

LAB ALERT

Date: June 12, 2018

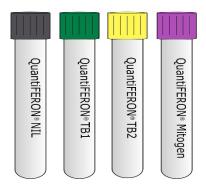
Changes in Quantiferon TB-Gold (TBINF) Collection

Dear Regional Pathology Services Clients,

Effective June 18th, 2018 the Quantiferon TB-Gold assay will require four blood collection tubes instead of three. We ask that clients please discard the old collection tubes and order the new collection kits either on-line on our supply portal or by calling client services at 402-559-6420.

The additional tube (TB 2 antigen) detects CD8⁺ T-Cell IFN-g production and enhances sensitivity of the assay, especially in those patients with recent exposure to *Mycobacterium tuberculosis*.

Please collect 1 ml of blood by venipuncture directly into each of the four Quantiferon-TB Plus blood collection tubes using only a vacutainer or syringe. The four tubes will consist of a gray cap (nil control), green cap (TB1 antigen), yellow cap (TB 2 antigen), and purple cap (mitogen positive control) as shown below. It is recommended to collect in the following order: gray cap, green cap, yellow cap, and purple cap.



Note that providers will receive results for both the TB1 and TB2 antigen tests. In addition, there will be no change regarding subsequent processing and incubation of the four collection tubes.

Client fees will not change with this new assay.

Clients also have the option of sending patients to one of our draw sites to get drawn. Our patient service centers can be found on our website at:

http://www.reglab.org/client-services/patient-service-centers/



REGIONAL PATHOLOGY SERVICES

Interfaced Clients: please delete the old order code TBINF and replace with the following

codes: New order code: TBINTF CPT code unchanged: 86480

New OrderCode	<u>OrderName</u>	ResultCode	<u>ResultName</u>
TBINTF	TB INTERFERON AG	TBAG1	TB1 ANTIGEN RESPONSE
TBINTF	TB INTERFERON AG	TBAG2	TB2 ANTIGEN RESPONSE
TBINTF	TB INTERFERON AG	TBINTI	TB INTERFERON INTERP

Collection Instructions:

A collection video can also be found at http://www.quantiferon.com/us/products/quantiferon-tb-gold-plus-us/laboratory-resources/training-videos-labs/

Collect: Collect 1 ml of blood by venipuncture directly into each of the QuantiFERON-TB Gold Plus (QFT-Plus) blood collection tubes using only a vacutainer or syringe. Four tubes must be collected for each patient: gray cap tube (Nil control), green cap tube (TB1 Antigen), yellow cap tube (TB2 Antigen), and purple cap tube (Mitogen control). It is recommended to draw in the order grey, green, yellow, purple. As the 1 ml tubes draw relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling. This will ensure the correct volume is drawn. If a "butterfly needle" is used, use a "purge" tube to ensure the tubing is filled with blood prior to filling the QFT-Plus blood collection tubes. The black indicator line on the side of the tube indicates the correct fill volume; the tubes must not be filled above or below this line.

Mix the tubes after the draw by shaking 10 times just firmly enough to ensure the entire inner surface of each tube is coated with blood; over vigorous shaking will disrupt the gel and could lead to erroneous results. The collection date and time is required on the tubes. Transport immediately at room temperature; do not refrigerate.

Storage and Transportation: Specimens must be sent to the laboratory immediately, at room temperature, since they must be processed by the laboratory within 16 hours of collection. Specimens are accepted at the laboratory 24 hrs/day, 7 days/week.

Unacceptable conditions: Specimens >16 hours old; centrifuged, refrigerated, or frozen specimens; missing collection date and time; blood collection tubes other than the QFT-Plus tubes; samples outside the acceptable fill range (black indicator line).

Notes: Test includes detection of interferon-γ by identifying CMI responses from CD4+ T-helper lymphocytes and CD8+ cytotoxic T lymphocytes.

Methodology: ELISA (enzyme-linked immunosorbent assay)

Performed: Serology/Microbiology, Tuesday and Friday. Specimens must be received by 1500 for initial processing the day before testing.

Reporting: Results are reported by 1600 the day of testing.

24/7 Client Services 1-800-334-0459