QuantiFERON® Control Panel Package Insert

REF 0594-0805 IVD CE

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Intended Use

The QuantiFERON Control Panel contains a set of 3 interferon-γ (IFN-γ) controls for optional use with QuantiFERON cell-mediated immune (CMI) assays. The IFN-γ controls are provided at three levels (1, 2 and 3) within the linear range of the QuantiFERON ELISA.

Summary and Explanation

The QuantiFERON Control Panel contains lyophilized recombinant human IFN-γ and must be reconstituted prior to use. The IFN-γ concentration of each QuantiFERON Control Panel will vary among lots. The assigned values of the QuantiFERON Control Panel are indicated on the product label.

Principles of the Procedure

The QuantiFERON Control Panel can be used to assess the performance of any QuantiFERON ELISA, which is used for the detection of CMI responses. The 3 control levels contain different concentrations of IFN-γ and provide results across the range of any QuantiFERON ELISA. Use the controls in the same manner as the plasma samples in any QuantiFERON ELISA.

Reagents and Storage

QuantiFERON Control Panel (cat. no. 0594-0805)	Quantity
QuantiFERON IFN-γ Control – Level 1	3 x vials
QuantiFERON IFN-γ Control – Level 2	3 x vials
QuantiFERON IFN-γ Control – Level 3	3 x vials
Package Insert	1

Store lyophilized QuantiFERON Controls at 2°C to 8°C. Do not use after the expiration date. Reconstituted QuantiFERON Controls must be stored at 2°C to 8°C and can be used within 28 days of reconstitution.

Warnings and Precautions

For in vitro diagnostic use

When working with chemicals, always use a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at **www.qiagen.com/safety** where you can find, view, and print the SDS for each kit and kit component.

Important: Inspect vials prior to use. Do not use control panel vials that show signs of damage or if the rubber seal has been compromised. Do not handle broken vials. Take appropriate safety precautions to dispose of them safely. Recommended: Use a vial decrimper to open control panel vials to minimize the risk of injury from the metal crimp.

Directions for Use

1. Equilibrate the set of 3 controls (Levels 1, 2, and 3) to room temperature (17°C to 27°C).
2. Reconstitute each of the vials with 0.25 ml of room temperature (17°C to 27°C) distilled or deionized water, ensuring complete resuspension. Mix by several gentle inversions to minimize frothing.
3. Add 50 µl of freshly prepared working strength conjugate to appropriate ELISA wells before control or sample addition.
4. Add 50 µl of each reconstituted control level to the appropriate ELISA wells.
5. Add 50 µl of the standards to the appropriate ELISA wells after control and sample additions, minimizing delays between additions as much as possible.
6. After use, immediately store the set of 3 reconstituted controls at 2°C to 8°C.

7. Test the 3 reconstituted controls as plasma samples, as directed in the QuantiFERON ELISA package insert applicable to the test being performed (see table below for suggested layouts).

Assay	Green Diluent	Level 1	Level 2	Level 3
QFT	N/A	Nil	TB Antigen	Mitogen
QFT-Plus	Nil	TB1	TB2	Mitogen
QF-CMV	N/A	Nil	CMV Antigen	Mitogen
QFM	N/A	Undiluted	Undiluted	Undiluted

Interpretation of Results

Determine the validity of a QuantiFERON ELISA as described in the associated QuantiFERON ELISA package insert. The control panel is intended as a guide for assessing the performance of the QuantiFERON ELISA in individual laboratories.

QuantiFERON analysis software may be used for calculating QuantiFERON Control Panel values. When using the QuantiFERON analysis software, select Control Panel wells as in the table above and use only the IU/ml values as the results for the controls.

If not using the optional QuantiFERON analysis software, calculate the results for the control panel samples as though they are patient samples, following the directions outlined in the respective QuantiFERON ELISA package insert.

Note: A laboratory may choose to establish its own expected range for each QuantiFERON Control Panel lot. Variations may be observed based on differences in laboratory technique, instrumentation, reagent lot, and other systemic and non-systemic errors.

Each lot of QuantiFERON Control Panel is Quality Control tested using multiple QuantiFERON ELISA kit lots to determine the assigned concentration range of IFN-γ. The mean concentration is printed on the label of each vial, and both the mean and expected ranges are provided on the Technical Data Label affixed to the inside of each kit box. The indicated mean and expected range of the mean are only intended as a guide for assessing the performance of the QuantiFERON ELISA in individual laboratories.

Limitations

Discard if there is any evidence of microbial contamination or excessive turbidity. Reproducible results are dependent on properly functioning and calibrated equipment.

Significant Changes

Significant changes in this edition of the QuantiFERON Control Panel Package Insert are summarized in the table below:

Section	Page	Change(s)
Warnings and Precautions	2	Remove GHS information

Symbols

	Legal manufacturer
	CE-IVD marked symbol
	For in vitro diagnostic use
	Batch code
	Catalog number
	Global Trade Item Number
	Use by date
	Temperature limitation
	Consult instructions for use
	Do not reuse
	Keep away from sunlight
	Authorized representative in the European Community

Contact Information

For technical assistance and more information, please call toll-free 00800-22-44-6000, see our Technical Support Center at **support.qiagen.com** or contact one of the QIAGEN Technical Service Departments (see back cover or visit **www.qiagen.com**).

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