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# Rotor-Gene AssayManager® v1.0 IVD (US) Quick-Start Guide

## For installation and setup of Rotor-Gene AssayManager v1.0


IVD

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# Contents

# Installing Rotor-Gene AssayManager v1.0

This Quick-Start Guide summarizes instructions for the installation and setup of Rotor-Gene AssayManager v1.0. Before using Rotor-Gene AssayManager v1.0, it is essential that you read "Getting Started" in the *Rotor-Gene AssayManager Core Application User Manual* HB-1350 (available as a .pdf file on the QIAGEN website) carefully and pay particular attention to the safety information.

Rotor-Gene AssayManager v1.0 uses a database (Microsoft® SQL Server® Express) to store all data. The database can be installed locally or on a remote system. The Microsoft SQL Server database provides backup and restore mechanisms. For detailed information about backup and restore instructions, refer to the "Maintenance" section in the *Rotor-Gene AssayManager Core Application User Manual*.

**Note**: Most screenshots in this document are created based on Windows 7 operating system. If the behavior between Windows 7 and Windows 10 is different, a separate description and screenshot are provided for Windows 10.Rotor-Gene AssayManager v1.0 can be installed with 3 different configurations:

| Task/configuration | Description |
|---|---|
| Install on stand-alone computer* | • A user with local system administration privileges installs the database (Microsoft SQL Server Express) including initial data, the Rotor-Gene AssayManager v1.0 application, and at least one Rotor-Gene AssayManager v1.0 plug-in on a computer.<br>• The user is completely guided by the installation wizard and will be prompted for input, if necessary. |
| Set up a stand-alone computer,* which is connected to a network, and install Rotor-Gene AssayManager v1.0 on an additional computer* connected to the first | • Proceed as described in "Install on stand-alone computer*".<br>• The computer* is connected to the local area network.<br>• Rotor-Gene AssayManager v1.0 and at least one Rotor-Gene AssayManager v1.0 plug-in is installed on one or multiple computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator. |

* The term "computer" is used to describe a notebook or a PC, and not a server.

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| Task/configuration | Description |
|---|---|
| Use existing database server and install Rotor-Gene AssayManager v1.0 on one or multiple computers* | • A user with all required database administration privileges uses the installation wizard to install only a new database instance including initial data on an existing database server.<br>• The database administrator is responsible for checking whether the database server fulfills the Rotor-Gene AssayManager v1.0 requirements. The administrator is also responsible for performing all database administration tasks necessary to back up the system before installation. Furthermore, the database administrator must guarantee the functionality of the system after the successful installation or a failed installation.<br>• Rotor-Gene AssayManager v1.0 and at least one Rotor-Gene AssayManager v1.0 plug-in are installed on one or multiple computers by a user with local administration privileges. During installation the user is prompted for connection to the database, which has to be provided by the database administrator. |

* The term “computer” is used to describe a notebook or a PC, and not a server.

## Minimum computer requirements

A laptop computer with the required specifications for operating the Rotor-Gene® Q MDx instrument and Rotor-Gene AssayManager v1.0 is provided by QIAGEN as part of the Rotor-Gene Q instrument. In general, the following minimum requirements must be met to run Rotor-Gene AssayManager v1.0:

**Minimum computer requirements**

| System | Requirements |
|---|---|
| Display | 1024 x 768 pixel resolution or higher |
| Supported operating systems | Windows® 7 Professional (32 or 64 bit) with Service Pack 1<br>Windows® 10 with version 1709 or newer (32 or 64 bit) |
| Disk space | 250 GB |
| Processor | Intel® Core™ i3-380M Processor or higher |
| Memory | 4 GB RAM recommended |
| USB interface | 4 USB 2.0 ports or higher. If necessary, a USB Hub can be ordered through QIAGEN<br>Contact **www.qiagen.com** for details |
| DVD-ROM drive | 1 |
| Pointing device | Touchpad or mouse or equivalent is required |
| Service packs required | Microsoft Windows® 7: Service Pack 1<br>Microsoft Windows® 10 Version 1709 or newer |
| Bluetooth® | Switched off |
| PDF viewer or similar | Already installed |
| Power options | Never turn off hard disks, hibernate or go to standby |

**Note**: Rotor-Gene AssayManager v1.0 consists of different components working together. The core application v1.0 is complemented by different plug-ins that provide assay type specific analysis and visualization of results. The core application v1.0 is mandatory for working with Rotor-Gene AssayManager v1.0. At least one plug-in must be installed. Optionally, additional plug-ins can be installed. Plug-ins may not be available worldwide. See **www.qiagen.com** for details.

**Note**: A stable power connection is required. Unstable power connections can cause loss of data.

## Configuration for Windows security

The laptop computers that are provided by QIAGEN for use with your Rotor-Gene Q instrument have Microsoft Windows 7 or 10 pre-installed and are configured with a standard (non-administrative) Windows user account and with an administrator account. In routine usage of the system, the standard account shall be used, since Rotor-Gene AssayManager v1.0 is designed to run without administrator rights. The administrator account shall only be used to install the Rotor-Gene AssayManager v1.0 software and a virus scanner (please see chapter for anti-virus software). Using the administrator account is indicated by a red desktop background. Please make sure, that you always log in as standard user for routine use.

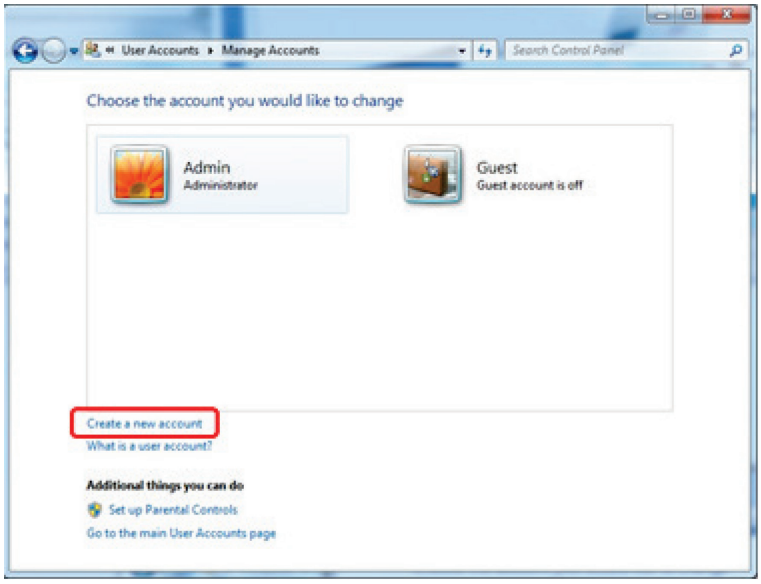
The default password of the administrator account is as follows: "Q1a#g3n!A6". Please change the administrator password after first login. Please make sure that the password is secure and does not get lost. There is no password for the standard account.

If your configuration is different and no non-administrative account is contained, system administrators shall set up an additional standard Windows user account to prevent access to critical system areas, such as "Program Files", "Windows" directory (e.g. access to installation or uninstallation functionality, including applications, operating system components, date/time settings, Windows updates, firewall, user rights & roles, anti-virus activation), or performance relevant settings like power saving. Multiple users can then be configured within the Rotor-Gene AssayManager v1.0 user management.

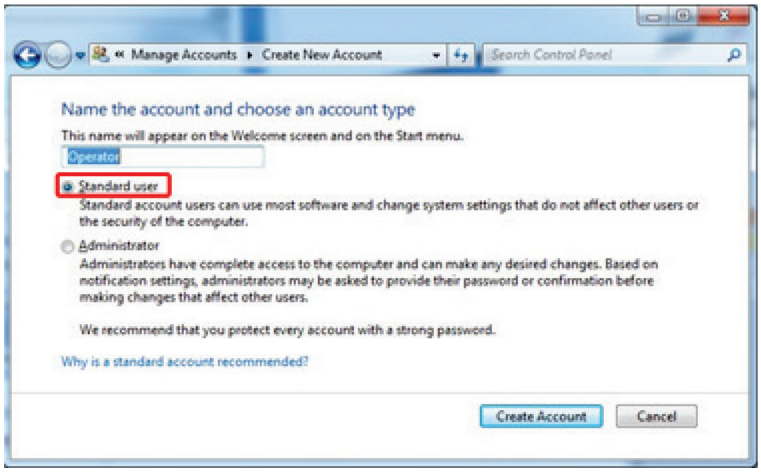
## Creation of standard user account for Windows 7

To create a standard user account, please follow these steps:

1. From the **Start** menu, open the **Control Panel** and select the **User Accounts/Manage Accounts**.
2. Choose **Create a new account**.



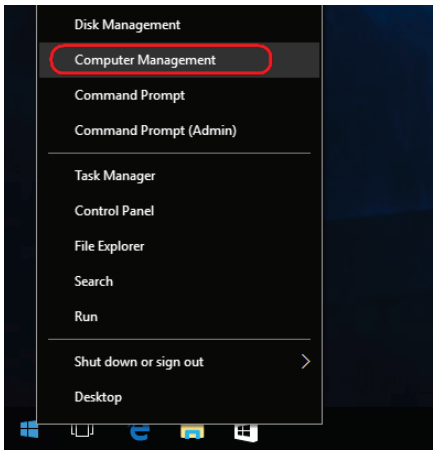

3. Name the account and select **Standard User** as the account type.



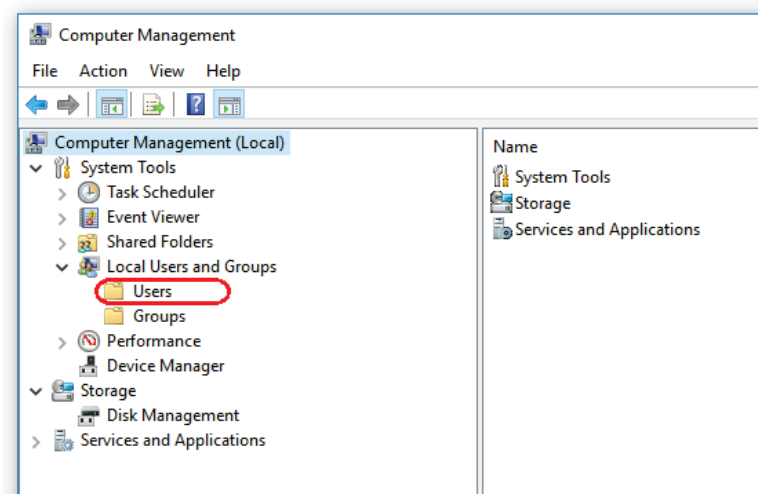

4. Click **Create Account**.

Creation of standard user account for Windows 10

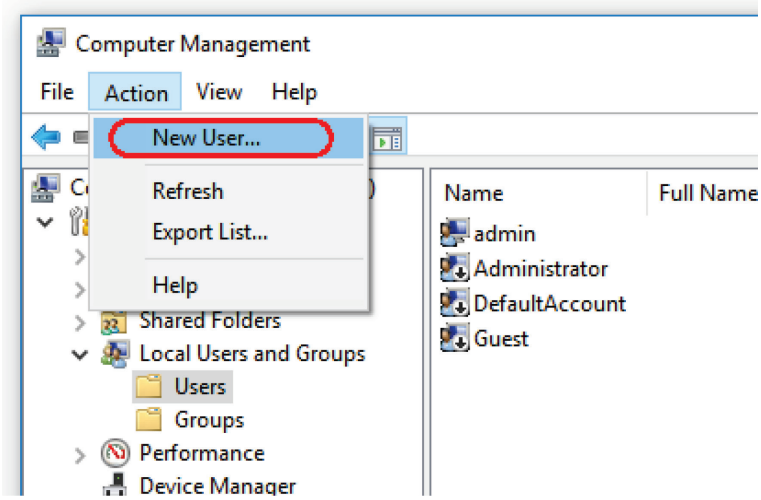
1. Right-click the Windows button and select **Computer Management**.



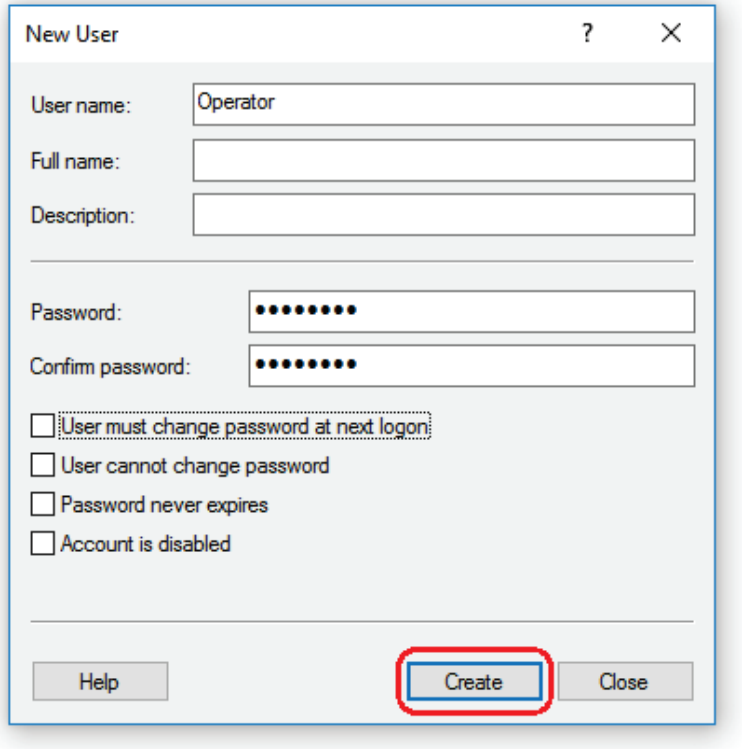

2. Expand the **Local Users and Groups** and click the **Users** folder.



3. While the **Users** folder is highlighted, click the **Action tab** and select **New User.**




4. Name the account, optionally set a password and click **Create.**



## General download and installation instructions

If you download software from the QIAGEN website on a different computer than that one on which the software shall be installed, please make sure that the flash drive used to transfer the software is free of viruses. QIAGEN strongly recommends to perform a virus scan using an up-to-date virus scanner on the flash drive to avoid a contamination.

**Note**: Checksum confirmation is required to secure software integrity after web download is successfully completed and before subsequent handling of the software. Therefore, software checksum verification is requested before installation of the downloaded plug-in is started. For detailed information on confirmation of software integrity during download and file transfer, please check the "QIAGEN software integrity verification process" description document, which is provided together with the software package on the QIAGEN webpage.

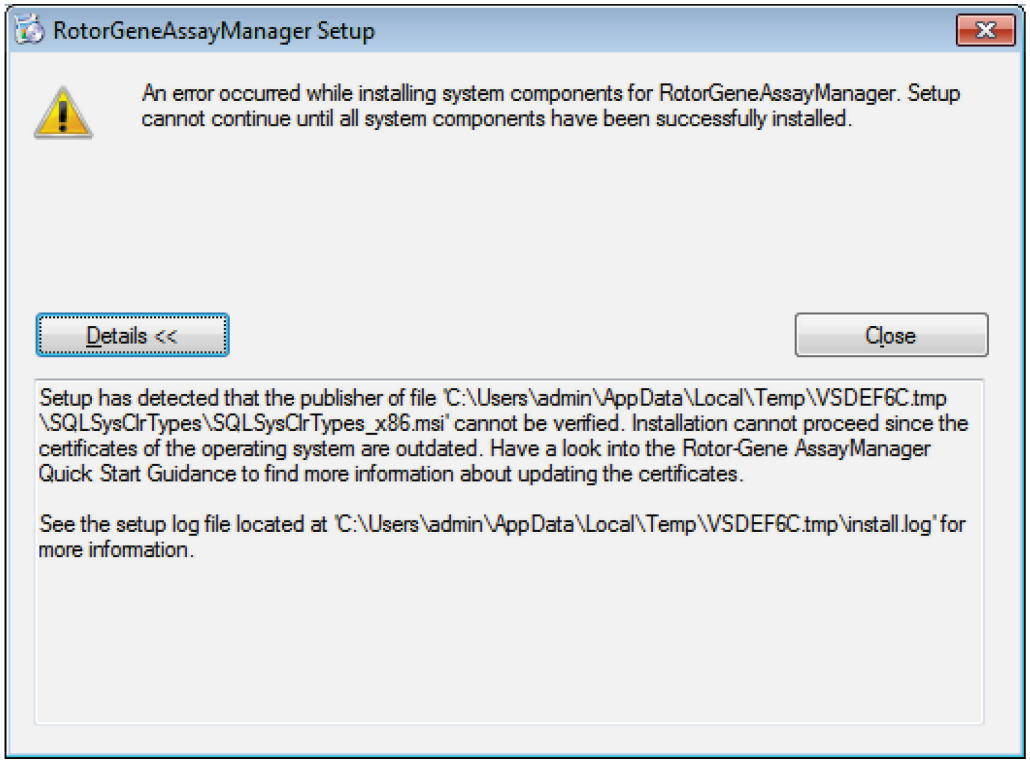
## Outdated certificates on Windows 7

All installation packages, contained in the Rotor-Gene AssayManager v1.0 installer are signed with validated certificates, trusted by Microsoft. This validity is checked by the operating system for every new program which shall be installed on the system. To be able to verify the validity of installer packages, the operating system maintains a list of trusted root certification authorities which is updated automatically by the **automatic root update mechanism** introduced by Microsoft during the lifetime of Windows 7.

If your operating system or the list of trusted root certification authorities is in an outdated state, Microsoft cannot verify the validity of the pre-requisite packages, installed by the Rotor-Gene AssayManager v1.0 installer. This will result in the following error message during installation:

"Setup has detected that the publisher of file '…' cannot be verified. Installation cannot proceed since the certificates of the operating system are outdated."

**Note**: The error message will only appear if you click **Details <<**. See screenshot below.




Visit the QIAGEN website for updates and instructions to solve this problem.

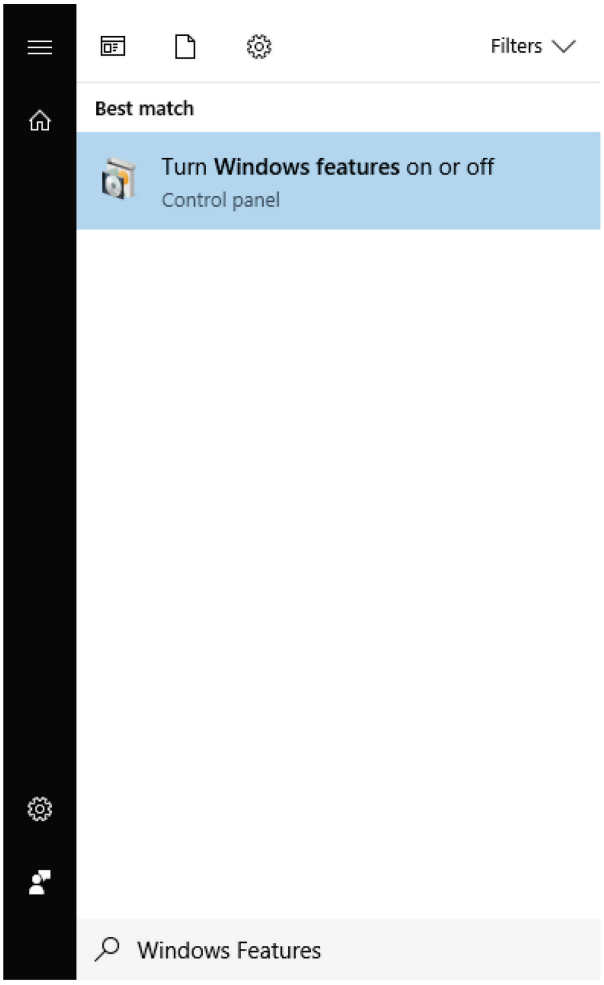
## Installation prerequisites on Windows 10

The Microsoft SQL Server installed together with Rotor-Gene AssayManager v1.0 needs a pre-installed Microsoft .NET Framework in version 3.5. If you use a laptop, distributed by QIAGEN, this installation is already done. If your configuration is different, you must install the .NET Framework 3.5 manually on Windows 10 operating systems using these two options.

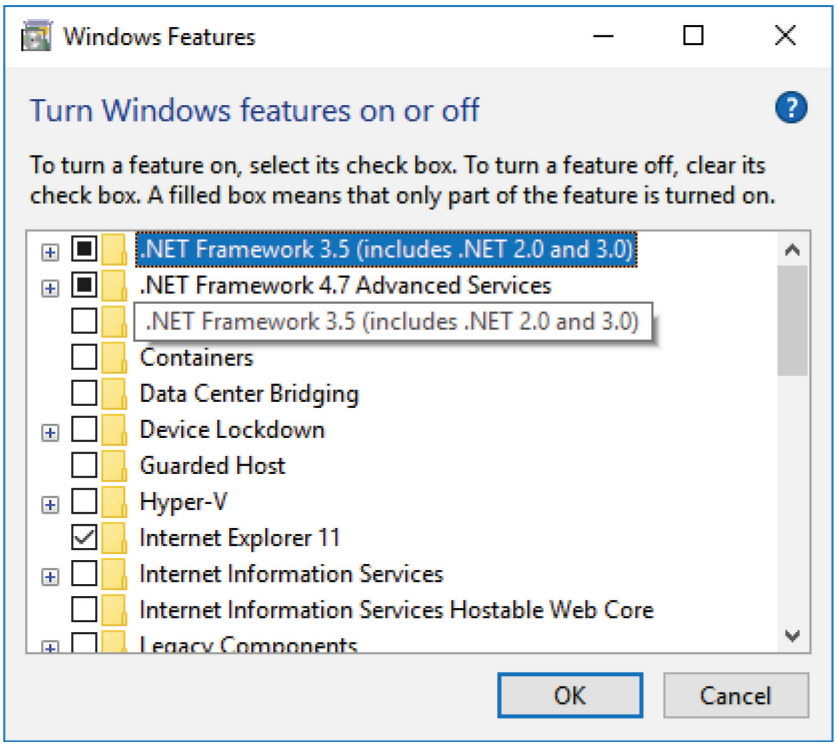
Installation with the feature manager (active Internet connection required)

1. Click **Start** and type **Windows Features**.

2. Click **Turn Windows features on or off**.

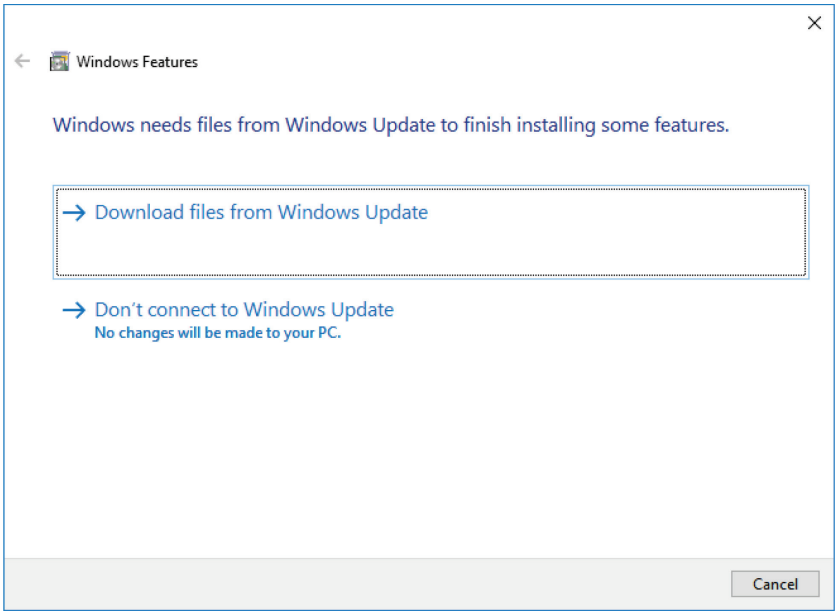


3. Select the **.NET Framework 3.5 (includes .NET 2.0 and 3.0)** check box and click **OK**.

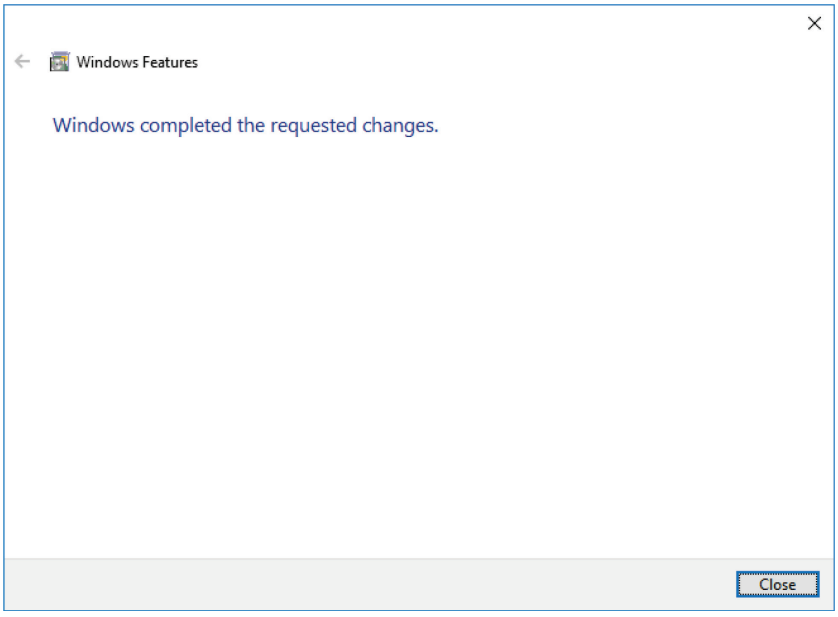



4. On the next window, select **Download files from Windows Update**.

   **Note**: You must be connected to the Internet.



5. When the installation process is completed successfully, a confirmation message will appear. You can continue installing Rotor-Gene AssayManager v1.0.



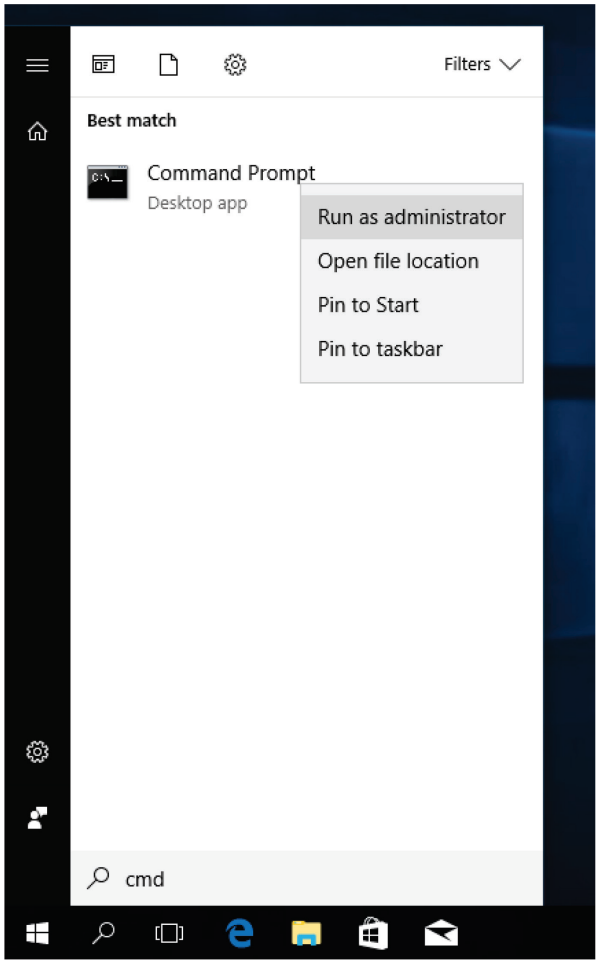

Installation with Windows 10 installation media (offline installation using Windows 10 DVD)

1. Insert the Windows 10 installation media (e.g., DVD).

2. Open a **command prompt** with **administration privileges**.

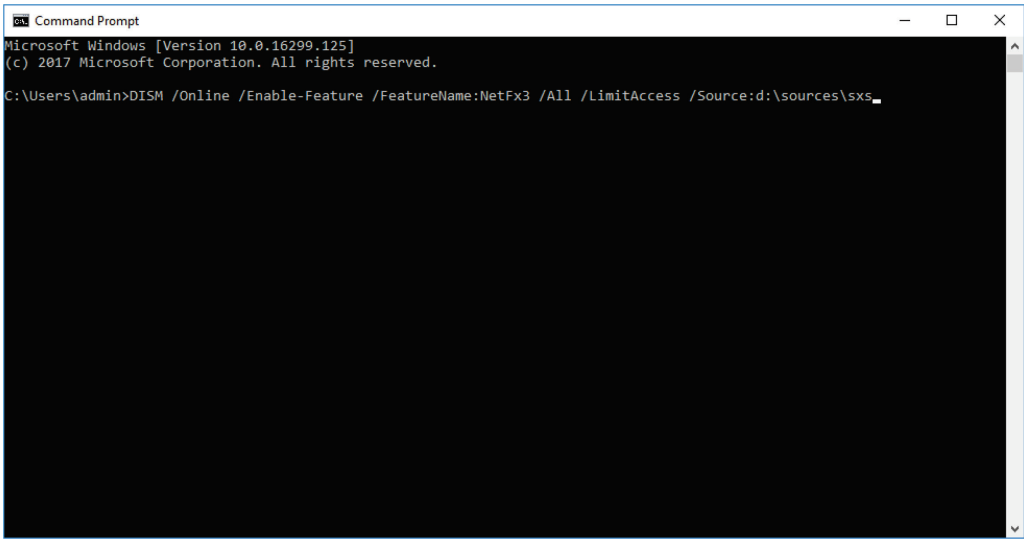
    a. Click **Start** and type **Command Prompt.**

    b. From the search result, right-click the **Command Prompt** and select **Run as administrator**.

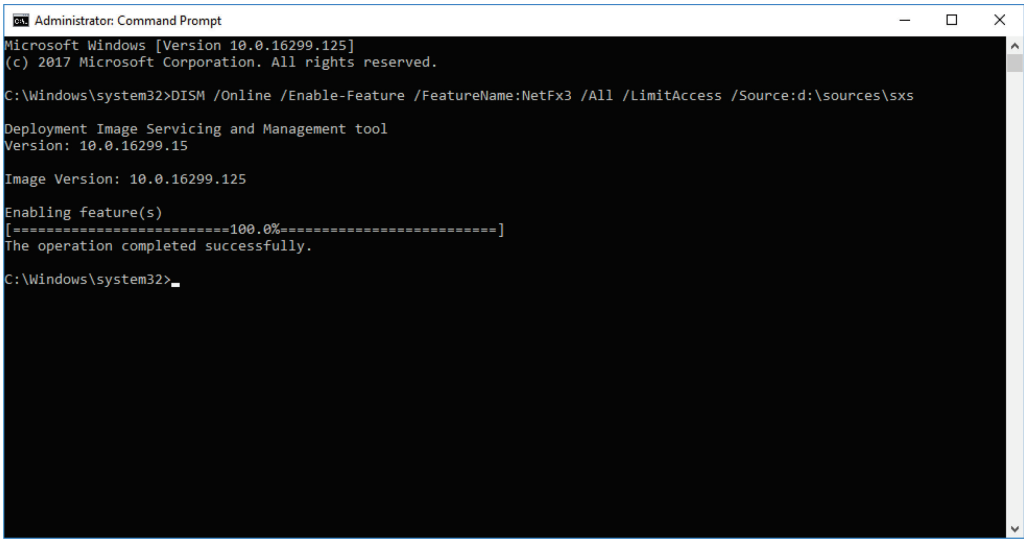



c. On the **User Account Control** window, click **Yes**. Enter a password if required.

3. Type the following command in the **Command Prompt** (without quotation marks):
   "**DISM /Online /Enable-Feature /FeatureName:NetFx3 /All /LimitAccess /Source:d:\sources\sxs**"
   If your installation media is not drive d (for, e.g., a Windows 10 DVD), please change "d:\sources\sxs" to the path matching to your system.




4. When the installation process is completed successfully, a confirmation message will appear. You can continue installing Rotor-Gene AssayManager v1.0.

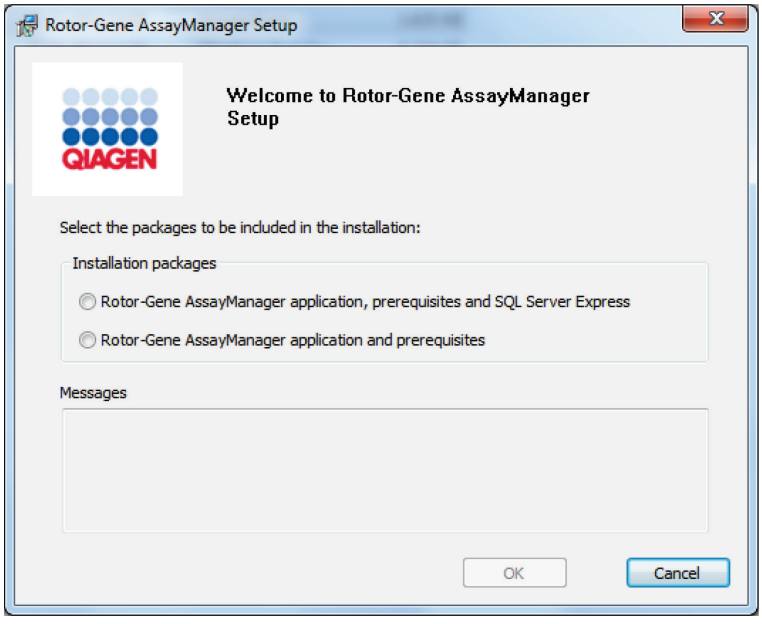


## Installation instructions for core application v1.0

**Note:** The Rotor-Gene AssayManager v1.0 and v2.1 are independent products and cannot be used in parallel on one system. In addition, Rotor-Gene AssayManager v2.1 does not replace the Rotor-Gene AssayManager v1.0.

1. Check if the instructions described in these sections need to be performed first:
   - Installation prerequisites on Windows 10
   - Outdated certificates on Windows 7
2. Place the Rotor-Gene AssayManager v1.0 core application installation DVD into the DVD drive of the computer.
3. Double-click **My Computer** and select the DVD drive.
4. Double-click **setup.exe**.

   The setup wizard automatically opens the **Rotor-Gene AssayManager Setup** window.

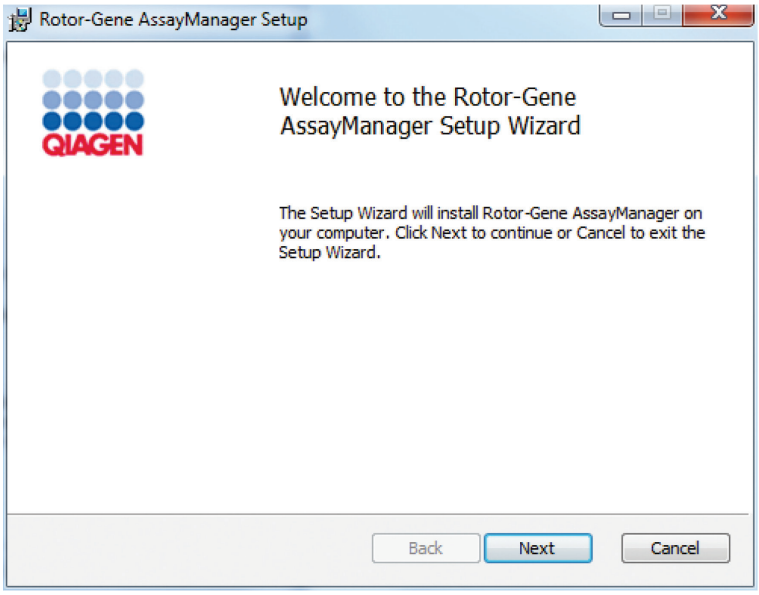



**Note**: Rotor-Gene AssayManager v1.0 requires an MS SQL Server 2014 Express instance with mixed mode authentication and TCP/IP network protocol activated for installation. The installation process depends on whether MS SQL Server 2014 Express is already installed or should be installed on the local system, or whether Rotor-Gene AssayManager v1.0 will be installed with a remote connection to an existing SQL Server on an external system. Details about the different installation configurations can be found in "Getting Started" in the *Rotor-Gene AssayManager IVD (US) Core Application User Manual*.

5. Select the required installation packages and click **OK**. Follow the instructions to set up the software.

   Rotor-Gene AssayManager v1.0 uses several software packages provided by third parties. If the packages are not available on the computer, these software packages are automatically installed at the beginning of the Rotor-Gene AssayManager v1.0 setup. Follow the instructions if necessary.

   **Note**: Depending on the software packages installed, a reboot of the system may be required before proceeding with the setup. After the reboot, the installation procedure is resumed automatically.




6. Follow the setup wizard steps. Details can be found in the "Getting Started" section of the *Rotor-Gene AssayManager IVD (US) Core Application User Manual*.

   After the core application v1.0 is installed successfully, continue with the plug-in installation.

**Note**: Future updates will be provided on the QIAGEN webpage and/or distributed by QIAGEN on CD/DVD to the customer.

## Installation instructions for a plug-in

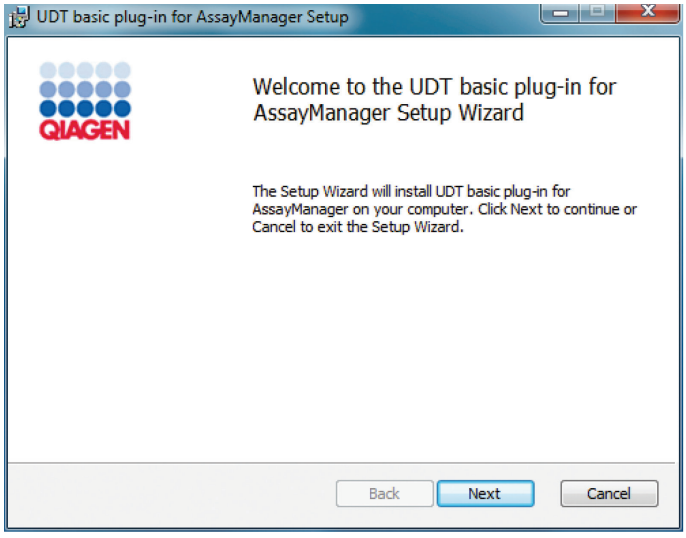
At least one plug-in must be installed for the use of Rotor-Gene AssayManager v1.0. Plug-ins can only be obtained on DVD.

**Note**: Plug-ins for Rotor-Gene AssayManager v1.0 are not compatible with Rotor-Gene AssayManager v2.1.

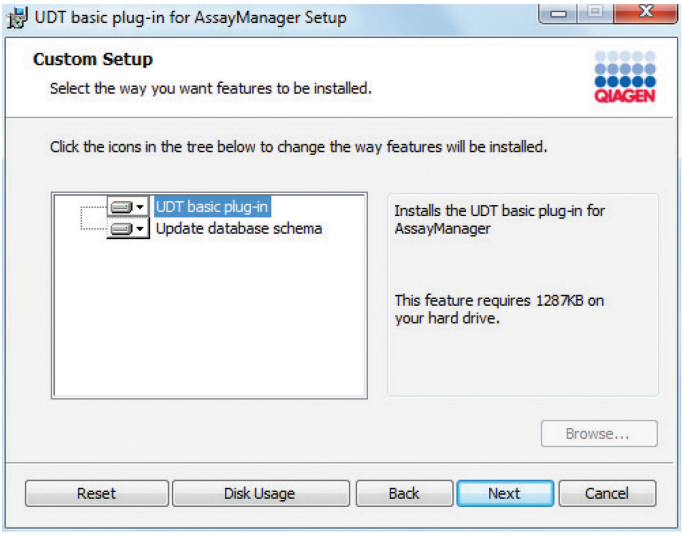
**Note**: The installation of the UDT Basic Plug-in is taken as an example for the installation of any plug-in.

**Note**: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.

1. Place the plug-in installation DVD (provided with the software) into the DVD drive of the computer or download the plug-in from the QIAGEN website, if available.
2. Double-click **My Computer** and select the DVD drive, if using a DVD.
3. To start the UDT Basic Plug-in setup wizard, double-click **UDTBasic.Installation.V1_0_6.msi** (the filename my change slightly depending on the used version).
4. Click **Next** to proceed. Follow the instructions to set up the software.



5. Select the features to be installed.




Explanation of features:

| | |
|---|---|
| **UDT basic plug-in** | This feature updates the Rotor-Gene AssayManager v1.0 application with the UDT Basic Plug-in.<br><br>**Note**: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.<br><br>This feature is needed always if Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if a database server without the Rotor-Gene AssayManager application is to be updated. |
| **Update database schema** | After the Rotor-Gene AssayManager v1.0 installation, the database schema contains unspecified Rotor-Gene AssayManager v1.0 tables only. This feature adds the UDT-specific tables.<br><br>This feature is needed if Rotor-Gene AssayManager v1.0 and its database are installed on one system. The feature can be deselected only if the database is installed on a separate server and was updated by a prior UDT Basic Plug-in installation. |

| | |
|---|---|
| **Disk Usage** | Click this button to show an overview of the available and required disc space. |
| **Back** | Click this button to return to the previous screen. |

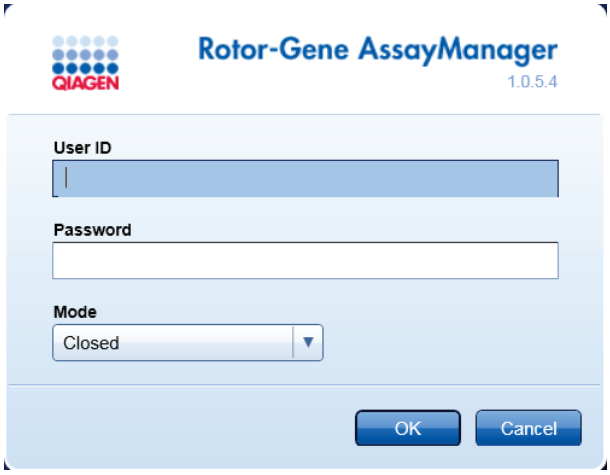
6. To proceed with the installation of the selected features, click **Next**.
7. Follow the setup wizard steps. Details can be found in the "Getting Started" section of the *Rotor-Gene AssayManager Core Application IVD (US) User Manual*.

# Getting started

For a detailed description of Rotor-Gene AssayManager v1.0, refer to "Basic Concepts and General Software Usage" in the *Rotor-Gene AssayManager Core Application IVD (US) User Manual* (available by clicking **User Manual** during the Rotor-Gene AssayManager v1.0 installation process).

1. To launch the Rotor-Gene AssayManager v1.0, click the **Start** menu and select **QIAGEN/Rotor-Gene AssayManager**. You can also double-click the **Rotor-Gene AssayManager** icon on your desktop.

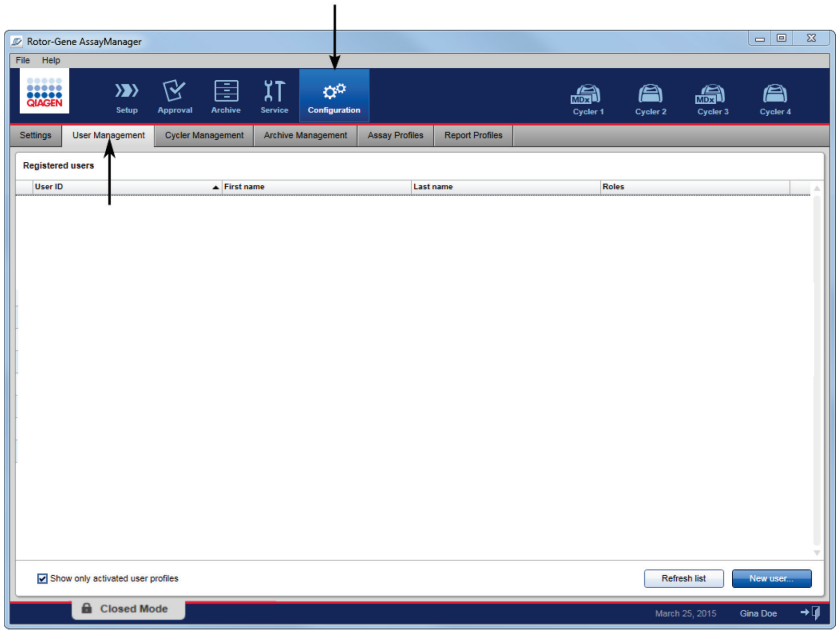

2. Enter **admin** in both **User ID** and **Password** fields. Select the mode from the **Mode** drop-down list and click **OK**.



Explanation of modes:

| | |
|---|---|
| **Closed** mode | The **Closed** mode is reserved only for validated assay profiles that have been preconfigured by QIAGEN. These assay profiles are signed by checksum and can only be modified by QIAGEN as part of the development and validation procedure of assays. |
| **User Defined Test** mode | The **User Defined Test** mode uses assay profiles created by laboratory users who predefine assay parameters using standard Rotor-Gene Q software. The UDT mode allows run and analysis of homebrew or third-party assays as well as self-developed assays.<br><br>**Note**: The UDT mode is not intended for use with FDA cleared or approved nucleic acid tests.<br><br>**Note**: For usage of the User Defined Test mode (UDT mode) functionalities, a compatible UDT mode plug-in is required to be installed. A log-in in UDT mode without installation of the corresponding plug-in will give you no access to administrative tasks and you can neither perform experiments nor any analysis. |

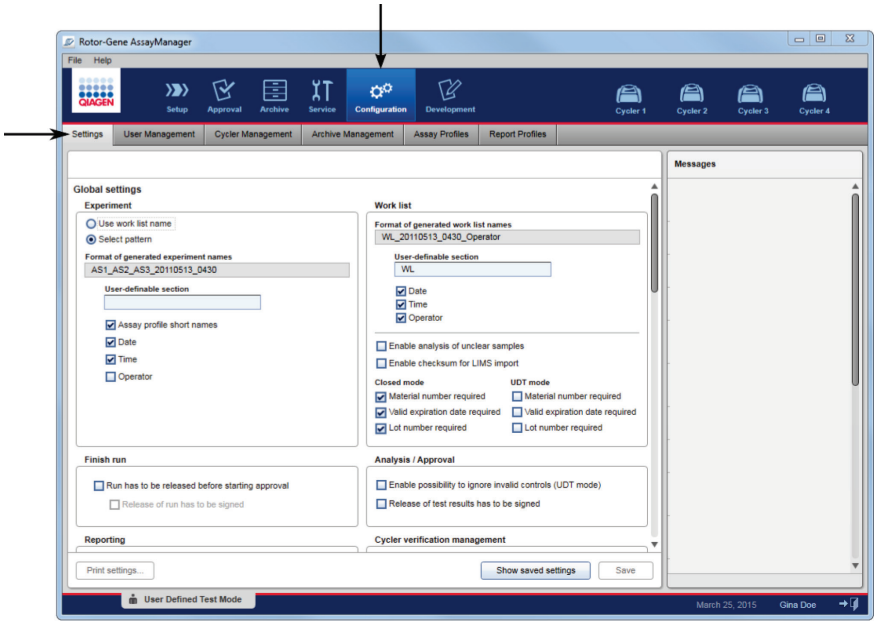
3. Enter a new, secure password.
4. To create user accounts, click the **Configuration** menu and select the **User Management** tab.



For more details, see the section “Managing Users” of the *Rotor-Gene AssayManager Core Application IVD (US) User Manual*.

**Note**: It is strongly recommended to create at least one additional user account, without an Administrator role, at first login. If a single user of Rotor-Gene AssayManager v1.0 aggregates different user roles including the “Administrator” role, there is a high risk that the access to the software will be completely blocked if this user forgets the password.

5. Click the **Settings** tab, and configure the settings for Rotor-Gene AssayManager v1.0.




For more details, see “Settings” in the *Rotor-Gene AssayManager Core Application IVD (US) User Manual*.

# Additional software on connected computers

Rotor-Gene AssayManager v1.0 software manages time-critical processes during the PCR run and the data acquisition process. For this reason, it is important to ensure that no other processes use significant system resources and thus slow down the Rotor-Gene AssayManager v1.0 software. It is particularly important to pay attention to the points listed below.

System administrators are advised to consider any impact that a modification to the system may have on the resources before implementing it.

## Anti-virus software

QIAGEN is aware of the threat that computer viruses cause to any computer that exchanges data with other computers. Rotor-Gene AssayManager v1.0 software is expected to be primarily installed in environments where local policies are in place to minimize this threat. However, QIAGEN recommends the use of a virus scanner in any case. The selection and installation of an appropriate virus scanning tool is in the customer's responsibility. However, QIAGEN has validated the Rotor-Gene AssayManager with the laptop computers provided by QIAGEN in combination with the following two virus scanners to show compatibility:

- Symantec Endpoint Protection V12.1.6
- Microsoft Security Essentials V4.10.209*

Please refer to the product page on QIAGEN.com for the latest versions of anti-virus software that have been validated in combination with Rotor-Gene AssayManager v1.0.

If a virus scanner is selected, make sure that it can be configured in a way that the database folder path can be excluded from the scan. Otherwise, there is the risk of database connection errors. Since Rotor-Gene AssayManager v1.0 creates new database archives dynamically, it is required to exclude the folder path to the files and not as single files. We do not recommend the use of virus scanners where only single files can be excluded, (e.g. McAfee Antivirus Plus V16.0.5). If the computer is used in an environment without network access, please also make sure that the virus scanner supports offline updates.

To get consistent results after installation of a virus scanner, a system administrator should ensure the following:

- As explained above, the database folder path of the Rotor-Gene AssayManager v1.0 needs to be excluded from file scans. The folder path is as follows depending on the MS SQL server version which initially created the database: C:\Program Files\Microsoft SQL Server\MSSQL10_50.RGAMINSTANCE\MSSQL\DATA or C:\Program Files\Microsoft SQL Server\MSSQL12.RGAMINSTANCE\MSSQL\DATA

- Updates to the virus database are not performed when the Rotor-Gene AssayManager v1.0 is in use.

* After installation of **Microsoft Security Essentials**, you shall check that Windows updates are deactivated since the installation might activate this setting (please read chapter "Operating system updates").

- Please make sure that full or partial scans of the hard drive are disabled during real-time PCR data acquisition. Otherwise there is a risk of adverse impact on the performance of the instrument.

Please read the manual of your selected virus scanner for configuration details.

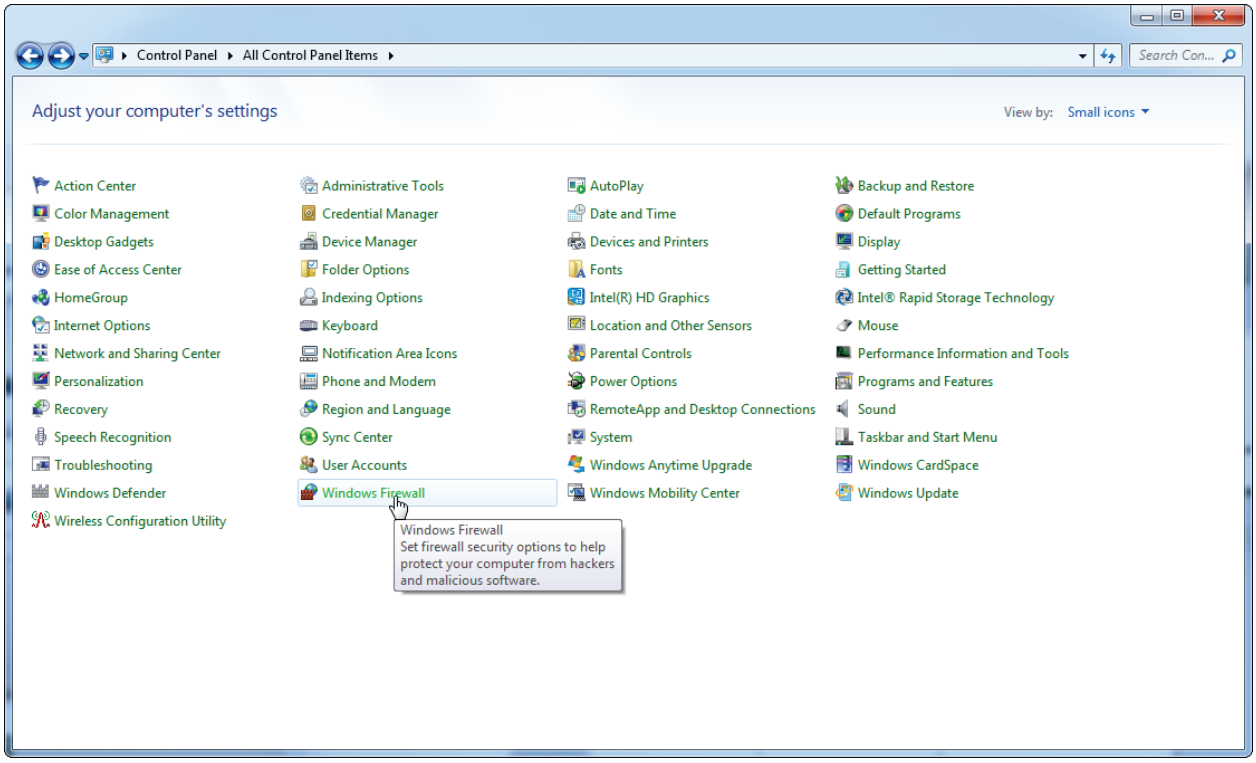
## Firewall and networks

The Rotor-Gene AssayManager v1.0 can run either on computers without network access (if the database is located on the same computer that controls the Rotor-Gene Q instrument), or can run in a network environment (if a remote database server is used). For networked operation, the firewall on the laptop computer provided by QIAGEN is configured in a way that inbound traffic is blocked for all ports, except those ones required to establish a network connection.

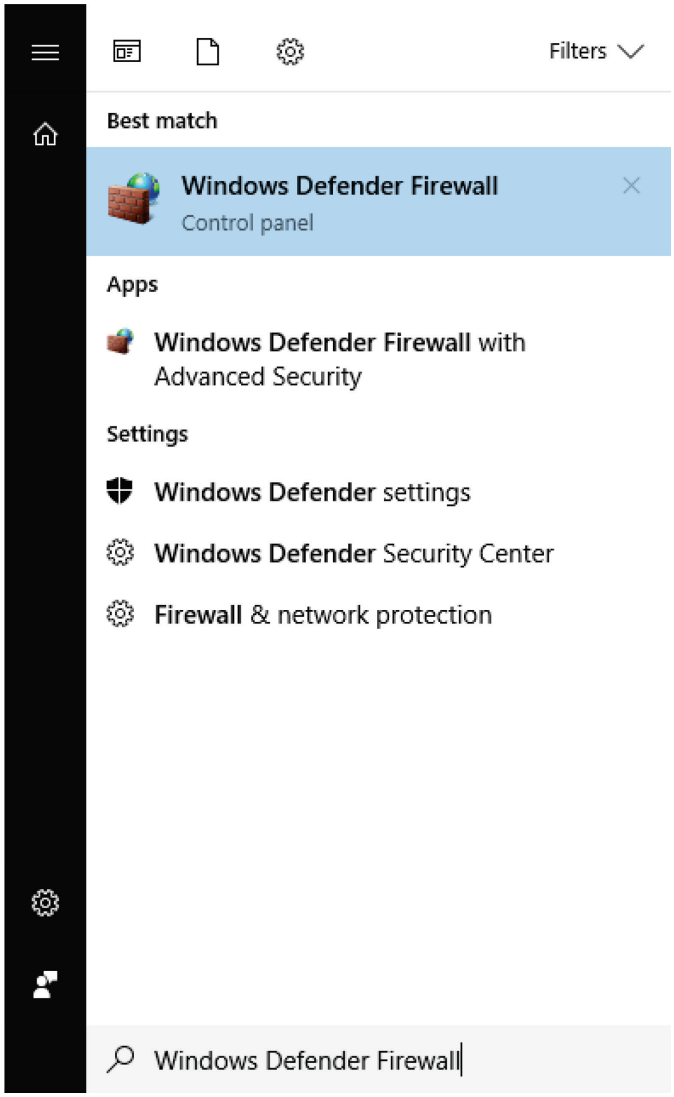
Please note that blocking incoming connections does not affect responses to requests triggered by the user such as updating anti-virus definition files, or connecting the Rotor-Gene AssayManager v1.0 to the centralized database server. Outgoing connections are allowed as this may be required for retrieving updates or when the Rotor-Gene AssayManager v1.0 is configured to work with a centralized database server.

If your configuration is different, QIAGEN recommends to configurate the firewall in the same way as described above. To this end, a system administrator has to login and has to perform the following steps:

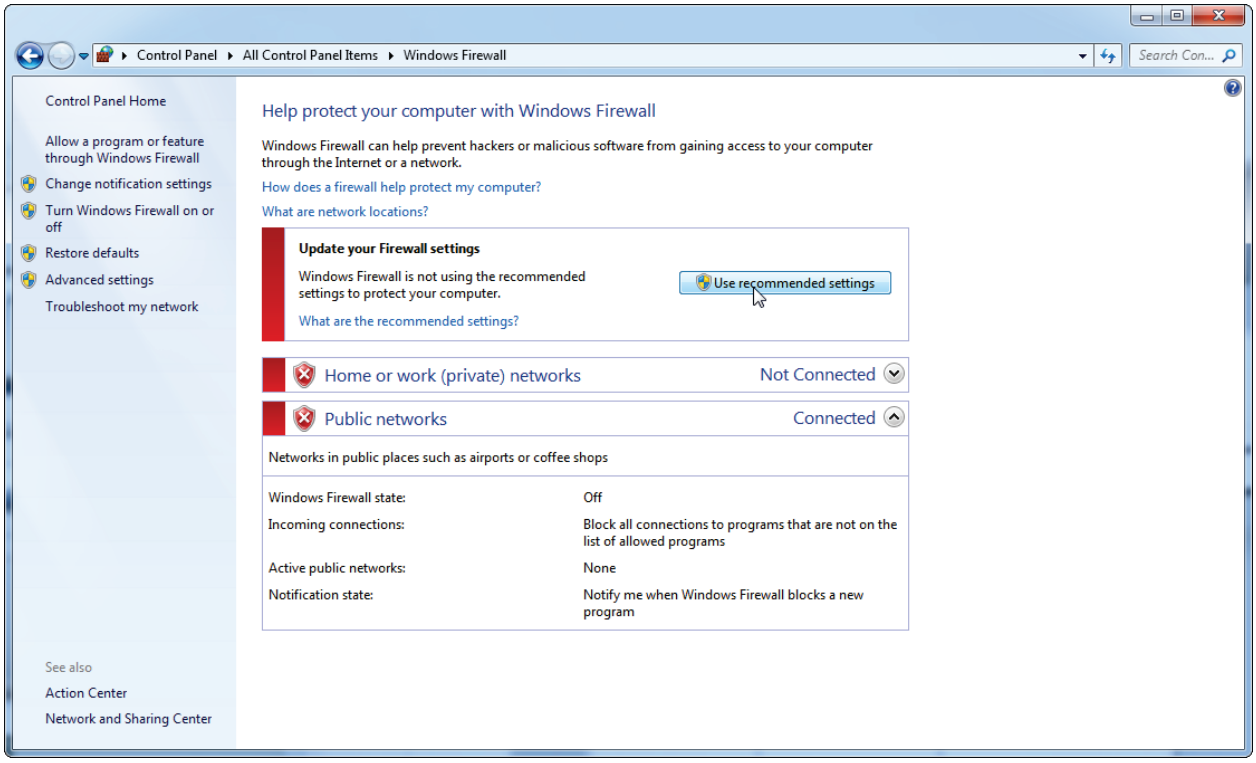
1. Open the **Control Panel** and select **Windows Firewall** on Windows 7.



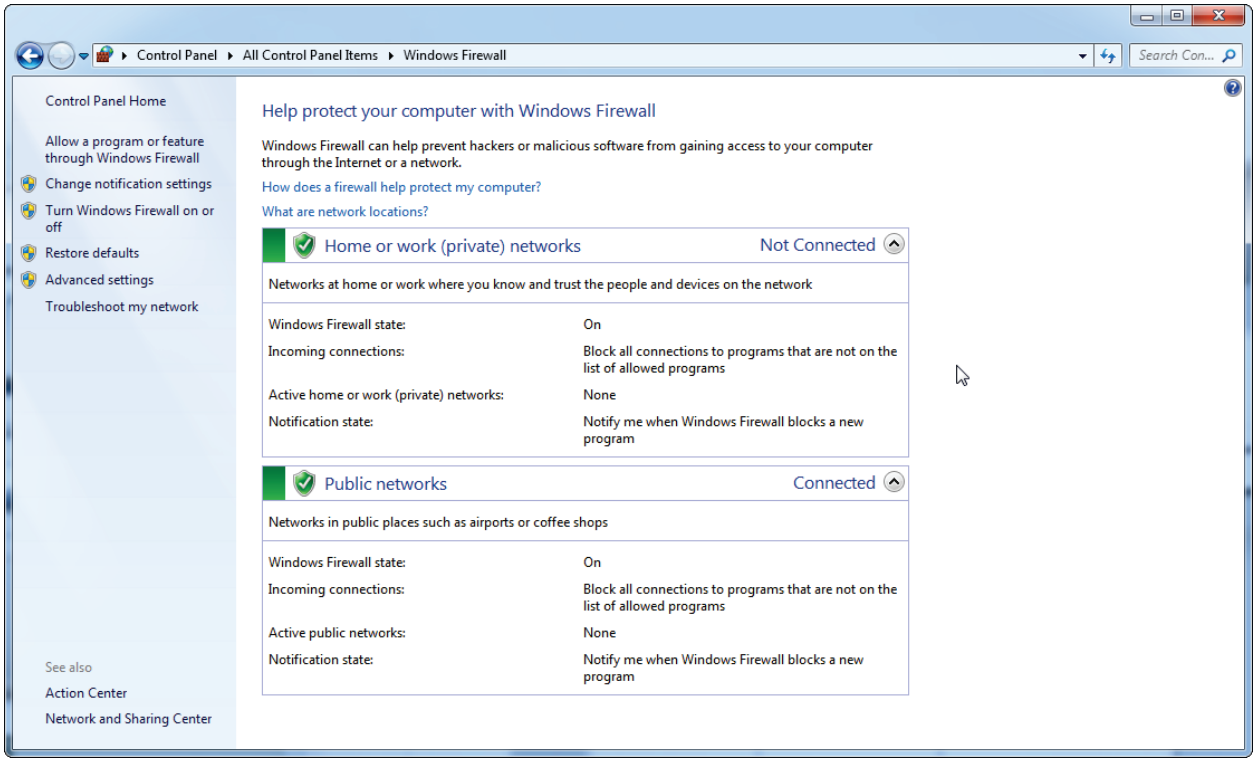
For Windows 10, click **Start** and type **Windows Defender Firewall**. From the search result, click **Windows Defender Firewall**.



2. Select Use **recommended settings**.



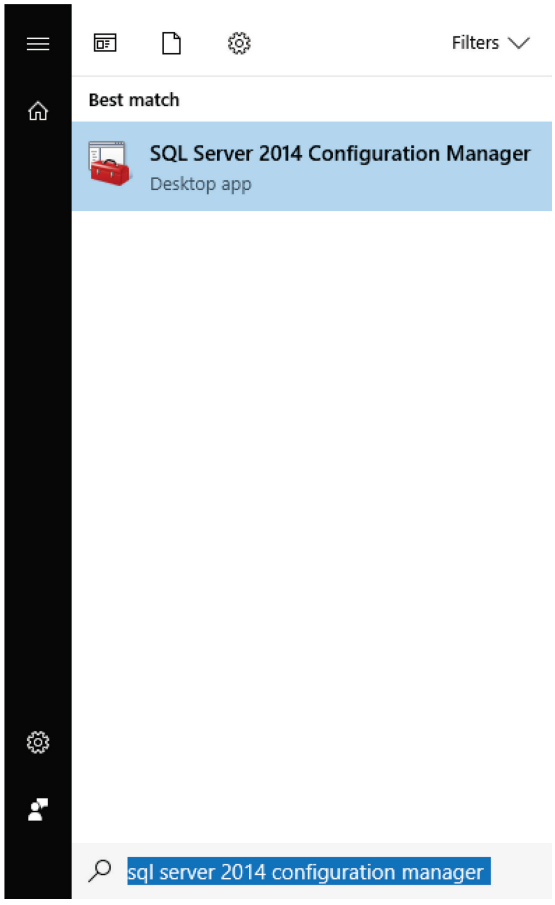
3. Check that the following settings are active:



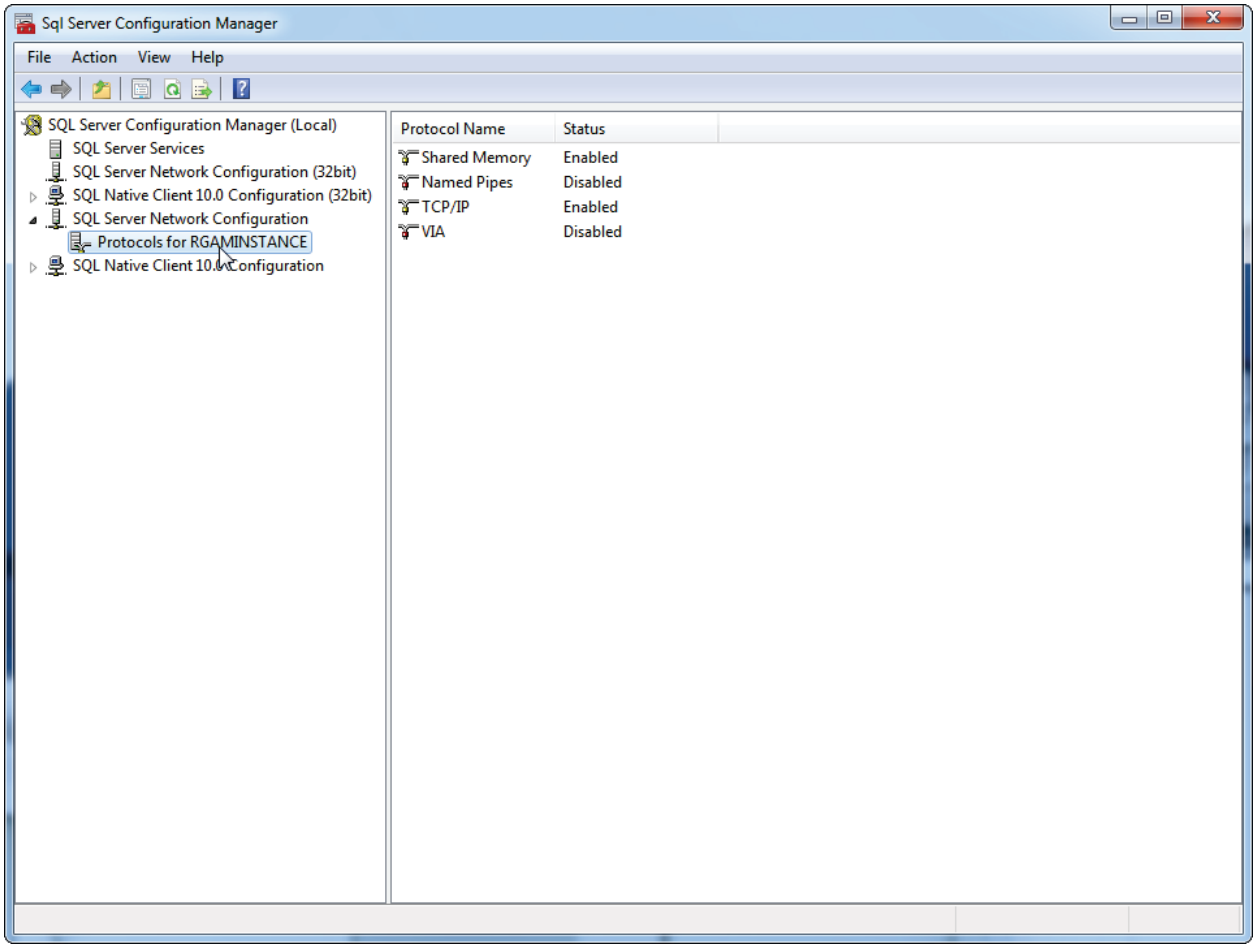
If you use a setup of a stand-alone computer, which is connected to a network and you want to install Rotor-Gene AssayManager v1.0 on another computer to connect to the first (cf. configuration), a system administrator must create an exception in the firewall configuration. This exception can be created by performing the following steps:

1. Select **SQL Server Configuration Manager** from the **Start** menu (on Windows 7).

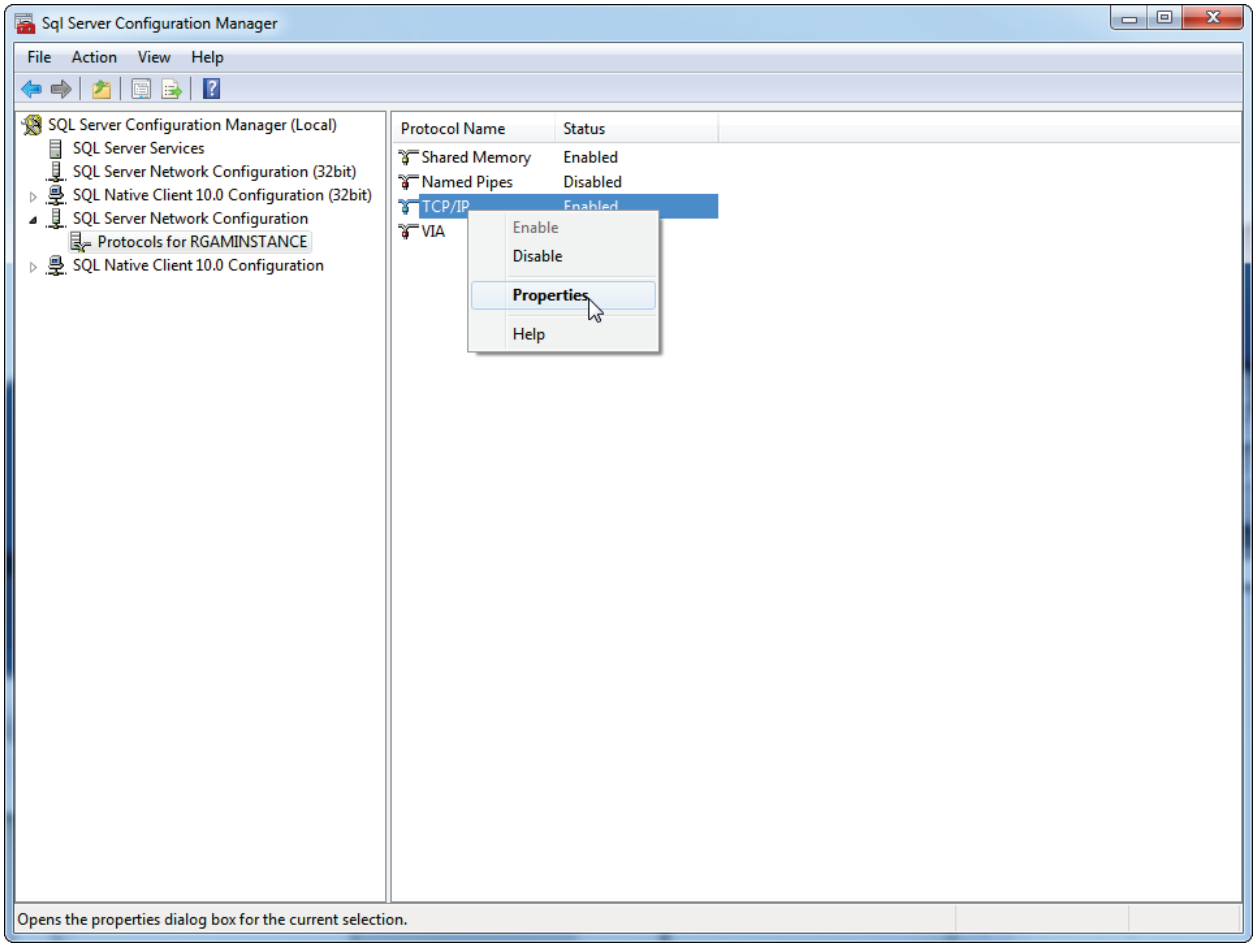
On Windows 10, click **Start** and type **SQL Server 2014 Configuration Manager**. From the search result, click **SQL Server 2014 Configuration Manager**.



2. Expand the **SQL Server Network Configuration** menu and select **Protocols for RGAMINSTANCE.**

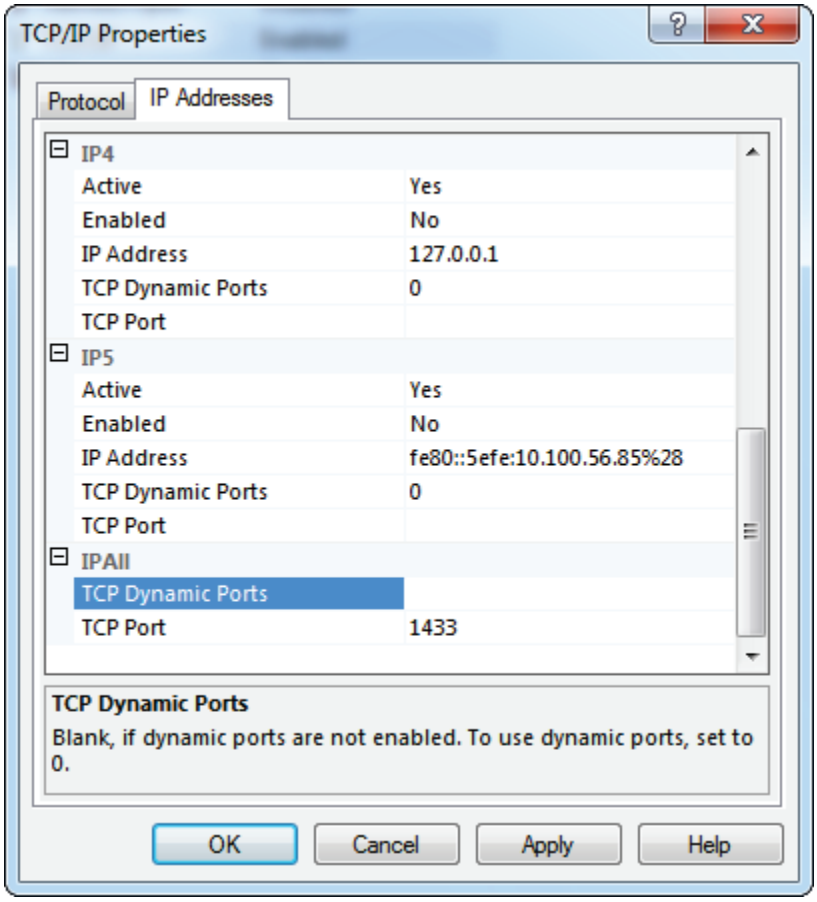


3. Point to **TCP/IP** protocol name, right-click and select **Properties**.

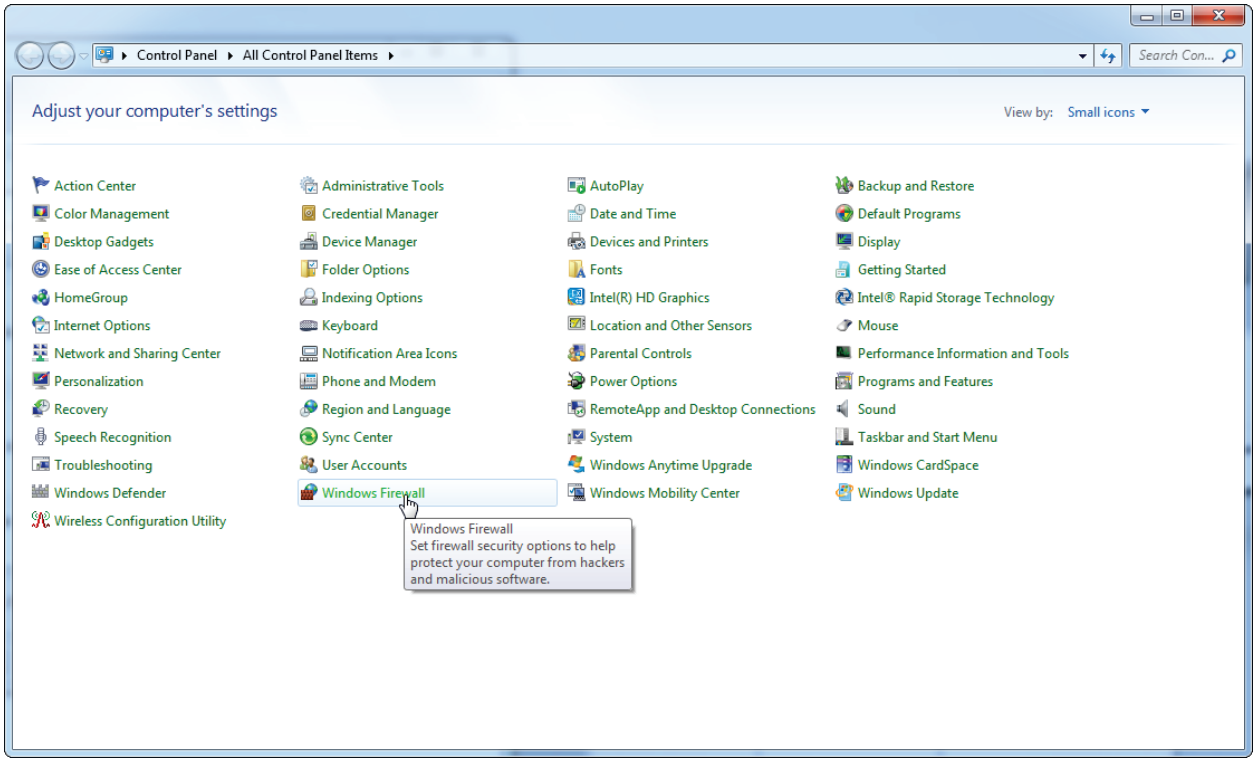


4. On the **IP Addresses** tab, remove the predefined value in the **TCP Dynamic Ports** field. Enter **1433** (i.e., the SQL standard port) in the **TCP Port** field and click **OK**.

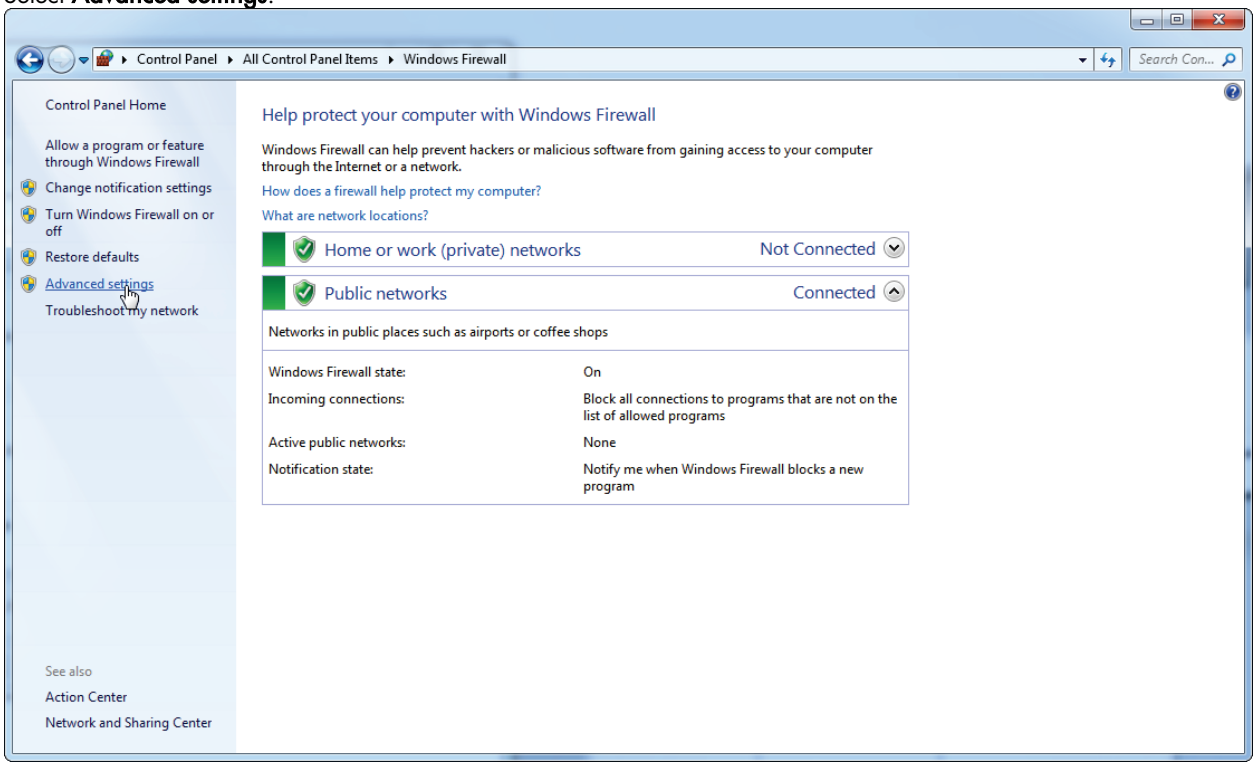
   **Note:** If the port is in use, you can use any other unused port.



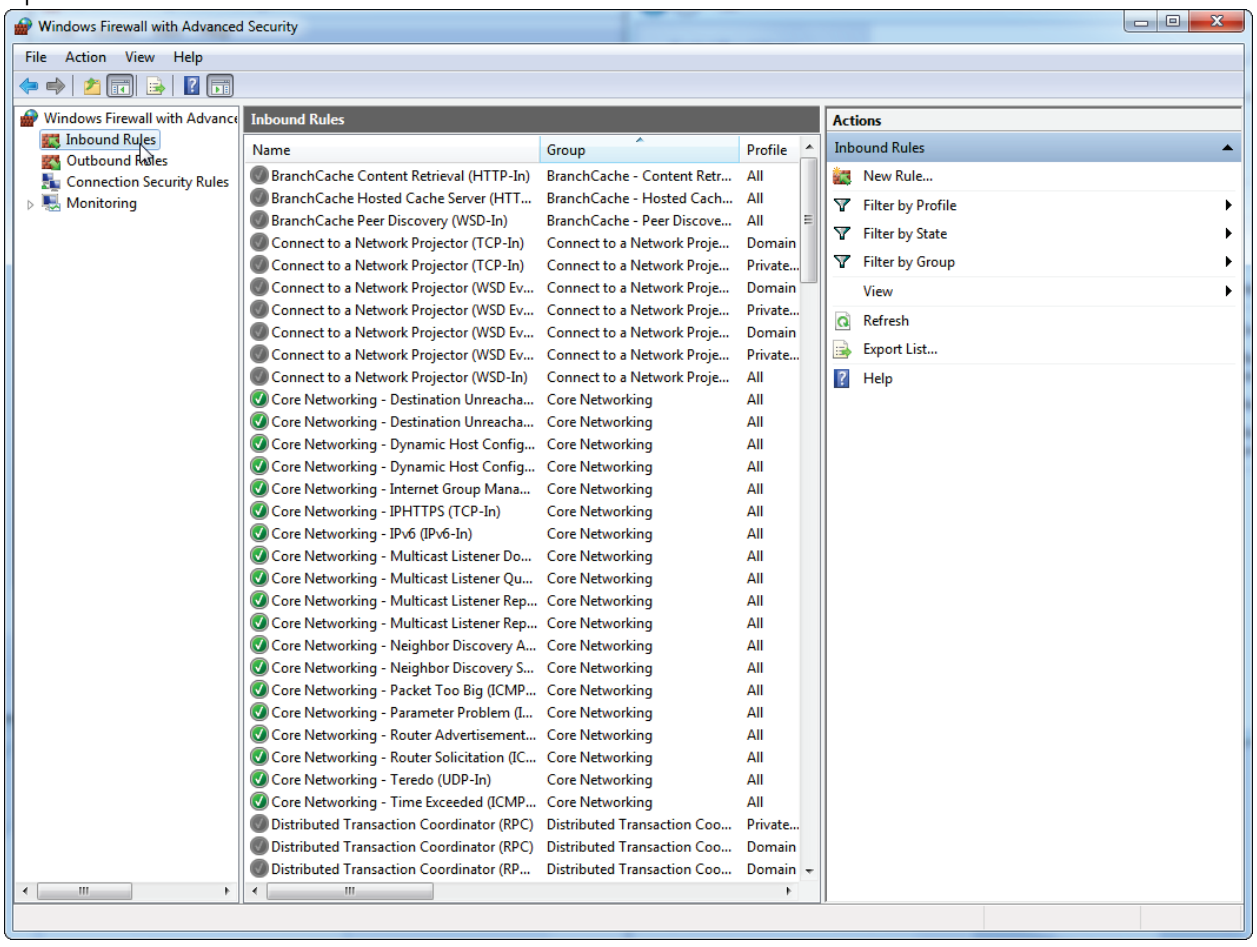
5. Open the **Control Panel** and select **Windows Firewall** (or search for **Windows Defender Firewall** on Windows 10).



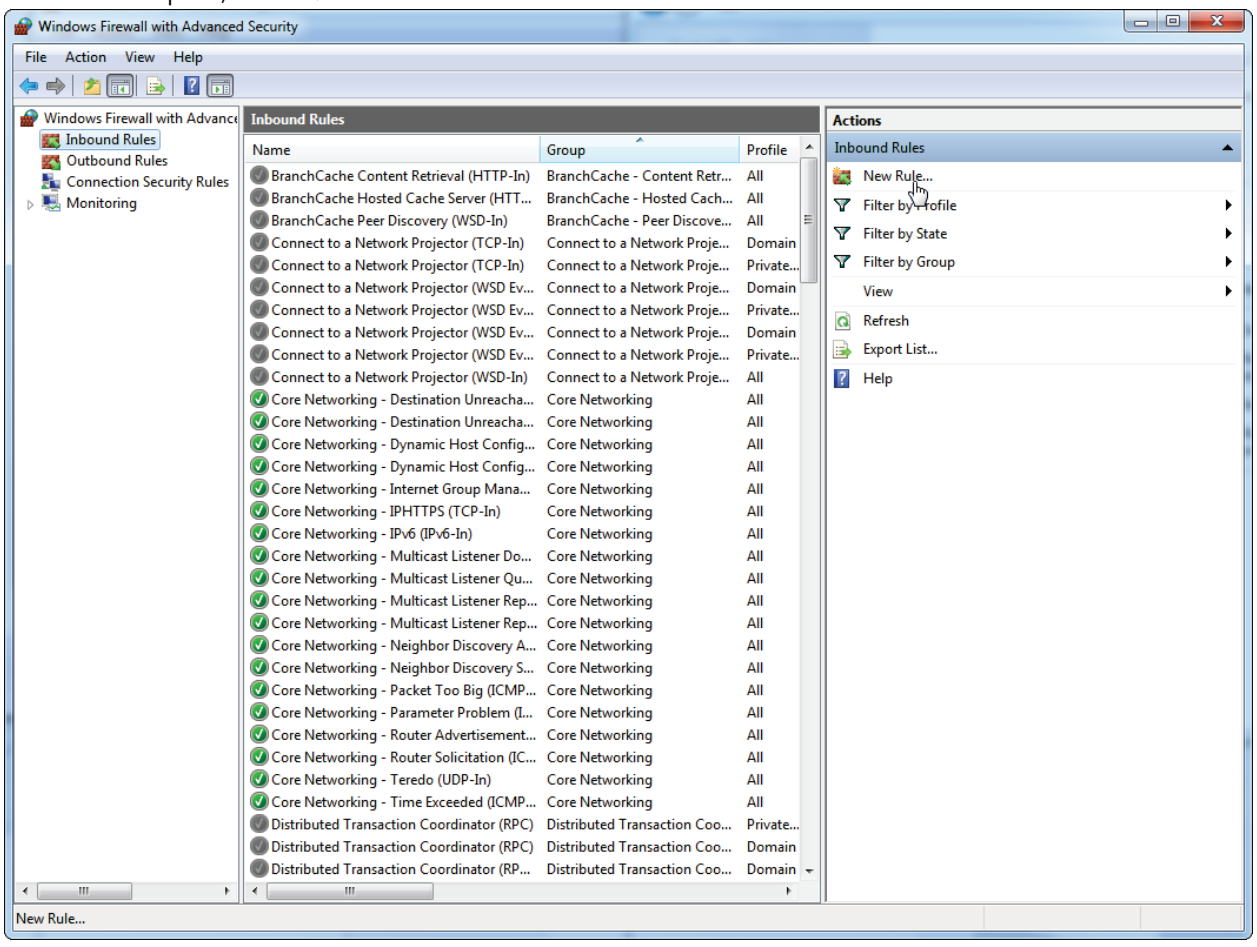
6. Select **Advanced settings**.



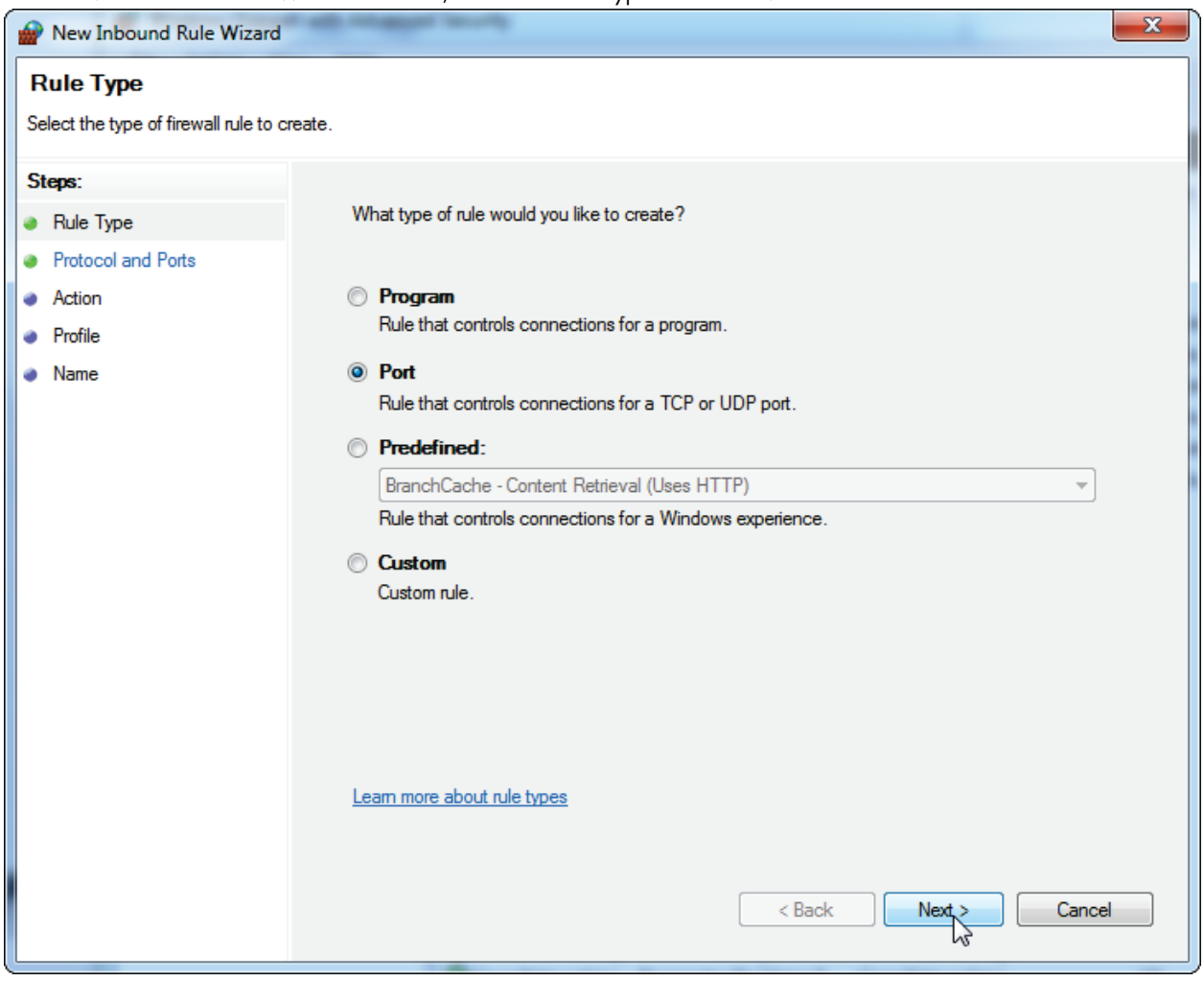
7. Open the **Inbound rules** menu.



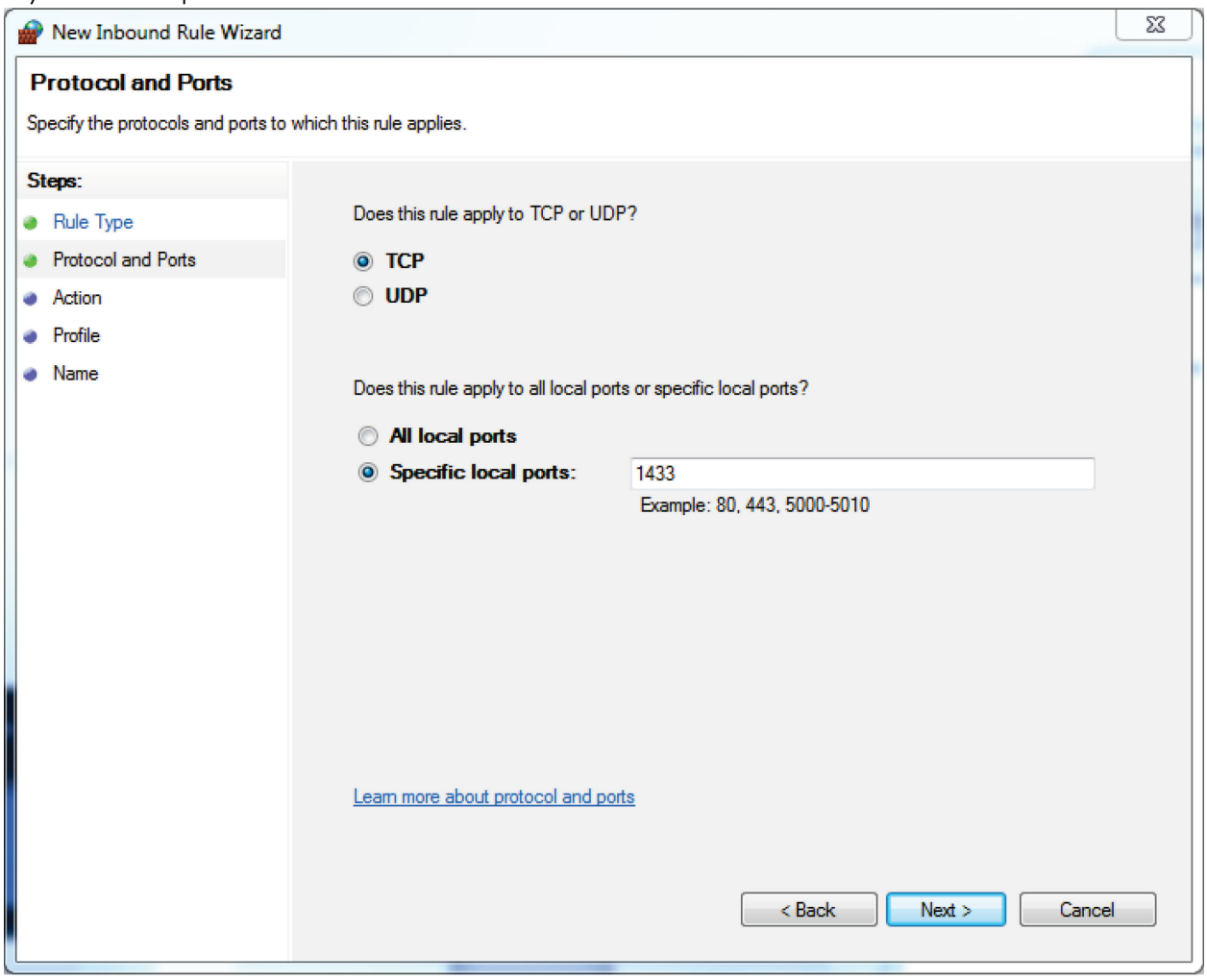
8. On the **Actions** pane, select **New Rule**.



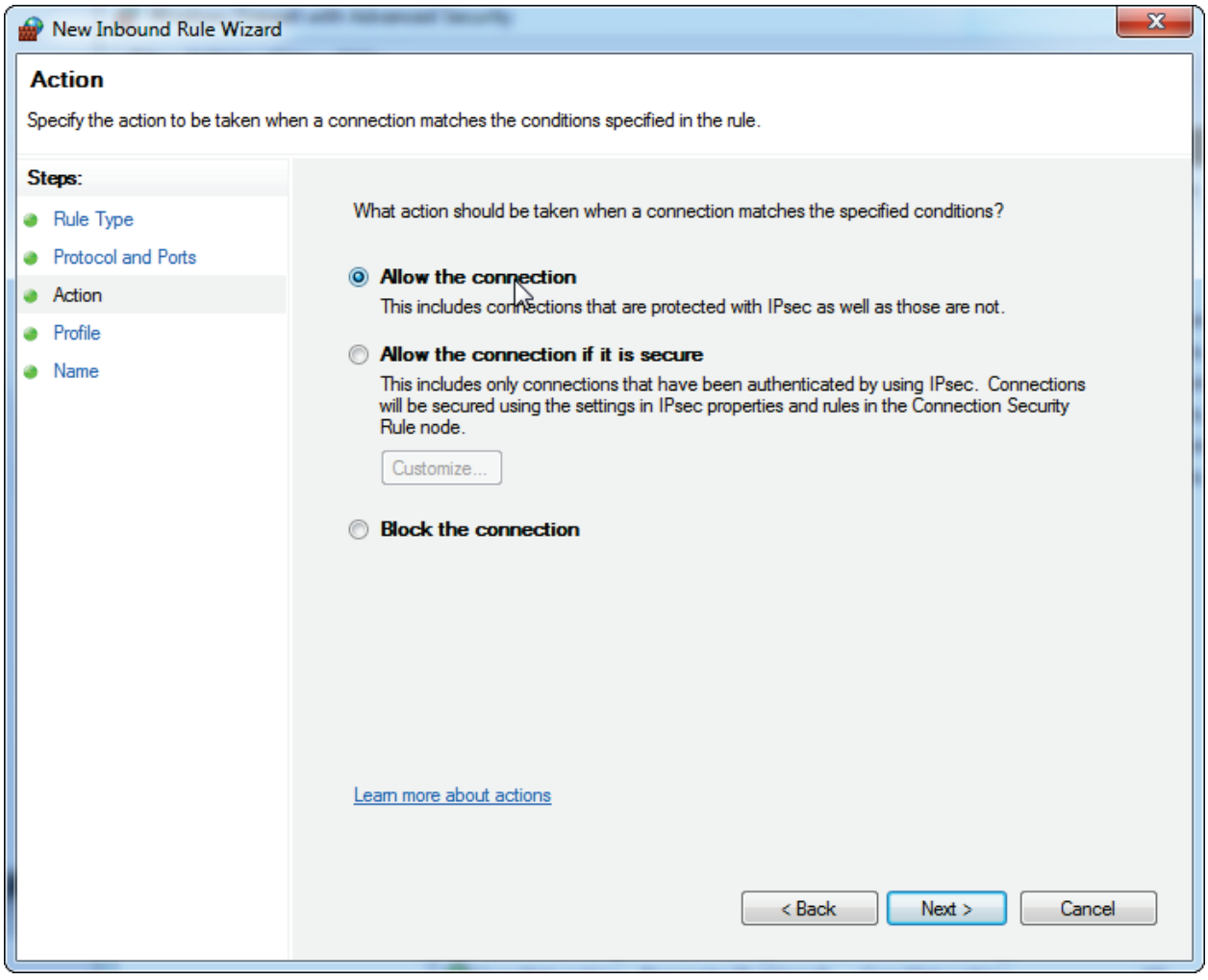
9. On the **New Inbound Rule Wizard** window, select **Port** rule type and click **Next**.



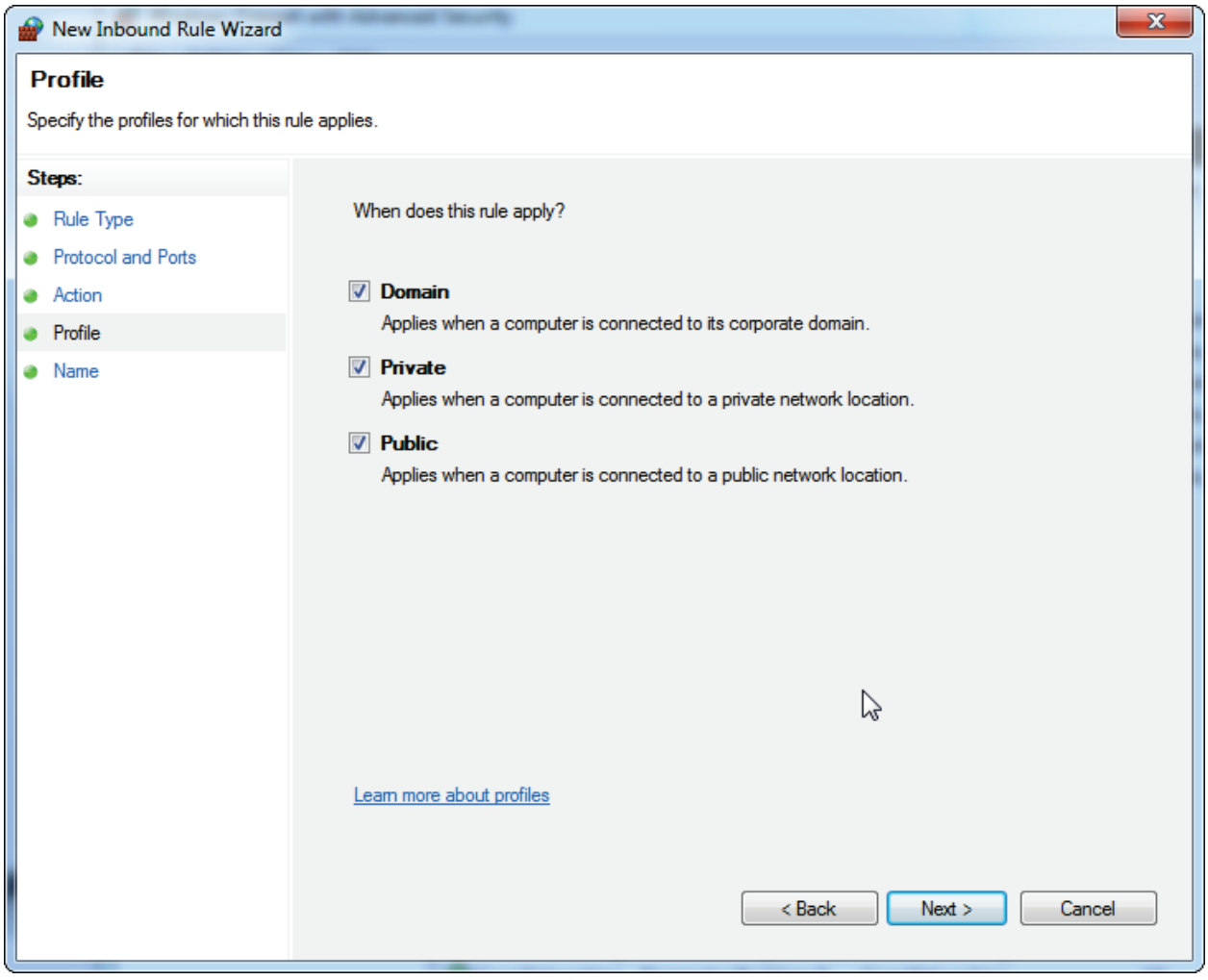
10. Select **TCP** and enter **1433** in the **Specific local ports** field. If the port is in use, you can use any other unused port. Click **Next**.



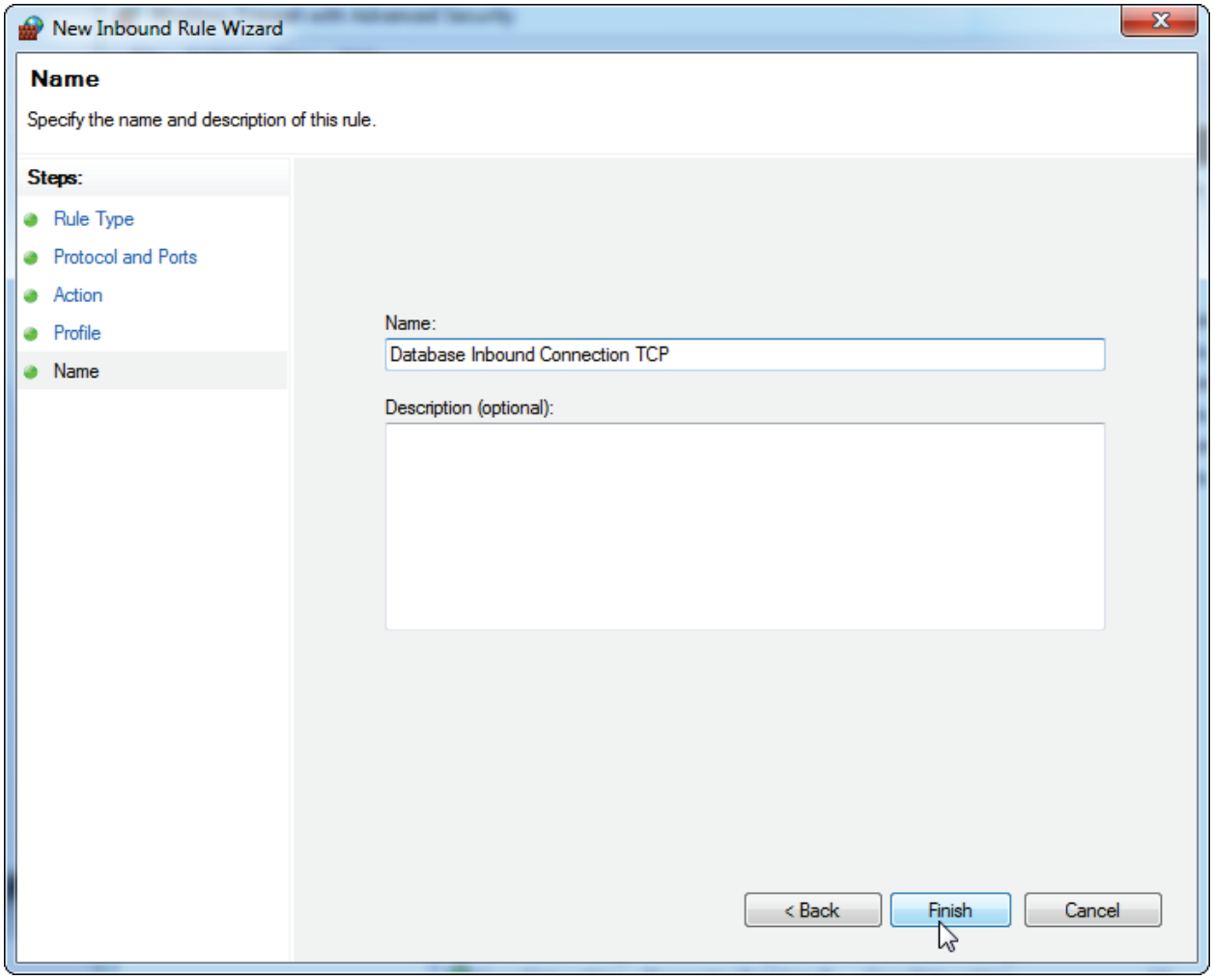
11. Select **Allow the connection** and click **Next**.



12. Check the **Domain**, **Private** and **Public** boxes, then click **Next**.

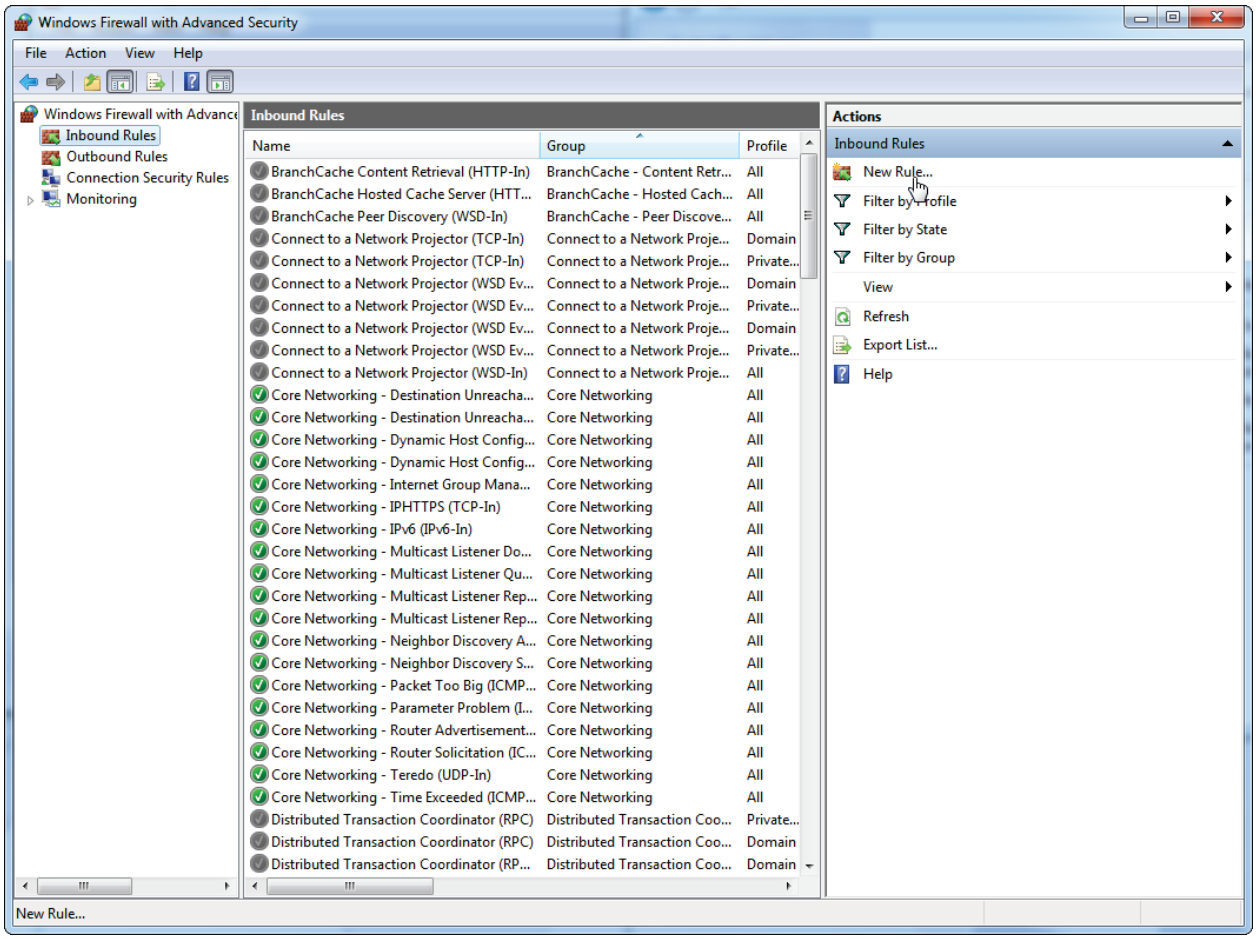


13. Define a name for the rule, for example, **Database Inbound Connection TCP**. Click **Finish**.

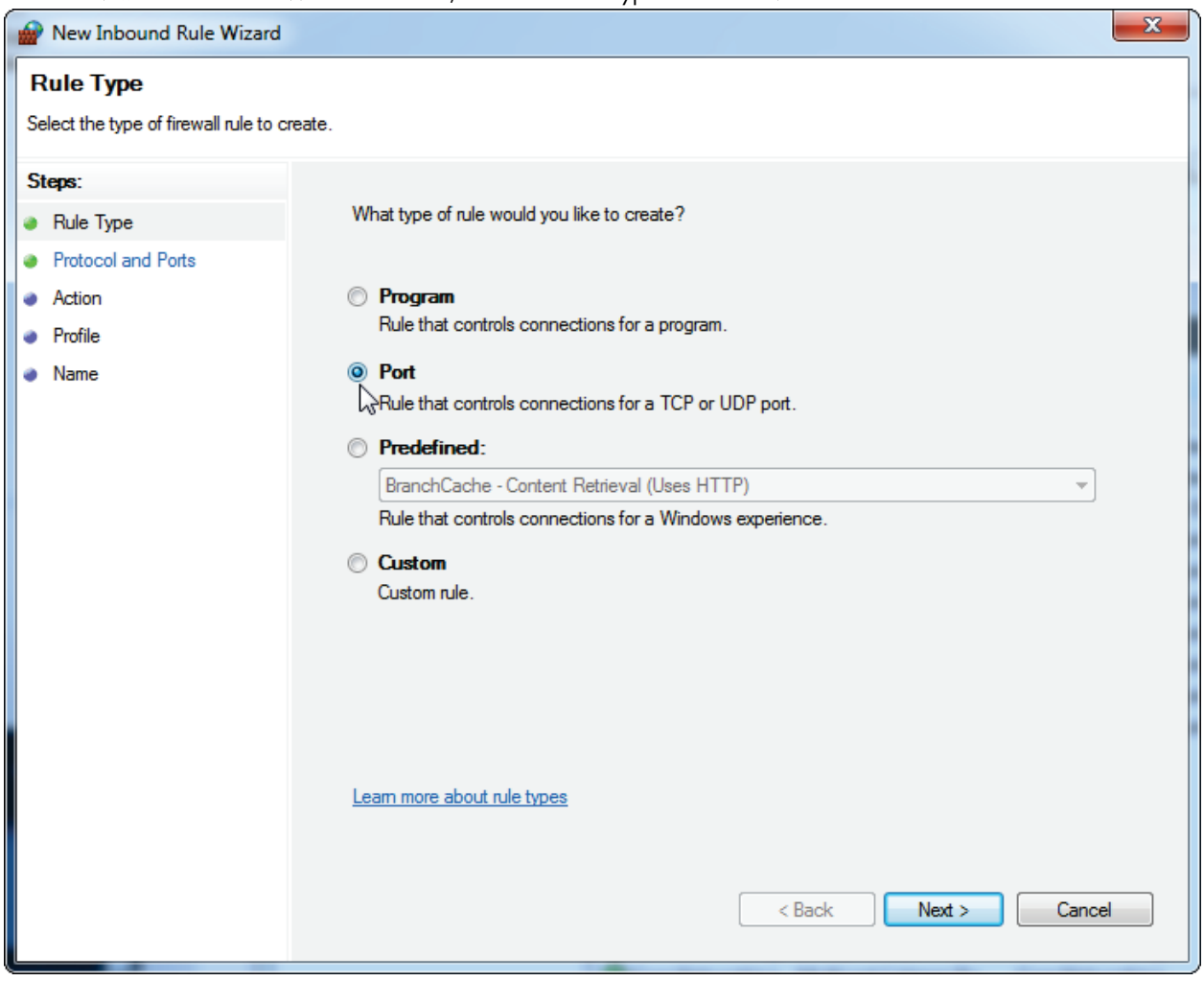


After creating the TCP protocol rule, you must create another rule for UDP, which is set to port **1434** by default.

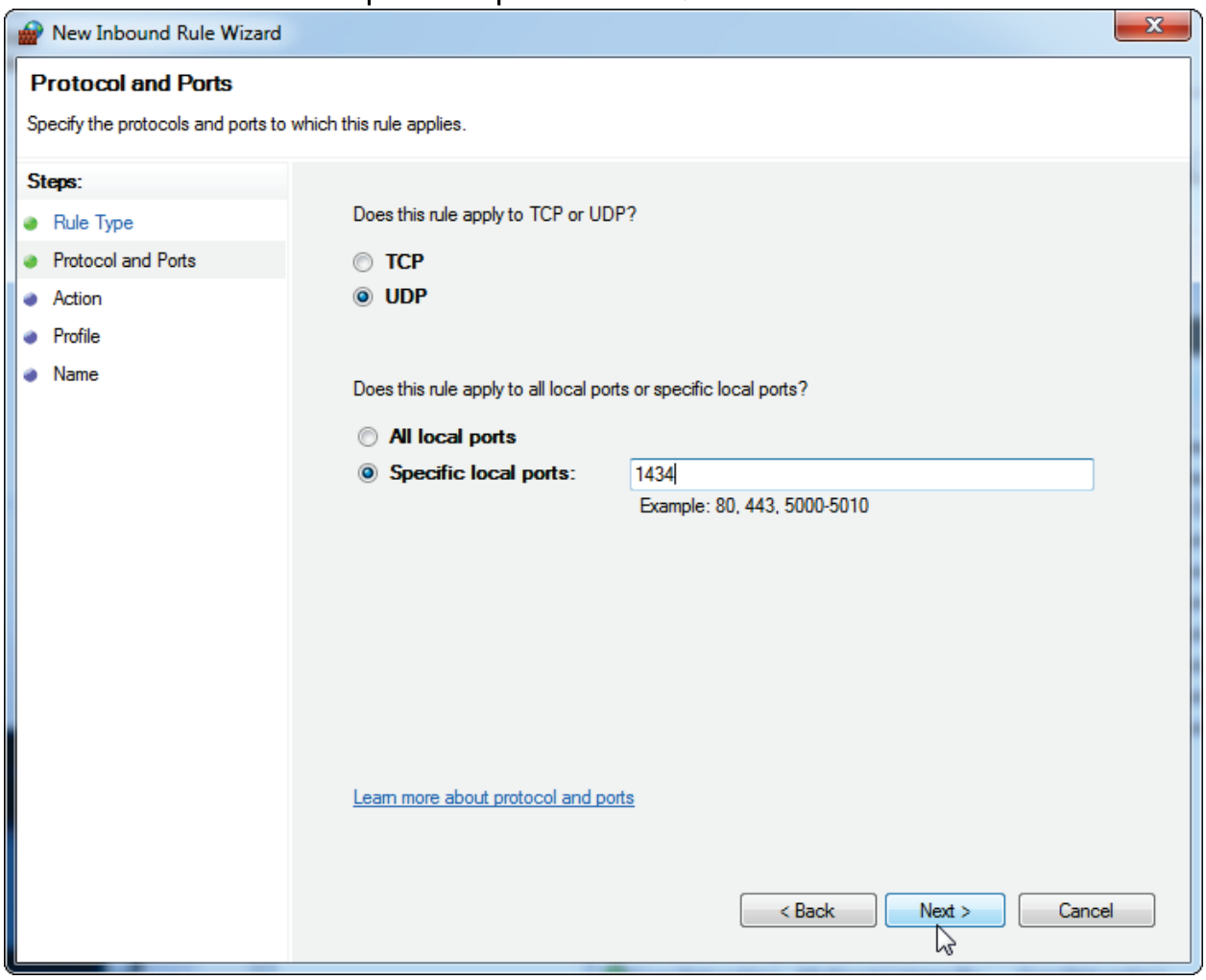
14. On the **Actions** pane, select **New Rule**.



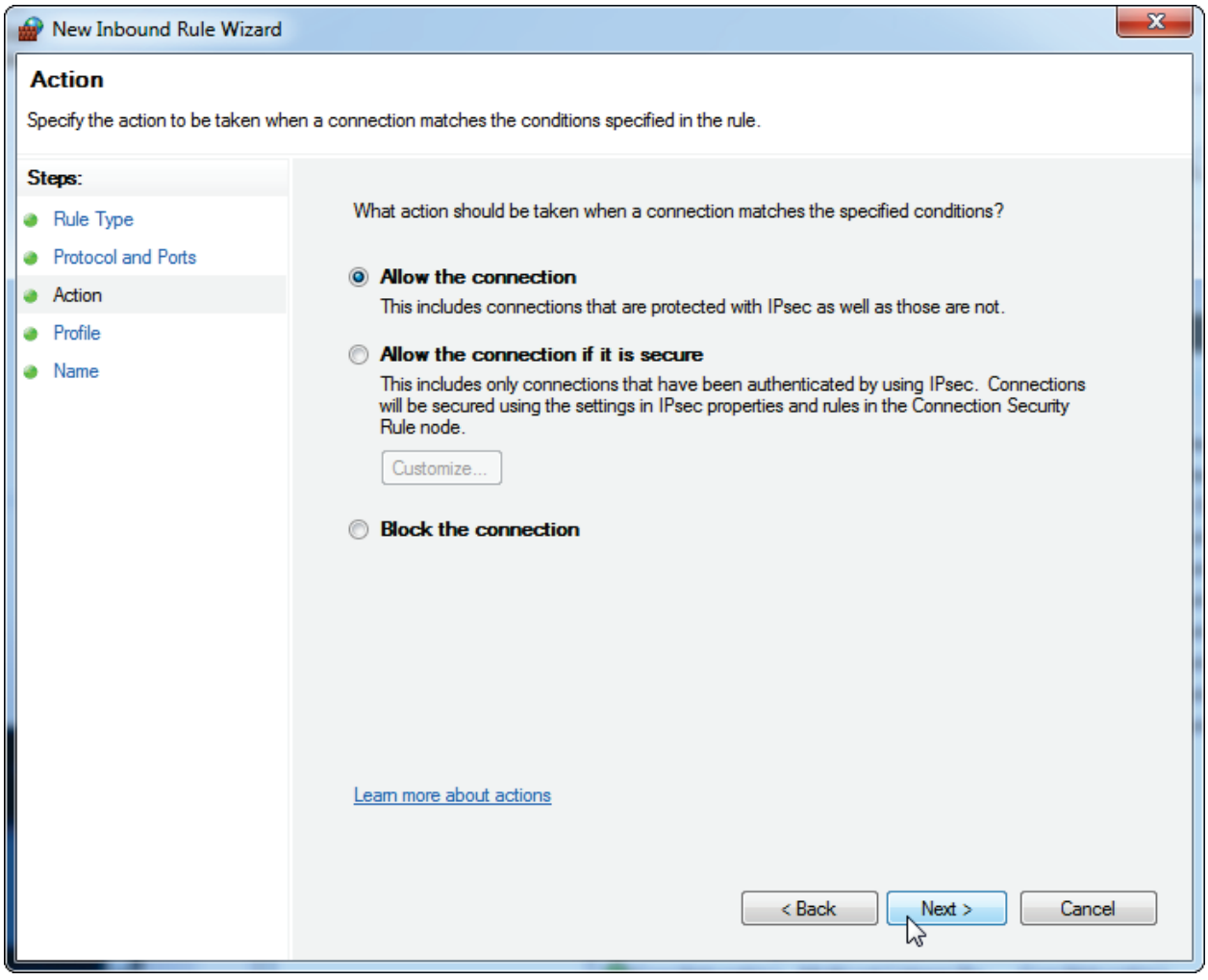
15. On the **New Inbound Rule Wizard** window, select **Port** rule type and click **Next**.



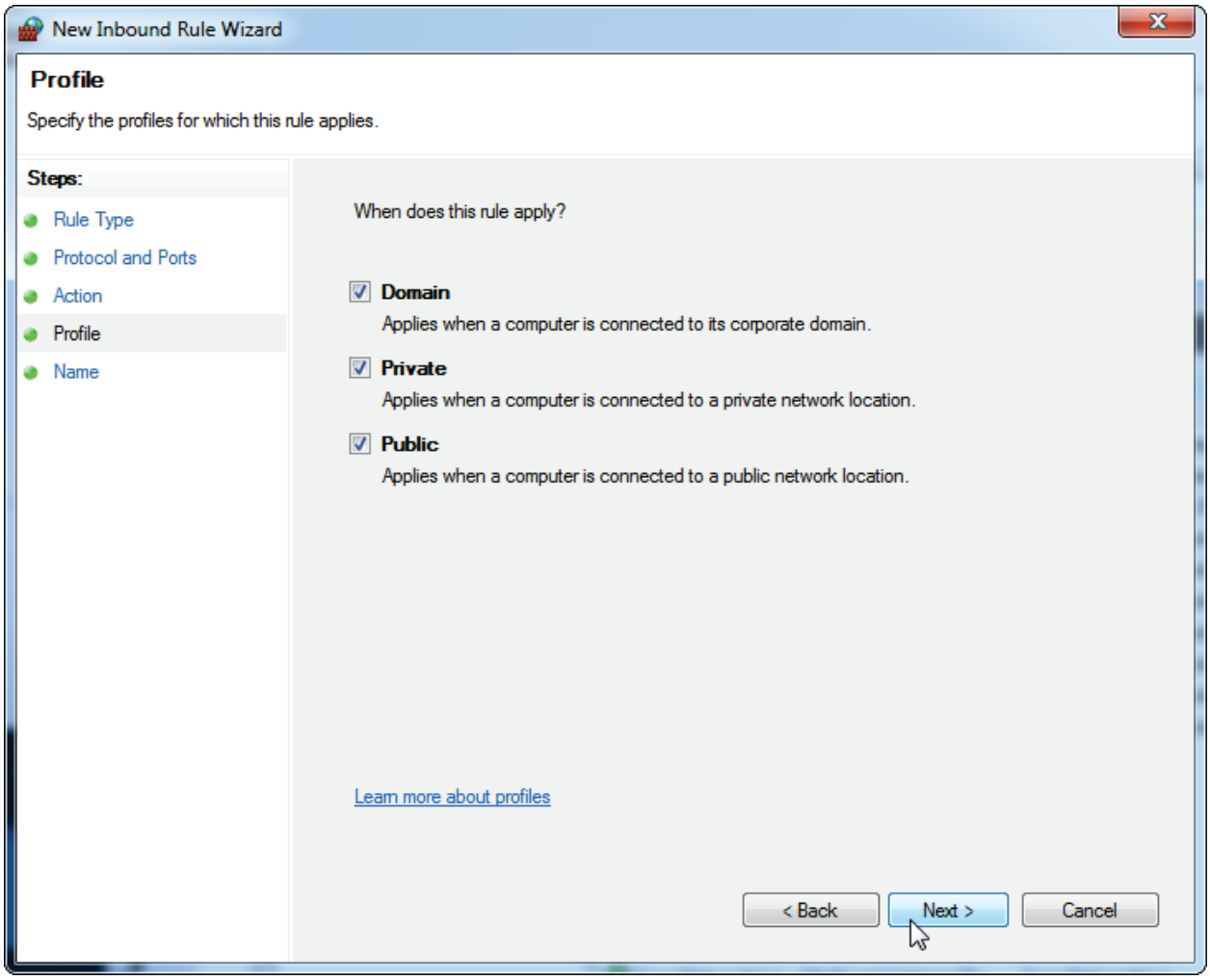
16. Select **UDP** and enter **1434** in the **Specific local ports** field. Click **Next**.



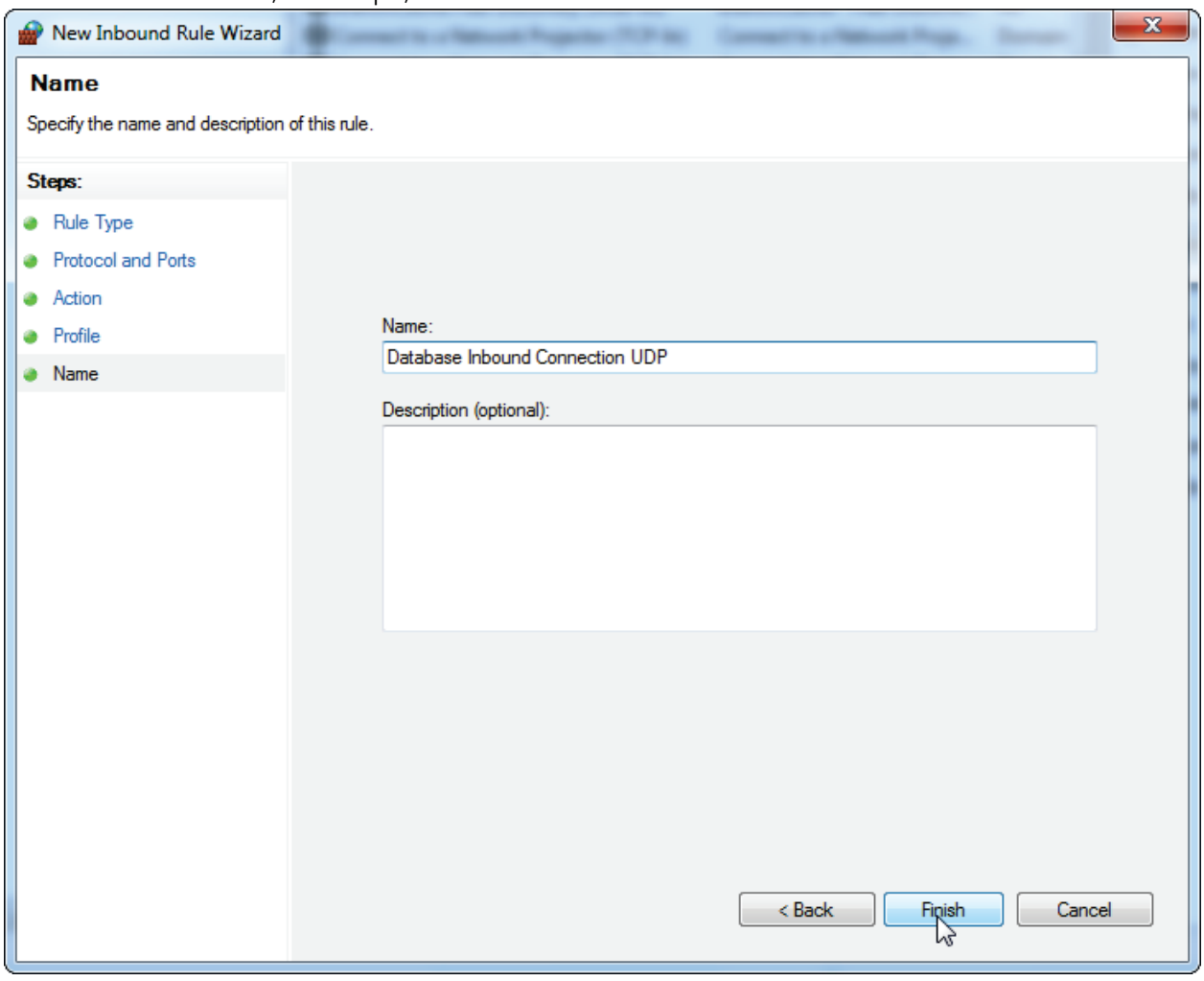
17. Select **Allow the connection** and click **Next**.



18. Check the **Domain**, **Private** and **Public** boxes, then click **Next**.

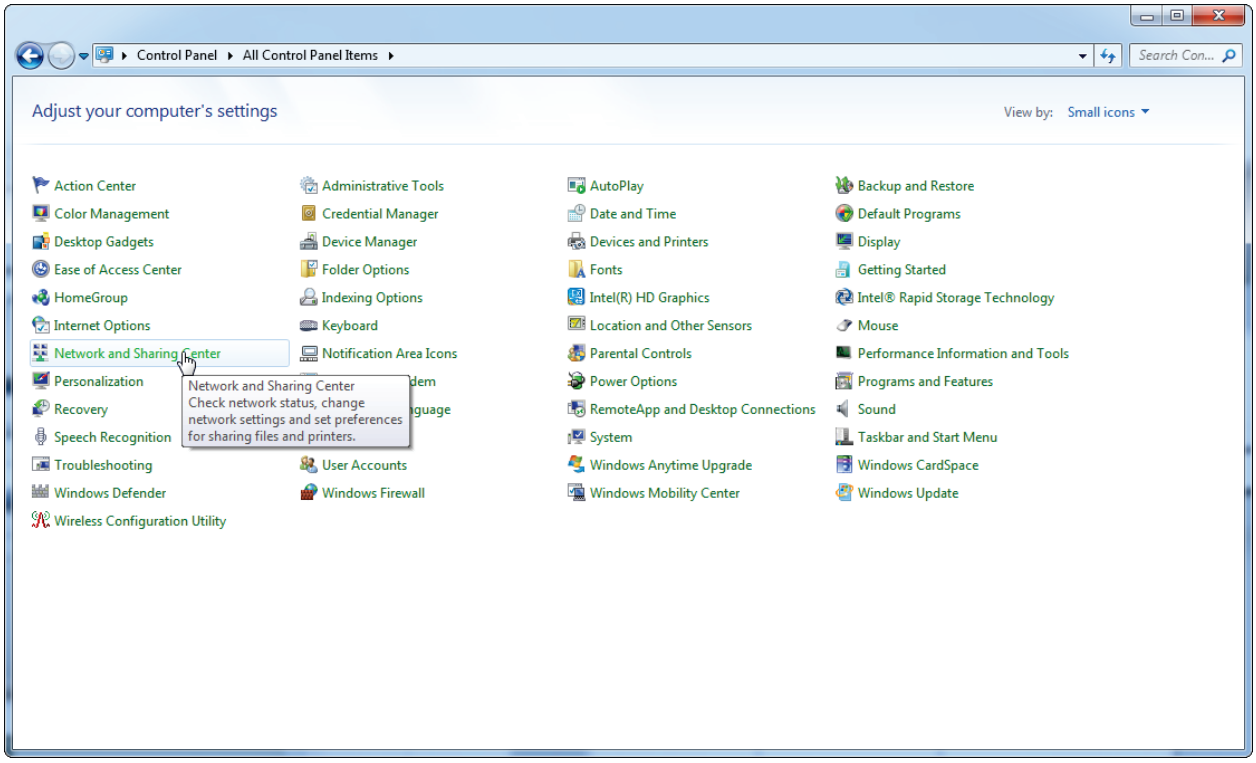


19. Define a name for the rule, for example, **Database Inbound Connection UDP**. Click **Finish**.

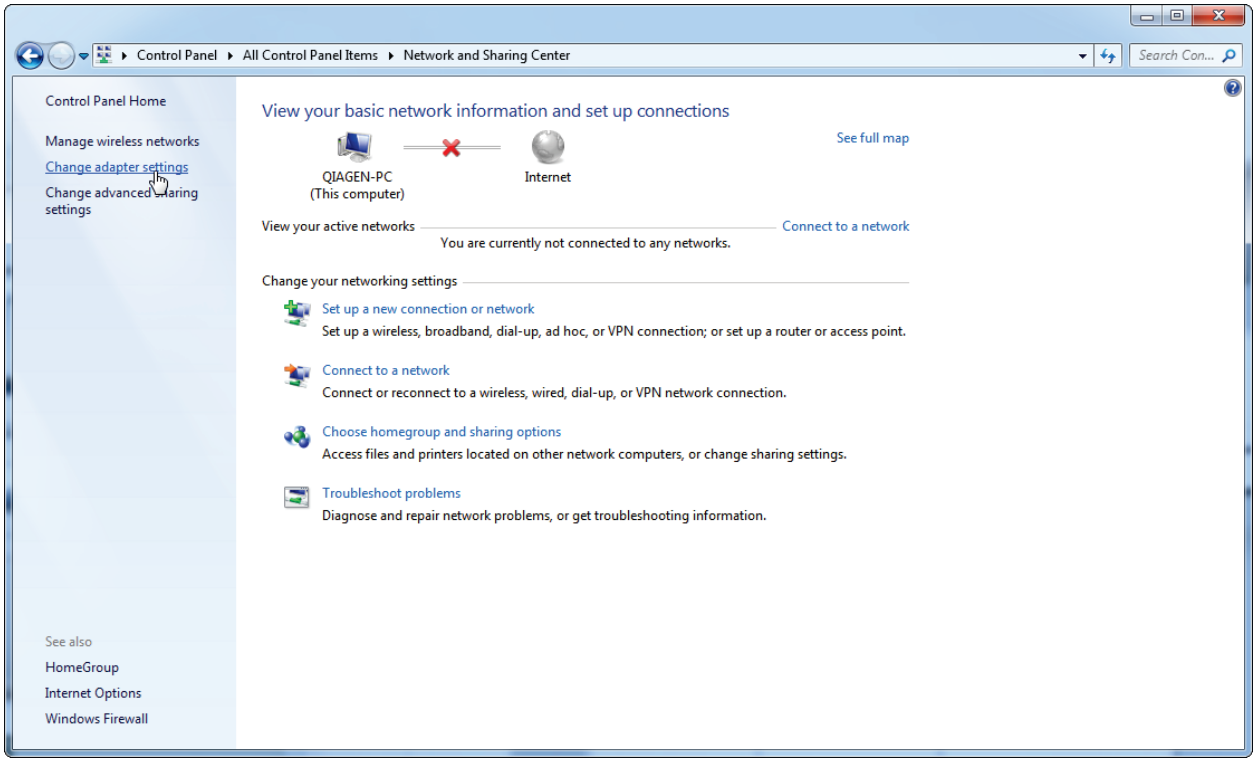


For security and reliability reasons, cable-based network access must be used instead of Wi-Fi. The laptop computers that are provided by QIAGEN have a disabled Wi-Fi adapter. If your configuration is different, a system administrator must disable the Wi-Fi adapter manually which can be done by the following steps:

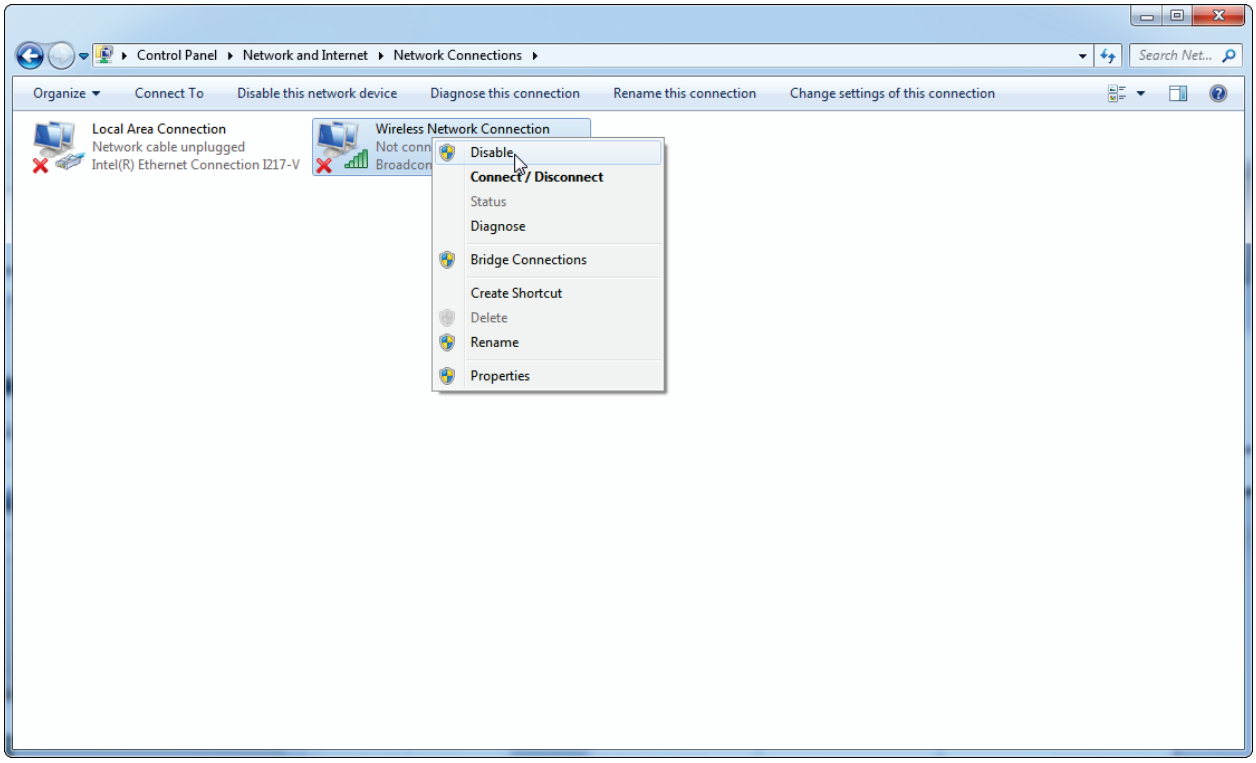
1. Open the **Control Panel** and select **Network and Sharing Center** (or search for **Control Panel** on Windows 10).



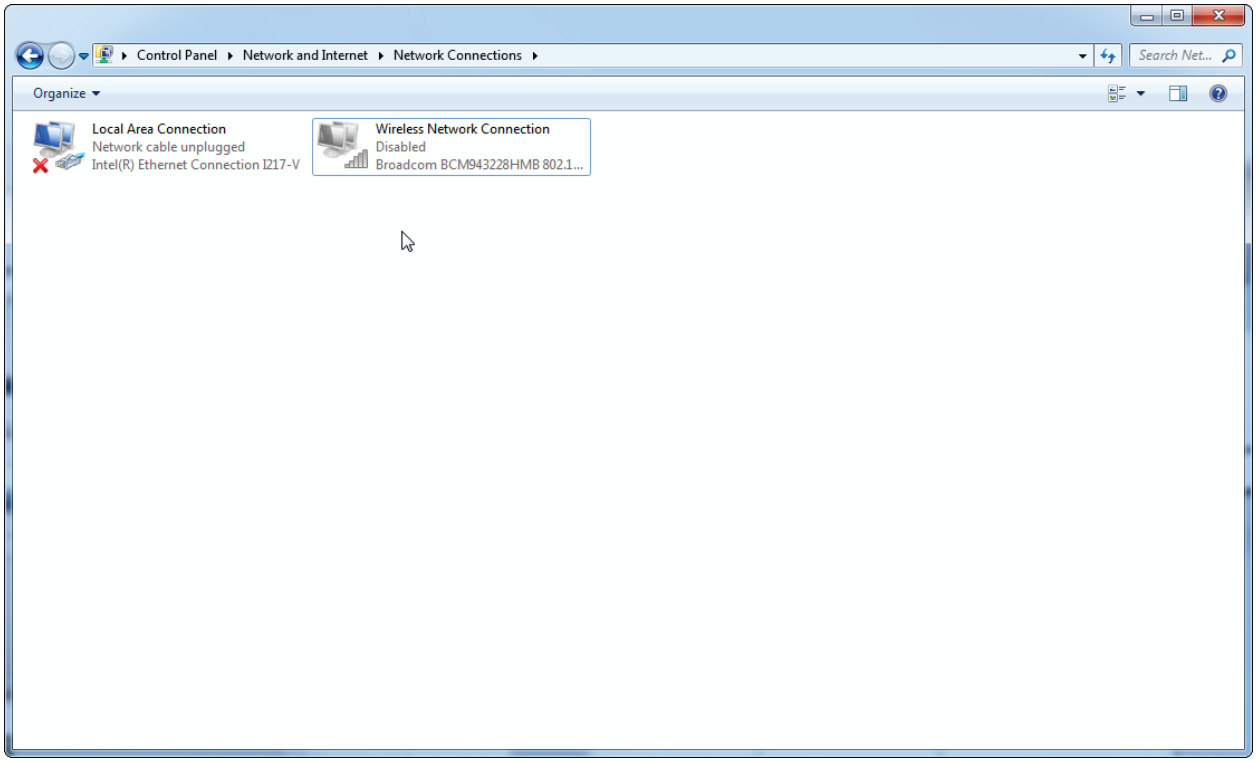
2. Select **Change adapter settings**.



3. Point to **Wireless Network Connection**, right-click and select **Disable**.



4. Check that the **Wireless Network Connection** is disabled.




## System tools

Many system tools may use significant system resources even without any user interaction. Typical examples of such tools are:

- File indexing, which is performed as a background task by many contemporary office applications
- Disk defragmentation, which often also employs a background task
- Any software that checks for updates on the Internet
- Remote monitoring and management tools

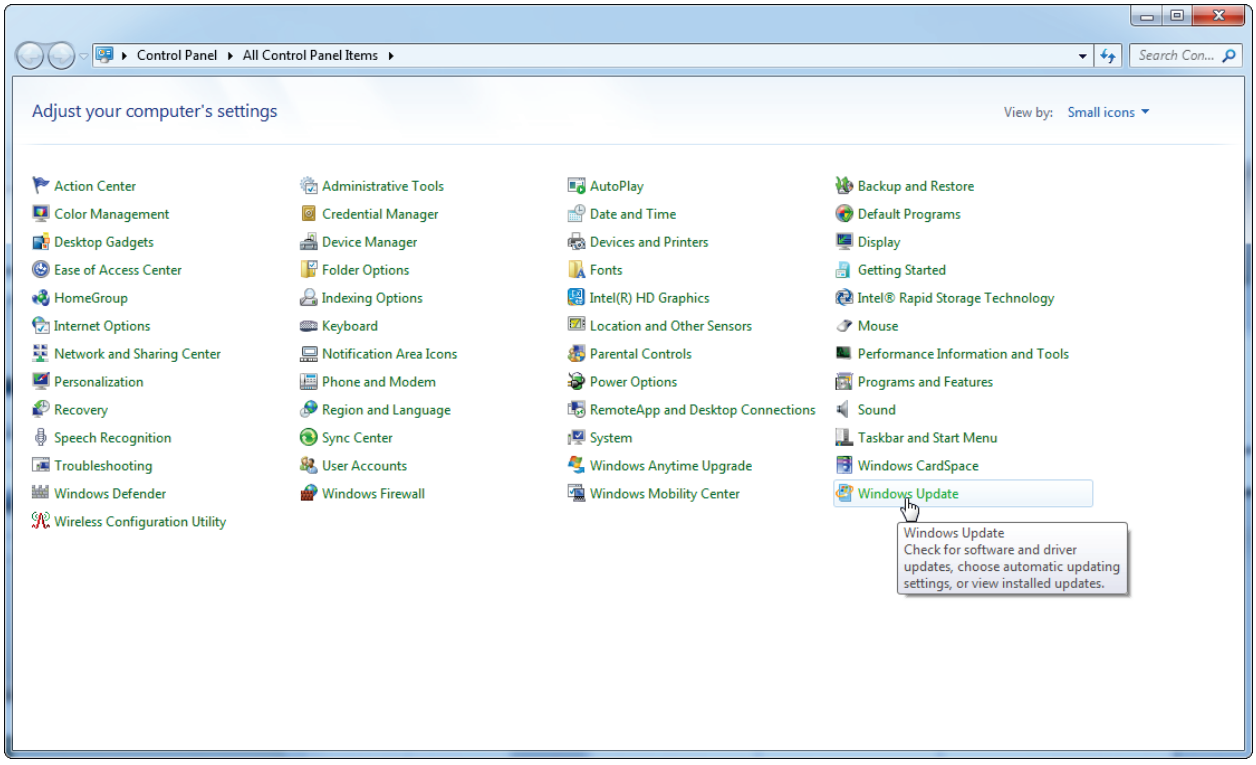
**Note**: Due to the dynamic nature of information technology products and systems, this list may be incomplete. Tools may be released that are not known at the time of writing. It is important that system administrators ensure that such tools are not active on the computer while Rotor-Gene AssayManager v1.0 performing a PCR run.

## Operating system updates

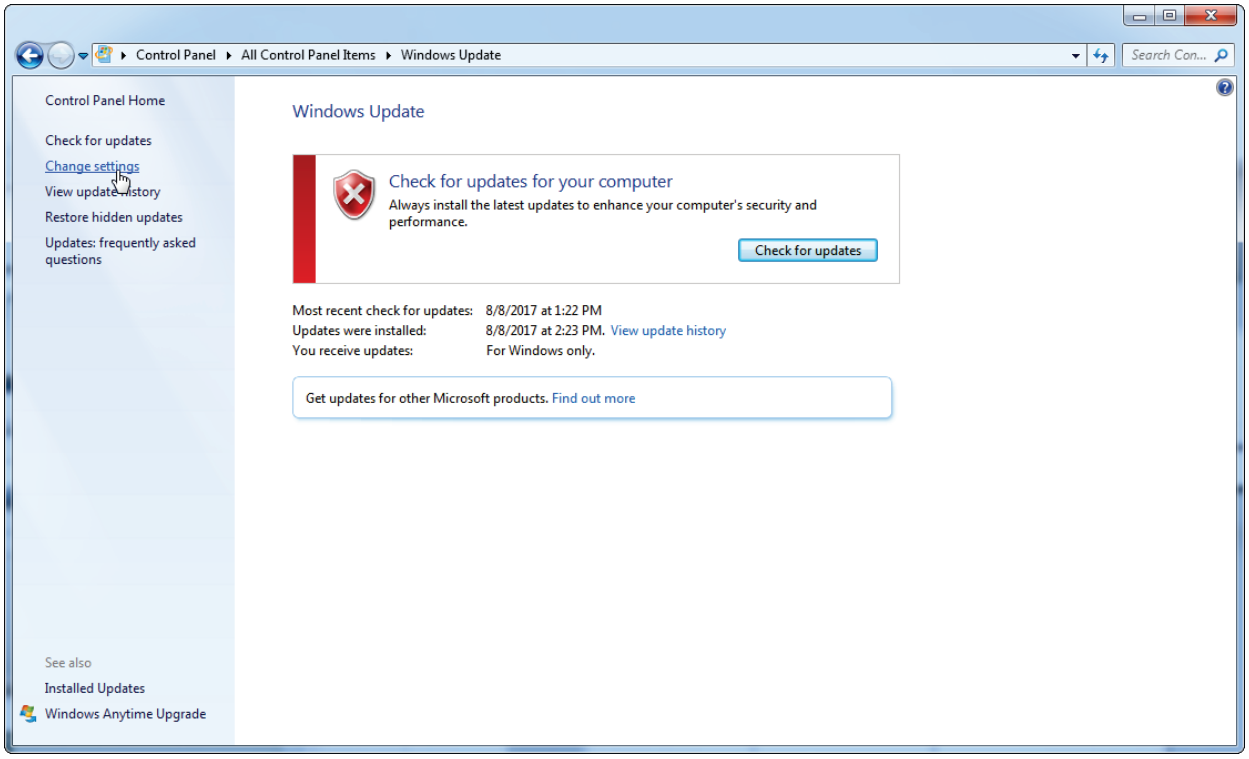
### Instructions for Windows 7

The laptop computers provided by QIAGEN are configured in a way that automatic updates of the operating system are disabled. If your configuration is different, a system administrator must disable any automatic update process of the operating system which can be done by the following steps:

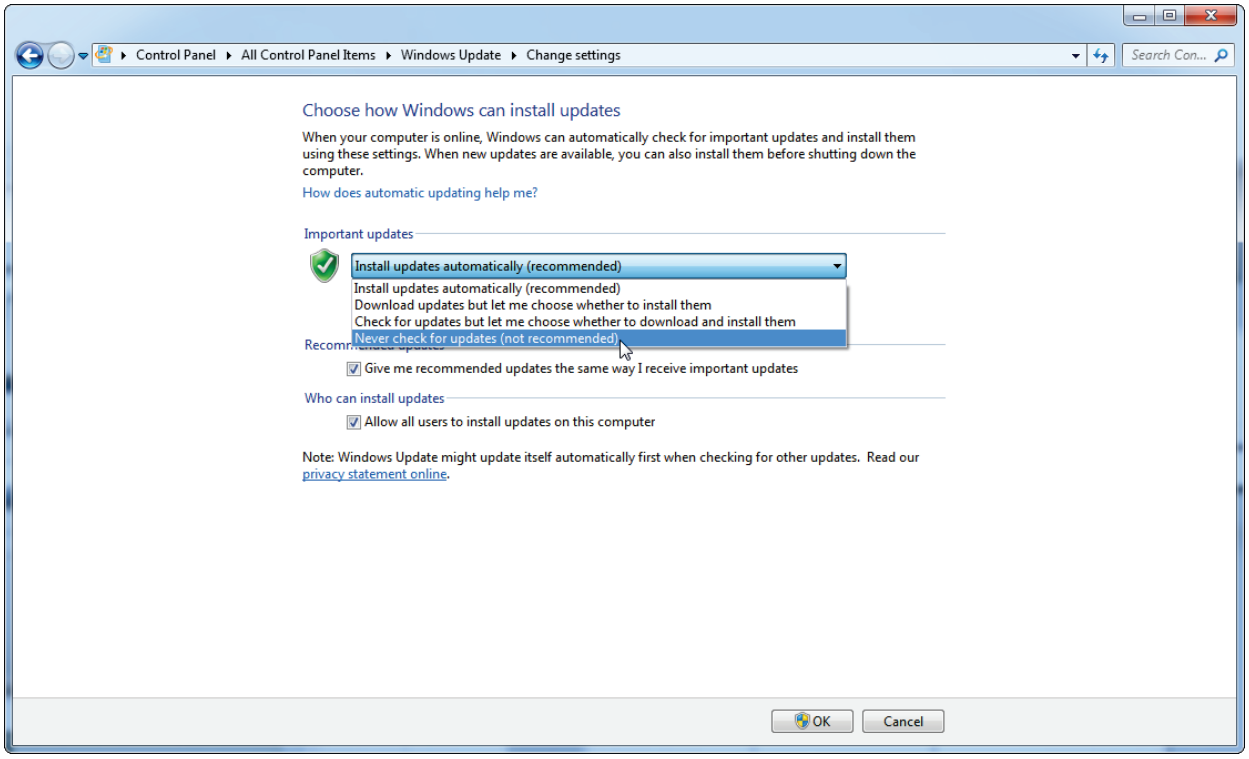
1. Open the **Control Panel** and select **Windows Update**.



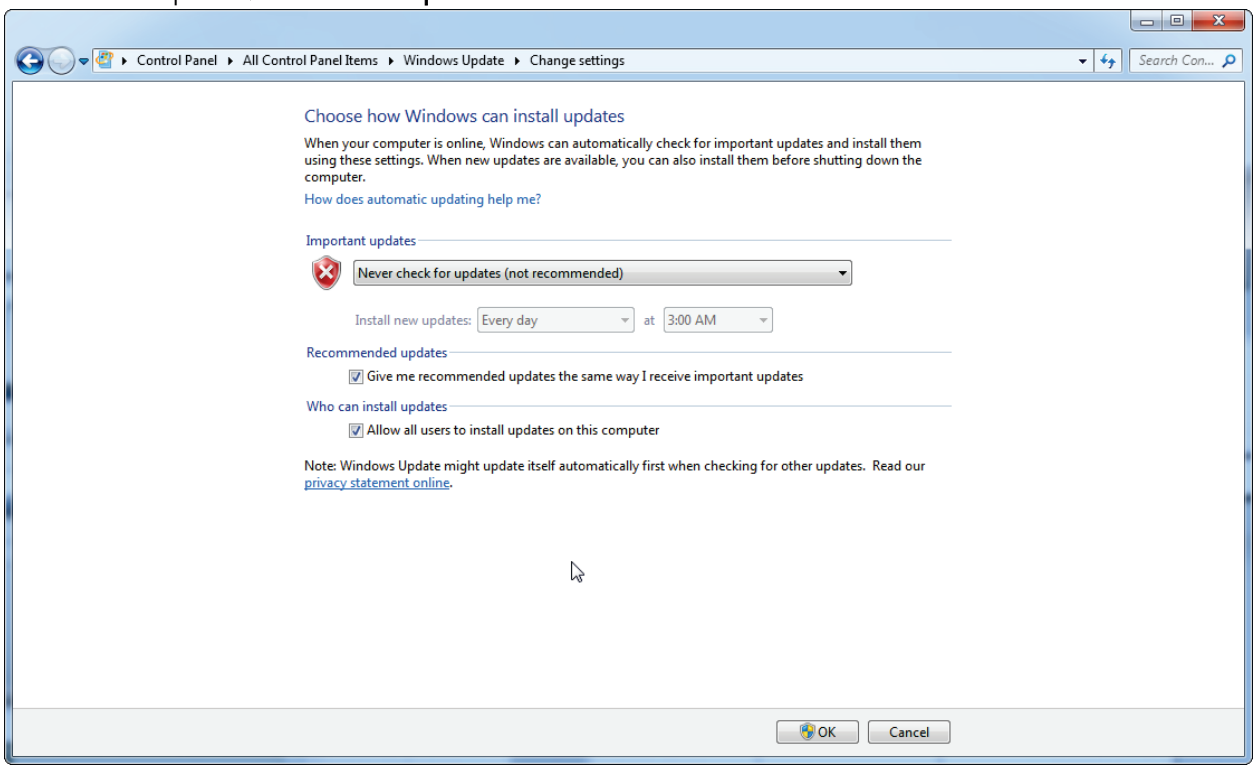
2. Select **Change settings**.



3. On the **Important updates** dropdown list, select **Never check for updates**.



4. Check that the option **Never check for updates** is active and click **OK**.




In case that updates are required due to uncovered security vulnerabilities, QIAGEN provides mechanisms to install a defined set of validated Windows security patches either online (if internet connection is available on laptop computers provided by QIAGEN), or as offline package, prepared on a separate computer with Internet connection.

Please visit the product page on QIAGEN.com for more information.

### Instructions for Windows 10

If you are using Windows 10, please visit the product page on QIAGEN.com for more information.

# FAQ

| Question | Answer |
|---|---|
| How can I uninstall a plug-in? | For regulatory reasons, plug-ins cannot be uninstalled. In case you want to uninstall a plug-in, the core application must be uninstalled together with the plug-in. |
| Why is Rotor-Gene AssayManager v1.0 unable to communicate with the cycler? | Check the cable connection between Rotor-Gene Q MDx and the computer. The USB cable might be loose or faulty. Reconnect or replace the cable. Only use cables and accessories supplied by QIAGEN. Switch off the Rotor-Gene Q MDx and switch it back on again. Restart Rotor-Gene AssayManager v1.0. |
| Can Rotor-Gene AssayManager v1.0 be used in parallel with the Rotor-Gene Q software on one computer? | Both programs can be installed in parallel on one computer. Make sure to have Rotor-Gene Q software version 2.3 or higher installed. However, the programs cannot be used in parallel for cycler control. As soon as the first program is started it will liaise to a switched-on Rotor-Gene Q MDx. This connection will be maintained until the program is closed or the Rotor-Gene Q MDx is switched off. If an active connection is established, the second program can only be started in virtual mode. |
| Why does Rotor-Gene AssayManager v1.0 not start? | a) Old version of Microsoft Windows<br>Rotor-Gene AssayManager v1.0 can only be operated with Windows 7 and Windows 10.<br>b) No plug-in installed<br>Rotor-Gene AssayManager v1.0 consists of the core software and plug-ins with application specific components. Besides the core software, at least one plug-in must be installed to be able to use Rotor-Gene AssayManager v1.0. |

Continued on next page

Continued from previous page

| Question | Answer |
|---|---|
| What is my initial user name and password after installation of Rotor-Gene AssayManager v1.0 | The initial user name and password for Rotor-Gene AssayManager v1.0 is "admin" for both. Directly after the first login you are required to change the password. Make sure to memorize the password for the "admin" account and crate additional user profiles in the Configuration environment afterwards. Note that if the password for a user account is entered incorrectly three times, the user account will be locked and can only be re-activated by a user with administrator role. If the administrator account gets locked, only a QIAGEN service technician can re-activate the Rotor-Gene AssayManager v1.0, which may cause additional charges. |
| After installation of Rotor-Gene AssayManager v1.0, I do not have access to the **Setup** and **Development** environments. What's wrong? | Upon first login to Rotor-Gene AssayManager v1.0, the "admin" user profile only has "Administrator" rights. Go to the user management tab in the **Configuration** environment, then update your access rights and create additional user profiles.<br>Activate the roles "Approver", "AssayDeveloper", and "Operator" in the appropriate user profile(s).<br>For details see the section "Getting Started" in the *Rotor-Gene AssayManager Core Application IVD (US) User Manual*. |

| Document Revision History | |
|---|---|
| 08/2018 | Updated the following parts for the new Rotor-Gene AssayManager 1.0.5 version:<br>- Added support and descriptions for Windows 10<br>- Added pre-requisites for the installation of RGAM on Windows 7 or Windows 10 systems<br>- Updated descriptions to be compatible with the most recent configurations for laptop computers provided by QIAGEN<br>- Updated and extended description of recommended virus scanner and firewall settings<br>- Updated and extended description of how to deal with operating system updates |

For further support with technical difficulties, please contact QIAGEN Technical Services at www.qiagen.com.

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