



LABORATORY UPDATE

ENZO CLINICAL LABS INTRODUCES

QuantIFERON® TB Gold Plus

Dear Physician(s) and Staff,

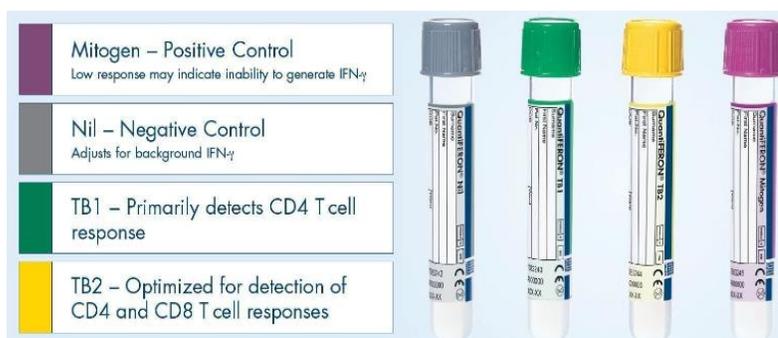
August 27, 2018

Effective Tuesday, September 4th, 2018, Enzo Clinical Labs will begin to offer the Qiagen QuantiFERON® -TB Gold Plus (QFT®-Plus) assay as we continue to offer the most up to date assays available. This FDA approved Interferon-gamma Release Assay (IGRA) for *Mycobacterium tuberculosis* infection is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations. QuantiFERON®-TB Gold Plus is the fourth generation in QuantiFERON®-TB testing technology assessing cell-mediated response through a quantitative measurement of IFN-γ in a whole blood sample. The CDC recommends IGRAs for the majority of the U.S. testing population and for most risk groups (those likely to be infected with TB, anyone with low or intermediate risk of disease progression or those for whom testing for latent TB infection is warranted). IGRAs are also strongly recommended for those who are BCG vaccinated or those unlikely to return to have their TST read. QFT®-Plus offers single visit testing which is highly accurate and reproducible with >97% specificity and >94% sensitivity.

The primary difference between the QFT®-Plus and the QFT® now offered is the collection kit. The QFT®-Plus collection kit contains 4 tubes (pictured below). All 4 tubes must be collected for each patient test. The QFT®-Plus collection kit contains four gel-barrier tubes: gray-top/white ring (nil), green top/white ring (TB1 antigens), yellow top/white ring (TB2 Antigens) and purple-top/white ring (mitogen). 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(R) tube to purge the butterfly line of air and then proceed with drawing the In QuantiFERON® tubes. Fill tubes to the black fill line on the tube label. If tubes are underfilled or overfilled (see kit insert), immediately redraw a replacement tube. Following proper fill, label the tubes appropriately, and shake tubes 10 times just 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. Do NOT centrifuge or refrigerate specimens. Return each of the four properly filled, labeled and shaken tubes to the laboratory within 16 hours of collection. Please indicate date and time of venipuncture on the test request form. Refer to collection instructions included with draw kit.

The current test QuantiFERON®-TB Gold (Order Code 2582) will be discontinued in the near future as Qiagen is discontinuing the manufacture of the assay.

TEST INFORMATION	
TEST NAME:	QuantiFERON® TB-Gold Plus
TEST CODE:	2583
SPECIMEN REQUIREMENTS:	Four tube QFT®-Plus collection kit
TESTING SCHEDULE:	Monday-Friday (excluding holidays)



We appreciate the continued opportunity to serve you and your patients and welcome any questions or concerns you may have. You can reach us at 631-755-5500 or talk to your Enzo Clinical Labs Sales and/or Service Representative for more information.

Sincerely,

Dieter Schapfel, MD
Medical Director