

QuantiFERON®-TB Gold Plus Analysis Software User Manual

Version 2.71

For use with QuantiFERON®-TB Gold Plus Assay



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Sample to Insight

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1 Introduction

This guide contains the information required to download QuantiFERON®-TB Gold Plus (QFT®-Plus) Analysis Software, Version 2.71. The QuantiFERON-TB Gold Plus Analysis Software is a PC-based program for calculating QuantiFERON-TB Gold Plus (QFT-Plus) test results. The software may be downloaded from **www.qiagen.com**. Alternatively, contact your authorized QuantiFERON distributor.

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-TB Gold Plus Analysis Software. It is recommended that you read these instructions before referring to the Software Quick Guide, available at **www.qiagen.com**.

1.1 About this user manual

This user manual provides information about the QuantiFERON-TB Gold Plus Analysis Software in the following sections:

- Introduction
- General Description
- Installation Procedures
- Operating Procedures
- Maintenance
- Troubleshooting
- Technical Specifications
- Appendices

The appendices contain the following information:

• Frequently Asked Questions

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-TB Gold Plus 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.

Website: support.qiagen.com

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QuantiFERON-TB Gold Plus Analysis Software version
- Error code
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Copy of log files

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-TB Gold Plus Analysis Software

QuantiFERON-TB Gold Plus Analysis Software is for optional use with the QuantiFERON-TB Gold Plus Assay.

For in vitro diagnostic use

Note: The QFT-Plus assay and software is to be used by trained personnel in a professional laboratory environment.

1.4 Symbols on the QuantiFERON-TB Gold Plus Analysis Software

The following symbols may appear in the user manual or on the packaging and labelling:

Symbol	Symbol definition
CE	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
EC REP	Authorized representative in the European Community / European Union
IVD	In vitro diagnostic medical device
REF	Catalog number
MAT	Material number (i.e., component labeling)
GTIN	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Manufacturer
Ξi	Consult instructions for use
	Warning/caution or Caution, consult accompanying documents

3 General Description

The QuantiFERON-TB Gold Plus (QFT-Plus) assay is an *in vitro* diagnostic test using a peptide cocktail simulating ESAT-6 and CFP-10 proteins to stimulate cells in heparinized whole blood. Detection of Interferon- γ (IFN- γ) by Enzyme-Linked Immunosorbent Assay (ELISA) is used to identify *in vitro* responses to those peptide antigens that are associated with Mycobacterium tuberculosis infection.

QFT-Plus is an indirect test for *M. tuberculos* is infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

QuantiFERON-TB Gold Plus Analysis Software is for optional use with the QuantiFERON-TB Gold Plus Assay.

For in vitro diagnostic use

Table 1. Release information

Parameter	Version
QuantiFERON-TB Gold Plus Analysis Software	2.71 (including all sub-versions)

3.1 Software features

QuantiFERON-TB Gold Plus Analysis Software is a PC-based program for calculating QuantiFERON-TB Gold Plus (QFT-Plus) Assay results.

The following features are available in QuantiFERON-TB Gold Plus Analysis Software version 2.71:

- 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 Installation Procedures

4.1 Software installation

The most recent version of QuantiFERON-TB Gold Plus Analysis software is available for download at **www.qiagen.com** under Technical Resources.

4.1.1 Downloading the QuantiFERON-TB Gold Plus Analysis Software

To download the software:

- 1. In the QuantiFERON-TB Gold Plus product webpage, click Technical Resources.
- 2. In the Analysis Software section, click Software Downloads.
- 3. Enter your contact information:
 - 3a. Enter your name in the First Name field.
 - 3b. Enter your surname in the Last Name field.
 - 3c. Specify an email address in the Email address field.
 - 3d. In the Phone field, enter a valid phone number.
 - 3e. Enter your job title in the Job Title field.
 - 3f. Specify the name of your organization in the **Organization** field.
 - 3g. Enter your location's zip code in the **ZIP code** field.
 - 3h. Select your country of residence from the Country list.
- Read the terms of agreement. Check the Yes, I accept the End-User Software License Agreement box to confirm.
- 5. Check the I'm not a robot captcha box.
- 6. Click Submit.

The software will be downloaded. Save the downloaded software zip file to your preferred location in your computer's hard drive.

Note: Optionally, you may create a shortcut on your desktop.

4.1.2 Installing the QuantiFERON-TB Gold Plus Analysis Software

To install the software:

- 7. Navigate to the folder where the zip file is located.
- 8. Extract the contents of the zip file in the same location.
- 9. Double-click the QFT_TB_GoldPlus_v.2.71.2.exe.

 In the Properties dialog box, click the Digital Signatures tab. Confirm that the downloaded file originates from QIAGEN.

The signature list should only contain QIAGEN GmbH as the name of the signer.

Note: During the first start-up, a QuantiFERON folder is created along with its subfolders on your personal directory (e.g., "My Documents\QuantiFERON" depending on your computer's operating system).

4.2 System requirements

System requirements are shown in Table 2.

Note: Appropriate user access control on any computer running the QFT-Plus Analysis software should be established by the computer administration to prevent information disclosure prior to use. Please ensure that malware protection is available and up to date prior to downloading the software.

Table 2. Workstation 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	Minimum screen resolution set to 800 x 600 pixels, but higher resolution is recommended
Operating system	Microsoft® Windows® 7, 8 or 10
Processor	Intel® Pentium® processor, or equivalent 1-GHz processor or higher, dependent on operating system

4.2.1 Software upgrade

You may need to update the QuantiFERON-TB Gold Plus Analysis Software in case a new version becomes available. Software updates for QuantiFERON-TB Gold Plus Analysis Software are available for download **www.qiagen.com**. Go to **Technical Resources** > **Analysis Software** to download the latest QuantiFERON -TB Gold Plus Analysis Software version. Save the downloaded file in your preferred location.

5 Operating Procedures

Before proceeding, we recommend that you familiarize yourself with the features of the software by referring to Software features.

5.1 Starting the QuantiFERON-TB Gold Plus Analysis Software

From your Home screen, double-click the **QFT-Plus v2.71** icon on your desktop to open the QuantiFERON-TB Gold Plus 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.

Raw Data

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

• Standards Results

O 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.

See Screens in the QFT-Plus Software for a detailed description of these screens.

5.2 Screens in the QFT-Plus Software

5.2.1 Run Details screen

Perform these steps in the Run Details screen:

1. Select your preferred language. Click **OK** to proceed.

QuantiFERON8-TB Gold Plus (Ver 2.71.2)	_ 0	23
QuantiFERON®-TB Gold Plus		
Analysis Software		
Please select a language: English		
OK		

Figure 1. Language selection screen.

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

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

- 4. Specify the run number in the **Run Number** field.
- 5. Specify the operator in the **Operator** field.
- 6. Click the Raw Data tab or click the arrow icon in the lower right of the screen to move to the next screen.

Raw Data	Standards Results	1			
	Raw Data Standards Results Subject Results				
Run Date	Tuesday , July	11, 2017 🖉 🗸			
Kit Batch Number	r 1				
Run Number	r 1				
Operator	r 1				
	An Run Date Kit Batch Number Run Number	Analysis Softw	Run Date Tuesday , July 11, 2017 T Kit Batch Number 1 Run Number 1	Run Date Tuesday , July 11, 2017 🐨 Kit Batch Number 1 Run Number 1	Run Date Tuesday , July 11, 2017 🗊* Kit Batch Number Run Number 1

Figure 2. Run Details screen.

5.2.2 Raw Data screen

The QuantiFERON-TB Gold Plus 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.

Close	New	Test	Load File	Save File	Loa Forr		Save Format	Print	Result Expor		Data Export	About
F	tun Details		Raw	Data	St	Standards Results			Subject Results			
	1	2	3	4	5	6	7	8	9	10	11	12
А												
В												
С												
D												
E												
F												
G												
н												
Past	e Raw Data	C	efault Forma	it Ma	nual Data E	intry	Manual Fo	rmat	View Nar	nes	Calcu	ulate



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 to first be exported into a spreadsheet.

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

🛛 Quantil	FERON®-TB	Gold Plus (V	er 2.71.2)									0 11
Close	New	Test	Load File	Save File	Loa Form		Save Format	Print	Resul Expo		Data xport	About
F	Run Details		Raw	Data	St	andards R	Results	Subject Results				
	1	2	3	4	5	6	7	8	9	10	11	12
Α												
В												
с												
D												
E												
F												
G												
н												
Past	te Raw Data	D	efault Forma	t Ma	nual Data E	ntry	Manual For	mat	View Na	mes	Calcu	ilate
¢												

Figure 4. Raw Data screen. 1 = "Paste Raw Data".

Clos	e N	lew Test	Load File	Save		.oad ormat	Save Format	Print		sults port	Data Export	Abou
	Run Detai	ls	Raw Data			Standards Results			Subject Results			
	1	2	3	4	5	6	7	8	9	10	11	12
A	0,034	0,123	0,012	0,015	0,026	1,445	1,475	0,023	0,013	0,015	2,235	0,567
В	0,045	0,145	0,345	0,016	0,025	0,356	0,371	0,123	0,657	0,015	2,645	0,546
С	0,061	2,156	0,456	0,015	0,034	0,123	0,109	0,154	0,016	0,893	2,234	0,732
D	3,248	3,675	2,134	1,02	0,034	0,022	0,021	3,020	3,056	3,012	3,098	3,002
E	0,38	0,017	0,027	0,023	0,134	0,135	0,014	0,016	0,13	0,034	0,034	0,056
F	0,502	0,016	0,037	0,135	0,12	0,169	0,017	0,984	2,91	0,602	0,034	0,012
G	2,35	1,125	0,037	0,024	0,023	0,409	0,724	0,392	2,464	0,807	0,034	2,291
н	3,123	3,098	OUT	OUT	1,124	OUT	2,192	3,322	3,417	3,311	3,123	3,764
Pa	ste Raw Da	ita	Default Forr	nat	Manual Dat	a Entry	Manual Fo	ormat	View N	Vames	Calo	ulate

Figure 5. "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-TB Gold Plus ELISA and may indicate the need to service the plate reader.

Manual data entry

Select **Manual Data Entry**. Click on 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.

New	Test	Load File	Save File		oad rmat	Save Format	Print	Resu Expo		Data Export	Abo
un Details		Ray	v Data		Standards	Results	Subje	ct Results	1		
1	2	3	4	5	6	7	8	9	10	11	12
)[
Raw Data		Default Form	hat M	anual Data	Entry	Manual Fo	rmat	View Na	imes	Cal	culate
Nev	Test	File	File			Format	Print			Export	Abou
un Details		Ran	w Data	1	Standards	Results	Subje	ct Results			
1	2	3	4	5	6				1	1	1
0,034				-		7	8	9	10	11	12
	0,123	0,012	0,015	0,026	1,445	1,475		9 0,013	10 0,015	2,235	0,567
0,045	0,123 0,145	0,012	0,015	0,026	1,445 0,356		0,023				
0,045 0,061						1,475	0,023	0,013	0,015	2,235	
	0,145	0,345	0,016	0,025	0,356	1,475 0,371	0,023	0,013 0,657	0,015 0,015	2,235	0,567
0,061	0,145 2,156	0,345 0,456	0,016	0,025	0,356	1,475 0,371 0,109	0,023 0,123 0,154	0,013 0,657	0,015 0,015 0,893	2,235	0,567 0,546 0,732 Σ
0,061 3,248	0,145 2,156 3,675	0,345 0,456 2,134	0,016 0,015 1,02	0,025 0,034 0,034	0,356 0,123 0,022	1,475 0,371 0,109 0,021	0,023 0,123 0,154 3,020	0,013 0,657	0,015 0,015 0,893 Manu	2,235 2,645 2,234	0,567 0,546 0,732 Σ
0,061 3,248 0,38	0,145 2,156 3,675 0,017	0,345 0,456 2,134 0,027	0,016 0,015 1,02 0,023	0,025 0,034 0,034 0,134	0,356 0,123 0,022 0,135	1,475 0,371 0,109 0,021 0,014	0,023 0,123 0,154 3,020 0,016	0,013	0,015 0,015 0,893 Manu	2,235 2,645 2,234 al Data Entry	0,567 0,546 0,732
0,061 3,248 0,38 0,502	0,145 2,156 3,675 0,017 0,016	0,345 0,456 2,134 0,027 0,037	0,016 0,015 1,02 0,023 0,135	0,025 0,034 0,034 0,134 0,12	0,356 0,123 0,022 0,135 0,169	1,475 0,371 0,109 0,021 0,014 0,017	0,023 0,123 0,154 3,020 0,016 0,984	0,013	0,015 0,015 0,893 Manu Clear	2,235 2,645 2,234 al Data Entry All Values	0,567 0,546 0,732
	1 Raw Data Rows-TB I	Raw Data	1 2 3 1 2 3 Raw Data Default Form ERON 8-18 Gold Plus (Ver 27.12) New Test Load File Raw	1 2 3 4 1 2 3 4 1 2 3 4 1 2 3 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 Raw Data Default Format M 1	1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 <td>1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 1 1 1 1 1 1 Raw Data Default Format Manual Data Entry Manual Data Entry Manual Data Entry ERON8-18 Gold Plus (Ver 2.71.2) File Sarre Load Format New Test Load Sarre Load Format Standards</td> <td>1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1</td> <td>1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1</td> <td>1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1</td> <td>1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1<td>1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1<!--</td--></td></td>	1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 2 3 4 5 6 1 1 1 1 1 1 1 Raw Data Default Format Manual Data Entry Manual Data Entry Manual Data Entry ERON8-18 Gold Plus (Ver 2.71.2) File Sarre Load Format New Test Load Sarre Load Format Standards	1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1	1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1 2 3 4 5 6 7 8 1	1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1 2 3 4 5 6 7 8 9 1	1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 <td>1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1<!--</td--></td>	1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1 2 3 4 5 6 7 8 9 10 11 1 </td

Figure 6. "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.

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. There are two methods for assigning a format.

Default format

Select "Default Format" to automatically assign the relevant QuantiFERON-recommended testing layout to the data. The standards and samples will be set out in the same configuration as outlined in *QuantiFERON-TB Gold Plus ELISA Instructions for Use*.

The format can be applied either before or after data entry. This allows formats to be prepared prior to obtaining the ELISA results. Depending on the number of strips of data entered, the "Default Format" option may or may not be available, due to the location/orientation of samples and standards for each QuantiFERON-TB Gold Plus ELISA method.

Close	e New	/ Test	Load File	Save File		Load Format F		Print	Resu Expo		Data kport	About
	Run Details		Raw	Data		Standards I	Results	Subje	ect Results			
	1	2	3	4	5	6	7	8	9	10	11	12
А	1N 0.034	3N 0.12	5N 0.012		9N 0.03	51 26 <u>1.44</u>	51 1.475	13N 0.023	15N 0.013	17N 0.015	19N 2.235	21N 0.
В	1TB1 0.045	3TB1 0.14	5 TB1 5 0.345		9TB1 0.02	5 <u>0.35</u>	6 <u>0.371</u>	13TB1 0.123	15TB1 0.657	17TB1 0.015	19TB1 2.645	21TB1 0.
C	1TB2 0.061	3TB2 2.15	5TB2 5 0.456		9TB2 0.03	53 4 <u>0.12</u>	3 <u>0.109</u>	13TB2 0.154	15TB2 0.016	17TB2 0.893	19TB2 2.234	21TB2 0.1
D	1M 3.248	3M 3.67	5M 2.134		9M 0.03	54 0.02	2 0.021	13M 3.020	15M 3.056	17M 3.012	19M 3.098	21M 3.0
Е	2N 0.380	4N 0.01	6N 0.027		10N 0.13	11N 0.13	12N 0.014	14N 0.016	16N 0.130	18N 0.034	20N 0.034	22N 0.0
F	2TB1 0.502	4TB1 0.01	6TB1 0.037		10TB1 0.13	11TB1	59 0.017	14TB1 0.984	16TB1 2.910	18TB1 0.602	20TB1 0.034	22TB1 0.0
G	2TB2 2.350	4TB2 1.12	6TB2 0.037		10TB2 0.02	11TB2 23 0.40	12TB2)9 0.724	14TB2 0.392	16TB2 2.464	18TB2 0.807	20TB2 0.034	22TB2 2.3
Н	2M 3.123	4M 3.093	6М 3 олт	8M OUT	10M 1.12	11M 24 OUT	12M 2.192	2 3.322	16M 3.417	18M 3.311	20M 3.123	22M 3.1
Pas	te Raw Data		efault Forma	it Ma	nual Data	Entry	Manual Fo	rmat	View Na	mes	Calcu	ate

Figure 7. "Default Format" selection menu.

Close	New	Test	Load File	Save File	Loa Form		Save Format	Print	Resul Expo		Data xport	Abo
Run Details			Raw	Data	St	Standards Results			ct Results			
	1	2	3	4	5	6	7	8	9	10	11	1
А	1N 0.034	3N 0.123	5N 0.012			<mark>51</mark> <u>1.445</u>	51 <u>1.475</u>	13N 0.023		17N 0.015	19N 2.235	21N (
В	1TB1 0.045	3TB1 0.145	5TB1 0.345		9TB1 0.025	52 0.356	52 0.371	13TB1 0.123	15TB1 0.657	17TB1 0.015	19TB1 2.645	21TB: C
С	1TB2 0.061	3TB2 2.156	5TB2 0.456		9TB2 0.034	53 <u>0.123</u>	53 0.109	13TB2 0.154	15TB2 0.016	17TB2 0.893	19TB2 2.234	21TB2 0
D	1M 3.248	3M 3.675	5M 2.134		9M 0.034	54 <u>0.022</u>	54 <u>0.021</u>	13M 3.020	15M 3.056	17M 3.012	19M 3.098	21M 3
E	2N 0.380	4N 0.017			10N 0.134	11N 0.135	12N 0.014	14N 0.016	16N 0.130	18N 0.034	20N 0.034	22N 0
F	2TB1 0.502	4TB1 0.016	6TB1 0.037			11TB1 0.169	12TB1 0.017	14TB1 0.984	16TB1 2.910	18TB1 0.602	20TB1 0.034	22TB1 0
G	2TB2 2.350	4TB2 1.125	6TB2 0.037		10TB2 0.023	11TB2 0.409	12TB2 0.724	14TB2 0.392	16TB2 2.464	18TB2 0.807	20TB2 0.034	22ТВ 2 2
н	2M 3.123	4M 3.098	6М ОUТ	8M OUT	10M 1.124	11M OUT	12M 2.192	14M 3.322	16M 3.417	18M 3.311	20M 3.123	22M 3
Past	Paste Raw Data Default Format Manual Data Entry Manual Format View Names Calculate											

Figure 8. "Raw Data" screen after "Default Format" is applied.

Once "Default Format" has been applied, it can be edited by selecting **Manual Format** and following the instructions outlined below.

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.

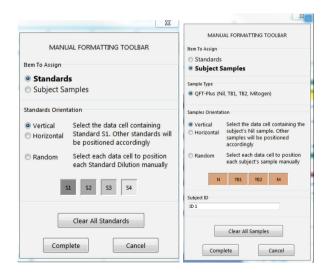


Figure 9. "Manual Formatting Toolbar" in "Standards" mode (left) and "Subject Samples" mode (right).

5.2.4 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.

	23				
MANU	JAL FORMATTING TOOLBAR				
Item To Assign					
Standard	s				
Subject Sa	imples				
Standards Orient	tation				
Vertical	Select the data cell containing				
O Horizontal Standard S1. Other standards will be positioned accordingly					
Random	Select each data cell to position each Standard Dilution manually				
s	il 52 53 54				
	Clear All Standards				
Comp	Cancel				

Figure 10. "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 the cell in the "Raw Data" screen that contains the data for standard S1. The selected 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, click **Random**, 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 the colored block and select **Delete Block** from the context menu. Alternatively, 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, click Subject Samples on the "Manual Formatting Toolbar".

To assign subject samples (either vertically or horizontally) select the corresponding radio button in the "Samples Orientation" section, then click the cell that contains the data for the subject's Nil sample. The selected cell will be designated as "Nil", and the other samples will be appropriately positioned in adjacent cells, in order.

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

И	MANU	AL FORMA	TTING T	OOLBAR	
Item To Ass	ign				
Stand					
Subj	ect S	amples			
Sample Typ	e				
QFT-PI	lus (Ni	I, TB1, TB2,	Mitoge	n)	
Samples O					
		on			
Vertical		Select the subject's			
O Horizo	ontal	samples			
		according	gly .		
Rando	m	Select ea			
		each subj	ect's sar	nple man	ually
- 1	N	TB1	TB2	м	
Subject ID					
ID 1					
		Clear All	Cample		
		Clear All	sample	`	
	Comp	lata		Cancel	

Figure 11. "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 20.

To delete a single subject sample, right-click the colored block and select **Delete Block** from the context 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, click **Complete** to finish. 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 26 for more information.

By default, "Subject Sample" mode opens with Nil, TB1, TB2, and Mitogen samples ready to be assigned in a vertical orientation. Settings can be changed by selecting the appropriate radio (round) buttons.

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-TB Gold Plus sample layouts.

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 via "View Names".

Subject names can be changed at any stage by left-clicking 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), click **View Names**. If all subject names begins with an identical prefix (e.g., A009), then these characters can be entered into the **ID Prefix** field. Then, left-click 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 the appropriate cells.

IN	n Details		Raw	-					Expo		xport	
1	1			Data		Standard	s Results	Subje	ect Results			
1N	-	2	3	4	5	6	7	8	9	10	11	12
A	N 0.034	3N 0.12	5N 3 0.012		9N 0.03	26 51 26 1 .4	145 <u>1.47</u>	13N 5 0.023		17N 0.015		21N 0
в	TB1 0.045	3TB1 0.14	5 0.345		9TB1 0.02	25 <u>0.3</u>	56 0.37	13TB1 1 0.123	15TB1 0.657	17TB1 0.015		21TB1 0
с 11	T <mark>B2</mark> 0.061	3TB2 2.15	5TB2 6 0.456		9TB2 0.03	34 0.1	53 23 0.10	13TB2 9 0.154	15TB2 0.016	17TB2 0.893		21TB2 0
D 1N	M 3.248	3M 3.67	5 5M 2.134		9M 0.03	34 54 0.0	0.02	13M 1 3.020	15M 3.056	17M 3.012		21M 3
E ^{2N}	N 0.380	4N 0.01	.7 0.027		10N 0.1	34 11N	Change Subje		16N	19N	<u>20N</u> ≅ 1.034	22N 0
F 2T	T B1 0.502	4TB1 0.01	6TB1 .6 0.037		10TB1 0.13	20 11TB1	s	ubject ID: I	D 7		L 1.034	22TB1 0
G 2T	TB2 2.350	4TB2 1.12	6TB2 5 0.037		10TB2 0.02	11TB2 23 0.4		ок	×	Cancel	1.034	22ТВ2 2
H 2N	M 3.123	4M 3.09	6M 0UT	8M OUT	10M 1.12	11M 24 OUT	2.19	2 3.322	3.417	3.311		22M 3
Paste R	Raw Data		Default Forma	at Ma	inual Data	a Entry	Manual Fo	rmat	View Na	mes	Calcul	ate

Figure 12. Renaming subject samples using "View Names".

Once the format has been generated, click **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.

5.2.7 Standard 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 further details of the acceptance criteria, see the *QuantiFERON-TB Gold Plus 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

🖵 QuantiF	ERON®-TB Gold I	Plus (Ver 2.71.2)						c	- 0 %
Close	New Test	Load File	Save File	Load Format	Save Format	Print	Results Export	Data Export	About
R	tun Details	Ra	w Data	Standard	is Results	Subject	Results		
Std	Conc	Mean	% CV	QC Result					
S1	4.00	1.460	1.5	PASS	1	Calc	ulated Plots		
S2	1.00	0.364	2.9	PASS	0.2				
S3	0.25	0.116	N/A	PASS	0.2				
S4	0.00	0.022	N/A	PASS	-0.2				
ELISA Resi	Intercept Correlation Coefficient SIA test run.	-0.9292	Slope P	0.9134	-0.6 -0.8 -1 -12 -1.4 -1.6 -1.8 -2	-1	• •		1
~									-

Figure 13. "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.

5.2.8 Standard curve

The standard curve is used to calculate a value (IU/ml of IFN- γ) for each patient'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 patient is reported.

Close	New Test	Load File	Save File	Load Format	Save Form		int	Results Export	Data Ab Export	out
Run	Details	Raw Da	ata	Stan	Standards Results Subject			esults		
S	ubject ID	Nil	TB1	TB2	Mitogen	TB1- Nil	TB2- Nil	Mitogen- Nil	Result	
ID 7		0.03	0.03	0.03	2.83	0.00	0.00	2.80	NEGATIVE	
ID 8		0.04	0.31	0.05	> 10#	0.27	0.01	> 10¶	NEGATIVE	
ID 9		0.05	0.05	0.07	0.07	0.00	0.02	0.02	INDETERMINATE	
ID 10		0.31	0.27	0.04	3.14	-0.04	-0.27	2.83	NEGATIVE	
ID 11		0.31	0.39	1.04	> 10#	0.08	0.73	> 10¶	POSITIVE	
ID 12		0.03	0.03	1.94	6.53	0.00	1.91	6.50	POSITIVE	
D 13		0.04	0.28	0.36	9.27	0.24	0.32	9.23	NEGATIVE	
D 14		0.03	2.72	0.99	> 10¶	2.69	0.96	> 10¶	POSITIVE	
D 15		0.02	1.75	0.03	9.40	1.73	0.01	9.38	POSITIVE	
ID 16		0.30	8.91	7.42	> 10¶	8.61	7.12	> 10¶	POSITIVE	
ID 17		0.03	0.03	2.44	9.25	0.00	2.41	9.22	POSITIVE	
D 18		0.07	1.59	2.19	> 10¶	1.52	2.12	> 10¶	POSITIVE	
ID 19		6.67	8.02	6.67	9.54	1.35	0.00	2.87	NEGATIVE	

Figure 14. "Subject Results" screen. \P = Sample result is outside the linear range of the assay.

In the unlikely event that a patient's result is reported as positive and their Mitogen minus Nil result is less than 0.5 IU/ml, the software will flag the result as a possible sample mix-up using the "*" symbol. This warning helps to limit the possibility of a false-positive result due to a mix-up of the TB antigen and Mitogen samples.

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 "¶" or "#" symbols. "¶" indicates that the result is outside the linear range of the assay. "#" 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-TB Gold Plus ELISA results, see the QuantiFERON-TB Gold Plus (QFT-Plus) ELISA Instructions for Use.

5.3 Data export

If needed, 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, perform these steps:

- 1. Click the Results Export tab.
- 2. The Export Type dialog box appears.
- 3. 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 that described above for "Results Export".

Note: The optional step of exporting data is not required to obtain QuantiFERON-TB Gold Plus 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 displays the various printing options available, while the lower section displays 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.

Print Options 🔲 Print Standar	rd Curve and Pla	ate Forma	atting						Close Print Window
Report Type All Subjects ((Group Report)								Save As PDE
O All Subjects (ort)							Save AS PDF
Single Subject		01		¥					Print
Quan	tiFERON Run D	Date: V	B G	of 3 old P day, June			ts		
Version 2.71.2 Ki Valid ELISA test	Opera Run Num it Batch Num t run.	ber: 1							
Ki Valid ELISA test	Run Num it Batch Num	ber: 1]	
K	Run Num it Batch Num	ber: 1		Mitogen	TB1- Nal	TB2- Nil	Mitogen- Nil	Result	
Ki Valid ELISA test Results (IU/mL)	Run Num it Batch Num t run.	lber: 1 lber: 1		-				Result	
Ki Valid ELISA test Results (IU/mL) Subject ID	Run Num it Batch Num t run.	ıber: 1 ıber: 1 TB1	TB2	-	Nil	Nil	Nil		
Ki Valid ELISA test Results (IU/mL) Subject ID ID 1	Run Num it Batch Num t run. Nil 0.07	ber: 1 ber: 1 TB1 0.09	TB2 0.13 7.05	> 10¶	Nil 0.02	Nil 0.06 6.09	Nil 9.97	NEGATIVE	
K: Valid ELISA test Results (IU/mL) Subject ID ID 1 ID 2	Num it Batch Num t run. Na 0.07 0.96	ber: 1 ber: 1 TB1 0.09 1.30	TB2 0.13 7.05	> 10¶ 9.62	Nil 0.02 0.34	Nil 0.06 6.09	Nil 9.97 8.66	NEGATIVE POSITIVE	
K: Valid ELISA test Results (IU/mL) Subject ID ID 2 ID 3	Run Num it Batch Num t run. Na 0.07 0.96 0.28	ber: 1 ber: 1 TB1 0.09 1.30 0.33	TB2 0.13 7.05 6.41	> 10¶ 9.62 > 10¶	Nal 0.02 0.34 0.05	Nil 0.06 6.09 6.13	Nil 9.97 8.66 >10¶ 9.51	NEGATIVE POSITIVE POSITIVE	
K: Valid ELISA test Subject ID ID 1 ID 2 ID 3 ID 4	Run Num it Batch Num t run. 0.07 0.96 0.28 0.03	ber: 1 TB1 0.09 1.30 0.33 0.03	TB2 0.13 7.05 6.41 3.15	> 10¶ 9.62 > 10¶ 9.54	Nal 0.02 0.34 0.05 0.00	Nil 0.06 6.09 6.13 3.12	Nil 9.97 8.66 >10¶ 9.51	NEGATIVE POSITIVE POSITIVE POSITIVE	
K: Valid ELISA test Subject ID ID 1 ID 2 ID 3 ID 4 ID 5	Run Num it Batch Num t run. 0.07 0.96 0.23 0.03 0.02	ber: 1 ber: 1 TB1 0.09 1.30 0.33 0.03 0.86	TB2 0.13 7.05 6.41 3.15 1.17	> 10¶ 9.62 > 10¶ 9.54 6.34	Nal 0.02 0.34 0.05 0.00 0.84	Nil 0.06 6.09 6.13 3.12 1.15	Nil 9.97 8.66 >10¶ 9.51 6.32	NEGATIVE POSITIVE POSITIVE POSITIVE POSITIVE	
K: Valid ELISA test Subject ID D1 ID 1 ID 3 ID 4 ID 5 ID 6	Run Num it Batch Num t run.	ber: 1 ber: 1 TB1 0.09 1.30 0.33 0.03 0.86 0.07	TB2 0.13 7.05 6.41 3.15 1.17 0.07 0.03	> 10¶ 9.62 > 10¶ 9.54 6.34 > 10#	Nal 0.02 0.34 0.05 0.00 0.84 0.02	Nil 0.06 6.09 6.13 3.12 1.15 0.02 0.00	Nil 9.97 8.66 > 10¶ 9.51 6.32 > 10¶ 2.80 > 10¶	NEGATIVE POSITIVE POSITIVE POSITIVE NEGATIVE	

Figure 15. 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 option prints the results for each subject on a separate page.
 - **Single Subject Report**: This option prints the results for one subject, as selected from the drop-down box.
- 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", page 26.

• After 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-TB Gold Plus Assay is 10 IU/ml. Therefore, samples determined to have an IFN- γ concentration greater than this range are reported as >10 IU/ml.

Although values above 10 IU/ml are reported as >10 IU/ml, the calculations for subtracting the Nil control value are based on the original value. Therefore, it is possible for a patient's TB1, TB2 or Mitogen value to be reported as ">10 IU/ml", yet their "minus Nil" value be less than 10 IU/ml.

5.5 Saving and loading files

5.5.1 Saving files

Upon opening the QFT-Plus 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	Sub-folder name	Default file name
Format	.qft	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 be used for record-keeping purposes. Note: PDF files contain all of the information available in the printed report.

Note: The data and result files as well as the reports are not protected, and information can be inadvertently altered. Ensure that enough space is available on the storage media.

5.5.2 Loading files

- Format files can be reloaded within the QFT-Plus 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.
 Note: Ensure that the loaded files originate from a trusted source and are free of malware and viruses.

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" function, the user can work on a second run without having to restart the software.
- Click New Test to clear all entered information. This enables the new assay data to be analyzed.
- Click **Close** to close the program.

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.

6 Troubleshooting

This section provides information about what to do if an error occurs when using the QuantiFERON-TB Gold Plus Analysis Software.

If further assistance is required, contact QIAGEN Technical Services using the contact information below:

Website: support.qiagen.com

When contacting QIAGEN Technical Services about an error with the QuantiFERON-TB Gold Plus Analysis Software, note the steps leading up to the error and any information appearing in any dialog boxes. This information will help the QIAGEN Technical Services solve the problem.

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QuantiFERON-TB Gold Plus version
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Detailed description of the error situation
- Photo of the error, if possible
- Copy of log files

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 Appendix A – Frequently Asked Questions

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

A. You can use your own spreadsheet to calculate QuantiFERON-TB Gold Plus 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-TB Gold Plus (QFT-Plus) ELISA Instructions for Use*.

The QuantiFERON-TB Gold Plus Analysis Software has already been validated to ensure that the quality control checks – and the results obtained – are accurate and reproducible. The QuantiFERON-TB Gold Plus 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-TB Gold Plus 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 QFT-Plus 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 locate the default QuantiFERON folder in the Start Menu (Start >QuantiFERON) and select **Uninstall**.

Alternatively, locate and remove the software using Start > Control Panel > Add/Remove Programs.

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-TB Gold Plus 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-TB Gold Plus ELISA results, blank values or text may reduce the quality of the standard curve.

Q. When I open the QuantiFERON-TB Gold Plus 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 "Default".

8 Ordering Information

Product	Contents	Cat. no.
QuantiFERON-TB Gold Plus Analysis Software	N/A	Downloadable at www.qiagen.com
Relative Products		
QuantiFERON-TB Gold Plus ELISA Kit	2-plate ELISA kit	622120
QuantiFERON-TB Gold Plus Reference Lab Pack	20-plate ELISA kit	622822

For up-to-date licensing and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

9 Document Revision History

Date Changes

R1, February 2021 I

Initial release

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Limited License Agreement for QuantiFERON-TB Gold Plus Analysis Software

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

- 1. The product may be used solely in accordance with the protocols provided with the product and this Instructions for Use and for use with components contained in the kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this kit with any components not included within this kit except as described in the protocols provided with the product, this Instructions for Use, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN users for Warants that they do not infringe the rights of third-parties.
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