February 2018

QuantiFERON®-CMV Analysis Software (v3.10) Instructional Guide

For installation, setup and use of the QuantiFERON-CMV (QF-CMV) Analysis Software

IVD	For in vitro diagnostic use
CE	
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www.QuantFERON.com

Contents

1 Introduction

This guide contains all the information required to download QuantiFERON-CMV (QF-CMV) Analysis Software, version 3.10. QuantiFERON-CMV Analysis Software is a PC-based program for calculating QuantiFERON-CMV (QF-CMV) test results. The software may be downloaded from **www.QuantiFERON.com**. Alternatively, contact your authorized QuantiFERON distributor to obtain a copy via email.

Customers will be advised by QIAGEN or their QuantiFERON distributor as new editions of the software are made available.

This guide provides detailed step-by-step instructions on the use of QuantiFERON-CMV Analysis Software. It is recommended that the user read these instructions before referring to the Software Quick Guide (available at **www.QuantiFERON.com**).

Table 1. Release information

Parameter	Version
QuantiFERON-CMV Analysis Software Version	3.10

1.1 General information

1.1.1 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-CMV 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 (see back cover).

For up-to-date information about QuantiFERON-CMV, visit **www.QuantiFERON.com**.

1.1.2 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 (see back cover).

1.1.3 Version management

This document is the QuantiFERON-CMV Analysis Software (v3.10) Instructional Guide version 1.0.

1.2 Intended use of QuantiFERON-CMV Analysis Software

QuantiFERON-CMV Analysis Software is for use with the QuantiFERON-CMV ELISA.

1.3 Requirements for QuantiFERON-CMV Analysis Software

System requirements are shown in Table 2.

Table 2. System requirements

Description	Minimum requirement
Operating system	Microsoft® Windows® 7 or 8
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	Minimum screen resolution set to 800 x 600 pixels, but higher resolution is recommended
Display text size	"Smaller – 100% (default)"

1.4 Software specifications

QuantiFERON-CMV Analysis Software, Version 3.10.

2 Installation

2.1 Software installation from web site

The most recent version of QuantiFERON-CMV Analysis software is available for download at **www.QuantiFERON.com** under Technical Info. To download the software you must enter your contact information, read and accept the terms of the End User License Agreement, and submit. The download screen will then appear and the software *.exe file can be saved to an appropriate location on the computer's hard drive. First, download the *.exe file from the website and save "QF-CMV v.3.10.exe" to a location on your hard drive. In addition, you may create a shortcut on your desktop. Start the software by double clicking on "QF-CMV v3.10.exe" or shortcut. During the very first startup, the software will create a folder "QuantiFERON" and subfolders on your personal directory (e.g., "My Documents\QuantiFERON", depending on your computer operating system).

3 Software Features

QuantiFERON-CMV Analysis Software is a PC-based program for calculating QuantiFERON-CMV (QF-CMV) ELISA results.

Software features:

- Record test-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 tests
- Assign subject's identity to each sample
- Obtain quality control analysis of standard curve
- Export data and results to other applications
- Select from an array of reporting options

4 Getting Started

4.1 Starting the QF-CMV v3.10 software

Double click on the "QF-CMV v3.10 Software" shortcut, or directly on the *.exe file, to open the QuantiFERON-CMV Analysis Software.

The program will open to the first of four screens that sequentially progress through the calculations. These four screens are:

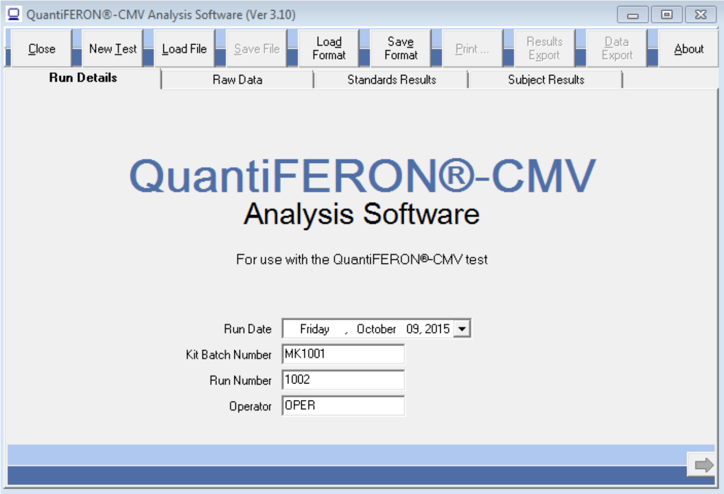
- **Run Details**: Enter general test details such as the Run Date, Run Number, Kit Batch Number, and Operator.
- **Raw Data**: Enter Optical Density (OD) values and apply a format that defines the standards and samples.
- **Standards Results**: View standard curve results, which indicate the validity of the ELISA.
- **Subject Results**: View test results for each sample. Save, print, and export data and results.

The four screens are described in more detail below and on the following pages.

4.2 Screens in the QF-CMV v3.10 software

4.2.1 Run Details and Raw Data screens

On the "Run Details" screen, enter the run date using the drop-down calendar, the kit batch number (shown on the QuantiFERON-CMV ELISA outer box label), the run number and the Operator. Select the "Raw Data" tab or click the arrow in the lower right corner to advance to the next screen.



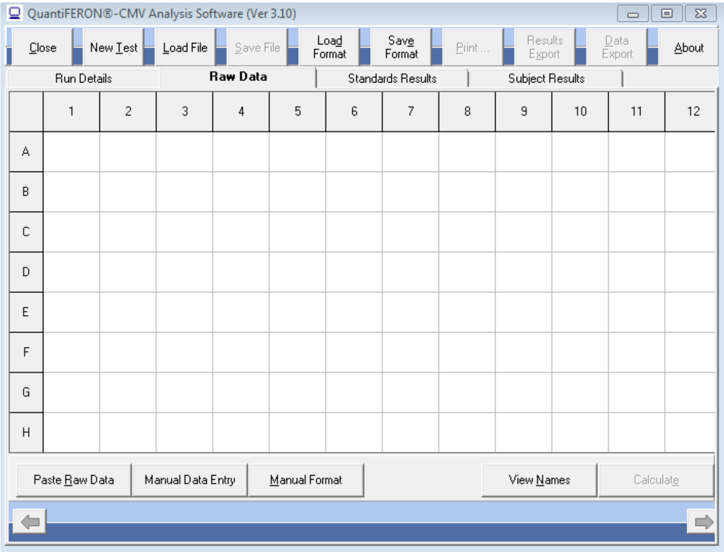
QuantiFERON®-CMV

Analysis Software

For use with the QuantiFERON®-CMV test

Run Date: Friday , October 09, 2015
Kit Batch Number: MK1001
Run Number: 1002
Operator: OPER

Figure 1. “Run details” screen.



	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Figure 2. “Raw data” screen.

4.2.2 Data entry

QuantiFERON-CMV Analysis Software uses optical density (OD) values as the basis for all calculations. The user does not need to perform any calculations prior to using the software, simply enter the raw data from the plate reader into the software.

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

4.2.2.1 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 to first be exported into a spreadsheet.

Select "Paste Raw Data". The data will be entered into the program's data cells.

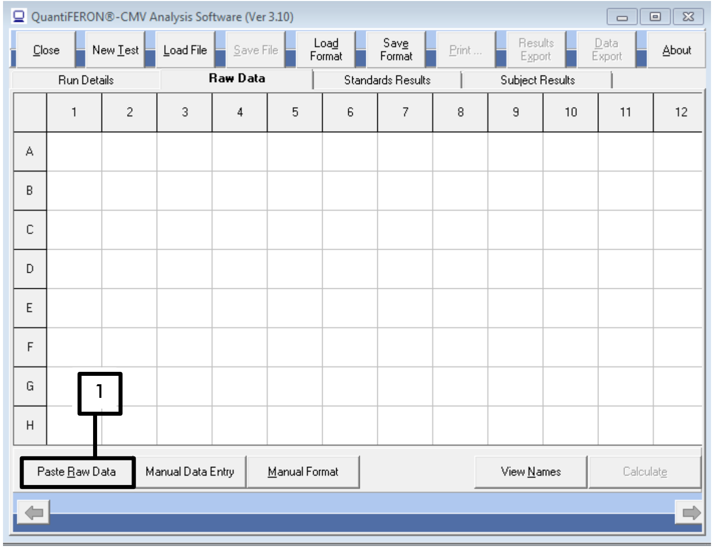
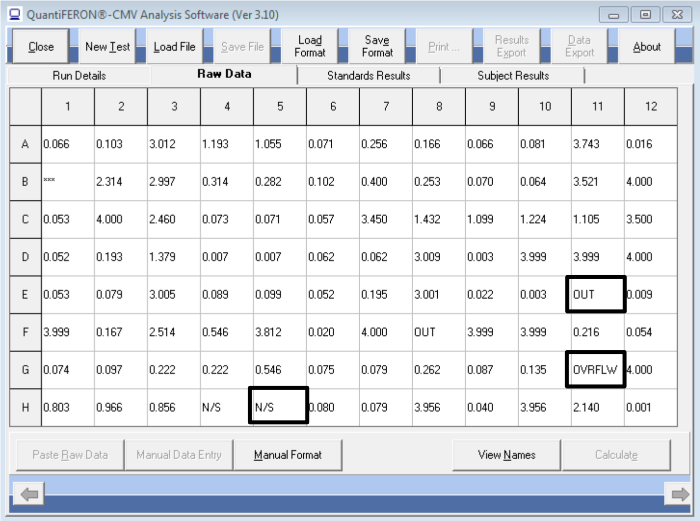


Figure 3. "Raw data" screen. 1 = "Paste Raw Data".



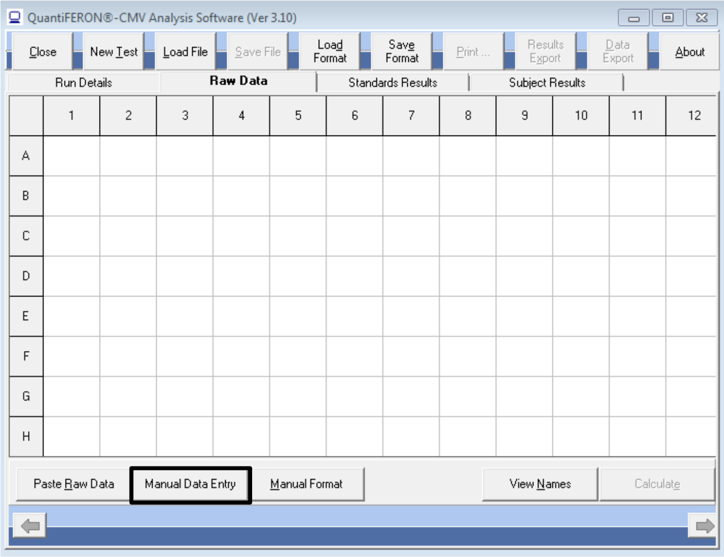
	1	2	3	4	5	6	7	8	9	10	11	12
A	0.066	0.103	3.012	1.193	1.055	0.071	0.256	0.166	0.066	0.081	3.743	0.016
B	***	2.314	2.997	0.314	0.282	0.102	0.400	0.253	0.070	0.064	3.521	4.000
C	0.053	4.000	2.460	0.073	0.071	0.057	3.450	1.432	1.099	1.224	1.105	3.500
D	0.052	0.193	1.379	0.007	0.007	0.062	0.062	3.009	0.003	3.999	3.999	4.000
E	0.053	0.079	3.005	0.089	0.099	0.052	0.195	3.001	0.022	0.003	OUT	0.009
F	3.999	0.167	2.514	0.546	3.812	0.020	4.000	OUT	3.999	3.999	0.216	0.054
G	0.074	0.097	0.222	0.222	0.546	0.075	0.079	0.262	0.087	0.135	OVRFLW	4.000
H	0.803	0.966	0.856	N/S	N/S	0.080	0.079	3.956	0.040	3.956	2.140	0.001

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.

4.2.2.2 Manual data entry

Select “Manual Data Entry”. Click on a cell to enter data manually. To store the value, click “Enter”. Alternatively, use the ↑ and ↓ arrows or the mouse to navigate to another cell or simply click on another cell.

When all data have been entered, click “Complete” on the “Manual Data Entry” toolbar to proceed.



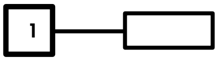


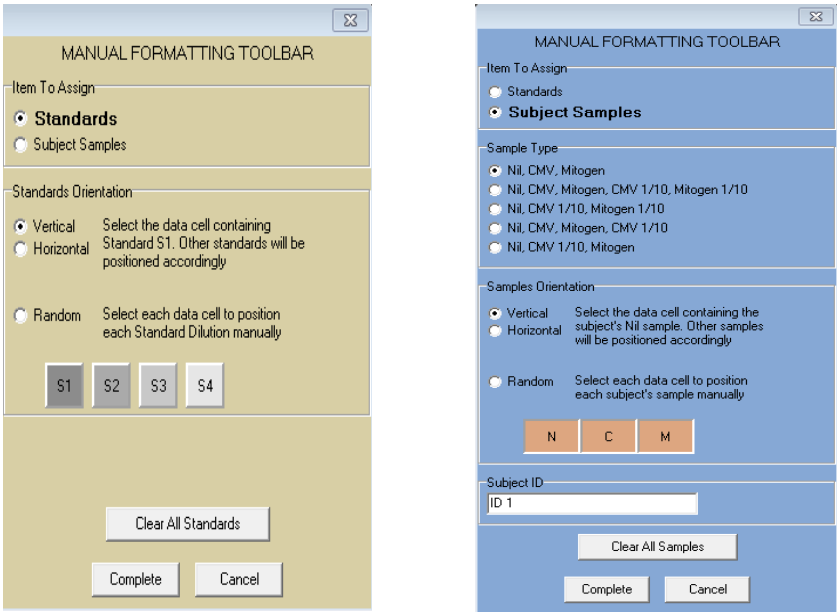
Figure 5. “Raw data” screen during manual data entry. 1 = Click “Complete” to end manual data entry.

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.

4.2.3 Analysis format

Before data can be analyzed, users must apply a format the cells that contain samples and those that are standards.

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.



MANUAL FORMATTING TOOLBAR

Item To Assign
● **Standards**
○ Subject Samples

Standards Orientation
● Vertical
○ Horizontal
Select the data cell containing Standard S1. Other standards will be positioned accordingly

○ Random
Select each data cell to position each Standard Dilution manually

MANUAL FORMATTING TOOLBAR

Item To Assign
○ Standards
● **Subject Samples**

Sample Type
● Nil, CMV, Mitogen
○ Nil, CMV, Mitogen, CMV 1/10, Mitogen 1/10
○ Nil, CMV 1/10, Mitogen 1/10
○ Nil, CMV, Mitogen, CMV 1/10
○ Nil, CMV 1/10, Mitogen

Samples Orientation
● Vertical
○ Horizontal
Select the data cell containing the subject's Nil sample. Other samples will be positioned accordingly

○ Random
Select each data cell to position each subject's sample manually

Subject ID
ID 1

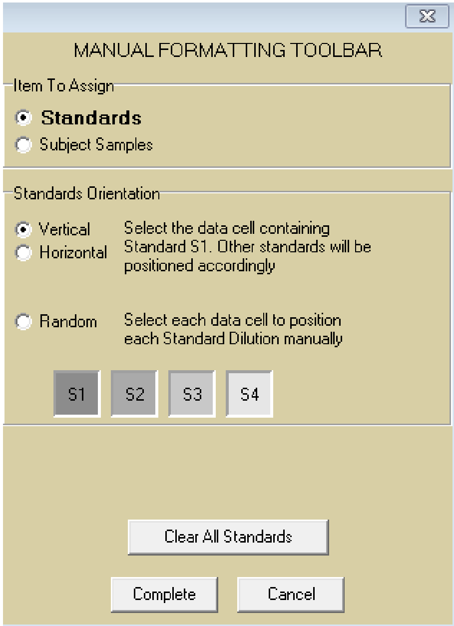
Figure 6. "Manual Formatting Toolbar" in "Standards" mode (left) and "Subject Samples" mode (right).

4.2.4 Standards

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

Once the set of standards, S1 to S4, has been assigned, the toolbar resets, 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.



MANUAL FORMATTING TOOLBAR

Item To Assign

● Standards
○ Subject Samples

Standards Orientation

● Vertical
○ Horizontal

Select the data cell containing Standard S1. Other standards will be positioned accordingly

○ Random

Select each data cell to position each Standard Dilution manually

Figure 7. "Manual Formatting Toolbar" in "Standards" mode.

To assign a set of standards (S1, S2, S3, S4), within "Standards" mode, select the radio button that corresponds to your choice of either vertical or horizontal standards orientation, then click on the cell in the "Raw Data" screen that contains the data for standard S1. The chosen cell will be 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 the "Random" radio button, and then manually position each of the standards S1 to S4, in order, by clicking on the appropriate cells within the "Raw Data" screen.

To delete a single set of standards, right-click on the colored block and select "Delete Block" from the pop-up menu. Alternatively, to delete all standards, select "Clear All Standards" on the "Manual Formatting Toolbar".

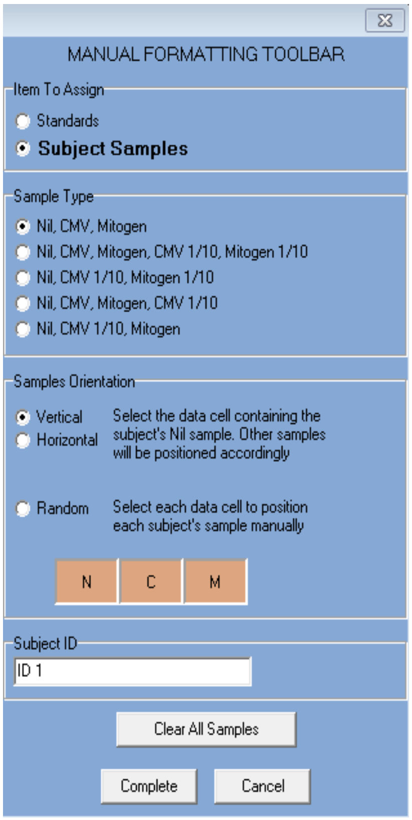
4.2.5 Subject Samples

To assign subject samples to the data, select “Subject Samples” on the “Manual Formatting Toolbar”.

To assign a dilution scheme to the data, select a radio button in the “Sample Type” list. This will assign the data into subject groups based on the dilution set selected.

To assign subject samples (either vertically or horizontally) select the corresponding radio button in the “Samples Orientation” list, then click on the cell in the “Raw Data” screen that contains the data for the first dilution of the subject group. The chosen cell will be designated as first dilution, and the other dilutions will be appropriately positioned in adjacent cells, in order.

To assign subject samples in a random manner, select “Random”, and then position each of the samples manually by clicking on the appropriate cells within the “Raw Data” screen.



MANUAL FORMATTING TOOLBAR

Item To Assign
○ Standards
● **Subject Samples**

Sample Type
● Nil, CMV, Mitogen
○ Nil, CMV, Mitogen, CMV 1/10, Mitogen 1/10
○ Nil, CMV 1/10, Mitogen 1/10
○ Nil, CMV, Mitogen, CMV 1/10
○ Nil, CMV 1/10, Mitogen

Samples Orientation
● Vertical
○ Horizontal
Select the data cell containing the subject's Nil sample. Other samples will be positioned accordingly

○ Random
Select each data cell to position each subject's sample manually

Subject ID
ID 1

Figure 8. “Manual Formatting Toolbar” in “Subject samples” mode.

Prior to assigning a sample to the data, the subject's name/ID can be entered into the "Subject ID" field on the toolbar. Alternatively, subject naming can be performed according to "Raw Data screen: Subject names" on page 15.

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

Once the standards and subject samples have been assigned, finish by selecting "Complete". Upon completing a format, it can be saved as a file and reloaded for analysis of future data, allowing the user to create just a few format files for all of their analysis needs.

See "Saving and Loading Files" on page 22 for more information.

By default, "Subject Sample" mode opens with undiluted samples ready to be assigned in a vertical orientation. Settings can be changed by selecting the appropriate radio (round) buttons.

It is recommended that the following samples are tested in parallel (and in this order):

- Nil, CMV Antigen, Mitogen, CMV Antigen (1/10), Mitogen (1/10)

The following subject sample options are also available:

- Nil, CMV Antigen, Mitogen
- Nil, CMV Antigen (1/10), Mitogen (1/10)
- Nil, CMV Antigen, Mitogen, CMV Antigen (1/10)
- Nil, CMV Antigen (1/10), Mitogen

Once the entire subject sample has been assigned, the toolbar is automatically ready to assign another sample of the same type. Subsequent subject samples are colored differently to assist recognition of individual subjects.

The "Sample Type" and "Sample Orientation" can be adjusted at any time in order to create a format containing a mixture of different QuantiFERON-CMV sample layouts.

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

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

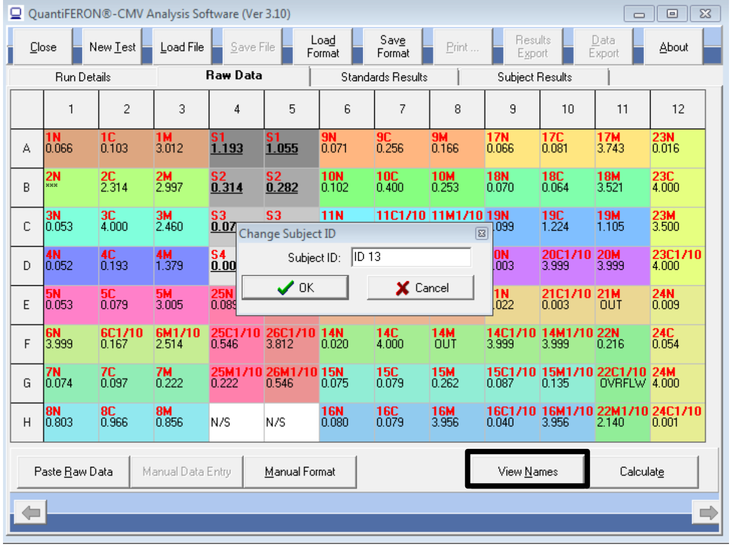
4.2.6 Raw Data screen: Subject names

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 via "View Names".

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

To change multiple subject names (IDs), select "View Names". If all subject names are to begin with an identical prefix (e.g., A009), then these characters can be entered into the "ID Prefix" field. Afterward, left-click on each subject's name in the list to add the remainder of the name manually.

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



Change Subject ID

Subject ID: ID 13

	1	2	3	4	5	6	7	8	9	10	11	12
A	1N 0.066	1C 0.103	1M 3.012	S1 1.193	S1 1.055	9N 0.071	9C 0.256	9M 0.166	17N 0.066	17C 0.081	17M 3.743	23N 0.016
B	2N ***	2C 2.314	2M 2.997	S2 0.314	S2 0.282	10N 0.102	10C 0.400	10M 0.253	18N 0.070	18C 0.064	18M 3.521	23C 4.000
C	3N 0.053	3C 4.000	3M 2.460	S3 0.07	S3	11N	11C1/10	11M1/10	19N .099	19C 1.224	19M 1.105	23M 3.500
D	4N 0.052	4C 0.193	4M 1.379	S4 0.00					0N .003	20C1/10 3.999	20M 3.999	23C1/10 4.000
E	5N 0.053	5C 0.079	5M 3.005	25N 0.08					1N .022	21C1/10 0.003	21M OUT	24N 0.009
F	6N 3.999	6C1/10 0.167	6M1/10 2.514	25C1/10 0.546	26C1/10 3.812	14N 0.020	14C 4.000	14M OUT	14C1/10 3.999	14M1/10 3.999	22N 0.216	24C 0.054
G	7N 0.074	7C 0.097	7M 0.222	25M1/10 0.222	26M1/10 0.546	15N 0.075	15C 0.079	15M 0.262	15C1/10 0.087	15M1/10 0.135	22C1/10 OVRFLW	24M 4.000
H	8N 0.803	8C 0.966	8M 0.856	N/S	N/S	16N 0.080	16C 0.079	16M 3.956	16C1/10 0.040	16M1/10 3.956	22M1/10 2.140	24C1/10 0.001

Figure 9. Renaming subject samples using "View Names".

Once the format has been generated, select "Calculate". The standard curve for the assay will be automatically analyzed, and the "Standards Results" screen will be displayed. For the "Calculate" function to be enabled, at least two blocks of Standards and one Subject Samples block must be assigned.

4.2.7 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.

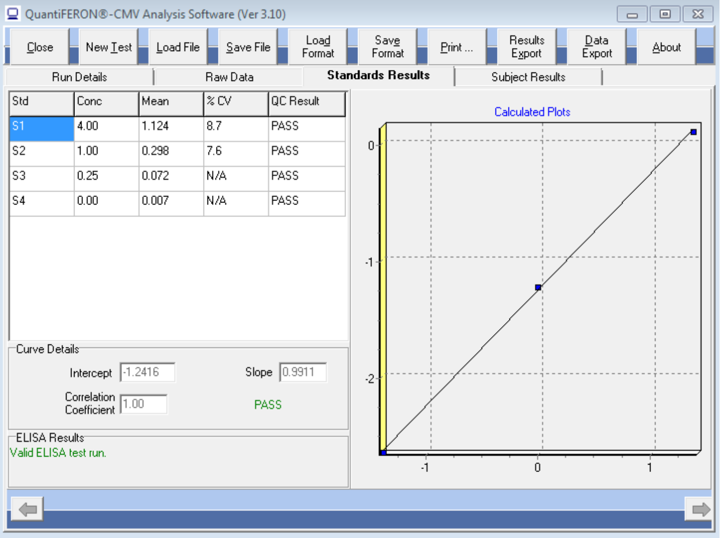
The "Standards Results" screen provides information that is directly related to the acceptance criteria of the ELISA:

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

The results of the QC acceptance criteria for the Standard Curve are shown as PASS or FAIL. For further details of the acceptance criteria, see the *QuantiFERON-CMV (QF-CMV) ELISA Package Insert*.

The following information is also displayed:

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



Std	Conc	Mean	% CV	QC Result
S1	4.00	1.124	8.7	PASS
S2	1.00	0.298	7.6	PASS
S3	0.25	0.072	N/A	PASS
S4	0.00	0.007	N/A	PASS

Curve Details
Intercept -1.2416
Slope 0.9911
Correlation Coefficient 1.00
PASS

ELISA Results
Valid ELISA test run.

Figure 10. "Standards Results" screen.

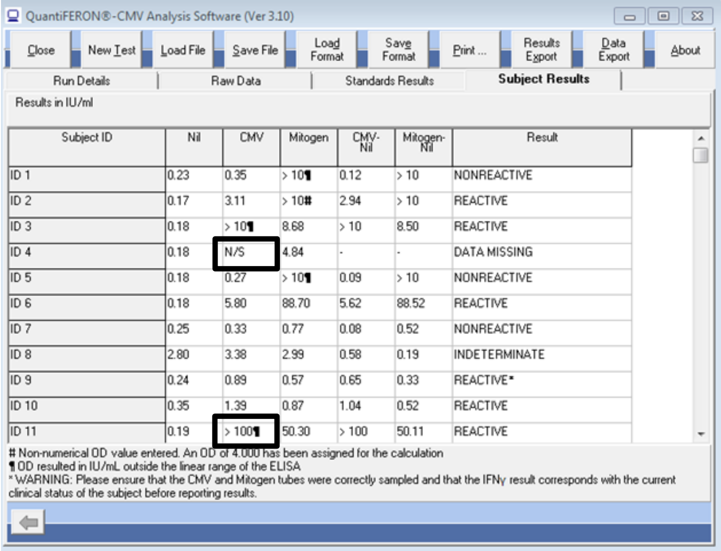
A statement indicating whether the ELISA is "Valid" or "Invalid", based on the QC criteria, is provided in the "ELISA Results" section (bottom left corner of the screen). This statement is also displayed on all printed and PDF reports.

- 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-γ) is greater than 0.150 OD units, a statement is displayed suggesting that ELISA plate washing procedures be investigated. This statement is also displayed on all printed and PDF reports.

Select the "Subject Results" tab to proceed to the next screen.

4.2.8 Standard curve

The standard curve is used to calculate a value (IU/ml of IFN-γ) for each subject's samples. The software multiplies the value of the plasma sample calculated from the standard curve by the dilution factor assigned at the sample formatting step; based on these values, the result (concentration of IFN-γ) for each subject is reported.



Results in IU/ml

Subject ID	Nil	CMV	Mitogen	CMV-Nil	Mitogen-Nil	Result
ID 1	0.23	0.35	> 10¶	0.12	> 10	NONREACTIVE
ID 2	0.17	3.11	> 10#	2.94	> 10	REACTIVE
ID 3	0.18	> 10¶	8.68	> 10	8.50	REACTIVE
ID 4	0.18	N/S	4.84	-	-	DATA MISSING
ID 5	0.18	0.27	> 10¶	0.09	> 10	NONREACTIVE
ID 6	0.18	5.80	88.70	5.62	88.52	REACTIVE
ID 7	0.25	0.33	0.77	0.08	0.52	NONREACTIVE
ID 8	2.80	3.38	2.99	0.58	0.19	INDETERMINATE
ID 9	0.24	0.89	0.57	0.65	0.33	REACTIVE*
ID 10	0.35	1.39	0.87	1.04	0.52	REACTIVE
ID 11	0.19	> 100¶	50.30	> 100	50.11	REACTIVE

Non-numerical OD value entered. An OD of 4.000 has been assigned for the calculation
¶ OD resulted in IU/mL outside the linear range of the ELISA
* WARNING: Please ensure that the CMV and Mitogen tubes were correctly sampled and that the IFNγ result corresponds with the current clinical status of the subject before reporting results.

Figure 11. "Subject Results" screen. NS = No sample in the well. ¶ = Sample result is outside the linear range of the assay.

The result "N/S" is reported if there is no sample in the indicated well. This also applies when a dilution series is selected and the highest dilution is missing and the lower dilution is beyond the linear OD range of the assay.

Samples that have results beyond the linear range of the assay are reported as ">10 IU/ml" or ">100 IU/ml" depending on the dilution factor of that sample, and are flagged using the "¶" symbol. "#" indicates a non-numerical OD value was entered and an OD of 4.000 has been assigned for the calculation. Non-numerical characters include "OUT", "OVRFLW" or "***". A "REACTIVE*" result is indiated by a "*" and is accompanied by the statement, "*WARNING: Please ensure that the CMV and Mitogen tubes were correctly sampled and that the IFN-γ result corresponds with the current clinical status of the subject before reporting results."

5 Data Export

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

To export results, select “Results Export”. An “Export Type” pop-up window appears with the two options for file export “Export to Clipboard” (default) and “Export to File”. If “Export to Clipboard” is selected by clicking “OK”, a “Results Copied to Windows Clipboard” pop-up window appears. After clicking “OK” on this pop-up window, data can be pasted into a spreadsheet.

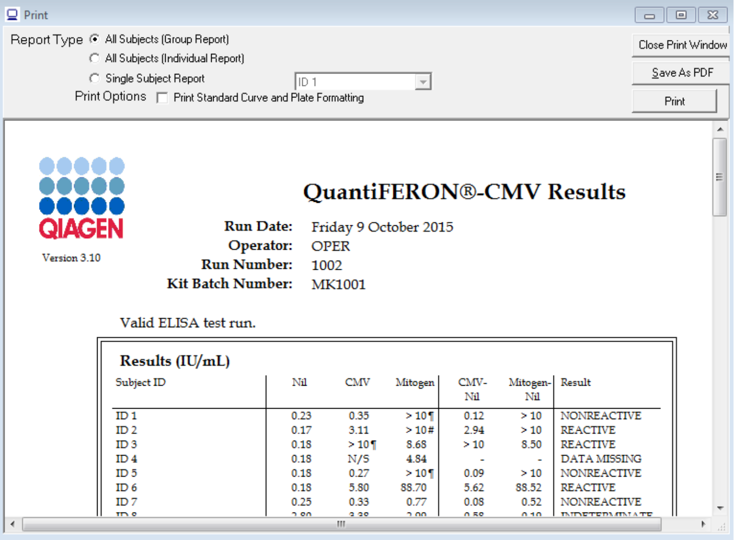
Alternatively, if the “Export to File” option is manually selecting by clicking “OK” in the “Export Type” window, another pop-up window appears, allowing you to save the results as a file on your computer. After clicking “Save” on this pop-up window, data are saved as a text file.

Similarly, selecting “Data Export” offers you the choice 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 that described above for “Results Export”.

Note: The optional step of exporting data is not required to obtain QuantiFERON-CMV 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.

6 Reports

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



Report Type ● All Subjects (Group Report)
○ All Subjects (Individual Report)
○ Single Subject Report ID 1
Print Options ☐ Print Standard Curve and Plate Formatting

QuantiFERON®-CMV Results

Run Date: Friday 9 October 2015
Operator: OPER
Run Number: 1002
Kit Batch Number: MK1001

Version 3.10

Valid ELISA test run.

Results (IU/mL)

Subject ID	Nil	CMV	Mitogen	CMV-Nil	Mitogen-Nil	Result
ID 1	0.23	0.35	> 10¶	0.12	> 10	NONREACTIVE
ID 2	0.17	3.11	> 10#	2.94	> 10	REACTIVE
ID 3	0.18	> 10¶	8.68	> 10	8.50	REACTIVE
ID 4	0.18	N/S	4.84	-	-	DATA MISSING
ID 5	0.18	0.27	> 10¶	0.09	> 10	NONREACTIVE
ID 6	0.18	5.80	88.70	5.62	88.52	REACTIVE
ID 7	0.25	0.33	0.77	0.08	0.52	NONREACTIVE

Figure 12. Summary report.

Select a “Report Type” radio button to print a particular report:

- “All Subjects (Group Report)” 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)” prints the results for each subject on a separate page.
- “Single Subject Report” prints the results for one subject, as selected from the drop-down box.

Select “Print Standard Curve and Plate Formatting” to generate an additional report page which includes the plate layout and standard curve.

Select the “Close Print Window” to close the printing screen and return to the main software.

Alternatively, reports can be saved as PDF files by selecting “Save As PDF”, as described in “Saving and Loading Files”, page 22.

Once the desired type of summary report is selected, click “Print” to print the report to the computer’s default printer.

The upper range of the QuantiFERON-CMV ELISA is 10 IU/ml. Therefore, samples determined to have an IFN-γ concentration greater than this range are reported as >10 IU/ml or >100 IU/ml.

7 Saving and Loading Files

7.1 Saving files

Upon opening the QF-CMV Analysis Software for the first time, the software creates a folder called "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	Sub-folder name	Default file name
Format	.qft	Format	OperatorDate
Results	.qdf	Save	Date_RunNumber
PDF results	.pdf	PDF	Date_RunNumber

File type and description:

- **Format files**. Select "Save Format" to save a completed format to file, which can be reloaded for use with future analysis.

  "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.

  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 be used for record-keeping purposes.

  PDF files contain all of the information available in the printed report, but do not contain space for signature and date

7.2 Loading files

- Format files can be reloaded within the QF-CMV Analysis Software by selecting "Load Format".
- Results can be reloaded by selecting "Load File" at any time.
- After reloading a results file, "Calculate" must be selected in order to regenerate results.

8 End of Analysis

- The software allows the user to work on one run at a time (single session mode).
- Using the “New Test” function, the user can work on a second run without having to restart the software.

  The information within the “Run details” tab will need to be updated.*
- Selecting “New Test” clears all entered information, enabling new assay data to be analyzed.
- Selecting “Close” will close the program.

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* For convenience, the information previously entered into the “Run Date”, “Kit Batch Details” and “Operator” fields on the Run Details screen is retained as default until the software is closed. These details can be modified as required.

9 Frequently Asked Questions

Q. Why do I need to use the QuantiFERON-CMV Analysis Software? Can I use my own spreadsheet to calculate results instead?

A. You can use your own spreadsheet to calculate QuantiFERON-CMV test results. However, the calculations required to obtain the correct IFN-γ values are logarithm based. Therefore, it is essential that you follow the instructions in the "Calculations and Test Interpretation" section of the QuantiFERON-CMV (QF-CMV) ELISA Package Insert.

The QuantiFERON-CMV Analysis Software has already been validated to ensure that the quality control checks – and the results obtained – are accurate and reproducible. The QuantiFERON-CMV Analysis Software also has the added flexibility of simple one-click formatting of standards and samples, allowing for the format to be easily updated as changes to your ELISA test layout arise.

Q. When a newer version of the software is available, should I uninstall the old version of the QuantiFERON-CMV Analysis Software? How do I do this?

A. Yes, you should always uninstall obsolete versions of the software before installing the new software. The new version of the QF-CMV software may contain changes to the test criteria; therefore, it is essential that only the current version of the software be available for use.

To uninstall the old software, simply remove the "QF-CMV v.3.10.exe" that was copied to your hard drive during installation.

Q. I would like to contact QIAGEN to discuss my data/results/technique. What information should I provide in order to obtain a prompt reply?

A. It is best to provide the QuantiFERON-CMV Analysis Software results file (*.qdf) which by default is located in the folder "My Documents\QuantiFERON\Save". It is best to provide a detailed outline of your enquiry, kit lot number and any other information you feel is relevant.

Q. Why can't data cells for standards be blank or contain text?

A. Because the standard curve is used to derive QuantiFERON-CMV ELISA results, blank values or text may reduce the quality of the standard curve.

Q. When I open the QuantiFERON-CMV Analysis Software, some of the text appears to be missing, as though it is covered by other text. What is the problem?

A. The computer's Display Settings may be incorrectly setup for the software. Make sure that the Display settings are set to "Smaller – 100% (default)".

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QuantiFERON-CMV Analysis Software is for use with QuantiFERON-CMV ELISA and Blood Collection Tubes. For comprehensive instructions for use, please refer to the *QuantiFERON-CMV ELISA Package Insert*, at **www.QuantiFERON.com**.

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