QuantiFERON-TB Gold In-Tube Indeterminate Results

Qiagen, the manufacturer of the QuantiFERON®-TB Gold In-Tube (QFT) test, recently informed providers that certain lot numbers of the TB-Antigen blood collection tube may produce a higher than expected rate of indeterminate results. We are seeing this increase in indeterminate reports in our patient population; however, positive and negative results are not affected and continue to be reliable.

The vendor has indicated that recent lots of mitogen tubes may be more sensitive to variability in blood sample handling. Because the QuantiFERON®-TB Gold In-Tube collection tubes are uniquely both a collection and testing device, collection and handling errors, such as improper tube shaking, can generate indeterminate results. Minimizing the length of time between drawing a blood specimen and incubating the collection tubes may also be helpful to reduce indeterminate results caused by this issue.

Qiagen directs physicians to the 2010 Updated CDC Guidelines for Interferon Gamma Release Assays (IGRAs) for appropriate guidance when an indeterminate result is obtained.

Repeating an IGRA or performing a TST might be useful when the initial IGRA result is indeterminate and a reason for testing persists. A second test also might be useful when assay measurements from the initial test are unusual, such as when the Mitogen value is lower than is expected for the population being tested (e.g. the mitogen response by QFT is <0.5 IU/mL). If an IGRA is to be repeated, a new blood sample should be used. In such situations, repeat testing with another blood sample usually provides interpretable results.


As with any diagnostic test for TB infection, QFT is an aid to assist clinicians in their diagnosis and should be used in conjunction with risk assessment, radiography, and other medical and diagnostic evaluations.

For more information, please contact Providence Regional Laboratory at (503) 215-6660.