified quality controls as defined by the assay protocol parameters
Max %CV	Column containing the maximum CV specification of the specified quality controls as defined by the assay protocol parameters
%CV	Column containing the CV result of the specified quality controls
RLU	Column containing the RLU result of the specified quality controls
Ratio	Column containing the ratio result of the quality control RLU to the CO for the assay

Column	Description
Status	Column containing the result status of the specified quality controls
Set for validation	Column containing whether the quality control is set for use in validation of the assay when added to the plate as defined by the quality control parameters; the value is either **Yes** or **No** To modify the parameters of a quality control, see "Modifying a quality control," page 156, for additional instructions.

7.36   Generating specimen reports

After measuring as specimen, reports can be generated for individual specimens. The available reports for specimens are the individual specimen and specimen history reports. The specimen reports are accessed on the **Assay Protocols** tab.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

    The **Specimen List** window opens.

2. Check the applicable boxes in the **Filter by Specimen Status** panel to filter the list of specimens displayed.

    See "Using the **Specimen List** window," page 74, for additional instructions.

3. In the list of specimens, select the applicable specimen ID for the report.

4. To view the individual specimen report, click the **View ISR** button. To view the specimen history report, click the **History** button.

    The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

5. Click **Close** to return to the **Specimen List** window.

7.36.1 Understanding the individual specimen report

The individual specimen report is only available for specimens that have been accepted. See "Accepting results," page 198, for additional instructions.

The individual specimen report includes the following information:

- Laboratory header information including the name of the laboratory and the address

  See "Modifying the laboratory information," page 113, for instructions to change the laboratory header information.

- The *digene* HC2 System Software version used to measure the plate
- Serial number of the DML instrument used to measure the plate
- Serial number of the RCS used to perform the test, as applicable

Example of the individual specimen report:

Date Reported: 3/19/2015 3:15:09 PM

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Physician: Doctor

Patient Information:

Patient ID	Patient	DOB	Sex
PAT-001	Patience,Constant	3/9/1999	Female

Specimen ID:
1364A-101

Results:

Protocol ID	Specimen ID	Edited	Measured	Result	Status
CopyCt-ID	1364A-101	Yes	3/11/2015	Equiv	Final

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The following table describes the fields in the individual specimen report.

Field	Description
Physician:	Physician of the patient
	Note: This information only displays if entered in the *digene* HC2 System Software.
Patient Information:	Information about the patient
	Note: This information only displays if entered in the *digene* HC2 System Software
Specimen ID:	Specimen ID of the specimen tested
Results:	Panel containing the results for the tested specimen
Protocol ID	Column containing the assay protocols used for the tested specimen
Specimen ID	Column containing the specimen IDs for the tested specimen
Edited	**Yes** or **No** indicates if the data were manually entered
Measured	Column containing the date the test result was determined for the tested specimen
Result	Column containing the test results for the tested specimen
Status	Column containing the test result status for the tested specimen

7.36.2 Understanding the specimen history report

The specimen history report displays the history of a specimen at the time the report is generated.

The specimen history report includes the following information:

- Laboratory header information including the name of the laboratory and the address
  See "Modifying the laboratory information," page 113, for instructions to change the laboratory header information.
- The *digene* HC2 System Software version used to measure the plate
- Serial number of the DML instrument used to measure the plate

The header of the specimen history report specifies the assay protocol ID and the specimen ID. Comments display below the specimen ID. As applicable, the report will have a comment for the following actions or status changes:

- The specimen is imported from a file
- The specimen ID or plate ID is modified during the creation of a plate from an output file of a pre-analytical instrument
- The specimen has an unclear or invalid status along with the comment from the output file
- The result status of unclear or invalid is cleared
- The specimen is modified
- The specimen is set to re-measure or QNS
- A retest is created for a specimen with a preliminary result status
- The plate containing the specimen is accepted
- The plate containing the specimen is transmitted

Example of the specimen history report:

The following table describes the fields in the specimen history report.

Field	Description
No.	Column containing the sequential listing, starting with the most recent, of tests or user actions performed for the applicable specimen
Tested Assay Protocol	Column containing the assay protocol ID used for testing the applicable specimen
Specimen ID	Column containing the specimen ID(s) for the applicable specimen
Retest ID	Displays the status of the retest algorithm; the field is blank if the specimen is not being retested **1** indicates the first retest (or second assay) of the specimen; **2** indicates the second retest (or third assay) of the specimen See "Understanding the retest algorithm," page 133, for additional instructions.

Field	Description
Edited	**Yes** or **No** indicates if the data were manually entered
Time of Event	Column containing the date and time of the action for the applicable specimen
User	Column containing the user ID that was logged in when the action occurred for the applicable specimen
Result	Column containing the result for the applicable specimen
Status	Column containing the result status of either **Preliminary** or **Final** for the applicable specimen
Ratio	Column containing the ratio result (RLU/CO) for the applicable specimen
RLU	Column containing the RLU results for the specified specimen

7.37   Understanding test results

A plate is validated according to the parameters of the assay protocol. Both valid and invalid capture plates will display in the **Measured Capture Plates** panel on the **Plates** tab. See "Understanding assay protocols," page 125, for additional information.

A successfully measured capture plate has the status of measured. According to the parameters of the assay protocol, specimens are given a result and a result status. The assay protocol type and parameters determine the result and result status associated with the specimens.

If the assay is invalid, the specimens will have a status of invalid and the *digene* HC2 System Software will not report results for the specimens. If an assay is invalid because the CV of the calibrators is out of range, the CO of the assay cannot be determined. The results for the quality controls on the plate are reported as **0.00**.

7.37.1 Viewing assay validation results

The results of plate measurement can be viewed using the different reports generated by the *digene* HC2 System Software. The assay report displays assay validation information in a tabular format. See "Generating test reports," page 176, for additional instructions.

7.37.2 Understanding split results

If a specimen is tested in duplicate on a plate, it is possible that the two replicates will have different results. The *digene* HC2 System Software handles split results based on the criteria in the following table.

Assay protocol type	"Results Final" parameter	Result status of a split result
Consensus	**No**	A retest ID for the specimen is created and the two replicates have a result status of preliminary.
		The final result for the specimen is determined by the third test of the specimen as determined by the retest algorithm.
Consensus	**Yes**	The result for the specimen is split with a result status of final.
Non-consensus	Not applicable	The result for the specimen is split with a result status of final.

7.37.3 Clearing the status of a specimen

If a specimen has a result status of unclear or invalid based on the output file of a pre-analytical instrument, the result status of the specimen must be cleared prior to attempting to measure the specimen again. Clearing the result status of a specimen changes the status of the specimen to unmeasured with a result status of no result.

The unclear or invalid result status of the specimen can only be cleared before the plate containing the specimen has been accepted. Also, a specimen with an unclear or invalid result status cannot be set to QNS.

If the result status of the specimen is not cleared, the *digene* HC2 System will not allow the same specimen ID to be imported or used in a plate. The *digene* HC2 System will consider the specimen ID a duplicate and require the user to change the specimen ID.

The action of clearing the specimen is retained in the specimen history.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. In the **Filter by Specimen Status** panel, uncheck all the boxes in the second column except **Processing Errors** box.

   The list will display only specimens that have a status of unclear or invalid.

3. Select the applicable specimen ID and click the **Clear Import** button.

   Note: Clear the status of multiple specimens by highlighting the applicable specimen IDs in the list and clicking the **Clear Import** button.

   A dialog box opens to confirm the clearing of the status for each specimen.

4. Click the applicable button to clear the status of the specimen.

   The status of the specimen will change to unassigned and the specimen will display in the unassigned specimen list for the assay protocol.

5. Click **OK** to close the **Specimen List** window.

7.37.4 Re-measuring a plate

A plate that was measured can be cleared of results if the plate has not been accepted. Setting a plate to re-measure changes the status of the plate to unmeasured. The status of the specimens on the plate is changed from measured to unassigned. The results from the measurement that was cleared and the action of changing the status of the specimens are retained in the specimen history report. See "Understanding the specimen history report," page 193, for additional information. This function is only available to users with supervisor access level.

1. On the **Plates** tab, select a measured plate in the **Measured Capture Plates** panel.

2. Click the **Re-measure** button.

   A dialog box opens to confirm the request to re-measure the plate.

3. Click the applicable button to re-measure the plate.

   The plate is removed from the **Measured Capture Plates** panel and displays in the **Unmeasured Hybridization Plates** panel. The specimens are given a status of unmeasured.

7.37.5 Re-measuring a specimen

A specimen that was measured can be cleared of results if the specimen plate that contained the specimen has not been accepted. Setting a specimen to be re-measured changes the status of the specimen from measured to unassigned. The results from the cleared measurement and the action of changing the status of the specimen are retained in the specimen history report. See "Understanding the specimen history report," page 193, for additional information.

This function is only available to users with supervisor access level.

1. On the **Assay Protocols** tab, select an assay protocol ID from the **Custom Assay Protocols** panel and click the **Specimens…** button.

   The **Specimen List** window opens.

2. Select the specimen ID to be re-measured and click the **Re-measure** button.

   Note: Select multiple specimens to re-measure by highlighting the applicable specimen IDs in the list and clicking the **Re-measure** button.

   A dialog box opens with a caution about deleting the results associated with the specimen.

3. Click **OK**.

   The **Set specimen for Remeasure?** dialog box opens.

4. Enter a comment in the dialog box, if desired.

   Note: The comment entered will be included in the specimen history report.

5. Click **OK**.

   The status of the specimen is changed to unassigned.

6. Click **OK** to close the **Specimen List** window.

7.38 Accepting results

Accepting results means an authorized user has determined that the results associated with a plate are acceptable to be reported as test results. The access level required for accepting a plate is based on the **Allow only Supervisor level acceptance of results** box on the **Utilities/Settings** tab. If a user does not have the required access level, a dialog box opens notifying the user of the inability to accept results. See "Determining the access level required to accept results," page 112, for additional instructions.

Only the results of measured capture plates can be accepted. Prior to accepting results, the user should review the various reports available to determine if the results are acceptable. See "Generating test reports," page 176, for additional information.

When an invalid plate is accepted, specimens on the plate are removed and will not display in the reports. The status of the removed specimens is changed to unassigned.

When a user accepts results, the electronic signature of the user is attached to the plate. The plate and assay reports will display the electronic signature of the user on the reports. See "Understanding the plate report," page 179, and "Understanding the assay report," page 185, for additional instructions.

A different user than the one currently logged in to the *digene* HC2 System Software can accept results by checking the **Sign as Guest** box, as described below.

Once the results are accepted, the test results cannot be modified, and the results are automatically added to the database for trending. Only accepted results can be exported.

1. On the **Plates** tab, select a capture plate ID in the list of the **Measured Capture Plates** panel and click the **Accept Results** button.

   The **eSignature** dialog box opens.

2. If the current user is accepting the results, enter the applicable eSign password in the **eSign Password:** dialog field.

   If a different user will accept the results, check the **Sign as Guest** box. The **Guest Login:** and **Login Password:** dialog fields appear. Enter the user ID and eSign password of the applicable user.

3. As applicable, check the **Change Password** box for the current user to change the associated eSign password during the acceptance of results.

   The **Old eSign Password:**, **New eSign password:** and **Confirm Password:** dialog fields appear. Enter the applicable information.

4. Click **OK**.

   A dialog box opens to confirm the acceptance of the results.

5. Click **Yes** to accept the results.

   If the plate contained an invalid assay, a dialog box opens stating the specimens associated with the invalid assay will be returned to the unassigned specimen list.

   The capture plate ID displays in the **Accepted Capture Plates** panel, the data associated with plate are added to the trend database, and the data can be exported to an LIS or to file.

7.39 Generating trending reports

The *digene* HC2 System Software maintains a database that is used to generate trending reports. A trending report may be generated for quality controls, calibrators, specimens or patients. If using a DML 2000, a trending report may be generated for background measurement readings. If modifications are made to the applicable information, the database is automatically updated.

All trending reports include the following information:

- Laboratory header information including the name of the laboratory and the address

  See "Modifying the laboratory information," page 113, for instructions to change the laboratory header information.

- The *digene* HC2 System Software version used to measure the plate
- Serial number of the DML instrument currently selected in the *digene* HC2 System Software

1. On the **Trends** tab, click the applicable radio button in the **Protocol Filter** panel.
2. Using the **Start Date:** and **End Date:** dialog fields in the **Trend Range** panel, enter the applicable time period for the trending report.
3. Click the applicable radio button in the **Trend Data** panel for the desired type of report.

   If generating a trending report for background measurements, select the applicable DML instrument from the drop-down list in the **Serial Number for Trend** panel.

   Note: Trending reports for plate background readings are only possible for DML 2000 instruments.

   If trend data exists for the type of report selected, the list populates with the IDs for which data are available.
4. Select the applicable ID in the list, and click the **Trend…** button.

   The **QIAGEN Report Viewer** window displays the report. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

7.39.1 Understanding the patient trending report

The patient trending report includes all specimens tested that are associated with a patient. For a trending report to be available, a patient must have more than one accepted specimen test result. The report includes a graph of the ratio for each specimen result. Different symbols indicate different specimen types on the graph, as applicable.

Example of a patient trending report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

High Risk HPV Patient Trending

Patient Name:	Constant Patience		Physician's Name:		Doctor	
Patient ID:	PAT-001					
	Date of Birth:	3/9/1999	Age: 16		Sex:	Female

Draw Date	Ratio	Comments	Specimen ID	Measure Date	Specimen Type
3/19/2015	2.85		ddd26	3/19/2015	PreservCyt
3/19/2015	3.07		ddd25	3/19/2015	PreservCyt
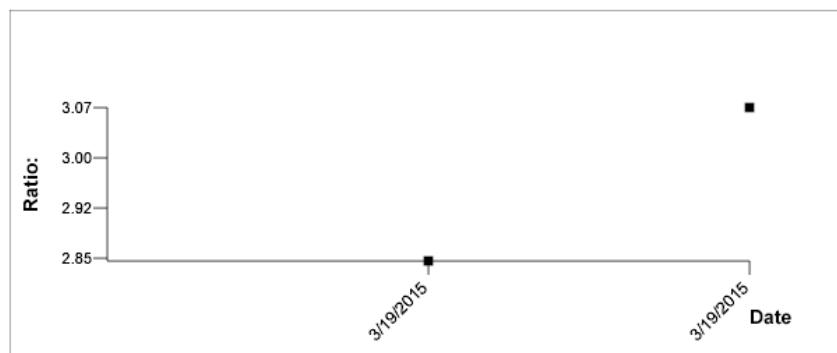
Medications:

Additional Data:

Date	Notes

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The following table describes the fields in the patient trending report.

Field	Description
Patient Name:	Name of the patient
Physician's Name:	Name of the physician
Patient ID:	ID associated with patient in the *digene* HC2 System Software
Date of Birth:	Date of birth of patient
Age:	Age of patient
Sex:	Gender of patient
Draw Date	Column containing the date the specimen was collected
Ratio	Column containing the ratio result (RLU/CO) for the specimen
Comments	Column containing any comments for the specimen
Specimen ID	Column containing the specimen ID
Measure Date	Column containing the date the capture plate containing the specimen was measured
Specimen Type	Column containing the specimen type of the specimen
Medications:	Dialog field containing any medications associated with the patient
Additional Data:	Dialog field containing any comments associated with the patient

7.39.2 Understanding the quality control trending report

The quality control trending report includes all results for a specific lot number of a quality control. The report includes a graph of the ratio result for each quality control result. Different symbols indicate different test kit lots on the graph, as applicable.

Example of the quality control trending report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Quality Control Trending

Quality Control: CT+   Lot #: qcctplus   Exp Date: 8/4/2016 11:59:59 PM

Upper Bounds   20.00
Lower Bounds   1.00

Assay Date	Ratio	Kit lot
3/4/2015	4.00	newkit
3/4/2015	4.00	newkit
3/4/2015	3.22	newkit
3/4/2015	3.28	newkit
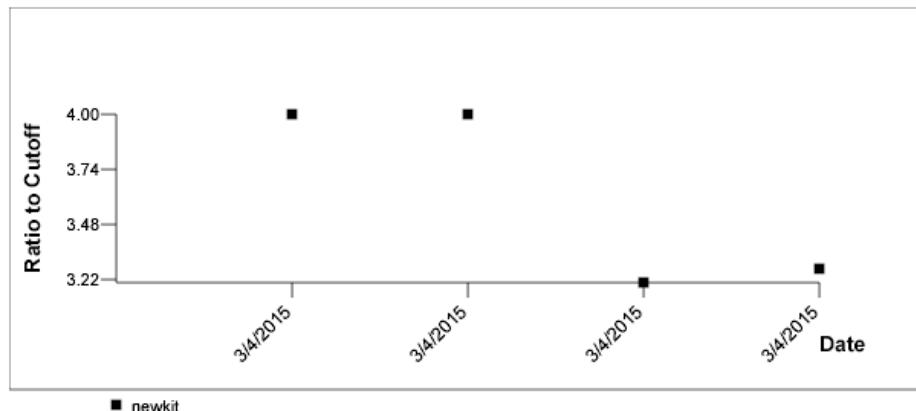
■ newkit

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The following table describes the fields in the quality control trending report.

Field	Description
Quality Control:	Quality control ID as defined by the parameters of the assay protocol
Lot #:	Lot number of the quality control
Exp Date:	Expiration date of the quality control
Upper Bounds	Upper limit specification for the ratio result (RLU/CO) of the quality control as defined by the parameters of the quality control
Lower Bounds	Lower limit specification for the ratio result (RLU/CO) of the quality control as defined by the parameters of the quality control
Assay Date:	Column containing the date the capture plate containing the quality control was measured
Ratio	Column containing the ratio result (RLU/CO) of the quality control
Kit lot	Column containing the test kit lot number

7.39.3 Understanding the calibrator trending by kit lot report

The calibrator trending by kit lot report includes a graph of the ratio results (RLU/CO) for the calibrators of an assay protocol. Different symbols indicate different kit lots on the graph, as applicable.

Example of the calibrator trending by kit lot report:

The following table describes the fields in the calibrator trending by kit lot report.

Field	Description
Protocol:	Assay protocol to which the calibrators are associated
Upper Bounds	Upper limit specification for the ratio result (RLU/CO) of the calibrators as defined by the parameters of the assay protocol
Lower Bounds	Lower limit specification for the ratio result (RLU/CO) of the calibrators as defined by the parameters of the assay protocol
Assay Date:	Column containing the date the capture plate containing the calibrators was measured
Kit lot	Column containing the test kit lot number
Ratio By Kit Lot – HRC/NC	Column containing the ratio result (RLU/CO) of the calibrators

7.39.4 Understanding the calibrator trending by user report

The calibrator trending by user report includes a graph of the ratio results (RLU/CO) for the calibrators of an assay protocol. Different symbols indicate different users on the graph, as applicable.

Example of the calibrator trending by user report:

The following table describes the fields in the calibrator trending by user report.

Field	Description
Protocol:	Assay protocol to which the calibrators are associated
Upper Bounds	Upper limit specification for the ratio result (RLU/CO) of the calibrators as defined by the parameters of the assay protocol
Lower Bounds	Lower limit specification for the ratio result (RLU/CO) of the calibrators as defined by the parameters of the assay protocol
Assay Date:	Column containing the date the capture plate containing the calibrators was measured
User	Column containing the user logged in when the capture plate was measured
Ratio By Kit Lot – HRC/NC	Column containing the ratio result (RLU/CO) of the calibrators

7.39.5 Understanding the specimen trending report

The specimen trending report includes all the results for a specimen. For a specimen trending report to be available, a specimen must have more than one accepted specimen test result.

Specimens with unclear or invalid results will not be included in the specimen trending report.

Example of the specimen trending report:

The following table describes the columns in the specimen trending report.

Column	Description
Assay Protocol	Column containing the assay protocol used to test the specimen
Draw Date	Column containing the date the specimen was collected
Patient ID	Column containing the patient ID associated with specimen
Hyb. ID	Column containing the hybridization plate ID associated with specimen
Specimen Type	Column containing the specimen type associated with the specimen
Cutoff Type	Column containing the cutoff type used to determine the result

Column	Description
Measure Date	Column containing the date the capture plate containing the specimen was measured
Primary Conc/Ratio	Column containing the ratio result (RLU/CO) for the specimen
Secondary Conc	This column contains no information relevant to qualitative assay protocols and will remain blank
Result	Column containing the results for the specimen
Comments	Column containing any comments associated with the specimen

7.39.6 Understanding the background baseline (100) trending report

The background baseline (100) trending report is only applicable to the DML 2000.

The report includes a graph of the average, minimum and maximum RLU results for each of the background baseline (100) readings performed for the specified DML instrument.

The background baseline (100) trending report should be reviewed periodically. The trending should be consistent with the average line, showing minimal upward or downward movement. Monitor any consistent trend upward or downward and contact QIAGEN Technical Services for assistance.

Example of the background baseline (100) trending report:

Emerald City Green Labs
1909 Yellow Brick Road
Munchkinlandz, Oz 68986

Printed on: 3/19/2015 2:57:56 PM

2000 Background Baseline (100) Trend Report from 3/18/2014 to 3/19/2015

Background Measurements
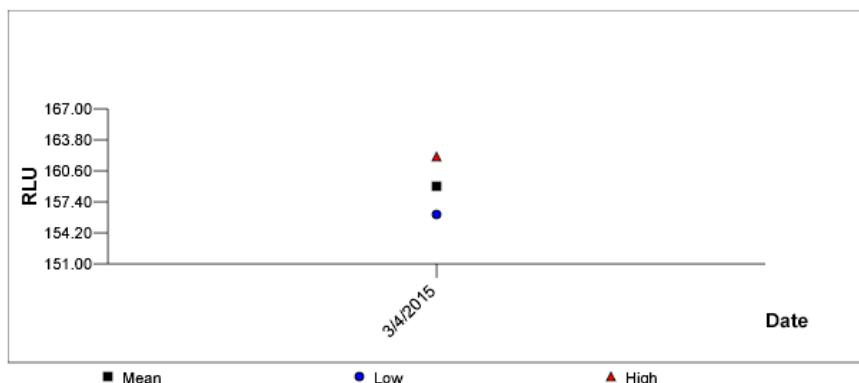
Date	Average	Range	Min	Max
3/4/2015	159	6	156	162

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Instrument Serial #: 2000

The following table describes the columns in the background baseline (100) trending report.

Column	Description
Date	Column containing the date of the background baseline (100) reading performed for the specified DML instrument
Average	Column containing the average RLU result of the background baseline (100) reading performed for the specific DML instrument
Range	Column containing the range of the background baseline (100) reading performed for the specific DML instrument
Min	Column containing the RLU minimum of the background baseline (100) reading performed for the specific DML instrument
Max	Column containing the RLU maximum of the background baseline (100) reading performed for the specific DML instrument

7.39.7 Understanding the plate background (10) trending report

The plate background (10) trending report is only applicable to the DML 2000.

The report includes a graph of the average, minimum and maximum RLU results for each of the plate background (10) readings performed for the specified DML instrument.

The plate background (10) trending report should be reviewed periodically. The trending should be consistent with the average line, showing minimal upward or downward movement. Monitor any consistent trend upward or downward and contact QIAGEN Technical Services for assistance.

Example of the plate background (10) trending report:

2000 Plate Background (10) Measurements from 3/18/2014 to 3/19/2015

Current Background Baseline

Date	Average	Range	Min	Max
3/4/2015	159	6	156	162

Plate Background Measurements

Date	Average	Range	Min	Max
3/4/2015	160	0	160	160
3/4/2015	160	4	160	164
3/4/2015	160	4	160	164
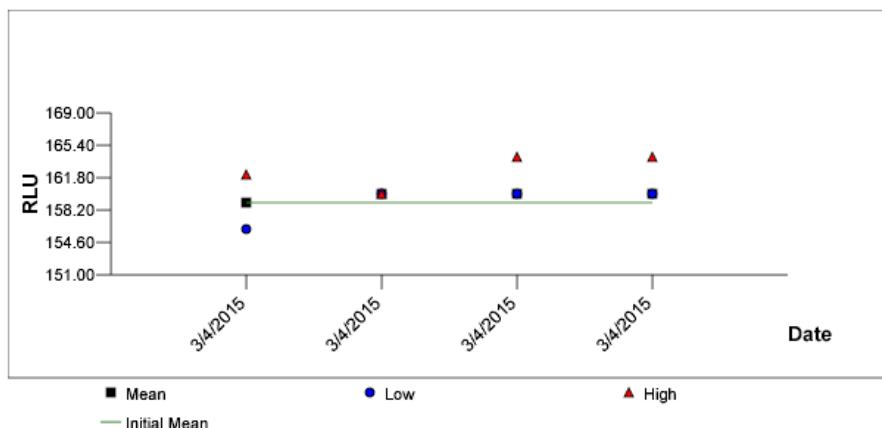
The following table describes the columns in the **Current Background Baseline** section of the plate background (10) trending report.

Column	Description
Date	Column containing the date of the last plate background (10) reading performed for the specified DML instrument
Average	Column containing the average RLU result of the last plate background (10) reading performed for the specific DML instrument

Column	Description
Range	Column containing the range of the last plate background (10) reading performed for the specific DML instrument
Min	Column containing the minimum RLU of the last plate background (10) reading performed for the specific DML instrument
Max	Column containing the maximum RLU of the last plate background (10) reading performed for the specific DML instrument

The following table describes the columns in the **Plate Background Measurements** section of the plate background (10) trending report.

Column	Description
Date	Column containing the date of the plate background (10) reading performed for the specified DML instrument
Average	Column containing the average RLU result of the plate background (10) reading performed for the specific DML instrument
Range	Column containing the range of the plate background (10) reading performed for the specific DML instrument
Min	Column containing the minimum RLU of the plate background (10) reading performed for the specific DML instrument
Max	Column containing the maximum RLU of the plate background (10) reading performed for the specific DML instrument

7.40 Backing up data

QIAGEN recommends maintaining an external back up of data at all times to reconstruct lost or altered files, data or programs. QIAGEN is not responsible for any loss of data. The entire hard disk should be maintained as part of the backup.

7.41 Exporting data

Data associated with accepted plates can be exported from the *digene* HC2 System Software to an LIS or a text file. Before a plate can be exported, the *digene* HC2 System Software must be configured for data export. See "Managing the data export settings," page 116, for additional instructions.

Exporting data to an LIS involves establishing a connection with an LIS host computer and exporting the data. Up to 3 attempts to connect with an LIS host computer are made before the data export fails. A plate can be exported multiple times.

The **LIS Transmit** column in the **Accepted Capture Plates** panel of the **Plates** tab displays the export status of each capture plate. During data export, only the capture plate ID is transmitted; the hybridization plate ID is not transmitted. Specimens with transmitted results will display **Transmitted** in the **Export State** column of the **Specimen List** window.

Whether the data of invalid assays are exported is determined based on whether the **Transmit Calibrator and Quality Control Data for Failed Assays** box is checked. See "Determining if calibrator and quality control results are exported for failed assays," page 119, for additional information.

When exporting to file, the exported files are saved in the **C:\Users\Public\QIAGEN\HC2 System Software\data\lis** directory. The user must save the files to a different directory or to a removable data storage device to keep the exported files. Exported files are automatically deleted the next time the *digene* HC2 System Software is started; however, the specimen and plate data remain in the *digene* HC2 System Software until an archive is performed.

Important: Exported files must be copied to another directory on the hard disk or to a removable data storage device as the files are deleted the next time the *digene* HC2 System Software is started.

Once data are archived, the archive containing the data must be loaded to export the data. See "Viewing an archive," page 217, for additional instructions.

If the *digene* HC2 System Software is exited before the transmission of data is complete, the data export will fail. See "Errors exporting data," page 228, for additional instructions.

1. On the **Plates** tab, select the applicable capture plate ID to be exported in the **Accepted Capture Plates** panel.

   Notes:

   - To filter the list displayed in the **Accepted Capture Plates** panel, select a column header or select either the **Not Transmitted** or **All** radio buttons in the **Filter** subpanel.
   - Multiple capture plates can be exported by highlighting multiple capture plates.

2. Click the **Export** button.

   Notes:

   - If saving to file, the data exported is saved in a file named after the hybridization plate ID and not the capture plate ID.
   - During data export, other functions, such as creating a plate, measuring a plate or viewing a report, can be performed.

3. If the data export fails, see "Errors exporting data," page 228, for additional instructions.

7.42   Creating an archive

Creating an archive removes accepted plates from the current data displayed in the *digene* HC2 System Software. During the creation of an archive, all accepted plates are copied to the archive, and then any plates that do not require further actions are removed from the current data. If it is later desired to export a plate that has been archived, view the archive and then export the plate. To view an archive, see "Viewing an archive," page 217, for additional instructions.

A plate cannot be removed from the current data if the plate contains a specimen with a preliminary result status as a result of the retest algorithm. Maintaining the plate allows the availability of a full specimen history until a final test result is achieved.

When an archive is created, either the data being archived can be retained in the current trend database or a new trend database can be created. If a new trend database is created, data in the current trend database are moved to the archive, and a new, empty trend database is created.

WARNING   **Incorrect test results**

Do not perform an archive during an RCS run. Performing an archive during the operation of the RCS could impact the timing of the test steps by slowing the RCS.

1. Back up the data on the HC2 System computer hard drive.

2. Close all other applications that may be open on the HC2 System computer.

3. On the **Utilities/Settings** tab, click the **Archive Data…** button in the **Archiving** panel.

   The **Archive Data** dialog box opens.

4. Select the applicable location to store the archive.

5. In the **Trend Database** panel, specify either **Retain Current Database** or **Create New Trend Database** radio button.

6. In the **Archive Description** dialog field, enter a short description that describes the archive.

   Recommendation: The description should describe the dates during which the data was collected.

7. Click **OK**.

   The data will be archived. The archive can be accessed on the **Utilities/Settings** tab. If the archive is not found using the **View Archive Data…** button, the archive can be recovered. See "Recovering an archive," page 218, for additional information.

7.42.1 Viewing an archive

Viewing an archive temporarily restores all data from the selected archive and excludes the current data in the *digene* HC2 System Software. New data cannot be created while viewing an archive. Reports while viewing an archive will only include data from the archive. All buttons and functions that would modify the data are disabled in the software. While viewing an archive, a plate can be exported. See "Exporting data," page 215, for additional instructions.

If the *digene* HC2 System Software is exited while viewing an archive, a dialog box will open the next time the *digene* HC2 System Software is opened to inform the user that an archive is being viewed. The current data must be restored before the full functionality of the *digene* HC2 System Software is allowed.

Make sure the settings for creating the archive are set appropriately. See "Managing the archive settings," page 114, for additional instructions.

1. On the **Utilities/Settings** tab, click the **View Archive Data…** button in the **Archiving** panel.

   The **View Archive Data** dialog box opens displaying a list of past archives. The **Date** and **Time** columns describe when the archive was performed. The **Comments** column is the information entered by the user during the archive process.

2. In the list below the **Select the Archive drive:** dialog field, select the applicable location that contains the archive.

3. In the list below the **Select the Archive to view:** dialog field, select the applicable archive to view.

4. Click **OK**. Alternatively, double-click the applicable archive.

   A dialog box opens to specifying that an archive is being viewed and no changes to the data will be saved.

5. Click **OK**.

6. View the archive.

7. When finished viewing the archive, click the **Restore Current Data** button on the **Utilities/Settings** tab.

   The **Restore Current Data** dialog box opens.

8. Click **OK** to restore the current data.

   The archive is returned to the original archive location, the current data are restored, and the full functionality of the *digene* HC2 System Software is allowed.

7.42.2 Recovering an archive

If an archive is not available, the archive may not be stored in the directory accessed by the *digene* HC2 System Software. To view the archive, the archive must be moved to the correct directory. The following procedure describes the steps to copy the archive to the directory accessed by the *digene* HC2 System Software.

1. Open the Windows Explorer program and navigate to the applicable folder containing the archive.

   Note: The format of the archive name is "YYYY_MM_DD_HH_SS".

2. Right-click on the archive and select **Copy** from the menu that displays.

3. Using the Windows Explorer program, navigate to the **C:\Users\Public\QIAGEN** directory.

4. Right-click on the **HC2 System Software** folder and select **Paste** from the menu that displays.

5. Open the **HC2 System Software** folder and make sure that the applicable archive has been copied successfully.

6. Exit the *digene* HC2 System Software.

7. Log in to the *digene* HC2 System Software.

   The archive should now be available in the **View Archive Data** dialog box. See "Viewing an archive," page 217, for additional instructions.

7.42.3 Transferring an archive to a USB storage device

An archive can be transferred to a USB storage device. This function is only possible after saving an archive to the local hard drive. See "Creating an archive," on page 216, for additional instructions.

1. Insert a USB storage device into a USB port on the HC2 System computer.
2. Using the Windows Explorer program, navigate to **C:\Users\Public\QIAGEN\HC2 System Software directory**, which contains the archive.

   Notes:
   - The format of the archive folder name is "YYYY_MM_DD_HH_MM_SS".
   - If the archive folder is not in the specified directory, the archive may be saved directly to the **C:** drive. Navigate to the **C:** drive to find the applicable archive.

3. Right-click on the applicable archive and select **Copy** from the menu that displays.
4. Using the Windows Explorer program, navigate to the to the USB storage device.
5. Right-click on the USB storage device folder and select **Paste** from the menu that displays.
6. Open the USB storage device folder and make sure that the applicable archive has been copied successfully.

7.43 Viewing the audit log

The *digene* HC2 System Software includes an audit log of certain events to track changes and to make troubleshooting easier. See "Using the **Audit Log** window," page 91, for additional instructions.

When an archive is created, the audit log is also archived. To view an audit log that has been archived, view the archive, and then view the audit log. To view an archive, see "Viewing an archive," page 217, for additional instructions.

1. On the **Utilities/Settings** tab, click the **Audit Log** button in the **Audit Log** panel.

   The **Audit Log** window opens.
2. Using the **Start Date:** and **End Date:** dialog fields in the **Date Range** panel, enter the applicable time period for the audit log.
3. Using the **User:** drop-down list, select the applicable users to include in audit log.
4. In the **Element:** panel, check the boxes for the applicable actions to include in the audit log.

5. If seeking information for a specific item, use the **Item ID:** dialog field to enter the specific item.

6. If seeking information for a specific assay protocol, use the **Protocol:** drop-down list to enter the specific assay protocol.

7. Click the **Apply Filter** button.

   The list in the **Audit Log** window updates based on the selected parameters. To print the list, click the **Print List** button. The **QIAGEN Report Viewer** window displays the audit log. See "Using the **QIAGEN Report Viewer** window," page 104, for additional instructions.

8. Click the **Close** button to exit the **Audit Log** window.

   The *digene* HC2 System Software returns to the **Utilities/Settings** tab.

8 Maintenance

Refer to the documentation provided by the manufacturer for information on maintaining the HC2 System computer and computer peripherals (monitor, keyboard, mouse, printer and cables).

For information on servicing the HC2 System computer and computer peripherals, please contact QIAGEN Technical Services.

9 Troubleshooting

This section provides information to assist in troubleshooting problems that may occur during use of the *digene* HC2 System Software. Refer to the applicable DML instrument user manual for additional troubleshooting information.

If further assistance is required, please contact QIAGEN Technical Services.

9.1   DML instrument performance problems and error messages

If the *digene* HC2 System Software is unable to communicate with the DML instrument, the *digene* HC2 System Software can still perform all functions that do not involve the use of the DML instrument.

9.1.1   Initialization or communication error messages between the HC2 System computer and the DML instrument

Possible causes:

- A faulty cable connection
- Using an incorrect serial port
- An incorrect serial port setting for the DML instrument in the *digene* HC2 System Software
- An incorrect **Instrument Type** setting for the DML instrument in the *digene* HC2 System Software

1. On the **Luminometer Settings** tab, click the **Settings** button in the **Luminometer Actions** panel.

   The **Luminometer Settings** dialog box opens.
2. Make sure the **Instrument Type:** dialog field displays the correct type of DML instrument.

   If the incorrect DML instrument type is displayed, the DML instrument must be deleted and added using the correct instrument type. See "Deleting a DML instrument," page 125, and "Adding a DML instrument," page 120, for additional instructions.
3. Make sure the **COM Port:** setting is correct.

   If the **COM Port:** setting is incorrect, select the correct COM port from the drop-down list.
4. Click **OK**.

   The **Luminometer Settings** dialog box closes.

5. Perform a mechanical test to check the communication between the *digene* HC2 System Software and the DML instrument. See "Performing a mechanical test," page 122, for additional instructions.

    If the communication continues to fail, continue with this procedure.

6. Power OFF all of the *digene* HC2 System components.

7. Disconnect and reconnect each of the cable connections.

8. Power ON all of the *digene* HC2 System components and make sure the applicable status lights display the correct functional status.

9. Make sure the cables between the DML instrument and the HC2 System computer are firmly connected.

    If using a DML 2000, make sure that the voltage setting is correct and that the fuses are functional. Refer to *DML 2000 User Manual* for additional instructions.

10. Perform a mechanical test to check the communication between the *digene* HC2 System Software and the DML instrument. See "Performing a mechanical test," page 122, for additional instructions.

    If the communication continues to fail, contact QIAGEN Technical Services.

9.1.2 Door is open message

Possible cause: The access door is not fully closed.

1. Close the access door securely.

2. Follow the instructions of the error dialog box.

3. If the error is not corrected, contact QIAGEN Technical Services.

9.1.3 Rattling noises in the DML instrument

Possible cause: The plate mask is not secure during plate carrier movement.

1. Stop the plate measurement. See "Canceling plate measurement," page 173, for additional instructions.

2. Power OFF the DML instrument.

3. Open the access door.

4. Make sure the plate is properly seated in the plate carrier.

5. Close the plate mask.

6. Power ON the DML instrument.

7. Measure the plate.

Possible cause: Communications failure.

See "Initialization or communication error messages between the HC2 System computer and the DML instrument," page 222, for additional instructions.

Possible cause: Plate carrier locking screw not removed from the DML 2000.

For a DML 2000, make sure that the plate carrier locking screw has been removed from the DML instrument. Refer to *DML 2000 User Manual* for additional instructions.

9.1.4   Very high RLU readings across the plate

Possible cause: External light source affecting plate measurement.

1. Make sure the access door is closed during plate measurement.
2. Make sure the seal on the access door is intact and not damaged.
3. Make sure the plate carrier has been thoroughly cleaned.
4. Perform a raw plate measurement without a plate in the plate carrier. See "Measuring a plate as raw data," page 173, for additional instructions.

   For the DML 3000, the RLU values should be less than 6; for the DML 2000, the RLU values should be less than 12. If the RLU values are greater than specified, contact QIAGEN Technical Services.

9.1.5   Iris failed to open message

This error is only applicable to the DML 2000.

If the iris fails to open during the mechanical test, a warning message displays. The options available to the user are as follows:

- Click the **Abort** button to cancel plate measurement.
- Make sure the access door is closed completely and click the **Retry** button to retry opening the iris.
- Click the **Ignore** button to disregard this test. The plate is not measured.

If this error persists, contact QIAGEN Technical Services.

9.1.6 Erratic results for empty wells and low intensity specimens

This error is only applicable to the DML 2000.

Possible cause: The DML instrument has not had enough time to warm up, or the DML instrument has a high background baseline (100) reading.

1. If the DML 2000 is not powered ON at all times, allow the DML instrument to warm up for at least one hour prior to plate measurement.

2. Perform a raw plate measurement without a plate in the plate carrier. See "Measuring a plate as raw data," page 173, for additional instructions.

   The RLU values should be less than 12. If the RLU values are greater than specified, contact QIAGEN Technical Services.

3. Perform a background baseline (100) reading. See "Performing a background baseline (100) reading," page 123, for additional instructions.

   If the difference between the minimum and maximum RLU result for the background baseline (100) reading is greater than 20, contact QIAGEN Technical Services.

9.2 Errors in associating capture plate IDs using the RCS Bar Code Reader

During RCS-automated testing using the RCS Bar Code Reader, the hybridization plate and capture plates are scanned at the beginning of the run and the capture plate is scanned again at the end of the run. The capture plate is scanned immediately before plate measurement to make sure the capture plate was not inadvertently switched by the user during RCS-automated testing. If a bar code scanning error occurs during RCS-automated testing, the RCS will continue with plate processing without acknowledging the error; the bar code scanning error will require the user to manually associate the capture plate ID in the *digene* HC2 System Software.

A general RCS Bar Code Reader error notification will only display once. The error notification displays either during the creation of the hybridization plate or during the manual association of the capture plate ID with a hybridization plate ID. If the general RCS Bar Code Reader error notification dialog box opens, a single or multiple errors may have occurred during the RCS run.

The following dialog box opens if RCS Bar Code Reader error occurs:

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One or more errors occurred when scanning plates on the RCS instrument:

- One or more Hybridization plates were unable to be scanned.
- One or more Capture plates were unable to be scanned during the initial scan.
- One or more completed Capture plates were unable to be scanned.
- One or more completed Capture plates did not match the ID of the Capture plate scanned at the initial scan.

Please confirm the RCS operations were completed correctly and manually associate the Hybridization Plate to the Capture Plate.

OK

9.2.1 No bar codes are scanned

Possible cause: Not using hybridization and capture plates with bar codes as supplied by QIAGEN.

Only use hybridization and capture plates supplied by QIAGEN. If the hybridization and capture plates used for RCS-automated testing do not have bar codes, the RCS will perform the bar code reading step and will continue with RCS-automated testing without impacting test results. The capture plate ID must be manually associated with the hybridization plate ID.

9.2.2 Initial scan of the hybridization plate failed

If a hybridization plate ID is not scanned, the hybridization plate must be created manually, and the capture plate ID must be manually associated with the hybridization plate ID. The general RCS Bar Code Reader error notification displays during the manual association of a capture plate ID with a hybridization plate ID.

1. Create the hybridization plate ID manually in the *digene* HC2 System Software. See "Creating a hybridization plate manually," page 162, for additional instructions.
2. During the association of the capture plate ID, select or enter the applicable capture plate ID in the **Capture Plate** drop-down list.

   Note: The drop-down list contains the capture plate ID acquired from the RCS run if the scan of the capture plate was completed correctly. If both scans of the capture plate ID failed, no capture plate ID will be available and must be entered manually.
3. Click **OK**.

   The capture plate ID is associated with the hybridization plate ID.

9.2.3 Initial scan of the capture plate failed

If the initial scan of the capture plate ID fails, the capture plate ID must be manually associated with the hybridization plate ID. The RCS Bar Code Reader error notification displays either during the creation of the hybridization plate (if the hybridization plate ID is not already in the *digene* HC2 System Software) or during the manual association of the capture plate ID with a hybridization plate ID.

1. Click the **OK** button to close the RCS Bar Code Reader error notification.

   The **Plate Association** dialog box opens.

2. Select or enter the applicable capture plate ID in the **Capture Plate** drop-down list.

   Note: The drop-down list contains the capture plate ID acquired from the final scan if the scan was completed correctly. If both scans of the capture plate ID failed, no capture plate ID will be available and must be entered manually.

3. Click **OK**.

   The capture plate ID is associated with the hybridization plate ID.

9.2.4 Final scan of the capture plate failed

If the final scan of the capture plate ID fails, the capture plate ID must be manually associated with the hybridization plate ID. The RCS Bar Code Reader error notification displays either during the creation of the hybridization plate (if the hybridization plate ID is not already in the *digene* HC2 System Software) or during the manual association of the capture plate ID with a hybridization plate ID.

1. Click the **OK** button to close the RCS Bar Code Reader error notification.

   The **Plate Association** dialog box opens.

2. Select or enter the applicable capture plate ID in the **Capture Plate** drop-down list.

   Note: The drop-down list contains the capture plate ID acquired from the initial scan if the scan was completed correctly. If both scans of the capture plate ID failed, no capture plate ID will be available and must be entered manually.

3. Click **OK**.

   The capture plate ID is associated with the hybridization plate ID.

9.2.5 Final scan of the capture plate did not match the initial scan of the capture plate

A mismatch of the initial capture plate ID and the final capture plate ID only occurs if a user stopped the RCS run and incorrectly moved the capture plate out of the correct position. The RCS Bar Code Reader error notification opens at the creation of the hybridization plate or during the association of the capture plate ID with the hybridization plate ID.

Important: Perform the following instructions only if the respective plate IDs are known. If the root cause of the bar code reader failure is unknown, do not continue with testing. Contact QIAGEN Technical Services for assistance.

1. Click the **OK** button to close the RCS Bar Code Reader error notification.

    The **Plate Association** dialog box opens.
2. Select or enter the applicable capture plate ID in the **Capture Plate** drop-down list.

    Note: The drop-down list contains the capture plate IDs acquired from the initial and final scan.
3. Click **OK**.

    The capture plate ID is associated with the hybridization plate ID.

9.3 Errors exporting data

9.3.1 Error during transmission to LIS

Possible cause: Error in the physical connection between the components.

Make sure the software interface between the *digene* HC2 System Software and the LIS is correctly configured. See "Managing the data export settings," page 116, for additional instructions.

9.3.2 Plate maintains an export status of transmitting

Possible cause: The *digene* HC2 System Software was exited during the transmission of data.

If the *digene* HC2 System Software is exited during transmission, a plate may remain with the export state of transmitting. The data are not actually being transmitted. Perform the export of the plate again. See "Exporting data," page 215, for additional instructions.

9.4   Plate background errors

This error is only applicable to the DML 2000.

The DML 2000 may experience a slight drift in the instruments internal noise that will affect the plate background (10) reading and, in time, cause it to exceed the specification.

All assays have calibrators that are used for assay validation. If the calibrators pass according to the assay protocol parameters, the assay is valid and the results are reportable regardless of the plate background (10) reading.

The DML instrument should be monitored for drifting trends and other anomalies as these may indicate problems with the DML instrument. Repeated out of specification plate background (10) readings may indicate problems with the DML instrument. For assistance, contact QIAGEN Technical Services.

To check the background of the DML instrument, perform a raw plate measurement without a plate in the plate carrier. See "Measuring a plate as raw data," page 173, for additional instructions.

The RLU values should be random throughout the plate and not clustered in one area. For the DML 3000, the RLU results should be less than 6; for the DML 2000, the RLU results should be less than 12. If the RLU values are greater than specified, contact QIAGEN Technical Services.

9.5 Failure creating a hybridization plate from a pre-analytical instrument

If the output file from the pre-analytical instrument contains an error that will not allow the creation of the plate, the *digene* HC2 System Software cancels the creation of the plate. The **Import Complete** dialog box displays with **Plate Aborted**, and the plate will not be created in the *digene* HC2 System Software.

Possible causes:

● Missing file checksum as the output file is not properly signed

● The position of the specimens on the plate, as defined in the output file, is invalid

● The status of the specimen, as defined in the output file, is not an accepted status for importing into the *digene* HC2 System Software

● The parameters of the plate, as defined in the output file, are not recognized by the digene HC2 System Software

If the *digene* HC2 System Software does not allow the creation of a plate from an output file, review the output file from the pre-analytical instrument for errors. The plate cannot be created from the output file, but a plate can be created manually. See "Creating a hybridization plate manually," page 162, for additional instructions.

10 Glossary

Term	Description
Alphanumeric	The characters of the English alphabet and numbers.
Assay	The performance of a test that is validated according to the applicable assay protocol parameters.
Assay validation	The process of the *digene* HC2 System Software validating an assay by comparing the results to the defined assay protocol parameters. If all the assay protocol parameters are met, the assay is valid, and specimen results are determined; if an assay fails an assay protocol parameter, the assay is invalid, and no results are reported.
Assay cutoff (CO)	The parameter calculated for each assay that determines if a test result is positive or negative. A test result equal to or greater than the CO is positive; a test result less than the CO is negative. The CO is determined by multiplying the positive calibrator (PC) average by the calibration adjustment factor (CAF). The CO is also defined in the *digene* HC2 System Software as the positive assay cutoff (PCO).
Assay protocol	Defines the parameters and settings by which specimens are measured, analyzed and validated. The assay protocol defines the required quality controls, assay cutoff and retest algorithm requirements.
Calibration adjustment factor (CAF)	An assay protocol parameter used to maintain consistent performance characteristics of a test based on some factor. The assay cutoff (CO) for each assay is determined by multiplying the positive calibrator average (PC) for the assay by the CAF.
Capture plate	The plate measured using the DML instrument to generate test results.
CAUTION	The term used to inform you about situations that could result in damage to the instrument or other equipment.
Chemiluminescence	The production of light as a result of a chemical reaction.

Term	Description
Consensus assay protocol	An assay protocol that always has constituent tests and uses an automatically tracked retest algorithm in the *digene* HC2 System Software.
Correction factor	An assay protocol parameter defined for each specimen type associated with an assay protocol. The correction factor is multiplied by the assay cutoff (CO) to normalize the specimen type, as applicable. A correction factor of **1.000** does not normalize the specimen type.
Cutoff factors	The assay protocol parameter defining the positive and negative assay cutoffs. Each specimen type associated with an assay protocol has cutoff factors. If the negative and positive cutoff factors are not equal, zone between the positive and negative assay cutoff is the retest/equivocal zone.
DML instrument	An instrument used to measure light that is emitted as a result of chemiluminescence.
Equivocal test result	For a non-consensus assay protocol, a test result that is in the retest/equivocal zone for the assay protocol and specimen type.
Final result status	A final result according to the parameters of the assay protocol.
Hybridization plate	The plate used to perform the hybridization step of a test.
Laboratory information system (LIS)	A system maintained by a laboratory for the management of information related to the testing of specimens.
LumiCheck Plate	A tool used to establish a set of specifications for a specific DML instrument. Based on the established specifications, the LumiCheck Plate is used to monitor the stability of the DML instrument. The LumiCheck Plate is used as an early warning of potential DML instrument failure and as a diagnostic tool.
Non-consensus assay protocol	An assay protocol that does not have a retest zone and all results are reported with a final result status.

Term	Description
Outlier rejection	An assay protocol parameter that determines if an outlier can be removed for the calculation of assay results.
	If outlier rejection is active and an assay protocol parameter fails during assay validation, the RLU result furthest the mean is excluded, and the assay protocol parameter is calculated. If the assay protocol parameter is within specification, the assay is valid; if the assay protocol parameter is not within specification, the assay is invalid.
Output file	An XML-formatted file created by the software of a pre-analytical instrument that contains data about a plate. The output file is used by the *digene* HC2 System Software to automate the creation of a hybridization plate.
Plate	A plate in the *digene* HC2 System Software is a collection of specimens tested as a group reflecting the physical 96-well plates used during the performance of the testing.
	A plate comprises the combination of the hybridization plate ID and the capture plate ID.
Plate layout grid	The graphical representation of a 96-well microplate as represented in the *digene* HC2 System Software. The placement of calibrators, quality controls and specimens in the plate layout grid reflects the physical placement of the calibrators, quality controls and specimens in the physical hybridization and capture microplates.
Pre-analytical instrument	An instrument that uses patient specimens to prepare samples.
Preliminary result status	The result for the specimen is incomplete as determined by the assay protocol parameters. The preliminary result status could be a result of the retest algorithm or split results.
Primary cutoff factor (1°)	The assay protocol parameter that defines whether a specimen is positive or negative the first time a specimen is tested.
Retest test result	A positive test result that is in the retest zone between the positive and negative cutoff factors for the assay protocol and the specimen type.

Term	Description
Retest zone	The difference between the negative and positive cutoff factors. Specimens with test results in the retest zone will be given a status of preliminary and require further testing to achieve a final result status.
Relative light unit (RLU)	The unit of measure used to quantify the chemiluminescence that is measured by a DML instrument.
RLU factor	A parameter used by the DML 2000 that is set by the manufacturer. The RLU factor is the scale used when measuring a plate and cannot be modified by a user.
Secondary cutoff factor (2°)	The assay protocol parameter that defines whether a specimen is positive or negative the second time a specimen is tested, if applicable.
Settle time	The amount of time the DML instrument pauses between the movement of the plate carrier and the measurement of a well. The settle time is set by the manufacturer and cannot be modified by a user.
Split test result	A test result that occurs when a specimen tested in duplicate has different test results (i.e., positive and negative). The *digene* HC2 System Software handles split test results based on if the assay protocol is consensus or non-consensus and the **Results Final** setting for the specimen type.
Tertiary cutoff factor (3°)	The assay protocol parameter that defines whether a specimen is positive or negative the third time a specimen is tested, as applicable.
WARNING	The term used to inform you about situations that could result in personal injury to you or others.

Appendix A — Technical Data

This section identifies the specifications and requirements of the HC2 System computer, peripherals and DML instrument.

Specifications of system computer and peripherals

Description	Specification
Central Processing Unit (CPU)	3.0 GHz 2 GB RAM
Disk drives	160 GB hard disk CD-RW/DVD-RW drive
I/O ports	1 DB-25 port (25 pin female) 1 DE-9, RS-232 port (9 pin male) 6 USB 2.0 ports 1 DE-15 port (15 pin female) 1 Ethernet 8P8C modular jack (female socket) 10–100 Mbits/s 2 auto-sensing mini-jack sockets
Cables	Country-specific power cord
Operating system	Windows 7 Professional SP1
Monitor	1024 x 768 or higher resolution; cable; power cord
Keyboard	Country-specific version USB keyboard
Mouse	USB optical mouse

Power and environmental requirements

Refer to the documentation provided by the manufacturer for power and environmental requirements of the HC2 System computer and printer.

DML instrument performance specifications and operating requirements

Refer to the applicable DML instrument user manual for performance specifications and operating requirements of the DML instrument.

DML instrument power and environmental requirements

Refer to the applicable DML instrument user manual for power and environmental requirements of the DML instrument.

Appendix B — Abbreviations

Term	Description
AC	Alternating current
ASTM	American Society for Testing and Methods
CAF	Calibration adjustment factor
CCD	Charge-coupled device
CO	Assay cutoff
CPU	Central processing unit
CV	Coefficient of variation
DML	*digene* Microplate Luminometer
HC2	Hybrid Capture 2
ISR	Individual specimen report
IT	Information technology
LIS	Laboratory information system
NC	Negative calibrator
PCO	Positive assay cutoff
PMT	Photomultiplier tube
QNS	Quantity not sufficient
RCS	Rapid Capture System
RLU	Relative light units
USB	Universal Serial Bus

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