QuantiFERON®-TB Gold (QFT®)



Blood Collection Tubes 1102923 Rev. 01 06/2016

Blood Collection Tubes		300 tubes	200 tubes	100 tubes
Catalog no.		T0590-0301	0590-0201	T0593-0201
QuantiFERON Nil Tube (gray cap, white ring)	Nil	100 tubes	100 tubes	
QuantiFERON TB Antigen Tube (red cap, white ring)	TB Antigen	100 tubes	100 tubes	
QuantiFERON Mitogen Tube (purple cap, white ring)	Mitogen	100 tubes		100 tubes
QFT Blood Collection Tubes Package Insert		1	1	1
High Altitude (HA) Blood Collection Tubes		300 Tubes	200 tubes	100 tubes
(for use between 1020 and 1875 meters)				
Catalog no.		T0590-0505	0590-0501	T0593-0501
QuantiFERON HA Nil Tube	Nil	100 tubes	100 tubes	
(gray cap, yellow ring)				
QuantiFERON HA TB Antigen Tube	TB Antigen	100 tubes	100 tubes	
(red cap, yellow ring)				
QuantiFERON HA Mitogen Tube	Mitogen	100 tubes		100 tubes
(purple cap, yellow ring)				
QFT Blood Collection Tubes Package Insert		1	1	1

Important note: The blood draw volume of a tube is affected by altitude. The High Altitude tubes have been specifically calibrated to ensure that the correct volume of blood is collected if you are using the QuantiFERON-TB Gold (QFT) tubes above 1020m (3350ft), but below 1875m (6150ft).

High Altitude (HA) tubes should be used at altitudes between 1020m (3350ft) and 1875m (6150ft). If using QFT blood collection tubes outside these altitude ranges (between 810m (2650ft) and 1020m (3350ft) or above 1875m (6150ft)), or if low blood draw volume does occur, blood can be collected using a syringe and 1mL transferred to each of the three tubes. For safety reasons, this is best performed by removing the syringe needle, **ensuring appropriate safety procedures**, removing the caps from the three QFT tubes and adding 1mL of blood to each (to the black mark on the side of the tube label). Replace the tube caps securely and mix as described below.

The blood collection tubes supplied are for use only with the QuantiFERON $^{\circledR}$ -TB Gold (QFT $^{\circledR}$) assay. Blood collection tubes should be stored at 4°C to 25°C. The following instructions relate solely to the use of QFT blood collection tubes. Instructions for the entire QFT assay incorporating the use of the blood collection tubes can be found in the Package Insert for the QFT ELISA kit (Catalogue No.: 0594-0201 or 0594-0501).

Antigens have been dried onto the inner wall of the blood collection tubes so it is essential that the contents of the tubes be thoroughly mixed with the blood. The tubes must be transferred to a 37°C incubator as soon as possible and within 16 hours of collection.

The following procedures should be followed for optimal results:

1. Blood Collection:

- 1.1 For each subject collect 1mL of blood by venipuncture directly into each of the QFT blood collection tubes. This procedure should be performed by a trained phlebotomist.
 - As 1mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling, to ensure that the correct volume is drawn.
 - The black mark on the side of the tubes indicates the 1mL fill volume. QFT blood collection tubes have been validated for volumes ranging from 0.8mL 1.2mL. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample.
 - If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT tubes being used.
- 1.2 Immediately after filling tubes, shake them ten (10) times just firmly enough to ensure the entire inner surface of the tube is coated with blood, to solubilise the antigens on tube walls.
 - Tube temperature should be between 17- 25°C (63 77°F) at the time of blood tube filling.
 - Overly vigorous shaking may cause gel disruption and could lead to aberrant results.
- 1.3 Label tubes appropriately.
- 1.4 The tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain the tubes at room temperature (22°C ± 5°C) (72°F ± 9°F). Do not refrigerate or freeze the blood samples.

2. Incubating Tubes and Harvesting Plasma:

- 2.1 If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation.
- 2.2 Incubate the tubes **UPRIGHT** at 37°C for 16 to 24 hours. The incubator does not require CO₂ or humidification.
- 2.3 After incubation at 37°C, blood collection tubes may be held between 4 27°C (40 81°F) for up to 3 days prior to centrifugation.
- 2.4 After incubation of the tubes at 37°C, harvesting of plasma is facilitated by centrifuging tubes for 15 minutes at 2000 to 3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be centrifuged again at a higher speed.
 - It is possible to harvest the plasma without centrifugation, however, additional care is required to remove the plasma without disturbing the cells.



- 2.5 After centrifugation, avoid pipetting up and down or mixing plasma by any means prior to harvesting. At all times, take care not to disturb material on the surface of the gel.
 - Plasma samples should only be harvested **using a pipette**.

Sterilized using irradiation

- Plasma samples can be loaded directly from centrifuged blood collection tubes into the QFT ELISA plate, including when automated ELISA workstations are used.
- Plasma samples can be stored for up to 28 days at 2 8°C or, if harvested, below -20°C (preferably less than -70°C) for extended periods.

STERILE R

Symbols	
ECREP	European Representative
	Legal manufacturer
C€	CE-IVD marked symbol
IVD	For in vitro diagnostic use
LOT	Batch code
REF	Catalog number
GTIN	Global Trade Item Number
	Use by date
	Temperature limitation
	Consult instructions for use
2	Do not reuse



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QIAGEN 19300 Germantown Road Germantown, MD 20874 USA Phone: +1-800-426-8157 Visit www.qiagen.com for technical support contact information.

EC REP QIAGEN GmbH QIAGEN Strasse 1 40724 Hilden, GERMANY Phone: +49-2103-29-0



www.QuantiFERON.com

