

QuantiFERON-TB GOLD Plus results are interpreted as follows.

Note: Diagnosing or excluding tuberculosis disease, and assessing the probability of LTBL, requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting QuantiFERON-TB Gold Plus results.


1. responses to the mitogen positive control (and occasionally tb antigens) can be outside the range of the microplate reader. This has no impact on test results. value > 10 ml are reported by qft-plus software as > 10 iu / ml .

2. Where M. tuberculosis infection is not suspected , initially positive results can be confirmed by retesting the original plasma samples in duplicate in the QFT-Plus ELISA. if repeat testing of one or both replicates is positive , the individual should be considered test positive.

3. Refer to the “Troubleshooting” section for possible causes.

4. in clinical studies, less than 0.25% of subjects had IFN- $\gamma$  levels of > 8.0 IU / ml for the Nil value.

The Mitogen control generally elicits the greatest IFN-gamma response of the 4 samples from each subject. In some cases, the Mitogen control OD value will be above the limit of the microplate reader, this has no impact on the test interpretation. The IFN-gamma level of the NIL control is considered background and is subtracted from both the TB1 and TB2 results and the Mitogen result for that subject. In clinical studies, less than 0.25% of subjects had IFN-gamma levels of > 8.0 IU/ml for the NIL control.

The cutoff for the QuantiFERCON-TB Gold Plus test is 0.35 IU/ml above the nil control ( and TB1 or TB2 minus Nil is >25% of the Nil control) for either or both TB tubes. Individuals displaying a response to either or both of the TB tubes above this cutoff are likely infected with M.tuberculosis.

The magnitude of the measured IFN gamma level cannot be correlated with stage or degree of infection, level of immune responsiveness, or likelihood for progression to active disease. A positive QuantiFERON-TB GOLD Plus result does not necessarily indicate the presence of active tuberculosis disease. Other diagnostic procedures, such as X-ray examination of the chest and microbiological examination of sputum, should be used when TB disease is suspected.

More detailed information can be found in the "Interpretation of Results" section of the QuantiFERON-TB Gold Plus Package Insert.
