

What is QuantiFERON®-TB Gold Plus?

The fourth generation of QFT®, QuantiFERON-TB Gold Plus (hereinafter abbreviated as QFT-Plus) has been approved as an in vitro diagnostic in Japan. So as a special edition I will explain about QFT-Plus comparing to QuantiFERON-TB Gold (hereinafter abbreviated as QFT-3G)

As features of QFT-Plus comparing with QFT-3G

- Signals of CD8 T cells as well as CD4 T cell are applied in the assay system of QFT-Plus.
- The option to extend specimen-storage-time from blood collection to culture is added, and the flexibility of assay operation is improved.
- The criteria of interpretation of the test results have become the same as the world.
- Technical terms for QFT in Japan have become standardized criteria across the world.



Clinical comparison study between QFT-Plus and QFT-3G was conducted as non-inferiority study to evaluate sensitivity and specificity using active TB patients and low-risk healthy individuals, respectively. Therefore, the clinical usefulness of QFT-Plus (measurement purpose) is the same as QFT-3G. However, as mentioned above, there is also a feature of QFT-Plus, the paper has already begun to suggest a new clinical usefulness as well as the performance of the kit.

QFT-Plus was first released in Europe in 2015 after obtained the CE mark, following approved in June 2017 in the United States and released in October, and has been used for more than 200 million tests in 75 countries to date. Currently, these countries have been switching from QFT-3G to QFT-Plus, and it is estimated that more than 10 million tests per year of QFT-Plus combined with QFT-3G are being tested in the world. QFT-Plus will continue to contribute to the global tuberculosis control..

Please refer to the table for the comparison of QFT-Plus with the QFT-3G.

Table. Comparison of QFT-3G and QFT-Plus

Items	QFT-3G	QFT-Plus	Comments
Official name in Japan	QuantiFERON-TB Gold	QuantiFERON-TB Gold Plus	Change to partial English notation
Purpose of measurement	Measurement of released interferon- γ by co-culture with whole blood 1. Diagnostic aids for active tuberculosis <ul style="list-style-type: none"> The person who suspects tuberculosis by X-ray findings and sputum smear cannot be confirmed, and other clinical findings etc. 2. Diagnostic aids for latent tuberculosis infection <ul style="list-style-type: none"> Contact with active tuberculosis patients in the case of a group outbreak as a contact investigation Medical workers with frequent contact with active TB patients 		No changes
Comparative test Results	—	Agreement rate : 93.8% (561/598) Compared to : QFT-3G	
Sensitivity	93.7% (89/95) Cultured positive active TB Patients Japan-only data	94.09% (398/423) (CI:91.4-96.0) Cultured positive active TB Patients From FDA Application data	Active tuberculosis Group with positive culture
Specificity	93.8% (150/160) Japan-only data	97.3 % (713/733) (CI:95.9- 98.4) From FDA Application data	At the time of approval, low risk groups
ELISA	—	—	No changes
Condition of blood collection method and preservation of the specimen	<ul style="list-style-type: none"> Three Blood collection by blood collection tube for QFT: Store at room temperature 17-27 °C, to start the culture within 16 hours. 1 Blood Collection by Heparin blood collection tube: More than 4 ml, Save 2 to 8 °C blood samples from blood collection and save up to 32 hours from blood collection.. 	<ul style="list-style-type: none"> Four QFT blood collection tube for blood Collection tube: Whole blood sample stored at room temperature 17-27 °C, to start the culture within 16 hours. Single Blood Collection by Heparin Lithium blood collection tube: More than 5 ml, Whole blood sample can be stored at 2 to 8°C for up to 48 hours 	<p>Blood collection tube is, the refrigerated (2 to 8 °C) storage time of the whole blood specimen was extended.</p> <p>As the operation time at room temperature, three hours from the blood collection to start of refrigerated (2 to 8 °C) storage, and two hours after end of refrigerated (2 to 8 °C) storage to start of incubation, are taken into consideration</p>
Blood Collection Tube	3 tubes; <ul style="list-style-type: none"> Negative control blood collection tube (gray cap) TB antigen blood collection tube (green cap) positive controller blood Collection tube (purple cap) 	4 tubes; <ul style="list-style-type: none"> QFT Nil Tube (gray cap) QFT TB1 Tube (green cap) QFT TB2 Tube (yellow cap) Mitogen Tube (purple cap) 	<p>The name of the blood collection tube is partially changed to English notation. Number of changes.</p> <p>The amount of blood collection per bottle is the same as 0.8 -1.2 ml.</p>

Items	QFT-3G	QFT-Plus	Comments
Easurement principle: Stimulus antigen and immune response cells	<ul style="list-style-type: none"> ESAT-6, CFP-10, TB7.7 peptides TB Antigen Blood Collection tube: Reaction signals with CD4 T cells 	<ul style="list-style-type: none"> ESAT-6, CFP-10 peptides QFT TB1 tube: Reaction signal of CD4 T cells QFT TB2 Tubes: Reaction signals of CD4 T cells and CD8 T cells 	New CD8 T cells involved, TB7.7 is not in QFT-Plus
Positive judgment	<ul style="list-style-type: none"> If the measurement value A is greater than 0.35 IU/ml, positive 	<ul style="list-style-type: none"> Positive if the nil value is less than 8, and the TB1 value or TB2 value is greater than or equal to 0.35 and 25% of nil 	Each number is IU/ml, the cutoff value is not changed, and the high value of nil is taken into account.
Negative judgment	<ul style="list-style-type: none"> If the measurement value is less than a 0.1 IU/ml, negative 	<ul style="list-style-type: none"> The nil value is less than 8, Mitogen value is 0.5 or higher, TB 1 value, TB2 value is less than 0.35 negative. The nil value is less than 8, Mitogen value is 0.5 or more, TB 1 value, TB2 value is less than 0.35 or more than 25% of the nil value is negative. 	Each value is IU/ml
Gray Zone	<ul style="list-style-type: none"> If the value A is less than 0.35 and 0.1 or more, the value M is 0.5 or more 	<ul style="list-style-type: none"> None 	Each number is IU/ml, no Gray zone
Indeterminate	<ul style="list-style-type: none"> If the measured value A is less than 0.35 and the measurement m is less than 0.5. 	<ul style="list-style-type: none"> If the nil value is greater than or equal to 8 If the nil value is less than 8, the Mitogen value is less than 0.5, TB 1, TB2 value is less than 0.35, or neither of which is less than 25% of the nil value. 	Each value is IU/ml, nil value is one of criteria of indeterminate



Mr. QFT

QFT-Plus is an in vitro diagnostic aid for detection of Mycobacterium tuberculosis infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations. QFT-Plus results alone cannot distinguish active TB disease from latent infection. QFT-Plus Package Inserts, available in multiple languages, as well as up-to-date licensing information and product-specific disclaimers can be found at www.QuantiFERON.com.

For up-to-date licensing information 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.

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QuantiferON TB ゴールド プラス

保険適用 体外診断用医薬品
 製造販売承認番号: 23000EZ00004000

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