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LumiCheck Plate and Software User Manual

For use with LumiCheck Plate Software versions
2.0.1, 2.0.2 and 2.0.3

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L02002 Rev. 05

Sample to Insight

QIAGEN

Contents

1 Introduction

Thank you for choosing the LumiCheck Plate. We are confident it will become an integral part of your laboratory.

Before using the instrument, 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 of the instrument and to maintain the instrument in a safe condition.

1.1 General information

This user manual provides instructions on using the LumiCheck Plate and associated software as a tool to monitor the performance of the *digene*® microplate luminometer (DML) instruments. Use this user manual, along with the other user manuals provided, as part of the *digene* Hybrid Capture® 2 (HC2®) System Suite.

1.1.1 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 regarding the instrument or QIAGEN products in general, 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.

1.1.2 Version management

This document is LumiCheck Plate and Software User Manual, L02002, Rev. 04. This user manual is for use with LumiCheck Plate Software versions 2.0.1, 2.0.2 and 2.0.3 and *digene* HC2 DNA tests as part of *digene* HC2 System Suite.

1.1.3 Software license agreement

This software license agreement applies only to the LumiCheck Plate Software provided as part of the *digene* HC2 System Suite. The license agreement sets forth the terms and conditions of the license and the limited warranty for the LumiCheck Plate.

1.1.4 License grant

The customer does not receive title to the LumiCheck Plate Software. The customer is granted a nonexclusive license to use the LumiCheck Plate Software subject to the restrictions and terms set forth in this agreement.

1.1.5 Restrictions

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

1.1.6 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 LumiCheck Plate Software and accompanying documentation. The customer may not transfer the LumiCheck Plate Software without prior written agreement.

1.1.7 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.

1.1.8 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 terms and conditions of this license agreement.

1.1.9 Warranty and special provisions

QIAGEN warrants that the LumiCheck Plate 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 LumiCheck Plate Software are limited to 90 days. Some countries, states or jurisdictions do not allow limitations on duration of an implied warranty.

The warranty of the LumiCheck Plate is 12 months from the date of shipment, excluding the battery.

1.1.10 Limitation of liability

Notwithstanding anything to the contrary contained herein, the liability of the seller (whether by reason of breach of warranty, breach of contract, tort or otherwise), including without limitation under any indemnification provision contained herein, shall be limited to replacement of goods returned to QIAGEN which are shown to reasonable satisfaction to QIAGEN to have been nonconforming or to refund the purchase price, or, if not paid, to a credit amount of the purchase price thereof.

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 Intended use

The LumiCheck Plate is intended to monitor the performance consistency of the DML instrument through periodic testing of the following:

- Absolute relative light units (RLU)
- Relative linearity over the dynamic range of the DML instrument
- Background stability
- Cross-talk

The LumiCheck Plate establishes 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 in the event of a failed *digene* HC2 DNA test. A failed periodic check using the

LumiCheck Plate does not invalidate prior assay results as each *digene* HC2 DNA test contains internal verification criteria that validate the assay.

1.1.1 Requirements for users

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

1.2 Operating software

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 following terms are used when naming features of the software.

Term	Description
Box	An item in a dialog box that can be checked or unchecked.
Button	An item in a dialog box or toolbar that 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 that the user clicks to display a drop-down list. A menu is also a list of items that 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 that 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 the instrument and to maintain the instrument 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 instrument, 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 instrument.

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

2.1 Proper use

WARNING/ CAUTION

Risk of personal injury and material damage

Improper use of the LumiCheck Plate may cause personal injuries to the user or damage the LumiCheck Plate.

The LumiCheck Plate must be used only in conjunction with the DML instrument and must only be operated by qualified personnel who have been appropriately trained.

CAUTION **Damage to the instrument**

The activation switch and battery test button are fragile parts. Handle with care and pay attention to prevent damage to these parts.

CAUTION **Damage to the instrument**

Do not immerse the LumiCheck Plate in water or allow water to enter the chamber of the LumiCheck Plate.

CAUTION **Risk of personal injury or incorrect results**

Do not operate the LumiCheck Plate with the battery cover removed or without all the cover fasteners in place.

CAUTION **Damage to the instrument**

To properly protect from damage during transport, only transport the LumiCheck Plate in the manufacturer's original packaging.

2.2 Electrical safety

- When not in use, power OFF the LumiCheck Plate.
- Avoid allowing the LumiCheck Plate to come into contact with liquids.
- Do not attempt to disassemble the LumiCheck Plate.

The 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 HC2 System component from an AC power outlet that has no ground connection.

Refer to the applicable user manual for additional safety information.

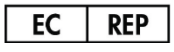
2.3 Waste disposal

To dispose of the LumiCheck Plate, follow all national, state and local health and safety regulation and laws for disposing of laboratory waste. For disposal of Waste Electrical and Electronic

Equipment (WEEE compliance), see "Appendix B — Waste Electrical and Electronic Equipment (WEEE)," page 91.

2.4 Symbols

The following symbols may be found on the instrument, in this user manual or on labels associated with the instrument.

Symbol	Location	Description
	On the instrument	Catalog number
	On the instrument	Serial number
	On the instrument	Consult instructions for use
	On the instrument	CE mark for Europe
	On the instrument	In vitro diagnostic medical device
	On the instrument	Waste Electrical and Electronic Equipment (WEEE)
	On the instrument	Manufacturer
	In this user manual	Authorized representative in the European Community

Symbol	Location	Description
	On the instrument	Indicates the battery test button
	On the instrument	Indicates the activation switch

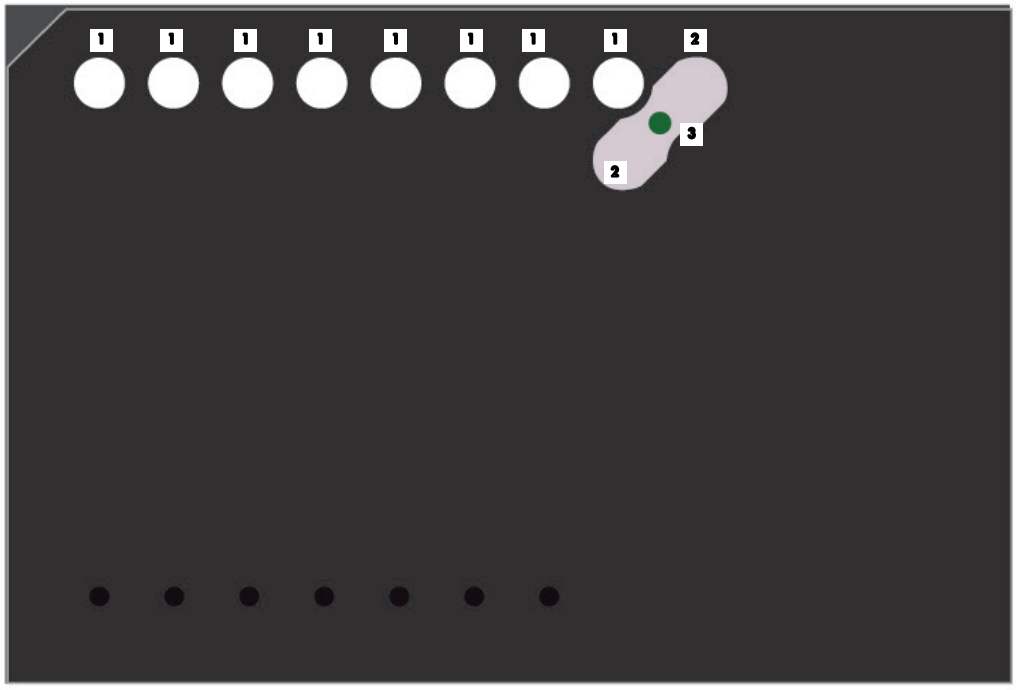
3 Functional Description

The LumiCheck Plate is designed to monitor the performance of the DML instrument over time. Light derived from the light-emitting diode (LED) sources is emitted at a dynamic range that extends over 6 decades. An internal circuit within the LumiCheck Plate stabilizes the internal lights. The measurement of the 8 LED wells of the LumiCheck Plate using a DML instrument establishes a set of specifications in the form of a master file.

Once a master file is established, a periodic check is performed by measuring the LumiCheck Plate using the DML instrument. During a periodic check, all the wells of the LumiCheck Plate are measured, including the wells that do not emit light. The LumiCheck Plate Software analyzes the data from the measurement and verifies that the data meet the specification criteria.

3.1 Hardware components

Top of the LumiCheck Plate:

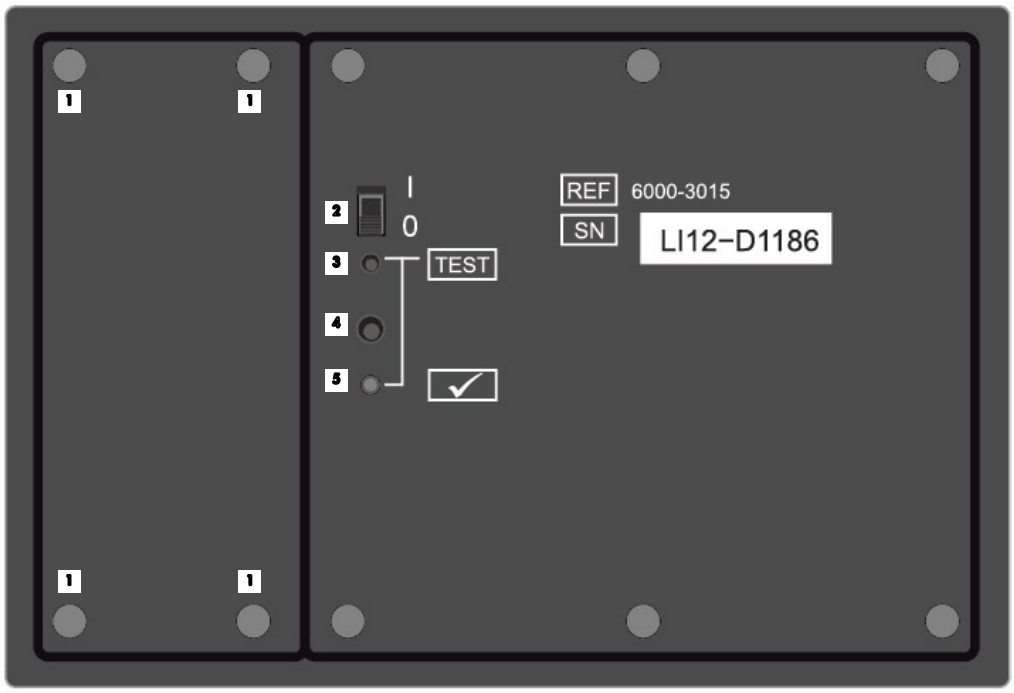


1 Light-emitting wells (A1–A8)

2 Cross-talk wells (A9 and B8)

3 Cross-talk light source

Bottom of the LumiCheck Plate:



1 Screws securing the battery

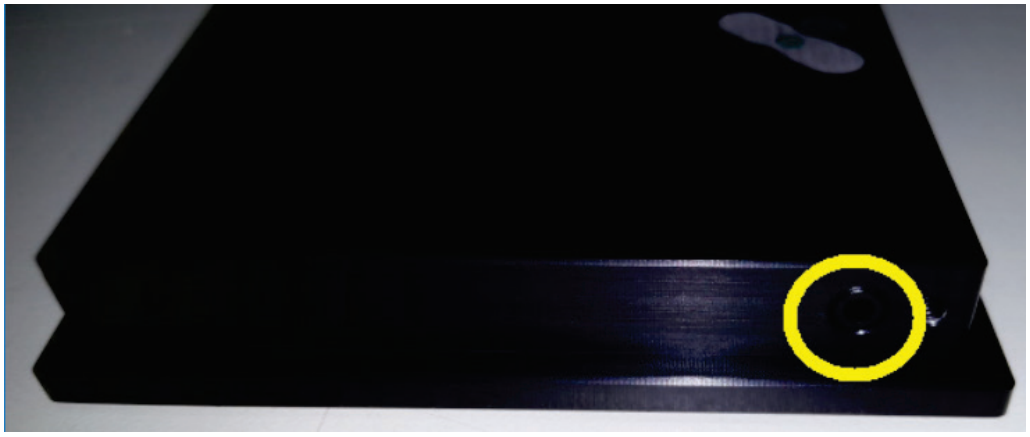
2 Power switch

3 Battery test button

4 Red LED

5 Activation switch

Bottom Edge of the Lumicheck plate



1 2.5mm Mono Phone Jack – For manufacturer use only

3.1.1 Light-emitting wells

The LumiCheck Plate has 8 wells that mimic the light emitted during plate measurement. The wells are A1 through A8 and increase in light output as the numerical value increases. The light of the wells is produced from 2 LED lights with one LED light providing the light for wells A1 through A7 and the second LED light providing the light for well A8. The light-emitting wells are used during the plate measurement of the LumiCheck Plate.

3.1.2 Cross-talk light source

Cross-talk is excessive light emitted from neighboring microplate wells that contributes to an artificially higher RLU result in the well that is being measured. The DML instrument, when used with the correct microplates, reduces or eliminates cross-talk by using a specialized optical pathway in combination with a plate mask that holds the microplate securely in place during measurement. The correct alignment of the plate mask and plate carrier is essential to minimize cross-talk.

The LumiCheck Plate includes a cross-talk light source that emits light between wells A9 and B8. The measurements of wells A9 and B8 are used to determine if cross-talk is within specification.

During a periodic check, all wells of the LumiCheck Plate are measured. The LumiCheck Plate Software calculates cross-talk by dividing the highest RLU value from either well A9 or well B8 by the RLU value of well A8 and multiplying that result by 100,000. Cross-talk is calculated as RLU per 1×10^5 RLU.

3.1.3 LumiCheck Plate battery

The LumiCheck Plate is powered by a replaceable battery. The LumiCheck Plate battery is estimated to operate for approximately 4–6 months based on the average use of 5 minutes per day for 5 days per week. The battery life is dependent on the amount of time the LumiCheck Plate is powered ON and the frequency of use. When stored at room temperature, the LumiCheck Plate battery loses approximately 5% power capacity per year. Under ideal storage conditions, the expected shelf life of the LumiCheck Plate battery is at least 5 years.

The battery life will decrease if the LumiCheck Plate is powered ON for more than the few minutes required to perform measurement. Make sure to power OFF the LumiCheck Plate when not in use.

Before using the LumiCheck Plate, check the battery. See "Checking the LumiCheck Plate battery," page 55, for additional instructions. As an indication that the battery power is failing, the LumiCheck Plate cuts power to the A8 well when the battery voltage is less than 4.7 volts.

During replacement of the battery, remove only the screws that secure the LumiCheck Plate battery. See "Replacing the LumiCheck Plate battery," page 82, for additional instructions.

Replacement batteries for the LumiCheck Plate are available from QIAGEN.

3.1.4 Power switch

The power switch is used to power ON and power OFF the LumiCheck Plate. The light-emitting wells are activated when the LumiCheck plate is powered ON. See "Powering ON and OFF the LumiCheck Plate," page 55, for additional instructions.

3.1.5 Activation switch

The activation switch controls the illumination of the light-emitting wells of the LumiCheck Plate. When loaded in the DML instrument, the activation switch is automatically pressed. While powered ON and loaded in the DML instrument, the light-emitting wells illuminate.

3.1.6 Battery test button

The battery test button is used to confirm the LumiCheck Plate battery has sufficient power and is not failing. When the activation switch and the test button are pressed, the red LED light on the back of the LumiCheck Plate is illuminated. See "Checking the LumiCheck Plate battery," page 55, for additional instructions.

3.1.7 2.5 mm mono phone jack

The 2.5 mm mono phone jack is reserved for manufacturer use only.

3.2 LumiCheck Plate Software components

The LumiCheck Plate Software is supplied on the HC2 System computer and runs using the Microsoft® Windows® XP operating system (for LumiCheck versions 2.0.1 and 2.0.2) or Windows 7 operating system (for LumiCheck version 2.0.3). The LumiCheck Plate Software works in conjunction with the DML instrument.

The LumiCheck Plate 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 LumiCheck Software and cause it to be inoperable. Accordingly, installation of programs not provided by QIAGEN on the HC2 System computer may render the LumiCheck Plate Software inoperable. Installation of additional software or connecting the HC2 System computer to the internet voids all warranties.

4 Installation

4.1 Unpacking

Before using the LumiCheck Plate for the first time, examine the exterior carton and the instrument itself for damage. In the event of shipping damage, contact your local QIAGEN representative or QIAGEN Technical Services.

The LumiCheck Plate is shipped in a cardboard box. When received, open the cardboard box and remove the black storage case. Open the black storage case and confirm all the components of the LumiCheck Plate are included.

The package should contain the following components:

- A black storage case
- A LumiCheck Plate
- A battery test tool
- A screwdriver
- A replacement pack containing 4 screws, a battery test tool and a battery

4.2 Installing the LumiCheck Plate software

The HC2 System computer should arrive with the LumiCheck Plate Software installed. Refer to the instructions in digene *HC2 System Software User Manual* if the installation of the LumiCheck Plate Software is required for some other reason.

The LumiCheck Plate Software requires a minimum of 50 megabytes of free hard disk space.

4.3 Uninstalling the LumiCheck Plate Software

As a component of the *digene* HC2 System Suite, the LumiCheck Plate Software cannot be uninstalled separately from the *digene* HC2 System Suite. To uninstall the LumiCheck Plate Software, refer to digene *HC2 System Software User Manual* for additional instructions.

5 Software Features

The LumiCheck Plate Software contains a series of tabs that display across the top of the software window. The **Periodic Check** tab is foremost when the LumiCheck Plate Software is started and when a user logs in. The footer of the window remains constant.

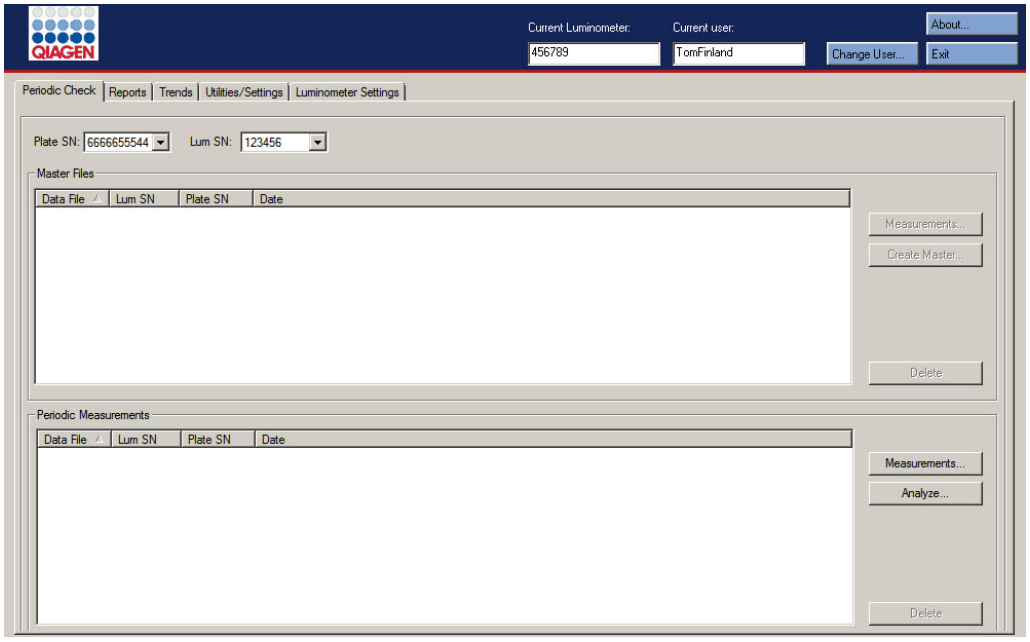
The window header provides the following functions:

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 LumiCheck Plate Software.
Change User… button	Opens the **User Login** dialog box. A new user must log in.
About… button	Opens the **About QIAGEN Microplate System** dialog box. The version and copyright information for the LumiCheck Plate Software is displayed.
Exit button	Opens the exit dialog box. Click **Yes** to exit the LumiCheck Plate Software or **No** to keep the LumiCheck Plate Software open.

5.1 Using the **Periodic Check** tab

The **Periodic Check** tab is used to create, modify and manage data files, master files and periodic checks.

Example of the **Periodic Check** tab:



The **Master Files** panel lists the master files that have been created for the LumiCheck Plate and DML instrument combination selected in the drop-down lists. The **Periodic Measurements** panel lists the periodic checks that have been completed for the LumiCheck Plate and DML instrument combination selected in the drop-down lists. Select **<All>** in the **Plate SN:** and **Lum SN:** drop-down lists to see all master files and periodic measurements.

The data displayed in the **Master Files** and **Periodic Measurements** panels can be sorted by selecting the applicable heading in the respective panel.

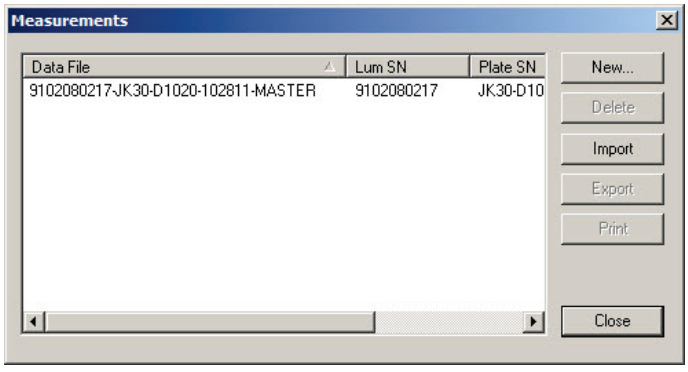
The following table describes the actions that can be performed in the **Periodic Check** tab.

To...	Click or select...
see the master files and periodic checks associated with a LumiCheck Plate	the LumiCheck Plate serial number from the **Plate SN:** drop-down list.
see the master files and periodic checks associated with a DML instrument	the DML instrument serial number from the **Lum SN:** drop-down list.
manage the measurements for master files	the **Measurements…** button in the **Master Files** panel. The **Measurements** dialog box opens. See "Using the **Measurements** dialog box," page 26, for additional instructions.
create a master file	the **Create Master…** button in the **Master Files** panel. The **Master File Data Analysis** dialog box opens. See "Creating a master file from measurements," page 58, for additional information.
delete a master file	the master file from the list in the **Master Files** panel and click the **Delete** button. See "Deleting a master file," page 59, for additional instructions.
manage the measurements for periodic checks	the **Measurements…** button in the **Periodic Measurements** panel. The **Measurements** dialog box opens. See "Using the **Measurements** dialog box," page 26, for additional instructions.
analyze the data of a periodic check	the **Analyze…** button in the **Periodic Measurements** panel. See "Analyzing a periodic check," page 62, for additional instructions.
delete the measurements for a periodic check	the data file from the list in the **Periodic Measurements** panel and click the **Delete** button. See "Deleting the measurements for a periodic check," page 62, for additional instructions.

5.1.1 Using the **Measurements** dialog box

The **Measurements** dialog box is used to manage the measurements for both master files and periodic checks. The **Measurements** dialog box is accessed by clicking the **Measurements...** button on the **Periodic Check** tab. The **Measurements...** button is located in both the **Master Files** and **Periodic Measurements** panels of the **Periodic Check** tab.

Example of the **Measurements** dialog box:



The following table describes the actions that can be performed in the **Measurements** dialog box.

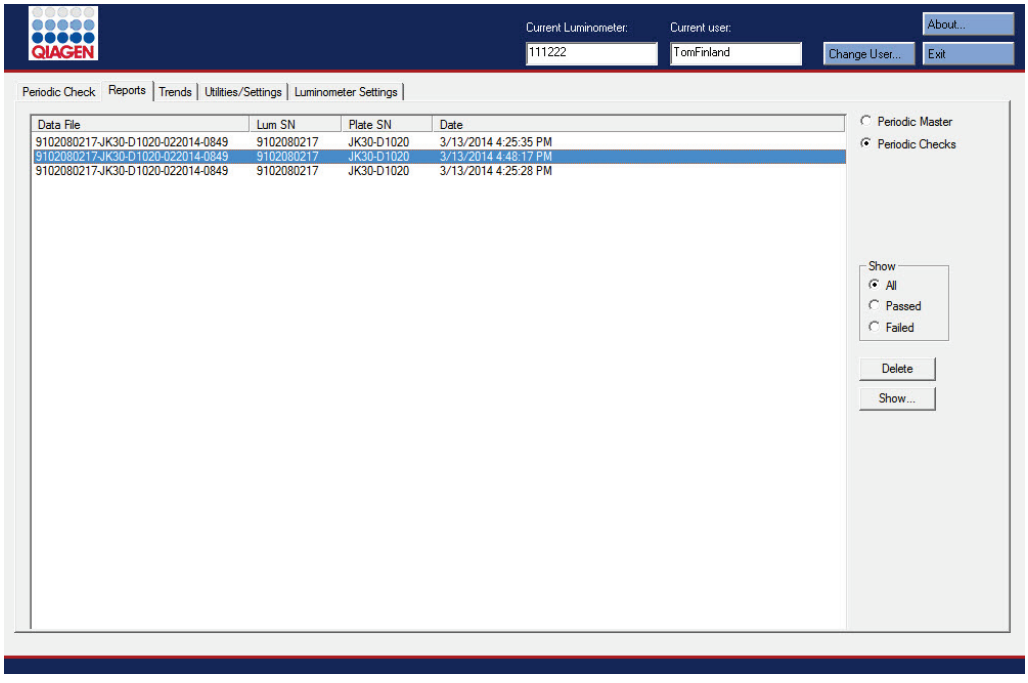
To...	**Click or select...**
take measurements for a master file or periodic check	the **New...** button. See "Taking measurements for a master file," page 56, and "Taking measurements for a periodic check," page 60, for additional instructions.
delete the measurements for a master file or a periodic check	the data file from the list and click the **Delete** button. See "Deleting the measurements for a master file," page 58, and "Deleting the measurements for a periodic check," page 62, for additional instructions.
import a data file	the **Import** button. See "Importing data," page 78, for additional instructions.
export a data file	the data file from the list and click the **Export** button. See "Exporting data," page 78, for additional instructions.

To...	Click or select...
print the data file	the data file from the list and click the **Print** button. See "Printing the measurements for a master file," page 57, and "Printing the measurements for a periodic check," page 61, for additional instructions.
close the **Measurements** dialog box	the **Close** button

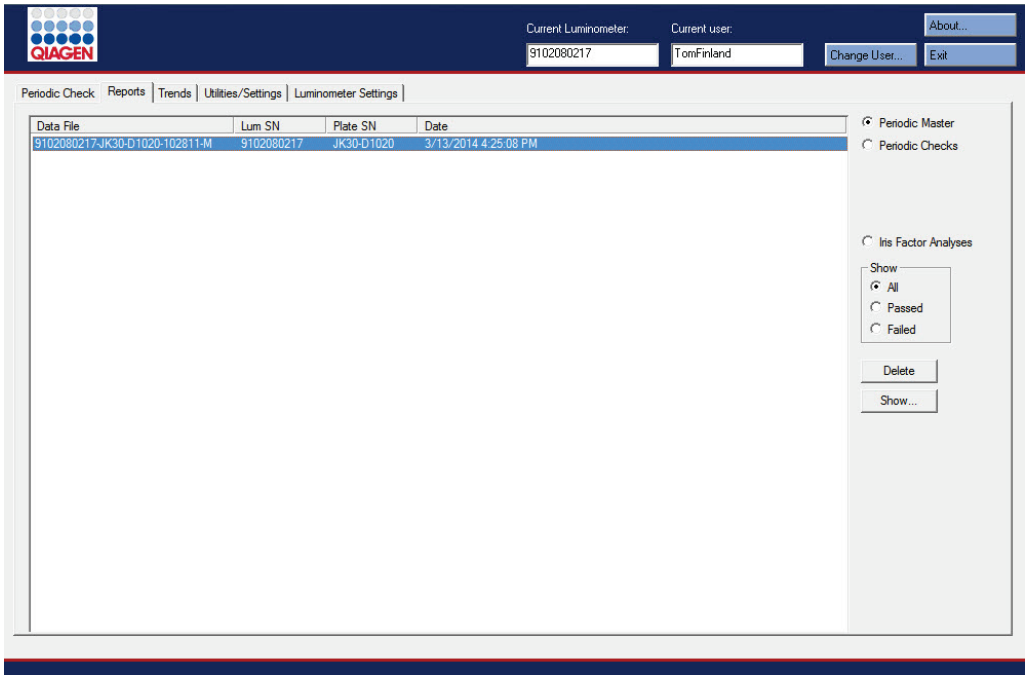
5.2 Using the **Reports** tab

The **Reports** tab is used to generate reports. See "Viewing reports," page 63, for additional instructions.

Example of the **Reports** tab with a DML 3000 selected as the DML instrument:



Example of the **Reports** tab with a DML 2000 selected as the DML instrument:



The following table describes the actions that can be performed in the **Reports** tab.

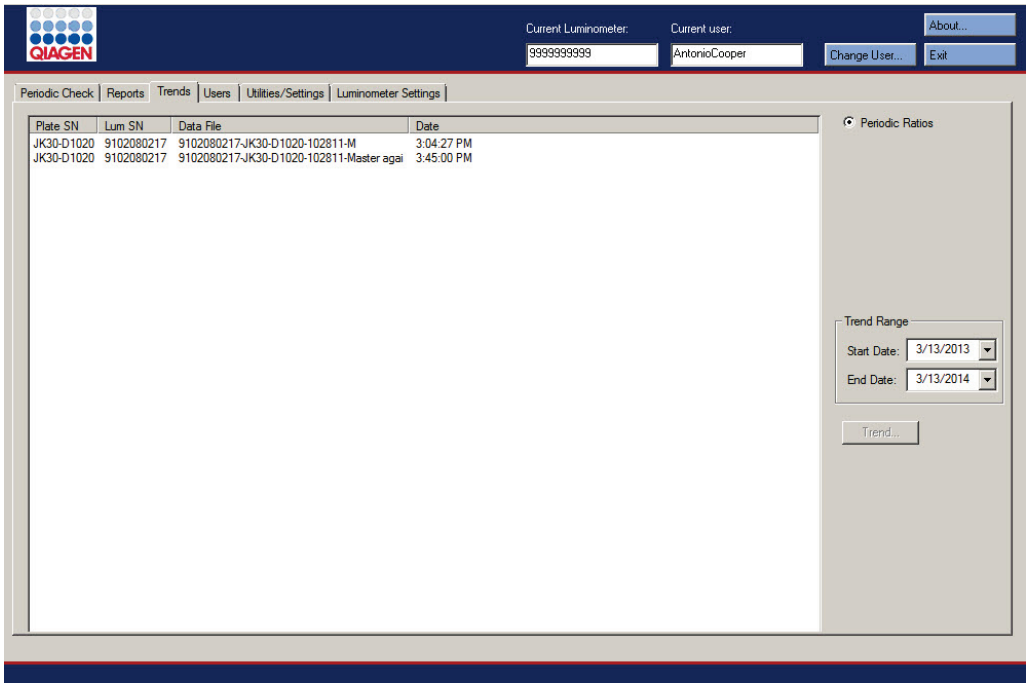
To...	**Click or select...**
specify the type of data for the report	the **Periodic Master**, **Periodic Checks** or **Iris Factor Analyses** radio button. **Note**: The **Iris Factor Analyses** radio button is only available for a DML 2000.
specify the status of the report	the **All**, **Passed** or **Failed** radio button in the **Show** panel.
delete a master file or a periodic check	the data file in the list and click the **Delete** button. See "Deleting a master file," page 59, or "Deleting a periodic check", page 63, for additional instructions.
generate a report with the parameters selected	the **Show...** button. The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

5.3 Using the **Trends** tab

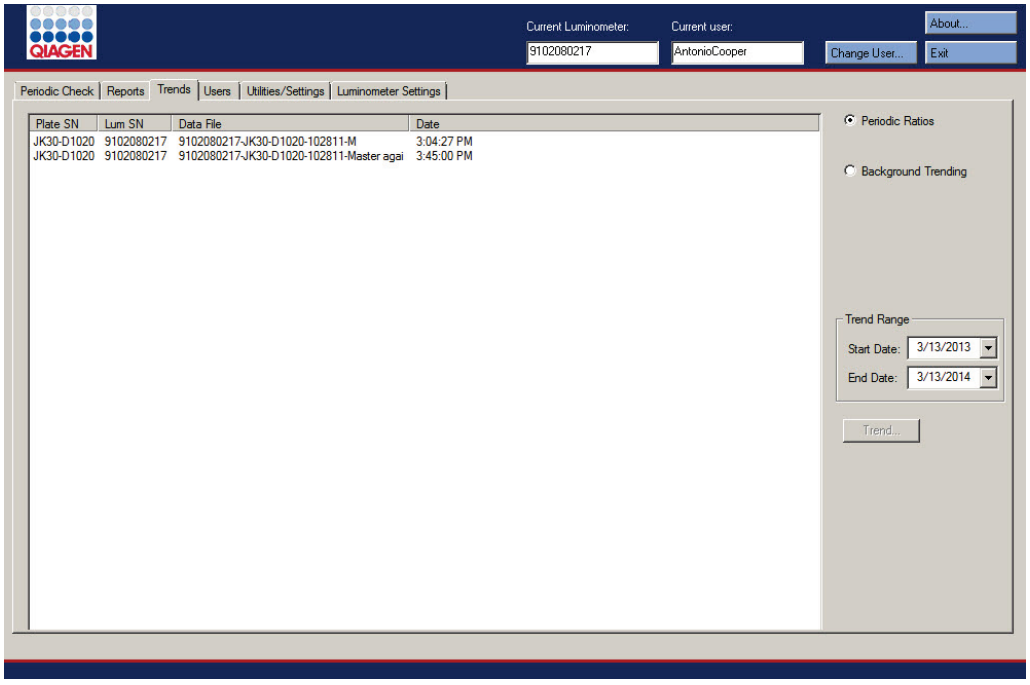
The **Trends** tab is used to view trending data based on the database maintained by the LumiCheck Plate Software. The trend reports for background measurements are only available for the DML 2000.

To generate trend reports, see “Generating trending reports,” page 72, for additional instructions.

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:



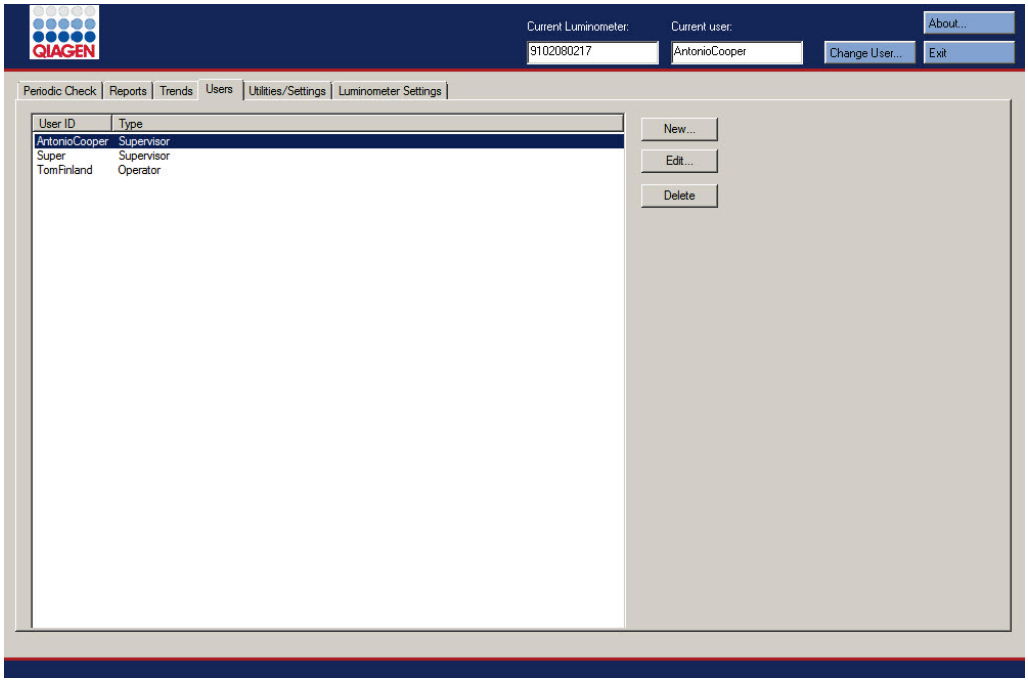
The following table describes the actions that can be performed in the **Trends** tab.

To...	Click or select...
specify the type of data for the trend report	the applicable radio button. **Note**: The only option for a DML 3000 is the **Periodic Ratios** radio button.
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.
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 44, for additional instructions.

5.4 Using the **Users** tab

The **Users** tab is used to modify user IDs, passwords and access levels. The **Users** tab only displays if a user has supervisor access level. See "Managing users," page 47, for additional instructions.

Example of the **Users** tab:



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

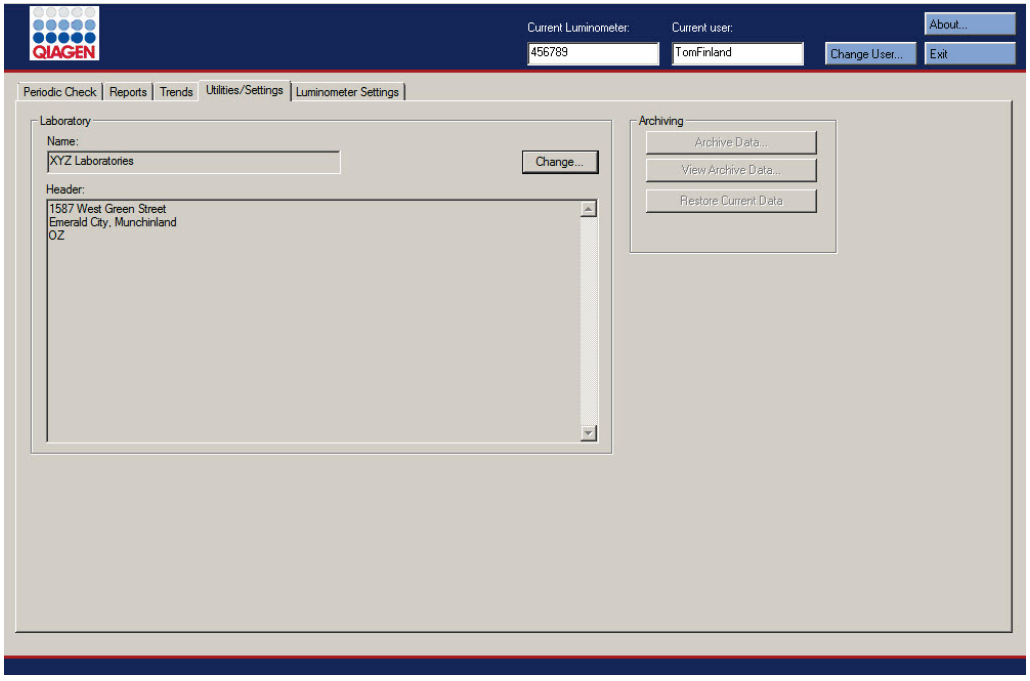
To...	**Click or select...**
add a user	the **New...** button. The **ID Entry** dialog box opens. See "Adding users," page 48, for additional instructions.
modify the password or access level of a user	the user ID from the list and click the **Edit...** button. The **Edit User** dialog box opens. See "Editing users," page 49, for additional instructions.

To...	Click or select...
delete a user	the user ID from the list and click the **Delete** button. See "Deleting a user," page 49, for additional instructions. **Note**: At least one supervisor ID is required.

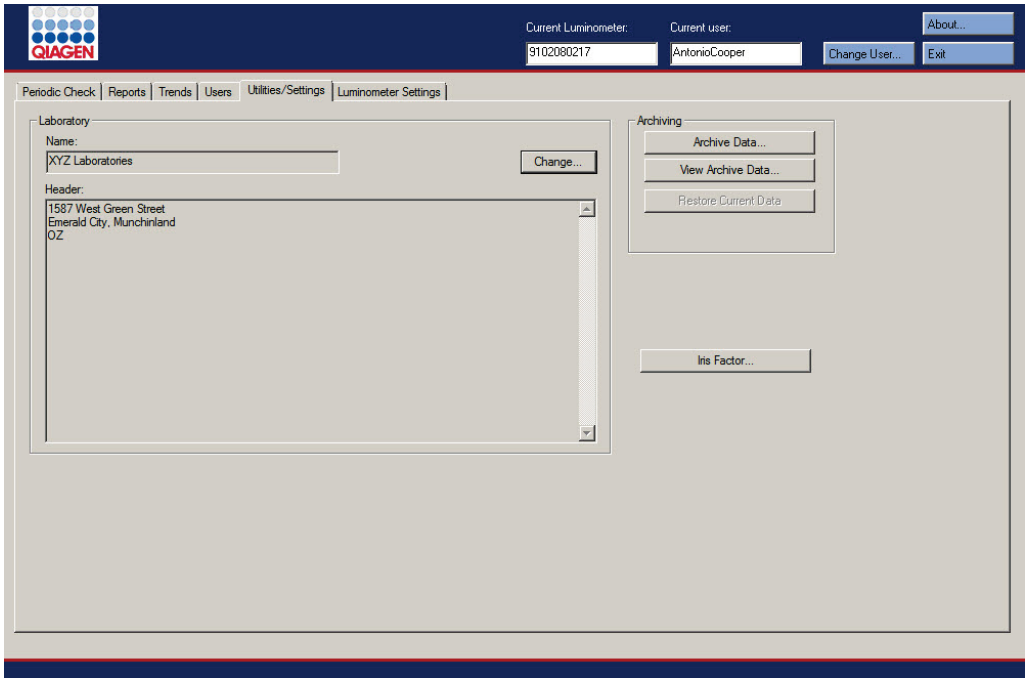
5.5 Using the **Utilities/Settings** tab

The **Utilities/Settings** tab is used to modify the laboratory name and header information, to archive data and to establish the iris factor.

Example of the **Utilities/Settings** tab with a DML 3000 selected as the DML instrument:



Example of the **Utilities/Settings** tab with a DML 2000 selected as the DML instrument:



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

To...	Click or select...
modify the laboratory and header information	the **Change...** button in the **Laboratory** panel. The **Edit Laboratory Information** dialog box opens. See "Modifying the laboratory header information," page 47, for additional instructions.
perform an archive	the **Archive Data...** button in the **Archiving** panel. The **Archive Data** dialog box opens. See "Archiving data," page 79, for additional instructions. **Note**: Only users with supervisor access level may perform this function.

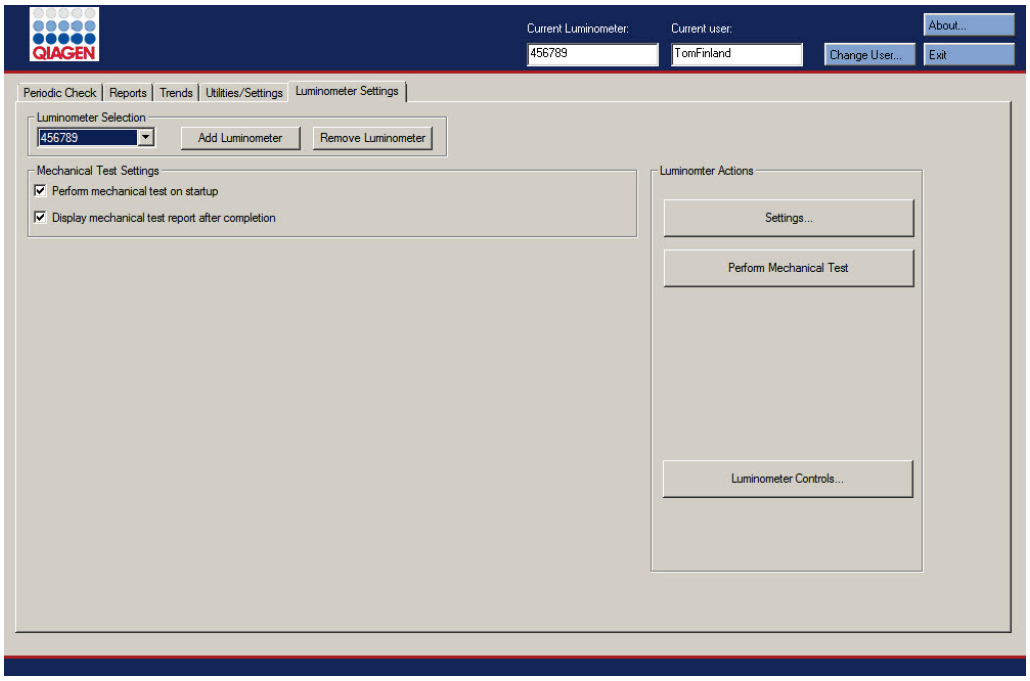
To...	Click or select...
view an archive	the **View Archive Data...** button in the **Archiving** panel. The **View Archive Data** dialog box opens. See "Viewing archived data," page 80, for additional instructions. **Note**: Only users with supervisor access level may perform this function.
restore the current data to the trend database	the **Restore Current Data** button in the **Archiving** panel. See "Viewing archived data," page 80, for additional instructions. **Notes**: • Only users with supervisor access level may perform this function. • If not currently viewing an archive, the **Restore Current Data** button is grayed-out.
establish the iris factor	the **Iris Factor...** button. The **New Iris Factor** dialog box opens. See "Establishing the iris factor," page 53, for additional instructions. **Note**: This function only applies to the DML 2000 and the **Iris Factor...** button will not appear if a DML 3000 is selected as the DML instrument.

5.6 Using the **Luminometer Settings** tab

The **Luminometer Settings** tab is used to manage the settings for the DML instruments, to perform DML instrument diagnostic tests and to test the connection between the HC2 System computer and the DML instrument. See "Managing the DML instrument," page 49, for additional instructions.

5.6.1 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 when a DML 3000 is selected.

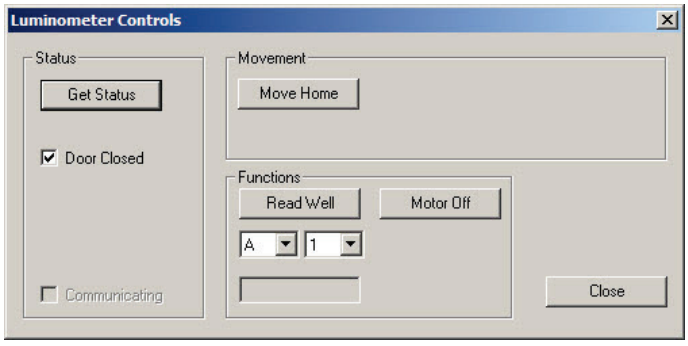
To...	**Click or select...**
change the current DML instrument used to measure a plate	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel.
add a new DML instrument	the **Add Luminometer** button in the **Luminometer Selection** panel. The **Luminometer Settings** dialog box opens. See "Adding a DML instrument," page 49, for additional instructions.

To...	Click or select...
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 54, for additional instructions.
set the LumiCheck Plate Software to perform a mechanical test of the DML instrument automatically when a user logs in or a 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 51, 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 51, for additional instructions.
modify the settings of a DML	the DML instrument serial number from the drop-down list in the **Luminometer Selection** panel and click the **Settings...** button. See "Modifying the settings of a DML instrument," page 51, 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 51, 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 "Manually controlling the DML instrument," page 54, for additional instructions.

5.6.2 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.

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 window when a DML 3000 is selected.

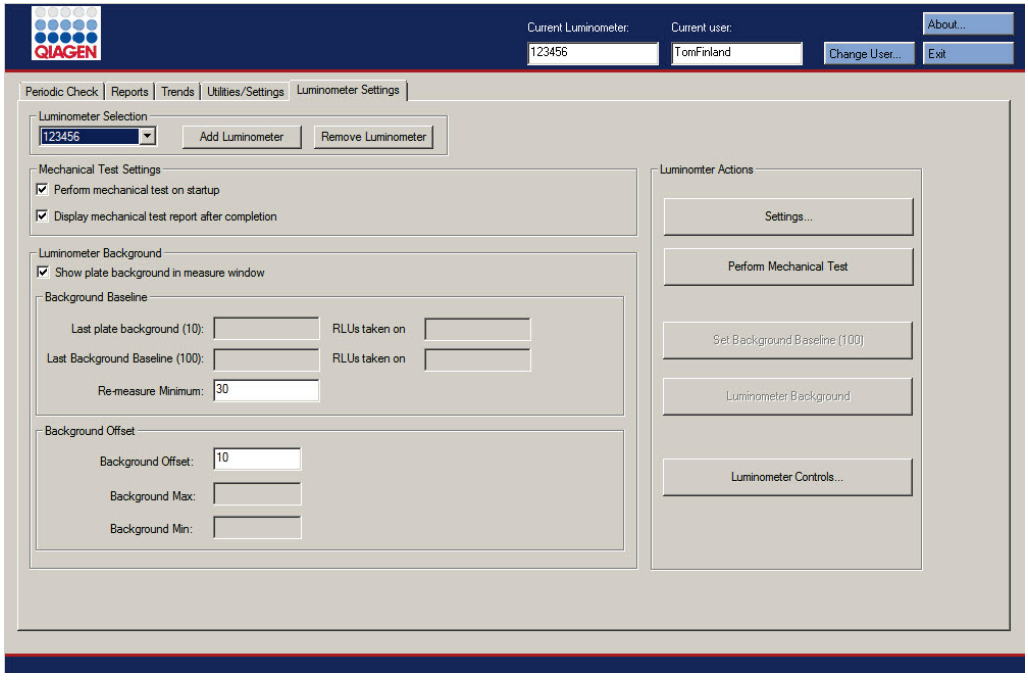
To...	**Click or select...**
get the status of the DML instrument	the **Get Status** button. The information in the **Luminometer Controls** dialog window will update on the current status of the DML instrument.
move the plate carrier to the home position	the **Move Home** button.
measure a specified well location	the specific location on the plate using the drop-down lists 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 when a DML 3000 is selected.

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.

5.6.3 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 when a DML 2000 is selected.

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 49, 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 54, for additional instructions.
set the LumiCheck Plate Software to perform a mechanical test of the DML instrument automatically when a user logs in	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 51, 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 51, 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 53, for additional instructions.

To...	Click or select...
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 parameter will be measured 3 times and the average reported as the RLU. **Important**: The default setting is **30**. Do not change this value.
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. **Note**: The RLU value specified must be greater than 0 but less than or equal to 420. See "Understanding the background baseline (100) reading," page 52, for additional instructions.
modify the settings of a DML	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 51, 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 51, 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 52.

To...	Click or select...
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 "Manually controlling the DML instrument," page 54, for additional instructions.

The following table describes the features that are available on the **Luminometer Settings** tab when a DML 2000 is selected.

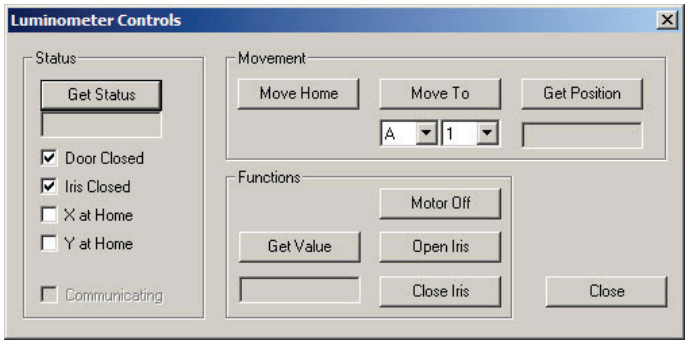
Feature	Function
Last plate background (10): and **RLUs taken on** dialog fields in the **Background Baseline** subpanel	Displays the result and date of the last plate background (10) reading for the DML instrument selected in the **Luminometer Selection** panel.
Last Background Baseline (100): and **RLUs 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 53, 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 53, for additional instructions.

Note: The **Luminometer Background** button is only for use by QIAGEN personnel. The **Luminometer Background** button will remain grayed-out when the user is logged into the LumiCheck Plate Software with operator or supervisor access level.

5.6.4 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.

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 when a DML 2000 is selected.

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 in the **Movement** panel.
move the plate carrier to a specified location	the specific location on the plate using the drop-down lists and click the **Move To** button in the **Movement** panel.
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.

To...	Click or select...
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 drop-down lists.
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.
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 when a DML 2000 is selected.

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.

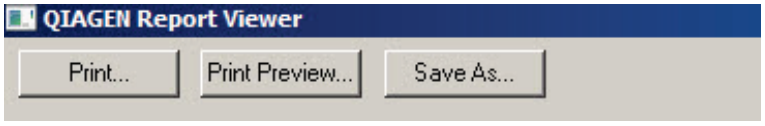
Feature	Function
Y at Home box	If this box is checked, the plate carrier was in the home position for the Y axis during the last status check of the DML instrument. If the box is not checked, the plate carrier was not in the home position for the Y axis during the last status check of the DML instrument.
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.

5.7 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.

To...	Click or select...
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.
exit the **QIAGEN Report Viewer** window	click the **Close** button.

6 General Operation

On days of testing with *digene* HC2 DNA tests, perform a periodic check using the LumiCheck Plate prior to measuring the first microplate.

To use the LumiCheck Plate with the DML instrument, the following is required:

- The LumiCheck Plate Software is set up.
- A user is added to the LumiCheck Plate Software.
- The DML instrument is initialized and has established communication with the HC2 System computer.
- A mechanical test has been performed.

If using a DML 2000, the following additional tasks are required:

- The iris factor for the DML 2000 is specified.
- The background baseline (100) is determined.

The LumiCheck Plate Software only accepts the English language character set. Only use English language characters when using the software.

6.1 Logging in

1. Power ON all the HC2 System hardware components.

   Refer to the applicable user manual for additional information.
2. Log in to the Windows operating system.

   Note: Refer to digene *HC2 System Software User Manual* for additional instructions.
3. Start the LumiCheck Plate Software by double-clicking the **LumiCheck** icon on the Windows desktop.

   Note: The LumiCheck Plate Software can also be started by clicking the Windows **Start** menu, selecting **All Programs**, selecting **HC2 System Software**, and selecting the applicable software version of **LumiCheck v2.0.1**, **LumiCheck v2.0.2** or **LumiCheck v2.0.3**.
4. In the **User Login** dialog box, enter the user ID and password in the applicable dialog fields and select the applicable serial number of the DML instrument from the **Luminometer Serial Number:** drop-down list. Click **OK**.

   Note: If a DML instrument has not been added, a dialog box opens informing the user to add a DML instrument. See "Adding a DML instrument," page 49, for additional instructions.

   The LumiCheck Plate Software opens with the **Periodic Check** tab at the forefront.

6.2 Modifying the laboratory header 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** 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 software returns to the **Utilities/Settings** tab, and the information displays in the respective dialog fields.

6.3 Managing users

A user ID and password are required to use the LumiCheck Plate Software. User IDs have an associated access level, either operator or supervisor, which determines the software functions the user can perform.

The LumiCheck Plate Software only requires one user that has supervisor access level. Using individual user IDs with the LumiCheck Plate Software provides control over software functions and data access based on the user ID.

Users with operator access level can perform the following functions:

- Manage DML instruments
- Modify DML instrument settings
- Select the DML instrument to use
- Initiate DML instrument mechanical tests
- Perform routine periodic checks of the DML instrument
- Print, view, delete and export master and periodic check reports
- View trend information

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

- Manage user IDs, passwords and access levels
- Manage laboratory name and report header information
- Perform periodic master measurements
- View periodic check reports to determine the degree of performance above the minimum acceptability
- Archive data, view archived data and restore the current data
- If using the DML 2000, perform an iris factor analysis to establish the iris factor for a specific luminometer

6.3.1 Adding users

The LumiCheck Plate Software installs with one user that has supervisor access level. Use the following case-sensitive credentials to log into the software the first time:

- User ID: Super
- Password: super

Recommendation: Reserve the user ID and password combination of "Super" and "super" for QIAGEN Technical Services. Do no 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 **ID Entry** dialog box opens.
2. Enter the new user ID in the **Enter new ID:** dialog box.

   Note: The user ID must consist of alphanumeric characters with a minimum of 5 characters and a maximum of 25 characters.
3. Click **OK**.

   The **Edit User** dialog box opens.
4. Enter the password for the user ID in the **Password:** and **Confirm password:** dialog boxes.

   Note: The password must consist of alphanumeric characters with a minimum of 5 characters and a maximum of 8 characters and is case-sensitive.
5. Select either the **Operator** or **Supervisor** access level from the **User Type:** drop-down list.
6. Click **OK**.

   The software returns to the **Users** tab, and the user ID displays in the list.

6.3.2 Editing users

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

1. On the **Users** tab, select the user ID to modify and click the **Edit...** button.
   The **Edit User** dialog box opens.
2. Edit the desired parameters.
   Edit the user ID password using the **Password:** and **Confirm password:** dialog boxes.
   Edit the user ID access level by selecting the applicable access level from the **User Type:** drop-down list.
3. Click **OK**.
   The software returns to the **Users** tab.

6.3.3 Deleting a user

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

1. On the **Users** tab, highlight the user ID to delete and click the **Delete** button.
   A dialog box opens to confirm the deletion of the user.
2. Select the applicable response to confirm the deletion of the user.
   The dialog box closes, and the user is deleted from the list.

6.4 Managing the DML instrument

The DML instrument measures the RLU of samples contained in a microplate that is 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 HC2 System are used to determine if the DML instrument is performing within specification; therefore, if the results of a *digene* HC2 DNA test meet the assay acceptance criteria, the DML instrument is functioning properly.

6.4.1 Adding a DML instrument

The LumiCheck Plate Software can maintain the data for multiple DML instruments; however, connect only one DML instrument 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 **Luminometer 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 the DML instrument.

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

   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 51, 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 52, for additional instructions.

   The DML instrument will be available for use with the LumiCheck Plate 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 LumiCheck Plate 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 LumiCheck Plate Software communicates with the DML instrument, the DML instrument executes the command. The DML instrument is ready for use.

6.4.2 Modifying the settings of a DML instrument

The settings of a DML instrument are modified using the **Luminometer Settings** dialog box.

1. On the **Luminometer 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.

6.4.3 Performing a mechanical test

A mechanical test for the DML instrument selected must have been completed and valid before the LumiCheck Plate can be used. During a mechanical test, the LumiCheck Plate 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 LumiCheck Plate Software based on the setting in the **Luminometer Settings** tab. See "Using the **Luminometer Settings** tab," page 34, 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 34, 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 44, for additional instructions.

6.4.4 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) 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 38, 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 53, for additional information.

6.4.5 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 51, for additional instructions.

1. On the **Luminometer 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 44, 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.

6.4.6 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 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 52, 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 LumiCheck Plate 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. Refer to digene *HC2 System Software Manual* for additional instructions to troubleshoot plate background problems.

6.4.7 Establishing the iris factor

The establishment of the iris factor is only required for the DML 2000. The iris factor is supplied in the technical documentation supplied with the DML 2000. If the iris factor cannot be found in the technical documentation, the LumiCheck Plate can be used to determine the iris factor.

When the iris factor is established using the LumiCheck Plate Software, the iris factor is automatically assigned to the associated DML 2000 and replaces the iris factor specification currently specified in the LumiCheck Plate Software.

Note: Only users with supervisor access level can establish the iris factor.

1. Power ON the LumiCheck Plate.

   See "Powering ON and OFF the LumiCheck Plate," page 55, for additional instructions.
2. Check the LumiCheck Plate battery.

   See "Checking the LumiCheck Plate battery," page 55, for additional instructions.
3. Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position.

   Refer to the applicable DML instrument user manual for additional information about loading a plate.
4. On the **Utilities/Settings** tab, click the **Iris Factor…** button.

   The **New Iris Factor** dialog box opens.
5. Click the **Measure…** button.

   The **Calculating Iris Factor** dialog box opens and displays a progress bar during the iris factor measurements.

   When the iris factor is established, the **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

6.4.8 Manually controlling the DML instrument

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 37, or "Using the **Luminometer Controls** dialog box with a DML 2000," page 42, for additional instructions.

If the DML instrument 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.

6.4.9 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.

6.5 Using the LumiCheck Plate

6.5.1 Powering ON and OFF the LumiCheck Plate

The LumiCheck Plate power switch is located on the bottom of the LumiCheck Plate. To power ON the LumiCheck Plate, use the blunt end of the battery test tool to move the switch to the "1" position. To power OFF the LumiCheck Plate, use the blunt end of the battery test tool to move the switch to the "0" position.

6.5.2 Checking the LumiCheck Plate battery

The battery life will decrease if the LumiCheck Plate is powered ON for more than the few minutes required to perform the periodic check. Make sure to power OFF the LumiCheck Plate when not in use.

CAUTION **Damage to the instrument**

The activation switch and battery test button are fragile parts. Handle with care and pay attention to prevent damage to these parts.

1. Power ON the LumiCheck Plate.

   To power ON the LumiCheck Plate, see "Powering ON and OFF the LumiCheck Plate," page 55, for additional instructions.

2. Using the blunt end of the battery test tool, lightly press the recessed battery test button and press the activation switch.

   Important: Do not press the recessed battery test button with excessive force as the switch can dislodge inside the LumiCheck Plate. If dislodged, the battery test button will remain pressed and cause the LumiCheck Plate battery to drain.

   The red LED should illuminate indicating that the LumiCheck Plate battery is functioning. If the red LED dims or does not illuminate, replace the LumiCheck Plate battery. See "Replacing the LumiCheck Plate battery," page 82, for additional instructions.

3. To make sure that the recessed battery test button is not dislodged, press the activation switch. The red LED should not illuminate.

   If the red LED illuminates while pressing the activation switch, the battery test button is likely dislodged. Contact QIAGEN Technical Services for assistance.

6.6 Managing master files

A master file is created to establish the specifications for a combination of a LumiCheck Plate and a DML instrument. The master file is created from measurements of the light-containing wells of the LumiCheck Plate. If the measurements are within specification, the master file is created that includes the expected RLU values and normalized ratios for the LumiCheck Plate and DML instrument combination.

The master file is stored and utilized as a reference to evaluate the stability of the DML instrument. After the master file is created, periodic checks of the DML instrument are performed by comparing the periodic check to the master file. Periodic check measurements not within the observed RLU to expected RLU ratio specification will fail.

Only users with supervisor access level can manage master files, with the exception of deleting a master file.

6.6.1 Taking measurements for a master file

A mechanical test is not required to take measurements with the DML 3000; however, it is recommended to complete the mechanical test before taking measurements.

Before taking measurement for a master file:

- The DML instrument must be added to the LumiCheck Plate Software and selected as the current DML instrument in the **Luminometer Settings** tab. See "Adding a DML instrument," page 49, for additional instructions.
- For the DML 2000, a background baseline (100) must be complete. See "Performing a background baseline (100) reading," page 52, for additional information.

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Master Files** panel.

   The **Measurements** dialog box opens.
2. Click the **New…** button.

   The **New Measurement** dialog box opens.
3. Select the LumiCheck Plate serial number from the **Plate SN:** drop-down list.

   If using the LumiCheck Plate for the first time, enter the LumiCheck Plate serial number in the **Plate SN:** dialog field.

   Note: The LumiCheck Plate serial number can be found on the bottom of the LumiCheck Plate.

4. Make sure the correct DML instrument serial number is displayed in the **Lum SN:** drop-down list.
5. If the incorrect DML instrument serial number is displayed, exit the dialog boxes and select the correct DML instrument in the **Luminometer Settings** tab.
6. Modify the name of the data file in the **Data File:** dialog field, as applicable.

   Note: The data file has a maximum of 40 characters, and the default name is provided in the following format: [DML instrument serial number]-[LumiCheck Plate serial number]-[date]-[time].
7. Click the **Measure…** button.

   The **LumiCheck Measurement** dialog box opens.
8. Remove the LumiCheck Plate from the protective case.
9. Power ON the LumiCheck Plate and check the LumiCheck Plate battery.

   See "Using the LumiCheck Plate," page 55, for additional instructions.
10. Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position.

    Refer to the applicable DML instrument user manual for additional information about loading a plate.
11. Click the **Start** button to start the measurement of the plate.

    The DML instrument measures wells A1 through A8 five times. Two status bars display during measurement. The upper status bar displays the status of the current measurement cycle; the lower status bar displays the status of all the measurements. The plate measurement process takes less than 3 minutes.
12. When the plate measurement is complete, click **OK**.

    A dialog box opens with instructions to remove and power OFF the LumiCheck Plate.
13. Remove and power OFF the LumiCheck Plate. Click **OK**.
14. Click the **Close** button.

6.6.2 Printing the measurements for a master file

The measurements for a master file may be printed from the **Measurements** dialog box or the **Master File Data Analysis** dialog box.

To print the measurements for a master file from the **Measurements** dialog box, follow this procedure:

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Master Files** panel.

   The **Measurements** dialog box opens.

2. Select the applicable data file in the list.
3. Click the **Print** button.

   The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.
4. Click the **Close** button to exit the **QIAGEN Report Viewer** window.
5. Click the **Close** button to exit the **Measurements** dialog box.

To print the measurements for a master file from the **Master File Data Analysis** dialog box, follow this procedure:

1. On the **Periodic Check** tab, click the **Create Master…** button in the **Master Files** panel.

   The **Master File Data Analysis** dialog box opens.
2. Select the applicable data file in the list.
3. Click the **Print** button.

   The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.
4. Click the **Close** button to exit the **QIAGEN Report Viewer** window.
5. Click the **Cancel** button to exit the **Master File Data Analysis** dialog box.

6.6.3 Deleting the measurements for a master file

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Master Files** panel.

   The **Measurements** dialog box opens.
2. Select the applicable data file form the list.
3. Click the **Delete** button.

   A dialog opens to confirm the deletion of the data file.
4. Click the **Yes** button.

   The data file is deleted and removed from the list in the **Measurements** dialog box.
5. Click the **Close** button to close the **Measurements** dialog box.

6.6.4 Creating a master file from measurements

1. On the **Periodic Check** tab, click the **Create Master…** button in the **Master Files** panel.

   The **Master File Data Analysis** dialog box opens.
2. For the applicable LumiCheck Plate and DML instrument combination, select the data file to use in creating the master file.

3. Click the **Analyze** button.

   The **ID Entry** dialog box opens.

4. The master file ID displays in the dialog field at the bottom of the dialog box. As applicable, rename the master file.

   Note: The master file ID can have has a maximum of 40 characters.

5. Click **OK**.

   The data are analyzed to make sure that the values are within the manufacturer's specifications. A dialog box opens that displays the status of the master file.

6. Click the **Yes** button to view the report for the master file or click the **No** button to close the **Master File Data Analysis** dialog box and return to the **Periodic Check** tab.

   If the **Yes** button was clicked, the **QIAGEN Report Viewer** window opens and displays the master file report. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

Master files with a status of pass display in the **Master Files** panel of the **Periodic Check** tab. Master files with a status of fail will not display in the **Master Files** panel but can be accessed on the **Reports** tab.

6.6.5 Deleting a master file

Deleting a master file removes the master file from the list in the **Master Files** panel of the **Periodic Check** tab. The periodic checks performed using the master file remain on the **Reports** tab, but the reports do not contain any analysis and report as **Fail** even if the periodic check had passed when originally performed using the deleted master file.

Deleting a master file does not delete the measurements that were used to create the master file. See "Deleting the measurements for a master file," page 58, for instructions to delete the measurements.

A master file may be deleted from the **Periodic Check** tab or the **Reports** tab.

To delete a master file from the **Periodic Check** tab, follow this procedure:

1. In the **Periodic Check** tab, select a master file in the **Master Files** panel.
2. Click the **Delete** button in the **Master Files** panel.

   A dialog opens to confirm the deletion of the master file.

3. Click the **Yes** button.

   The master file is deleted and removed from the list in the **Master Files** panel.

To delete a master file from the **Reports** tab, follow this procedure:

1. In the **Reports** tab, select the **Periodic Master** radio button.
2. Select a master file in the displayed list.
3. Click the **Delete** button.

   A dialog opens to confirm the deletion of the master file.
4. Click the **Yes** button.

   The master file is deleted and removed from the list.

6.7 Managing periodic checks

On days of testing, perform a periodic check once prior to reading the first plate. During a periodic check, each of the 96 microplate wells is measured. The measurements are analyzed to determine if the DML instrument is within the specifications based on the associated master file.

Before performing a periodic check:

- The DML instrument must be added to the LumiCheck Plate Software and selected as the current DML instrument in the **Luminometer Settings** tab. See "Adding a DML instrument," page 49, for additional instructions.
- A master file should be created. A periodic test can be completed without a master file, but a report will not be generated, and there will not be any results of the periodic check. See "Managing master files," page 56, for additional instructions.
- For the DML 2000, the background baseline (100) must be complete. See "Performing a background baseline (100) reading," page 52, for additional instructions.

6.7.1 Taking measurements for a periodic check

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Periodic Measurements** panel.

   The **Measurements** dialog box opens.
2. Click the **New…** button.

   The **New Measurement** dialog box opens.
3. Select the LumiCheck Plate serial number from the **Plate SN:** drop-down list.

   If using the LumiCheck Plate for the first time, enter the LumiCheck Plate serial number in the **Plate SN:** dialog field.

   Note: The LumiCheck Plate serial number can be found on the bottom of the LumiCheck Plate.

4. Make sure the correct DML instrument serial number is displayed in the **Lum SN:** drop-down list.
5. If the incorrect DML instrument serial number is displayed, exit the dialog boxes and select the correct DML instrument in the **Luminometer Settings** tab.
6. Modify the name of the data file in the **Data File:** dialog field, as applicable.

   Note: The data file has a maximum of 40 characters, and the default name is provided in the following format: [DML instrument serial number]-[LumiCheck Plate serial number]-[date]-[time].
7. Click the **Measure…** button.

   The **LumiCheck Measurement** dialog box opens.
8. Remove the LumiCheck Plate from the protective case.
9. Power ON the LumiCheck Plate and check the LumiCheck Plate battery.
   See "Using the LumiCheck Plate," page 55, for additional instructions.
10. Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position.

    Refer to the applicable DML instrument user manual for additional information about loading a plate.
11. Click the **Start** button to start the measurement of the plate.

    The DML instrument measures all 96 wells of the plate. A status bar displays the progress of the measurement.
12. When the plate measurement is complete, click **OK**.

    A dialog box opens with instructions to remove and power OFF the LumiCheck Plate.
13. Remove and power OFF the LumiCheck Plate. Click **OK**.
14. Click the **Close** button.

6.7.2 Printing the measurements for a periodic check

The measurements for a periodic check may be printed from the **Measurements** dialog box.

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Periodic Measurements** panel.

   The **Measurements** dialog box opens.
2. Select the applicable data file in the list.
3. Click the **Print** button.

   The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

4. Click the **Close** button to exit the **QIAGEN Report Viewer** window.
5. Click the **Close** button to exit the **Measurements** dialog box.

6.7.3 Deleting the measurements for a periodic check

The measurements for a periodic check may be deleted from the **Periodic Measurements** panel or the **Measurements** dialog box.

To delete the measurements for a periodic check from the **Periodic Measurements** panel, follow this procedure:

1. In the **Periodic Check** tab, select a master file in the **Periodic Measurements** panel.
2. Click the **Delete** button in the **Periodic Measurements** panel.

   A dialog opens to confirm the deletion of the master file.
3. Click the **Yes** button.

   The master file is deleted and removed from the list in the **Master Files** panel.

To delete the measurements for a periodic check from the **Measurements** dialog box, follow this procedure:

1. On the **Periodic Check** tab, click the **Measurements…** button in the **Periodic Measurements** panel.

   The **Measurements** dialog box opens.
2. Select the applicable data file form the list.
3. Click the **Delete** button.

   A dialog opens to confirm the deletion of the data file.
4. Click the **Yes** button.

   The data file is deleted and removed from the list in the **Measurements** dialog box.
5. Click the **Close** button to close the **Measurements** dialog box.

6.7.4 Analyzing a periodic check

1. On the **Periodic Check** tab, select the applicable LumiCheck Plate and DML instrument serial numbers in the **Plate SN:** and **Lum SN:** drop-down lists.

   The available data files will display in the **Periodic Measurements** panel.
2. Click the **Analyze…** button in the **Periodic Measurements** panel.

   The **Periodic Check** dialog box opens.

3. Select the applicable master file from the **Select Master File:** drop-down list to use in performing the periodic check.

   Note: The master file selected must have been created using the same LumiCheck Plate and DML instrument.

4. In the **Measurements** panel, select the applicable data file to analyze.
5. Click the **Analyze** button.

   The measurements of the periodic check are analyzed according to the specifications of the master file, and an analysis file is created. A dialog box opens and displays the status of the periodic check.

6. Click the **Yes** button.

   The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

6.7.5 Deleting a periodic check

Deleting a periodic check removes the periodic check from the list in the **Reports** tab. Deleting a periodic check does not delete the measurements that were used to create the periodic check. See "Deleting the measurements for a periodic check," page 62, for instructions to delete the measurements.

1. In the **Reports** tab, select the **Periodic Checks** radio button.
2. Select a data file in the displayed list.
3. Click the **Delete** button.

   A dialog opens to confirm the deletion of the periodic check.

4. Click the **Yes** button.

   The periodic check is deleted and removed from the list.

6.8 Viewing reports

After creating a master file or completing a periodic check, reports can be viewed using the **Reports** tab.

The available reports are as follows:

- LumiCheck periodic master set values
- LumiCheck periodic test report
- Iris factor analysis

All reports include the following information:

- Date of the measurements
- The LumiCheck Plate Software version used to measure the plate
- Serial number of the DML instrument used to measure the plate
- Serial number of the LumiCheck Plate used to perform the measurements
- Lines for a supervisor to sign and date the report

1. On the **Reports** tab, select either the **Periodic Master** or **Periodic Checks** radio button.
2. In the **Show** panel, select the **All**, **Passed** or **Failed** radio button to view the applicable data files.

   Note: When viewing all data files, data files that failed are highlighted in red.
3. In the list, select the applicable data file.
4. Click the **Show...** button.

   The **QIAGEN Report Viewer** window opens. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.
5. Click the **Close** button to exit the **QIAGEN Report Viewer** window.

6.8.1 Understanding the LumiCheck periodic master set values report

The LumiCheck periodic master set values report includes the pass or fail result for each microplate well and the acceptable ranges for future periodic checks based on the master file.

Example of the LumiCheck periodic master set values report:

XYZ Laboratories
1587 West Green Street
Emerald City, Munchinland
OZ

Data Record: **9102080217-JK30-D1020-102811-M**
Measurement Record: **9102080217-JK30-D1020-102811-MASTER**
User ID: **AntonioCooper**

LumiCheck Periodic Master Set Values **Date: 10/28/2011** **RLUs are Valid**

Raw Data

	Measurement #1	Measurement #2	Measurement #3	Measurement #4	Measurement #5	Average
Well #1	57	57	56	58	56	57
Well #2	376	373	370	368	374	372
Well #3	1316	1324	1317	1322	1318	1319
Well #4	7143	7153	7143	7146	7148	7147
Well #5	28314	28314	28272	28216	28251	28273
Well #6	226105	226996	226385	226147	225965	226320
Well #7	1102649	1106574	1104516	1102919	1102769	1103885
Well #8	2217126	2229416	2224671	2221195	2219200	2222322

Normalized Ratios

	Measurement #1	Measurement #2	Measurement #3	Measurement #4	Measurement #5	Average
Well #1	0.04	0.04	0.04	0.04	0.04	0.04
Well #2	0.29	0.28	0.28	0.28	0.28	0.28
Well #3	1.00	1.00	1.00	1.00	1.00	1.00
Well #4	5.43	5.40	5.42	5.41	5.42	5.42
Well #5	21.52	21.39	21.47	21.34	21.43	21.43
Well #6	171.81	171.45	171.89	171.06	171.45	171.53
Well #7	837.88	835.78	838.66	834.28	836.70	836.66
Well #8	1684.75	1683.85	1689.20	1680.18	1683.76	1684.35

Master Set Up Verification

	MAX %CV Spec	%CV	Pass/Fail
Well #1	15.00	1.47	Pass
Well #2	10.00	0.86	Pass
Well #3	5.00	0.26	Pass
Well #4	3.00	0.06	Pass
Well #5	3.00	0.15	Pass
Well #6	3.00	0.18	Pass
Well #7	3.00	0.15	Pass
Well #8	3.00	0.22	Pass

Master Set Expected Ranges

Normalized Ratios	QIAGEN Specs Minimum	QIAGEN Specs Maximum	Calculated Acceptable Values Average	Calculated Acceptable Values Minimum	Calculated Acceptable Values Maximum
Well #1	0.70	1.30	0.04	0.03	0.06
Well #2	0.75	1.25	0.28	0.21	0.35
Well #3	0.80	1.20	1.00	0.80	1.20
Well #4	0.80	1.20	5.42	4.33	6.50
Well #5	0.80	1.20	21.43	17.14	25.71
Well #6	0.80	1.20	171.53	137.23	205.84
Well #7	0.80	1.25	836.66	669.33	1045.83
Well #8	0.80	1.25	1684.35	1347.48	2105.43
RLUs					
Well #3	0.70	1.30	1319.00	923	1714
Well #8	0.80	1.20	2222322.00	1777857	2666786

LumiCheck Software v.2.0.2
Instrument Serial #: 9102080217
Plate ID: JK30-D1020

Supervisor: _____

Date: _____

The header of the LumiCheck periodic master set values report includes the laboratory header information. See "Modifying the laboratory header information," page 47, for instructions to change the laboratory header information.

The status of the master file is listed in the header. Valid results have **RLUs are Valid** in the header.

The following table describes the fields in the header of the LumiCheck periodic master set values report.

Field	Description
Data Record:	ID of the created master file
Measurement Record:	ID of the data file that contains the measurements used to create the master file
User ID:	User ID logged into the LumiCheck Plate Software during the creation of the master file

The **Raw Data** section provides the RLU values for each of the measurements and the average measurement for each of the 8 light-emitting wells. The **Normalized Ratios** section provides the normalized ratios and the average normalized ratio for each of the 8 light-emitting wells. The **Master Set Up Verification** section provides the specification for the coefficient of variation (CV), the CV result and the pass/fail result for each of the 8 light-emitting wells. The **Master Set Expected Ranges** section provides the specifications to which the periodic check must meet for a pass result.

The following table describes the fields in the **Master Set Expected Ranges** panel.

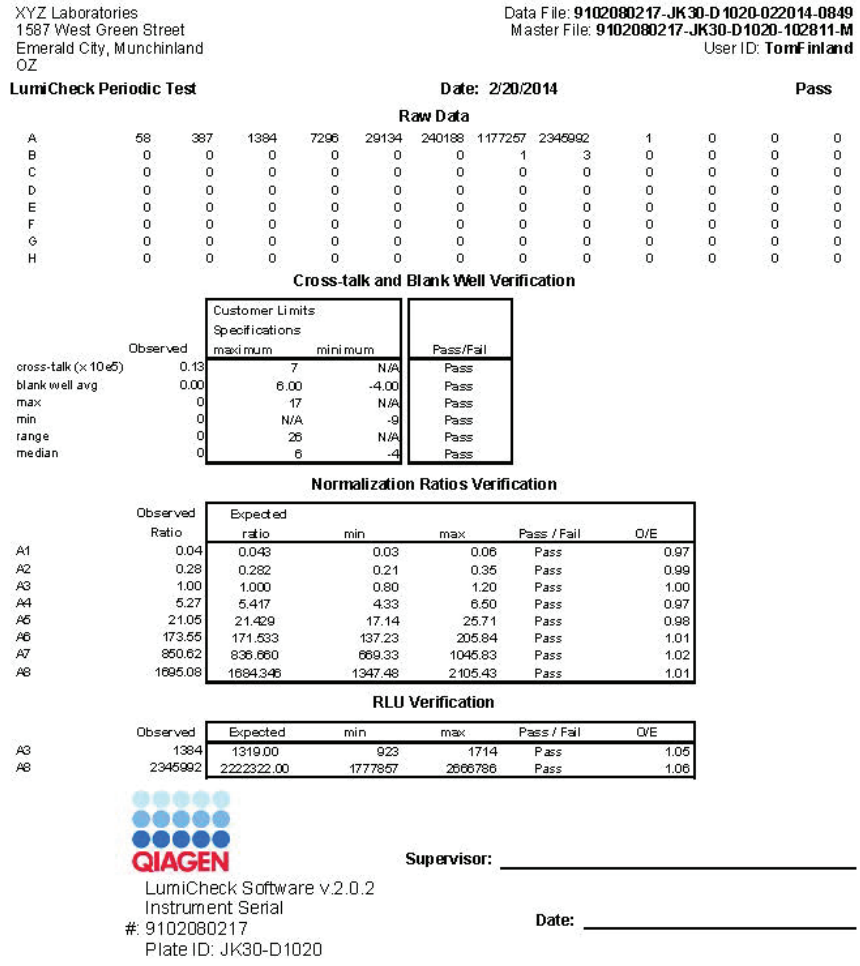
Field	Description
Normalized ratios [and] **RLUs**	The light-emitting well of the LumiCheck Plate that was measured
QIAGEN Specs Minimum	Specification defined by QIAGEN

Field	Description
QIAGEN Specs Maximum	Specification defined by QIAGEN
Calculated Acceptable Values Average	The normalized ratio average or RLU average as calculated from the measurements of the light-emitting well
Calculated Acceptable Values Minimum	The normalized ratio average or RLU average as calculated by multiplying the **Calculated Acceptable Values Average** result by the **QIAGEN Specs Minimum**
Calculated Acceptable Values Maximum	The normalized ratio average or RLU average as calculated by multiplying the **Calculated Acceptable Values Average** result by the **QIAGEN Specs Maximum**
RLUs	The light-emitting well of the LumiCheck Plate that was measured

6.8.2 Understanding the LumiCheck periodic test report

The LumiCheck periodic check report displays the results of the periodic check. The periodic check report includes the RLU, cross-talk, blank well, normalized ratios and RLU verification results. The normalized ratios for the individually measured wells are calculated and analyzed against the applicable master file. The periodic check report includes the expected ranges for the pass/fail criteria for each test.

Example of the LumiCheck periodic test report:



XYZ Laboratories
1587 West Green Street
Emerald City, Munchinland
OZ

Data File: **9102080217-JK30-D1020-022014-0849**
Master File: **9102080217-JK30-D1020-102811-M**
User ID: **TomFinland**

LumiCheck Periodic Test **Date: 2/20/2014** **Pass**

Raw Data

A	58	387	1384	7296	29134	240188	1177257	2345992	1	0	0	0
B	0	0	0	0	0	0	1	3	0	0	0	0
C	0	0	0	0	0	0	0	0	0	0	0	0
D	0	0	0	0	0	0	0	0	0	0	0	0
E	0	0	0	0	0	0	0	0	0	0	0	0
F	0	0	0	0	0	0	0	0	0	0	0	0
G	0	0	0	0	0	0	0	0	0	0	0	0
H	0	0	0	0	0	0	0	0	0	0	0	0

Cross-talk and Blank Well Verification

	Observed	Customer Limits Specifications maximum	minimum	Pass/Fail
cross-talk (x 10e5)	0.13	7	N/A	Pass
blank well avg	0.00	6.00	-4.00	Pass
max	0	17	N/A	Pass
min	0	N/A	-9	Pass
range	0	26	N/A	Pass
median	0	6	-4	Pass

Normalization Ratios Verification

	Observed Ratio	Expected ratio	min	max	Pass / Fail	O/E
A1	0.04	0.043	0.03	0.06	Pass	0.97
A2	0.28	0.282	0.21	0.35	Pass	0.99
A3	1.00	1.000	0.80	1.20	Pass	1.00
A4	5.27	5.417	4.33	6.50	Pass	0.97
A5	21.05	21.429	17.14	25.71	Pass	0.98
A6	173.55	171.533	137.23	205.84	Pass	1.01
A7	850.62	836.660	669.33	1045.83	Pass	1.02
A8	1695.08	1684.346	1347.48	2105.43	Pass	1.01

RLU Verification

	Observed	Expected	min	max	Pass / Fail	O/E
A3	1384	1319.00	923	1714	Pass	1.05
A8	2345992	2222322.00	1777857	2666786	Pass	1.06

QIAGEN

LumiCheck Software v.2.0.2
Instrument Serial #: 9102080217
Plate ID: JK30-D1020

Supervisor: _____

Date: _____

The header of the LumiCheck periodic test report includes the laboratory header information. See "Modifying the laboratory header information," page 47, for instructions to change the laboratory header information.

The status of the periodic check is listed in the header. Valid results have **Pass** in the header.

The following table describes the fields in the header of the LumiCheck periodic test report.

Field	Description
Data File:	ID of the data file that contains the measurements for the periodic check
Master File:	ID of the master file that is the reference for the periodic check
User ID:	User ID logged into the LumiCheck Plate Software during the periodic check

The **Raw Data** section provides the RLU values for each of the wells of the LumiCheck Plate. The **Cross-talk and Blank Well Verification** section provides the results for the LumiCheck Plate wells that do not emit light. The **Normalization Ratios Verification** section provides the results for each of the 8 light-emitting wells. The **RLU Verification** section provides the results for light-emitting wells A3 and A8.

The following table describes the fields in the **Cross-talk and Blank Well Verification** panel.

Field	Description
Observed	The parameter applicable to the blank wells and the average results for all of the blank wells
Customer Limits Specification maximum	Specification defined by QIAGEN
Customer Limits Specification minimum	Specification defined by QIAGEN
Pass/Fail	Determination of result status by comparing the observed result to the specification

The following table describes the fields in the **Normalization Ratios Verification** panel.

Field	Description
Observed ratio	The normalized ratio for the light-emitting wells
Expected ratio	Specification defined by the master file
min	Specification defined by the master file
max	Specification defined by the master file
Pass/Fail	Determination of result status by comparing the observed normalized ratio to the specifications
O/E	The ratio of the observed normalized ratio result divided by the expected normalized ratio

The following table describes the fields in the **RLU Verification** panel.

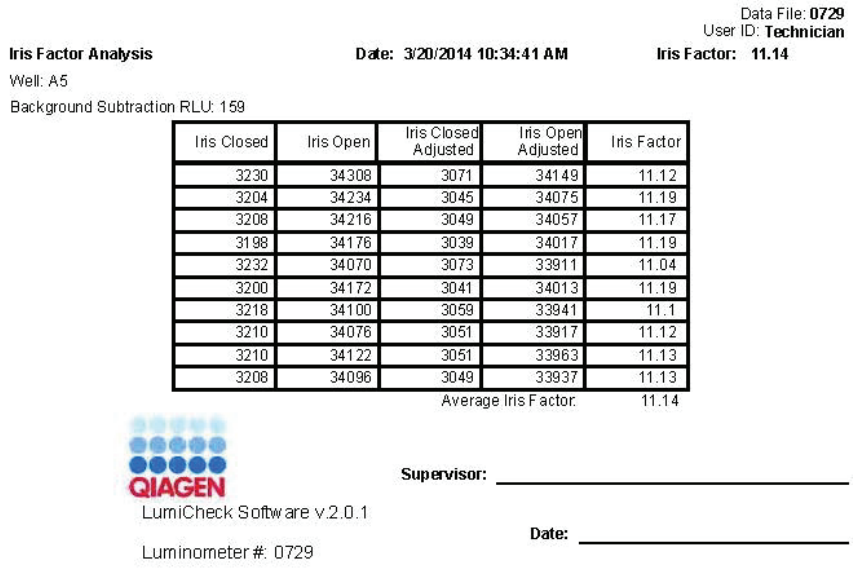
Field	Description
Observed	The RLU result for the light-emitting wells
Expected	Specification defined by the master file
min	Specification defined by the master file
max	Specification defined by the master file
Pass/Fail	Determination of result status by comparing the observed RLU to the specifications
O/E	The ratio of the observed RLU result divided by the expected RLU result

6.8.3 Understanding the iris factor analysis report

The iris factor analysis report displays the result of the measurements taken during the establishment of the iris factor. See “Establishing the iris factor,” page 53, for additional instructions.

The iris factor analysis report is only applicable to the DML 2000.

Example of the iris factor analysis report:



Data File: **0729**
User ID: **Technician**

Iris Factor Analysis **Date: 3/20/2014 10:34:41 AM** **Iris Factor: 11.14**

Well: A5

Background Subtraction RLU: 159

Iris Closed	Iris Open	Iris Closed Adjusted	Iris Open Adjusted	Iris Factor
3230	34308	3071	34149	11.12
3204	34234	3045	34075	11.19
3208	34216	3049	34057	11.17
3198	34176	3039	34017	11.19
3232	34070	3073	33911	11.04
3200	34172	3041	34013	11.19
3218	34100	3059	33941	11.1
3210	34076	3051	33917	11.12
3210	34122	3051	33963	11.13
3208	34096	3049	33937	11.13
			Average Iris Factor:	11.14

QIAGEN

LumiCheck Software v.2.0.1

Luminometer #: 0729

Supervisor: _____

Date: _____

The following table describes the fields in the header of the iris factor analysis report.

Field	Description
Data File:	ID of the data file that contains the measurements for the iris factor analysis
User ID:	User ID logged into the LumiCheck Plate Software during the iris factor analysis
Iris Factor:	The average of the iris factor measurements that should be used as the specification for the DML 2000

Field	Description
Well:	The well that is measured during iris factor analysis
Background subtraction RLU:	The value of the background that is subtracted from the raw RLU measurements of the iris factor analysis

The following table describes the fields of the iris factor analysis report.

Field	Description
Iris Closed	The RLU result for the well with the iris closed
Iris Open	The RLU result for the well with the iris open
Iris Closed Adjusted	The RLU result for the well with the iris closed and the background subtraction RLU subtracted
Iris Open Adjusted	The RLU result for the well with the iris open and the background subtraction RLU subtracted
Iris Factor	The iris factor result as determined by dividing the **Iris Open Adjusted** result by the **Iris Closed Adjusted** result
Average Iris Factor	The average of the **Iris Factor** results

6.9 Generating trending reports

The LumiCheck Plate Software maintains a database that is used to generate trending reports. A trending report may be generated for the periodic check results. If using a DML 2000, a trending report may be generated for background measurement readings.

Use trending reports to observe trends in the performance of the DML instrument over time.

1. Select the applicable radio button for the type of report.

   If using a DML 3000, the only option available is the **Periodic Check** radio button. If using a DML 2000, the options are the **Periodic Check** or **Background Trending** radio buttons.

2. If generating a background trending report, select the applicable DML instrument from the **Serial Number for Trend:** dialog field.

   Note: Trending reports for plate background readings are only possible for DML 2000 instruments.

3. Using the **Start Date:** and **End Date:** dialog fields in the **Trend Range** panel, enter the applicable time period for the trending report.

   If trend data exist for the type of report selected, the applicable data files populate in the list.

4. Select the applicable item in the displayed list and click the **Trend...** button.

   The **QIAGEN Report Viewer** window displays the report. See "Using the **QIAGEN Report Viewer** window," page 44, for additional instructions.

6.9.1 Understanding the periodic check trending report

Each periodic check that passes is added to the database; failed periodic tests are not added to the database. For each light-emitting well, the observed normalized ratio divided by the expected ratios is plotted versus the date of analysis. In addition, the observed RLU result divided by the expected RLU result for wells 3 and 8 is plotted versus the date of analysis.

Example of the periodic check trending report:

	Data File:	RLU #3	RLU #8	1	2	3	4	5	6	7	8
3/22/2013 9:44:42 AM	9102071004-IA18-D0779-032213-0944	1.00	0.98	1.01	1.01	1.00	1.01	1.01	0.97	0.97	0.97
4/19/2013 12:16:22 PM	9102071004-IA18-D0779-041913-1216	0.98	0.98	1.02	1.00	1.00	1.00	1.00	1.00	0.99	1.00
5/17/2013 11:05:30 AM	9102071004-IA18-D0779-051713-1105	1.00	1.00	1.00	0.99	1.00	1.00	1.00	1.00	1.00	1.00
6/17/2013 5:00:57 PM	9102071004-IA18-D0779-061713-1700	0.99	1.00	1.04	1.01	1.00	1.00	0.99	0.99	0.99	1.01
7/15/2013 9:44:12 AM	9102071004-IA18-D0779-071513-0944	0.97	0.98	1.00	1.02	1.00	1.01	1.00	1.00	1.00	1.01
8/15/2013 10:45:27 AM	9102071004-IA18-D0779-081513-1045	0.97	0.99	1.03	1.01	1.00	1.01	1.01	1.00	1.00	1.02
9/13/2013 9:22:10 AM	9102071004-IA18-D0779-091313-0922	0.97	0.99	1.00	1.00	1.00	1.00	1.00	1.00	0.99	1.02
10/11/2013 9:36:07 AM	9102071004-IA18-D0779-101113-0936	0.98	1.00	1.01	1.01	1.00	1.01	1.00	1.00	1.00	1.01
11/11/2013 10:08:18 AM	9102071004-IA18-D0779-111113-1008	0.99	1.01	1.02	1.00	1.00	1.02	1.01	1.01	1.00	1.02
12/11/2013 10:38:08 AM	9102071004-IA18-D0779-121113-1037	1.01	1.00	1.04	1.01	1.00	1.01	1.00	1.00	1.00	1.00
1/10/2014 8:23:09 AM	9102071004-IA18-D0779-011014-0823	1.01	1.01	1.00	1.01	1.00	1.00	1.00	1.00	1.00	1.00
2/10/2014 10:53:11 AM	9102071004-IA18-D0779-021014-1053	1.01	1.00	1.00	0.99	1.00	1.01	1.00	1.00	1.00	1.00
3/10/2014 8:48:03 AM	9102071004-IA18-D0779-031014-0848	1.00	1.00	1.01	1.03	1.00	1.02	1.01	1.01	1.01	1.00

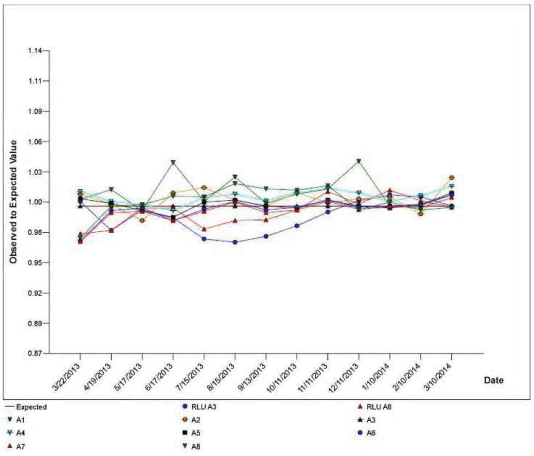
Periodic Trend Plot for IA18-D0779 and 9102071004

QIAGEN

LumiCheck® Software v.2.0.1
Instrument Serial #: 9102071004
Plate ID: IA18-D0779

Supervisor: _____

Date: _____



QIAGEN

LumiCheck® Software v.2.0.1
Instrument Serial #: 9102071004
Plate ID: IA18-D0779

Supervisor: _____

Date: _____

6.9.2 Understanding the background baseline (100) trending report

The background baseline (100) trending report applies only 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.

Periodically review the background baseline (100) trending report. 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.

The following table describes the columns in the **Background Baseline Measurements** section of the background baseline (100) trending report.

Column	Description
Date	Column containing the dates of the background baseline (100) readings performed for the specified DML instrument
Average	Column containing the average RLU results of the background baseline (100) readings performed for the specific DML instrument
Range	Column containing the RLU ranges of the background baseline (100) readings performed for the specific DML instrument
Min	Column containing the RLU minimums of the background baseline (100) readings performed for the specific DML instrument
Max	Column containing the RLU maximums of the background baseline (100) readings performed for the specific DML instrument

6.9.3 Understanding the plate background (10) trending report

The plate background (10) trending report applies only 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.

Periodically review the plate background (10) trending report. 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.

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 dates of the last plate background (10) readings performed for the specified DML instrument
Average	Column containing the average RLU results of the last plate background (10) readings performed for the specific DML instrument
Range	Column containing the RLU ranges of the last plate background (10) readings performed for the specific DML instrument
Min	Column containing the RLU minimums of the last plate background (10) readings performed for the specific DML instrument
Max	Column containing the RLU maximums of the last plate background (10) readings performed for the specific DML instrument

6.10 Importing and exporting data

Data can be exported and imported from a HC2 System computer onto another HC2 System computer. The import and export functions only transfer data files. Once the data have been imported, the master file must be created using the imported data.

6.10.1 Exporting data

1. On the **Periodic Check** tab, click the **Measurements…** button in either the **Master Files** or **Periodic Measurements** panel, as applicable.

   The **Measurements** dialog box opens.
2. Select the data file to export in the list and click the **Export** button.

   A directory dialog box opens.

   Note: If exporting master file raw data, select the data file from which the current master file was created.
3. Enter the name of the file and, using the directory, navigate to the location to which the file will be saved.
4. Click the **Save** button.

   The exported file will be saved as an *.lcx file.

6.10.2 Importing data

1. On the **Periodic Check** tab, click the **Measurements…** button in either the **Master Files** or **Periodic Measurements** panel, as applicable.

   The **Measurements** dialog box opens.

   Note: Only users with supervisor access level can import data from the **Master Files** panel.
2. Click the **Import** button.

   A directory dialog box opens.
3. Using the directory, navigate to the location to which the file is saved.
4. Select the *.lcx file to import.
5. Click the **Open** button.

   The data are imported into the LumiCheck Plate Software, and a dialog box opens stating the import is complete.
6. Click **OK**.

   The data appear in the **Measurements** dialog box.
7. Click the **Close** button.

   The data appear in the **Periodic Measurements** panel.

6.11 Archiving data

The data generated by the LumiCheck Plate can be archived to the hard drive of the HC2 System computer. As data accumulate in the LumiCheck Plate Software database, the response time for starting the LumiCheck Plate Software and viewing reports increases. If the response time becomes unacceptable, archive the data for faster performance.

Once archived, the data will not display unless the archive is viewed. The data can never be returned to the active data set displayed in the LumiCheck Plate Software. During archive viewing, the data are displayed as the current data. Reports and trending reports can be generated, but data cannot be added to the archive or modified. The archive data are removed and the current data are activated when the current data are restored. The master files are never archived.

The LumiCheck Plate Software does not support archival to or retrieval from a Universal Serial Bus (USB) storage device.

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

Important: Archiving data will remove all data for all DML instruments from displaying in the LumiCheck Plate Software, and the data cannot be returned to the active data set.

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

   The **Archive Data** dialog box opens.
2. Select the **C:** drive that will store the archive.

   Important: Do not select any other drive as the data file must store in the correct location for the archive to be viewed.
3. In the **Archive Description** dialog box, type a short name that describes the type of data being archived.
4. Click **OK**.

   The current data set for all DML instruments is archived and can only be viewed using the **View Archive Data…** button. See “Viewing archived data,” page 80, for additional instructions.

6.11.1 Viewing archived data

1. On the **Utilities/Settings** tab, click the **View Archive Data…** button.

   The **View Archive Data** dialog box opens and lists the past archives. Each archive has the date and time the archive was performed as well as the description entered by the user.
2. In the **Select the Archive Drive:** dialog field, select the drive containing the archive.
3. In the **Select the Archive to view:** dialog field, select the archive to view.
4. Click **OK**.

   The **Archived Data Warning** dialog box opens and displays the following message:

   "You are currently viewing archived data. Your changes will NOT be permanently saved. To restore the current data, click 'Restore Current Data' from the Utilities/Settings Tab."
5. Click **OK**.
6. View the archive.

   Important: Do not edit or generate data while viewing an archive as the changes will not be saved.
7. When finished viewing the archive, click the **Restore Current Data** on the **Utilities/Settings** tab to return the archive to the archive folder.

   The **Restore Current Data** dialog box opens and displays the following message:

   "This will stop the viewing of archived data and restore the current data. Are you sure you wish to continue?"
8. Click **OK**.

7 Maintenance

CAUTION **Damage to the instrument**

Do not immerse the LumiCheck Plate in water or allow water to enter the chamber of the LumiCheck Plate.

7.1 Routine cleaning

Periodically clean the LumiCheck Plate with a soft low-lint paper towel moistened with deionized or distilled water. Avoid contact with the light-emitting wells unless dirt or debris is present. Cleaning the light-emitting wells excessively can alter the light output and cause the periodic check to fail. Do not use chemicals during the cleaning as the LumiCheck Plate can be damaged.

When not in use, move the battery switch to the OFF position. Store the LumiCheck Plate in its case.

7.2 Calibration

The LumiCheck Plate cannot be calibrated. The LumiCheck Plate is used to evaluate the stability of the DML instrument and monitor the instrument performance by periodically testing the functions of the DML instrument.

The LumiCheck Plate Software establishes a set of specifications for a specific DML instrument. The specifications of the periodic check for the specific DML instrument are based on the specifications established with the master file. The trending file based on the periodic checks of a specific LumiCheck Plate and DML instrument provides trending information on the performance of the LumiCheck Plate.

The LumiCheck Plate is used as an early warning of potential DML instrument failure and as a diagnostic tool in the event of a failed *digene* HC2 DNA test. A failed periodic check using the LumiCheck Plate does not invalidate prior assay results as each *digene* HC2 DNA test contains internal verification criteria that validate the assay.

The LumiCheck Plate and DML instrument combination is trended over time by conducting periodic checks using the LumiCheck Plate Software. After each periodic check, the acceptance criteria and results are available in the generated report.

The LumiCheck Plate is designed with an internal monitoring mechanism to make sure that the LumiCheck Plate is functioning within the specified voltage range.

7.3 Replacing the LumiCheck Plate battery

Replace the LumiCheck Plate battery as needed. To confirm the LumiCheck Plate battery requires replacement, see "Checking the LumiCheck Plate battery," page 55, for additional instructions.

Replacement batteries for the LumiCheck Plate are available from QIAGEN. The LumiCheck Plate Battery Replacement Package includes a battery assembly, 4 screws and a battery test tool.

1. Make sure the LumiCheck Plate is powered OFF.

   See "Powering ON and OFF the LumiCheck Plate," page 55, for additional instructions.
2. Remove the 4 battery access screws using the provided screwdriver and remove the access panel.

   Note: Do not remove any other screws. Removing other screws will alter the LumiCheck Plate characteristics.
3. Disconnect the leads of the LumiCheck Plate battery.
4. Connect the leads of the new LumiCheck Plate battery.
5. Replace the access panel and tighten the 4 battery access screws. Use the extra screws provided if the original screws are misplaced.
6. Perform a battery check to make sure the new battery is operating properly.

   See "Checking the LumiCheck Plate battery," page 55, for additional instructions.

7.4 Disposing of the LumiCheck Plate battery

Dispose of the LumiCheck Plate battery in accordance with national and local regulations.

8 Troubleshooting

Use this section for error handling and troubleshooting. Also refer to digene *HC2 System Software User Manual* and the applicable DML instrument user manual for additional information. If the recommended steps do not resolve the problem, contact QIAGEN Technical Services for assistance.

8.1 Master file or periodic check fails

		Comments and suggestions
The RLUs are not above the plate background (10)		
a)	The LumiCheck Plate battery is not activated or is depleted	Power ON the LumiCheck Plate. See "Powering ON and OFF the LumiCheck Plate," page 55, for additional information. Check the LumiCheck Plate battery. See "Checking the LumiCheck Plate battery," page 55, for additional instructions. Repeat the LumiCheck Plate measurement.
b)	The LumiCheck Plate orientation is incorrect in the DML instrument	Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position. Refer to the applicable DML instrument user manual for additional information about loading a plate. Repeat the LumiCheck Plate measurement.
c)	The DML instrument fails	Contact QIAGEN Technical Services.
The RLUs are above the plate background (10 RLU)		
a)	System or communication error	Power OFF the HC2 System, including the HC2 System computer and the DML instrument. Refer to the applicable user manuals for additional instructions. Wait 30 seconds and power ON the HC2 System. Repeat the LumiCheck Plate measurement.

		Comments and suggestions
b)	DML instrument malfunction	Contact QIAGEN technical Services.
c)	The DML instrument is not warmed up for a full hour **Note**: Only applicable to the DML 2000.	Allow the DML instrument to warm up for at least 1 hour. Repeat the LumiCheck Plate measurement. **Recommendation**: Leave the DML instrument powered on at all times.

8.2 Periodic check measurement fails

		Comments and suggestions
Periodic check fails the cross-talk specifications		
a)	The LumiCheck Plate orientation is incorrect in the DML instrument	Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position. Refer to the applicable DML instrument user manual for additional information about loading a plate. Repeat the LumiCheck Plate measurement.
b)	The LumiCheck Plate is dirty or the plate mask or plate carrier of the DML instrument is dirty	Clean the LumiCheck Plate with a low-lint paper towel moistened with distilled or deionized water. Clean the DML instrument; refer to the applicable user manual for additional instructions. Repeat the LumiCheck Plate measurement.
c)	The DML instrument fails	Contact QIAGEN Technical Services.
Periodic check fails the blank well specifications		
a)	The LumiCheck Plate is dirty or the plate mask or plate carrier of the DML instrument is dirty	Clean the LumiCheck Plate with a low-lint paper towel moistened with distilled or deionized water. Clean the DML instrument; refer to the applicable user manual for additional instructions. Repeat the LumiCheck Plate measurement.

		Comments and suggestions
b)	System or communication error	Power OFF the HC2 System, including the HC2 System computer and the DML instrument. Refer to the applicable user manuals for additional instructions. Wait 30 seconds and power ON the HC2 System. Repeat the LumiCheck Plate measurement.
c)	The DML instrument fails	Contact QIAGEN Technical Services.

Well A8 fails the specifications for normalized ratio or RLU

	The LumiCheck Plate battery is not activated or is depleted	Power ON the LumiCheck Plate. See "Powering ON and OFF the LumiCheck Plate," page 55, for additional information. Check the LumiCheck Plate battery. See "Checking the LumiCheck Plate battery," page 55, for additional instructions. Repeat the LumiCheck Plate measurement.

Individual well failure of wells A1 to A7

a)	System or communication error	Power OFF the HC2 System, including the HC2 System computer and the DML instrument. Refer to the applicable user manuals for additional instructions. Wait 30 seconds and power ON the HC2 System. Repeat the LumiCheck Plate measurement.
b)	The LumiCheck Plate is dirty or the plate mask or plate carrier of the DML instrument is dirty	Clean the LumiCheck Plate with a low-lint paper towel moistened with distilled or deionized water. Clean the DML instrument; refer to the applicable user manual for additional instructions. Repeat the LumiCheck Plate measurement.
c)	The individual well is damaged	Contact QIAGEN Technical Services.
d)	The DML instrument fails	Contact QIAGEN Technical Services.

		Comments and suggestions
Multiple wells fail		
a)	The LumiCheck Plate orientation is incorrect in the DML instrument	Load the LumiCheck Plate into the DML instrument with the notched corner in the upper-right position. Refer to the applicable DML instrument user manual for additional information about loading a plate. Repeat the LumiCheck Plate measurement.
b)	The LumiCheck Plate battery is not activated or is depleted	Power ON the LumiCheck Plate. See "Powering ON and OFF the LumiCheck Plate," page 55, for additional information. Check the LumiCheck Plate battery. See "Checking the LumiCheck Plate battery," page 55, for additional instructions. Repeat the LumiCheck Plate measurement.
c)	System or communication error	Power OFF the HC2 System, including the HC2 System computer and the DML instrument. Refer to the applicable user manuals for additional instructions. Wait 30 seconds and power ON the HC2 System. Repeat the LumiCheck Plate measurement.
d)	The DML instrument fails	Contact QIAGEN Technical Services.
e)	The LumiCheck Plate fails	Contact QIAGEN Technical Services.

8.3 Software messages

	Comments and suggestions
The most recent data file does not appear in the list of data files	
Software overload	Exit the LumiCheck Plate Software and restart the software.
The following message is displayed: "Instrument background out of the allowed range. Do you want to continue measuring anyway?"	
a) Average of 10 background measurements prior to well measurement is outside of the established background range	Power OFF the HC2 System, including the HC2 System computer and the DML instrument. Refer to the applicable user manuals for additional instructions. Wait 30 seconds and power ON the HC2 System. Repeat the LumiCheck Plate measurement.
b) The DML instrument fails	Contact QIAGEN Technical Services.

Ordering Information

Product	Contents	Cat. no.
LumiCheck Plate	LumiCheck Plate, storage case, screwdriver, battery test tool, battery replacement package	6000-5013
LumiCheck Plate Battery Replacement Package	Replacement battery, 4 screws and battery test tool	6000-5012

Appendix A — Technical Data

Characteristic	Parameter
Dimensions (h x w x d)	1.43 x 8.54 x 12.79 cm (0.56 x 3.36 x 5.04 inches)
Weight	227 g (8 ounces)
Construction	Computer Numeric Control (CNC) machined aluminum body Stainless steel back covers Acrylic lens
Finish	Black anodized aluminum
Stainless steel	Black matte paint
Battery	Lithium battery pack, 6.4V DC, 1 Ah
Light source	2 independently closed, loop controlled, constant light level, green LEDs
Light output	7 levels (wells A1–A7) derived from 1 LED source, ranging over 6 decades of dynamic range 1 well (A8) derived from a second LED source
Stability of the RLU values of the LED-based lights	± 10% for well A1; ± 5% for wells A2–A8
Operating Conditions	
Air Temperature	15 - 32°C
Relative Humidity	15 - 75% (noncondensing)
Place of operation	For indoor use only

Pollution Level	II
Transportation Conditions (in manufacturer's package)	
Air Temperature	-25 - 60°C
Relative Humidity	15 - 75% (noncondensing)
Storage Conditions (in manufacturer's package)	
Air Temperature	5 - 40°C
Relative Humidity	15 - 75% (noncondensing)

Appendix B — Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

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