CLINICAL LABS OF HAWAII

Client Communication

Feb 2024

QuantiFERON® TB Gold Plus Assay-

Report Interpretation Test Update

On October 30, 2023, Clinical Labs of Hawaii (CLH) launched Quantiferon testing on the Diasorin Liaison XL® (CLIA) analyzer. After reviewing feedback from our valued providers and to simplify the interpretation of results, CLH will be updating the report.

Effective February 5, 2024, the Quantiferon report will display a test result (positive, negative, or indeterminate) without a numerical reference range to better align with the manufacturer's algorithm. This test result is based on the interferon gamma secretion of the various collection tubes in the assay.

Nil (IU/mL)	TB1 minus Nil (IU/mL)	TB2 minus Nil (IU/mL)	Mitogen minus Nil (IU/mL)	LIAISON® QuantiFERON® -TB Gold Plus result	Report/ Interpretation
≤ 8.0	≥ 0.35 and ≥ 25% of Nil	Any	Any	Positive†	*M. tuberculosis* infection likely
	Any	≥ 0.35 and ≥ 25% of Nil			
	< 0.35 OR ≥ 0.35 and < 25% of Nil	< 0.35 OR ≥ 0.35 and < 25% of Nil	≥ 0.5	Negative	*M. tuberculosis* infection NOT likely
	< 0.35 OR ≥ 0.35 and < 25% of Nil	< 0.35 OR ≥ 0.35 and < 25% of Nil	< 0.5	Indeterminate*	Likelihood of *M. tuberculosis* infection cannot be determined
> 8.0	Any				

- This Interferon-Gamma Release Assay (IGRA) test measures interferon gamma secreted from specimens collected from four collection tubes. A qualitative result (negative, positive, or indeterminate) is based on interpretation of the four values (Nil, Mitogen minus Nil, TB1 minus Nil, and TB2 minus Nil). The Nil value represents non-specific reactivity produced by the patient's specimen. The Mitogen minus Nil value serves as the positive control for the patient's specimen, demonstrating successful lymphocyte activity. The TB1 minus Nil tube specifically detects CD4+ lymphocytic reactivity, specifically stimulated by the TB1 antigens. The TB2 minus Nil tube specifically detects CD4+ and CD8+ lymphocytic reactivity, specifically stimulated by the TB2 antigens.

- A positive result indicates active or latent infection by *M. tuberculosis* complex but not from BCG-vaccinated individuals without disease or risk for latent TB infections. A false positive result in the absence of other clinical evidence of TB infection can occur. The magnitude of the interferon gamma level does not correlate with the stage or degree of infection, level of immune responsiveness, or the likelihood of progressing to active disease.
- Serial testing of patients with results in the range of 0.35 and 1.11 IU/mL have shown fluctuation with their test interpretations between negative and positive.[1,2] For such patients, repeat analysis after a clinically suitable period of time or alternate testing may be informative.
- An indeterminate result may occur due to excessive levels of gamma interferon, heterophil antibodies, anergy or pre-analytical issues. Repeat analysis is recommended after a clinically suitable period of time or repeat testing by an alternate method.
- A negative result does not completely rule out TB infection.
- False negatives may occasionally be seen with impaired immune function or from testing too early after exposure.
- This test should not be used as the sole means for diagnosing tuberculosis nor should it be used for excluding active or latent tuberculosis. For more information, refer to the CDC guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection.[3]

If you have any questions, please contact our Client Services Department at 808-677-7998 (Oahu) or 1-866-281-6816 (toll-free).

References:

1. Pulmonary Medicine, vol. 2012, Article ID 291294.
2. Liaison® QuantiFERON® TB Gold Plus ({REF} 311020 7/23)
3. MMWR 2010;59 (RR-05):1-25.

Thank you for choosing Clinical Labs of Hawaii.