

QUANTIFERON TB GOLD PLUS 4-TUBE TEST

EFFECTIVE MARCH 18, 2019

QUANTIFERON TB GOLD PLUS 4-TUBE TEST IMPLEMENTATION

Effective March 18, 2019, Wisconsin Diagnostic Laboratories (WDL) will be replacing the 3-tube QuantiFERON TB Gold test with the 4-Tube QuantiFERON TB Gold Plus test. The 4-Tube Gold Plus test enables a more comprehensive assessment of cell-mediated immune response to TB infection. While the 3-tube Gold test only examined the immune response of CD4+ T cells, the 4-Tube Gold Plus test examines the immune responses of both CD4+ and CD8+ T cells. Please note the intended use of this test remains unchanged.

There are two minor differences in specimen collection:

1. The addition of a fourth blood collection tube.
2. The tubes no longer have to be drawn in a specific order.

Instructions and Distribution:

- Comprehensive specimen collection instructions are included with this memo.
- **WDL will begin distribution of the new 4-Tube Collection Kits on March 4, 2019.**
- **4-Tube Collection Kits are to be used beginning March 18, 2019.**
- Please note the **3-Tube kits will not be accepted beginning March 18, 2019** and should be discarded.

Summary:

New Test	Mnemonic	Test Code	CPT Code
QuantiferON TB Gold Plus 4-Tube	QTFRN TB P	4500886	86481

Old Test	Mnemonic	Test Code	CPT Code
QuantiferON TB	QTFRN TB	4500885	86480

For technical questions or additional information, please contact:

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QUANTIFERON TB GOLD PLUS 4-TUBE TEST

QuantIFERON-TB Gold Plus Collection Instructions

READ ALL INSTRUCTIONS & CAUTIONS BEFORE DRAWING THE PATIENT

You will notice three changes in the blood collection tubes used in the new test (4-Tube Gold Plus) compared to the old test (3-tube Gold).

1. The old test's red tube (TB antigen) has been replaced with two new tubes: green (TB1 antigen) and yellow (TB2 antigen). The new test uses gray (nil) and purple (mitogen) tubes, as before.
2. The tube labels have updated formatting.
3. The black fill-mark is now thicker and easier to see.

Collection instructions:

1. **Before drawing the patient, confirm you are using the 4 QuantiFERON tubes:**

Grey Top Tube (NIL)
Green Top Tube (TB1 ANTIGEN)
Yellow Top Tube (TB2 ANTIGEN)
Purple Top Tube (MITOGEN)



- *Each tube will draw 1 mL of blood.*
 - *Notice the black fill-mark on the lower left side of the label.*
 - *This is the correct fill-level of blood when the tube is in the upright position.*
 - *The blood may be slightly above or below this mark & still be acceptable.*
 - *Tubes should be at room temperature (between 63-77° F) at the time of blood filling.*
2. There is no order of draw for the collection. If a “butterfly needle” is used to collect blood, a “purge” tube (plain red-top tube, no additives) should be used to ensure the tubing is filled with blood prior to the QTB-Plus blood collection tubes being used.
 - Blood flow may be slow. Hold tube on needle for 2-3 seconds after flow ceases.
 - Once the tube is removed from the needle, look at the black fill-mark on the label to ensure the tube is filled correctly. Check the fill level of all tubes before shaking.
 3. **Immediately after filling, shake all 4 tubes ten (10) times just firmly enough to ensure that the inner surfaces of the tubes are coated in blood. Over-vigorous shaking may cause gel disruption and could lead to aberrant results. This step is very important.**
 4. Label all 4 tubes with patient name, medical record number or date of birth, and collection date and time.
 5. Keep the tubes at room temperature. Do not centrifuge, refrigerate or freeze.
 6. Transport to Wisconsin Diagnostic Laboratories.
 - **Tubes must be received in the laboratory within 16 hours from time of collection.**

CAUTIONS:

1. These tubes are for QuantiFERON-TB Gold Plus testing only. They cannot be used for other laboratory testing.
2. Ordinary blood collection tubes with the same color cap cannot be substituted for these special tubes.
3. If using a butterfly needle, draw a purge tube (plain red-top tube, no additives) first to remove air from the tubing.
4. Follow standard blood handling precautions.