

JUVENILE COURT HEALTH SERVICES LABORATORY PROCEDURES

Subject: QuantiFERON TB Gold Plus	Original Issue Date: 6/30/2021	Policy #: C-007
	Supersedes:	Effective Date: 6/30/2021
Departments Consulted: Department of Nursing	Approved By: (Signature on File) Laboratory Supervisor (Signature on File) Laboratory Director	Approved by: (Signature on File) Health Services Administrator

PURPOSE

QuantiFERON-TB Gold Plus is an in vitro diagnostic test using a peptide cocktail of CD4+ and CD8+ T cell antigens to stimulate cells in heparinized whole blood. Detection of interferon-gamma by enzyme-linked immunosorbent assay (ELISA) is used to identify in vitro responses to these peptide antigens that are associated with *Mycobacterium tuberculosis* infection. QuantiFERON-TB Gold Plus is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

LIMITATIONS

A negative QFT-Plus result does not preclude the possibility of *M. tuberculosis* infection or tuberculosis disease: false negative results can be due to stage of infection, co-morbid conditions that affect immune function, incorrect handling of the blood collection tubes following venipuncture, incorrect performance of the assay, or other individual immunological variables. Heterophile antibodies or non-specific interferon-gamma production from other inflammatory conditions may mask specific responses to CD4+ and CD8+ T cell antigens. A positive QFT-Plus result should not be the sole or definitive basis for determining infection with *M. tuberculosis*. Incorrect performance of the assay may cause false-positive results. A positive QFT-Plus result should be followed by further medical evaluation for active tuberculosis disease.

INDICATION

A QuantiFERON test will be done on all youth admitted to juvenile hall who:

1. This is their first admission, or
2. Has had a tuberculosis skin test (e.g., Purified Protein Derivative (PPD)) place more than a year from the date of admission.

If the youth had a verified history of a latent/active tuberculosis infection, a QuantiFERON test does not need to be done.

Collections will be done on Monday to Thursday mornings

- Orders are placed in PEMRS
- Labels are to be left for the lab staff to draw blood for QuantiFERON
- Lab staff will also draw other routine admission labs (e.g, HIV, syphilis test)

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QuantiFERON will not be collected on Fridays, Saturdays, Sundays, or the day before and on a Los Angeles County holiday.

METHODOLOGY

Whole blood interferon-gamma test measuring responses to CD4+ and CD8+ T cell antigens

SPECIMEN REQUIREMENTS

Specimen

Whole blood

Volume

1 mL x four tubes in QuantiFERON-TB Gold Plus kit

Minimum Volume

1 mL x four tubes in QuantiFERON-TB Gold Plus kit

CONTAINER

The QuantiFERON®-TB Gold Plus collection kit contains the instructions for the collection and handling of (one each): (1) gray-top (with white ring), uncoated (nil); (2) green cap with white ring, TB1 tube; (3) yellow cap with white ring, TB2 tube; (4) purple top with white ring, mitogen-coated. A high-altitude kit is also available for locations between 3350 and 6150 feet; a cap with a yellow ring differentiates the tubes.

COLLECTION

- **Blood collection will be done Monday - Thursday between 6 am – 10 am.**
- Specimen tubes should be at room temperature at the time of collection.
- Refer to collection instructions included with draw kit.
 - Special specimen collection kit contains four gel-barrier tubes as noted above.
 - All four tubes are required for a single test result.
 - Each tube is designed to draw only 1 mL and fill time may be longer than other blood collection tubes.
- Because of the limited vacuum in these tubes, use a needle and holder (**not** a butterfly) to collect QuantiFERON® specimens.
 - If a butterfly is required, first collect other required tubes or use another Vacutainer® tube to purge the butterfly line of air and then proceed with drawing the QuantiFERON tubes.
- Fill tubes to the black fill line on the tube.
- If tubes are underfilled or overfilled (see kit insert), immediately collect a replacement tube.
- Following proper fill,
 - Label the tubes appropriately
 - Shake tubes 10 times firmly enough to ensure the entire surface of the tube is coated with blood cells to solubilize the antigen on the tube walls
- After shaking, the volume may fall below the fill line.

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INCUBATION

- The 4 QuantiFERON tubes are labelled and kept upright in a rack at room temperature for a maximum of 16 hours until Centrifugation.
- Incubate at 37 degrees Celsius +/-1, starting 10 am Mon – Thurs.
- Remix the tubes by inverting 10 times immediately prior to start of incubation.
- Place the samples upright in the incubator at 10 am.
- Record the date, time and incubator temperature on the QFT specimen tracking log.
- Samples are incubated until 9 am the next day (total of 23 hours) (Acceptable Incubation time range: 16-24 hours).
- Once incubation is complete,
 - Remove samples
 - Label the tubes as “Incubated”
 - Record date, time, and incubator temperature on the QFT Specimen Tracking Log.

CENTRIFUGATION

- Centrifuge the samples starting at 9 am Tues - Fri (make sure the tubes are balanced in the centrifuge).
- Centrifuge at 2000–3000 RCF (g) for 15 min.
- Following centrifugation, samples are transported as **refrigerated samples** with a copy of the QFT specimen tracking log to CJH Lab and from there to the Public Health Laboratory.
- Place original QFT tracking Log in the QuantiFERON Lab Binder.

STORAGE INSTRUCTIONS

Maintain specimen at room temperature for four tube collection kit until incubation.

Stability:

- Kit **must** be incubated within 16 hours of collection.
- After Centrifugation, store and transport as refrigerated samples.

CAUSES FOR REJECTION

- Expired collection tubes
- Frozen specimen
- Not refrigerated after centrifugation

ATTACHMENT

QFT Tracking Log

REFERENCE

QuantiFERON QIAGEN 2013-2021