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# QuantiFERON® R&D Analysis RUO Software User Manual

For installation, setup, and use of QuantiFERON R&D Analysis RUO Software version 5.03.0

For Research Use Only



1095642



www.qiagen.com



QIAGEN, 19300 Germantown Road, Germantown, MD 20874, USA



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# 1 Introduction

This guide contains all the information required to download QuantiFERON® R&D Analysis Software. The QuantiFERON R&D Analysis Software is a PC-based program for analyzing QuantiFERON ELISA raw data. The software may be downloaded from the **www.qiagen.com** website. Alternatively, contact your local QIAGEN representative to obtain a copy via email.

This guide provides detailed step-by-step instructions on the use of QuantiFERON R&D Analysis Software.

Table 1. Release information

Parameter	Version
QuantiFERON R&D Analysis Software	5.03.0

#### 1.1 About this user manual

This user manual provides information about the QuantiFERON R&D Analysis Software in the following sections:

- Introduction
- General Description
- Installation Procedures
- Operating Procedures
- Maintenance
- Troubleshooting

#### 1.2 General information

#### 1.2.1 Technical assistance

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QuantiFERON R&D Analysis Software or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services.

#### 1.2.2 Policy statement

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

# 1.3 Intended use of the QuantiFERON R&D Analysis Software

QuantiFERON R&D Analysis Software is for optional use with QuantiFERON ELISA.

# 1.4 Requirements for QuantiFERON R&D Analysis Software

The table below shows the system requirements for QuantiFERON R&D Analysis Software:

Table 2. System requirements

Description	Minimum requirement
Operating system	Microsoft® Windows® 7, 8, or 10
Processor	Intel® Pentium® processor, or equivalent  1-GHz processor or higher, dependent on operating system
Main memory	1 GB RAM or higher
Hard disk space	5 MB available hard disk space
Monitor	800 x 600 pixels (minimum screen resolution)*

<sup>\*</sup> Higher resolution is recommended.

# 1.5 Software specifications

QuantiFERON R&D Analysis Software, version 5.03.0 (including all sub-versions).

# 3 General Description

# 3.1 Software features

QuantiFERON R&D Analysis Software is a PC-based program for analyzing QuantiFERON ELISA raw data.

The following features are available in QuantiFERON R&D Analysis Software version 5.03.0:

- Record assay-related information
- Automatically import or manually enter raw data
- Highlight standards and samples to create an Analysis Format
- Save Analysis Format for use with future assays
- Assign subject's identity to each sample
- Obtain quality control analysis of standard curve
- Export data and results to other applications

# 4 Installation Procedures

#### 4.1 Software installation from website

The most recent version of the QuantiFERON R&D Analysis Software is available for download at **www.qiagen.com**. Navigate to the QuantiFERON product webpage at **www.qiagen.com**.

#### 4.1.1 Downloading the QuantiFERON R&D Analysis Software

Note: To download the software, ensure that you are logged in to your QIAGEN account.

To download the QuantiFERON R&D Analysis Software:

- In the QuantiFERON product page, go to Product Resources > Operating Software to download the QuantiFERON R&D Analysis Software.
- 2. Click Show Details.

You will be redirected to the download page of the software.

- 3. Click Download.
- 4. After the download is complete, save the downloaded zip file to an appropriate location within the computer.

#### 4.1.2 Installing the QuantiFERON R&D Analysis Software

To install the QuantiFERON R&D Analysis Software:

- 1. Navigate to the folder where the zip file is located.
- 2. Extract the contents of the zip file in the same location.
- 3. Double-click QuantiFERON\_RD\_V5.03.0\_Build08.exe.

# 4.2 Getting started

To open the QuantiFERON R&D Analysis Software, double-click the **QuantiFERON\_RD\_V5.03.0\_Build08** shortcut or directly from the downloaded .exe file.

# 4.3 Software upgrade

You may need to update the QuantiFERON R&D Analysis Software in case a new version becomes available. Software updates for QuantiFERON R&D Analysis Software are available for download in the QuantiFERON product webpage at **www.qiagen.com**. Go to **Product Resources** > **Operating Software** to download the latest QuantiFERON R&D Analysis Software version. Save the downloaded file in your preferred location.

For more information about updating the software, see Upgrading the QuantiFERON R&D Analysis Software.

# 5 Operating Procedures

# 5.1 Starting the QuantiFERON R&D Analysis Software

From your Home screen, double-click the QuantiFERON\_RD\_V5.03.0\_Build08 icon on your desktop to open the QuantiFERON R&D Analysis Software.

The program will open to the first of four screens that sequentially progresses through the calculations.

#### Run Details

- Enter general test details such as the Run Date, Run Number, Kit Batch Number, and Operator.
- O Select the Standard Curve Type (4-Point or 8-Point Standard Curve).
- Select the Concentration Value Type (Default 4, 1, 0.25, and 0 for 4-Point and 8, 4, 2, 1, 0.5, 0.25, 0.125, and 0 for 8-Point Standard Curves or Manual Values).

#### Raw Data

 Enter Optical Density (OD) values and apply a format that defines the standards and samples.

#### Standard Results

O View standard curve results, which indicate the validity of the ELISA.

#### Subject Results

O View test results for each sample. Save, print, and export data and results.

For more information about these screens, see Screens in the QuantiFERON R&D Analysis Software.

# 5.2 Screens in the QuantiFERON R&D Analysis Software

#### 5.2.1 Run Details screen

Perform these steps in the Run Details screen:

- 1. In the Run Date field, use the drop-down calendar to enter the run date.
- 2. Enter the kit batch number in the Kit Batch Number field.

Note: The kit batch number can be found on the QuantiFERON ELISA outer box label.

- 3. Specify the run number in the Run Number field.
- 4. Specify the operator in the **Operator** field.
- 5. In the Curve Type section, select 4-point Standard Curve or 8-point Standard Curve.
- 6. In the Concentration Value Type, select **Default Values** or **Manual Values**.
- 7. Click the Raw Data tab or click the arrow icon in the lower right of the screen to move to the next screen.

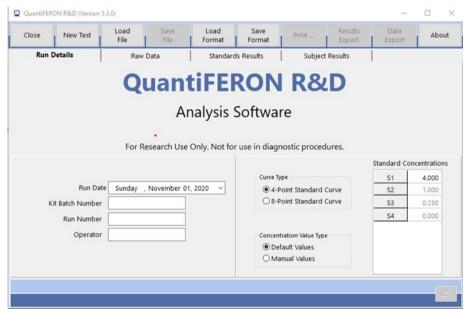


Figure 1. Run Details screen

#### 5.2.2 Raw Data screen

QuantiFERON R&D Analysis Software uses optical density (OD) values as the basis for all calculations. The user does not need to perform calculations prior to using the software. Simply enter the raw data from the plate reader into the software.

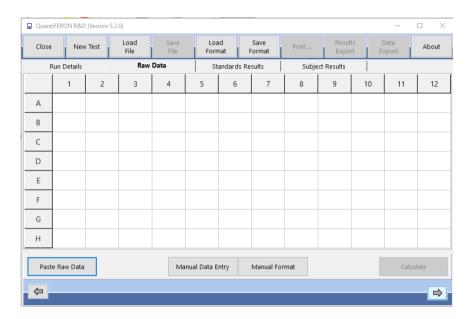


Figure 2. Raw Data screen.

There are two methods of data entry: automatic data entry and manual data entry.

#### Automatic data entry

Copy the raw data (OD values) to be analyzed from the ELISA plate reader program. Some plate reader programs require the data be exported first into a spreadsheet.

Select Paste Raw Data. The data will be entered into the program's data cells (Figures 3 and 4).

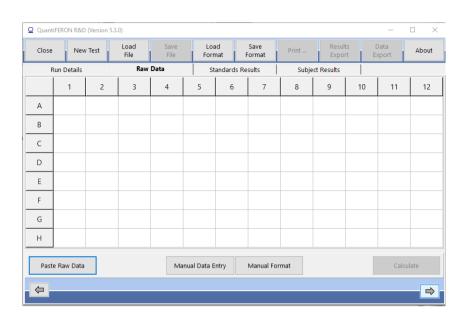


Figure 3. Raw Data screen. 1 = Paste Raw Data.

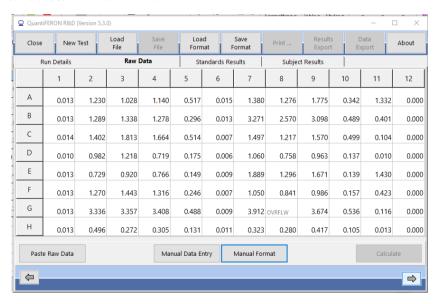


Figure 4. Raw data screen after pasting raw data. If a cell is missing data, the cell is denoted N/S (no sample) and takes no further part in the analysis. If a cell contains text, such as \*\*\*, Out, OVRFLW, etc.), the software interprets the OD value as being off-scale and the sample is given an OD value of 4.000 units.

Data from plates with less than 12 strips can be analyzed. However, each strip of data pasted must contain eight values (including empty cells, if necessary). Data cells for standards cannot be blank or contain text. If such a situation arises, the analysis software will report this as an Invalid ELISA.

Due to the logarithmic calculations performed by the software, negative OD values cannot be analyzed. Negative OD values are not normally obtained for the QuantiFERON ELISA and may indicate the need to service the plate reader.

#### Manual data entry

Select **Manual Data Entry**. Click a cell to enter data manually. To store the value, click **Enter**. Alternatively, use the  $\uparrow$  and  $\downarrow$  arrows or the mouse to navigate to another cell or simply click another cell.

When all data have been entered, click **Complete** on the Manual Data Entry toolbar to proceed (Figure 5).

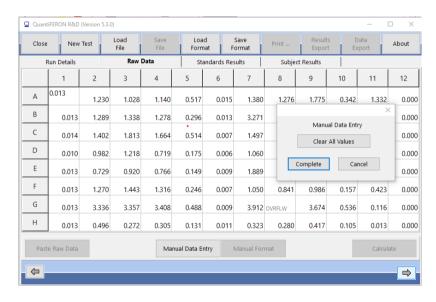


Figure 5. "Raw data" screen during manual data entry. 1 = Click Complete to end manual data entry.

**Note**: Manual entry is more prone to errors, and the user should take additional care to ensure data entry accuracy.

**Important**: It is critical to compare the original raw OD data/format with data on the report, as errors in manual data entry (or copy/paste errors) can cause incorrect report results.

#### 5.2.3 Analysis format

Before data can be analyzed, users must apply a format to nominate the cells that contain samples and those that are standards. The format is assigned using manual format.

#### Manual format

The Manual Formatting Toolbar is used to manually assign both standards and subject samples to the data's format. By default, the toolbar opens in Standards mode with standards ready to be assigned in a vertical orientation. The settings can be changed by selecting the appropriate radio buttons.

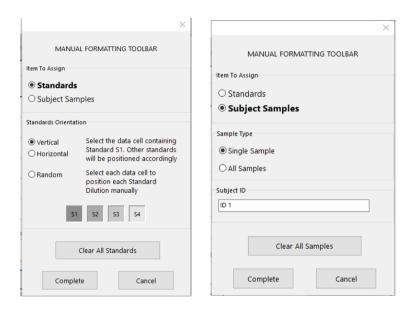


Figure 6. Manual Formatting Toolbar in Standards mode (left) for 4-point Standard Curve and Subject Samples mode (right).

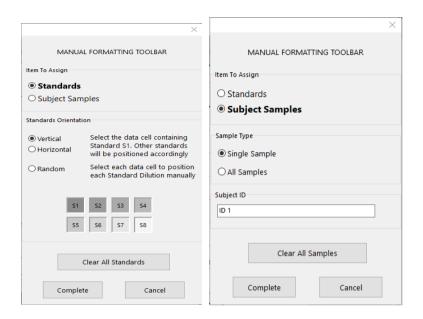


Figure 7. Manual Formatting Toolbar in Standards mode (left) for 8-point Standard Curve and Subject Samples mode (right).

#### 5.2.4 Standards

#### For 4-point Standard Curve

Standard S1 is the highest standard, containing 4.0 IU/ml of interferon-gamma (IFN- $\gamma$ ). Standard S4 is the lowest standard, containing 0 IU/ml of IFN- $\gamma$ .

Once the set of standards, S1 to S4, has been assigned, the toolbar resets and ready to automatically assign another set of standards.

The standard orientation can be adjusted at any time, allowing replicates of standards to have different orientations in the one format.

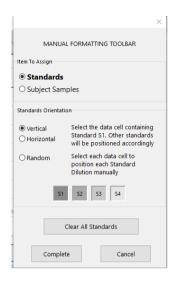


Figure 8. Manual Formatting Toolbar in Standards mode for 4-point Standard Curve

- To assign a set of standards (S1, S2, S3, S4) within Standards mode, select Vertical or Horizontal in the Standards Orientation list. Then, click the cell in the Raw Data screen that contains the data for standard S1. The selected cell is designated as S1, and the other standards will be appropriately positioned in adjacent cells in order.
- To assign a set of standards in a random manner, select Random. Then, click the appropriate
  cells within the Raw Data screen to manually position each of the standards S1 to S4 in order.
- To delete a single set of standards, right-click the colored block and select Delete Block from the context menu. To delete all standards, select Clear All Standards on the Manual Formatting Toolbar.

#### For 8-point Standard Curve

Standard S1 is the highest standard, containing 8.0 IU/ml of interferon-gamma (IFN- $\gamma$ ). Standard S8 is the lowest standard, containing 0 IU/ml of IFN- $\gamma$ .

Once the set of standards, S1 to S8, has been assigned, the toolbar resets and ready to automatically assign another set of standards.

The standard orientation can be adjusted at any time, allowing replicates of standards to have different orientations in one format.



Figure 9. Manual Formatting Toolbar in Standards mode for 8-point Standard Curve

- To assign a set of standards (S1, S2, S3, S4, S5, S6, S7, S8) within Standards mode, select Vertical or Horizontal in the Standards Orientation list. Then, click the cell in the Raw Data screen that contains the data for standard S1. The selected cell is designated as S1, and the other standards will be appropriately positioned in adjacent cells in order.
- To assign a set of standards in a random manner, select Random. Then, click the appropriate cells within the Raw Data screen to manually position each of the standards S1 to S8 in order.
- To delete a single set of standards, right-click the colored block and select Delete Block from the context menu. To delete all standards, click Clear All Standards on the Manual Formatting Toolbar.

#### 5.2.5 Subject (patient) samples

- To assign subject samples to the data, select Subject Samples from the Item to Assign list on the Manual Formatting Toolbar.
- To assign single subject sample, select the Single Sample in the Sample Type list. Then, click
  the cell that contains the data for the subject sample.
- To assign all subject Samples at the same time, select All Sample in the Sample Type list. Then, click the first cell that contains data for the subject samples.

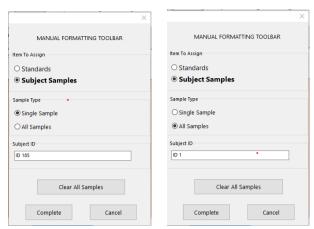


Figure 10. Manual Formatting Toolbar in Single Sample mode (left) and All Samples mode (right)

For Single Sample mode, the subject's name/ID can be entered into the **Subject ID** field on the toolbar prior to assigning a sample to the data. For more information about subject naming, see Raw Data screen: Subject names.

If a subject's name/ID is not entered, the first selected cell will be automatically designated as ID1. Each following sample selected will be designated sequentially as ID2, ID3... unless designated with a different Sample ID.

For All Sample mode, only the first subject's name/ID can be entered into the **Subject ID** field on the toolbar prior to assigning a sample to the data.

If a subject's name/ID is not entered, the first selected cell will be automatically designated as ID1. The following samples will be sequentially designated ID2 to ID88 when a 4-Point Standard Curve is run and sequentially designated ID2 to ID80 when an 8-Point Standard Curve is run.

To delete a single subject sample, right-click the colored block and select **Delete Block** from the context menu. To delete all subject samples, click **Clear All Samples** on the Manual Formatting Toolbar.

After the standards and subject samples have been assigned, click **Complete**. Upon completing a format, it can be saved as a file and reloaded for analysis of future data, allowing the user to create a few format files for all of their analysis needs. For more information about saving format files, see Saving and loading files.

To delete all standards and subject samples, right-click any colored block and select **Clear Format** from the context menu.

Non-format information, such as run details and subject (patient) names, is not retained as part of the saved format file. These details are, however, retained as part of all saved result files.

#### 5.2.6 Raw Data screen: Subject names

Subject names can be up to 15 characters in length. For this reason, they are not displayed on the Raw Data screen. Instead, the stored subject names can be viewed by left-clicking the cell.

Subject names can be changed at any stage by left-clicking the colored block for each subject and entering the new name in the Change Subject ID dialog box that appears.

To assign subject samples in a random manner, each of the samples must be positioned manually by clicking the appropriate cells.

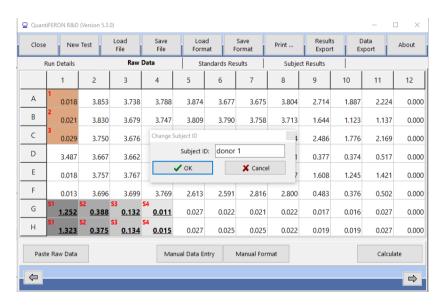


Figure 11. Viewing Subject ID by left-clicking the cell.

After the format is generated, click **Calculate**. The standard curve for the assay will be automatically analyzed, and the Standards Results screen will be displayed. For the **Calculate** button to be enabled, at least two blocks of Standards and one Subject Samples block must be assigned.

#### 5.2.7 Standards Results screen: Quality control of standard curve

The accuracy of test results is dependent on the accuracy of the standard curve. The software automatically performs quality control (QC) analysis of the standard curve prior to interpreting test sample results.

The Standards Results screen provides information that is directly related to the acceptance criteria of the ELISA:

- Mean of the replicate standards
- Coefficient of variation (%CV) of the replicate standards
- Correlation coefficient of OD values and known IFN-γ concentrations (Conc)

The results of the QC acceptance criteria for the Standard Curve are shown as PASS or FAIL. For more information about the acceptance criteria, see the *QuantiFERON ELISA Instructions for Use*.

The following information is also displayed:

- A graph of the Standard Curve including linear regression line
- Intercept and slope of the linear regression



Figure 12. Standards Results screen. (Top) 4-point Standard Curve; (Bottom) 8-point Standard Curve.

A message indicating whether the ELISA is Valid or Invalid based on the QC criteria is provided in the ELISA Results section (bottom left corner of the screen). This message is also displayed on all printed and PDF reports.

Important: If any of the QC criteria are not met, the ELISA test run is Invalid and must be repeated.

In the event that the Mean value of the zero standard (zero IFN $_{\gamma}$ ) is greater than 0.150 OD units, a message is displayed suggesting that ELISA plate washing procedures be investigated. This message is also displayed on all printed and PDF reports.

To proceed to the next screen, click the Subject Results tab.

#### 5.2.8 Standard Curve

The standard curve is used to calculate a value (IU/ml of IFN $\gamma$ ) for each patient's samples.

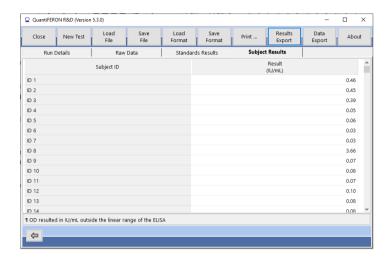


Figure 13. Subject Results screen.  $\P$  = Sample result is outside the linear range of the assay.

The result Data Missing is reported if any of a patient's plasma samples display the value N/S (No Sample).

Samples that have results beyond the linear range of the assay are reported as >10 IU/ml and are flagged using the  $\P$  or # symbols. The  $\P$  symbol indicates that the result is outside the linear range of the assay. The # symbol indicates that a value outside the plate reader range was used to determine the result — non-numerical characters include **OUT** or \*\*\*. In the case of non-numerical entries, an OD of 4.000 is used to calculate the IU/ml result.

For further information regarding the calculation of QuantiFERON ELISA results, see the QuantiFERON ELISA Instructions for Use.

### 5.3 Data export

If needed, the user can export results and/or data through Windows Clipboard or structured text file to external spreadsheet applications, such as Microsoft® Excel®.

To export results, perform these steps:

- Click the Results Export tab.
   The Export Type dialog box appears.
- 2. Select your preferred export type, and click OK.
  - Export to Clipboard: This is the default option. If this option is selected, the Results
     Copied to Windows Clipboard dialog box appears. Click OK. The data can then be
     pasted into a spreadsheet.
  - Export to File: If this option is selected, another dialog box appears enabling you to save the results as a file on your computer. Click Save to proceed. The data is then saved as a .txt file.

Similarly, the Data Export tab provides you the option of exporting the assay details, raw data, and QC results to either the Windows Clipboard or a text file. The process for exporting data using Data Export is the same as the procedure for exporting results.

**Note**: The optional step of exporting data is not required to obtain QuantiFERON ELISA results. It may be employed by the user for pooling and trending data. Take care when pasting data into spreadsheet programs, due to the possibility of the spreadsheet's default formatting affecting the presentation of the data.

## 5.4 Reports

The Print tab displays a print screen that is divided into two sections. The upper section shows the various printing options available, while the lower section shows a summary report of the ELISA details and results.

**Important**: It is critical to compare the original raw OD data/format with data on the report, as errors in manual data entry or copy/paste errors can cause incorrect report results.

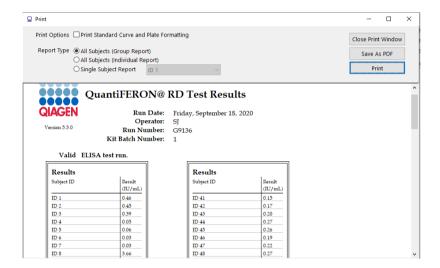


Figure 14. Summary report.

- Select one of the following options in the **Report Type** list to print a particular report:
  - All Subjects (Group Report): This option prints the results for all subjects on one page. The Raw OD values used to generate the Standard Curve are highlighted (bold and underlined) in this report.
  - All Subjects (Individual Report): This options prints the results for each subjects on a separate page.
  - O Single Subject Report: This option prints the results for one subject selected from the list.
- To generate an additional report page that includes the plate layout and standard curve, check the Print Standard Curve and Plate Formatting box.
- To close the printing screen and return to the main window, click Close Print Window.
- Alternatively, reports can be saved as PDF files by clicking Save As PDF. For more
  information, see Saving and loading files.
- After the desired type of summary report is selected, click Print to print the report.

**Note**: The upper range of the QuantiFERON ELISA is 10 IU/ml. Therefore, samples determined to have an IFN- $\gamma$  concentration greater than this range are reported as >10 IU/ml.

# 5.5 Saving and loading files

#### 5.5.1 Saving files

Upon opening the QuantiFERON R&D Analysis Software for the first time, the software creates the folder path **My Documents\QuantiFERON** or **Documents\QuantiFERON** depending on your Windows operating system. By default, all files are saved to subfolders within this folder, and are given default file names (Table 3).

Table 3. File names and extensions

File type	File extension	Subfolder name	Default file name
Format	.qff	Format	OperatorDate
Results	.qdf	Save	Date_RunNumber
PDF results	.pdf	PDF	Date_RunNumber

#### File types and description

• Format files: Select Save Format to save a completed format to file which can be reloaded for use with future analysis.

Note: Run Details information is not retained within a saved format file.

 Results files: Select Save File to save a copy of the results to file which can be reloaded for further analysis.

Note: Run Details information is retained within a saved result file.

 PDF files: Select Save As PDF to save the results report in PDF format for electronic viewing by others. It is recommended that PDF files are used for record-keeping purposes.

Note: PDF files contain all information available in the printed report.

#### 5.5.2 Loading files

- Format files can be reloaded within the QuantiFERON R&D Analysis Software by selecting Load Format.
- Results can be reloaded by selecting Load File at any time.
- After reloading a results file, click Calculate to regenerate results.

# 5.6 End of analysis

- The software enables the user to work on one run at a time (single session mode).
- Using the New Test feature, the user can work on a second run without having to restart the software.
- Click **New Test** to clear all entered information. This enables new assay data to be analyzed.
- Click **Close** to close the program.

For your convenience, the information previously entered into the **Run Date**, **Kit Batch Details** and **Operator** fields in the Run Details screen is retained as default until the software is closed.

These details can be modified as required.

# 6 Maintenance

# 6.1 Upgrading the QuantiFERON R&D Analysis Software

You may need to update the QuantiFERON R&D Analysis Software in case a new version becomes available.

6.1.1 Downloading the QuantiFERON R&D Analysis Software version update

Software updates for QuantiFERON R&D Analysis Software are available at the QuantiFERON product webpage at **www.qiagen.com**.

Note: You will be notified when a software upgrade is needed.

To download the software version update:

- 1. In the QuantiFERON product webpage, go to Product Resources > Operating Software.
- 2. Click Show Details.

You will be redirected to the download page of the software.

- 3. Click Download.
- 4. After the download is complete, save the downloaded zip file to an appropriate location within the computer.
- 6.1.2 Uninstalling the existing QuantiFERON R&D Analysis Software version

Note: Before you upgrade the software, ensure that you have uninstalled the existing version

To uninstall the existing software version:

- 1. From your Home screen, navigate to Control Panel > Programs and Features.
- In the Uninstall or change a program window, select the.exe file for the existing QuantiFERON R&D Analysis Software version.
- 3. Click Uninstall.
- 4. Wait until the uninstallation status becomes completed.

#### 6.1.3 Installing the QuantiFERON R&D Analysis Software version update

Note: Before you install the software version update, ensure that you have uninstalled your existing version of the QuantiFERON R&D Analysis Software. For more information about uninstalling the existing version of the software, see Uninstalling the existing QuantiFERON R&D Analysis Software version.

- Navigate to the folder where the downloaded zip file is located. For more information about downloading the software update, see Downloading the QuantiFERON R&D Analysis Software version update.
- 2. Extract the contents of the zip file in the same location.
- 3. Double-click .exe file.

# 7 Troubleshooting

# 7.1 Contacting QIAGEN Technical Services

Whenever you encountered a QuantiFERON R&D Analysis Software error, ensure that you have the following information at hand:

- Software version
- Sample input material
- Detailed description of the error situation

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

**Note**: Information about the latest software and protocol versions can be found at **www.qiagen.com**. In some cases, updates may be available for addressing specific problems.

# 7.2 Error messages in QuantiFERON R&D Analysis Software

Refer to this table for the description of the error messages in QuantiFERON R&D Analysis Software.

Table 4. Description of error messages

Error message	Description
QC Result Fail: ELISA test run invalid	The Standard Curve did not meet the QC criteria and the ELISA must be repeated to have a valid plate.
Note: The mean OD value for the Zero Standard should be ≤0.150. Plate washing procedures should be investigated	The OD value of the Zero Standard >0.150 is likely caused by insufficient washing of the plate.
	Plate washing procedure should be investigated to ensure validity of results.
>10 IU/ml are flagged using the ¶ or # symbols	The ¶ symbol indicates that the result is outside the linear range of the assay. The # symbol indicates that a value outside the plate reader range was used to determine the result –non numerical characters include OUT or ***.
	In the case of non-numerical entries, an OD of 4.000 is used to calculate the $IU/ml$ result.

# 8 Ordering Information

Product	Contents	Cat. no.	
QuantiFERON R&D Analysis Software	n/a	1095642	
Related Products			
QuantiFERON ELISA	Contains Microtiter Plate, Conjugate (100x), IFN Gamma Standard, Green Diluent, Wash Buffer 20x, Enzyme Substrate Solution, and Enzyme Stopping Solution	626410	

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# 9 Document Revision History

Date	Changes
December 2020	Initial release

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