



POSITION STATEMENT: The Utilization of QuantiFERON®-TB Gold in California

CTCA recommends that the QuantiFERON®-TB Gold (QFT-Gold), including the QuantiFERON®-TB Gold In-Tube, blood test may be used as an alternative to the tuberculin skin test (TST) for the diagnosis of latent tuberculosis infection in California, in accordance with CDC Guidelines (1). As more data becomes available, we plan to amend all relevant CTCA Guidelines to incorporate this recommendation. The QFT-Gold offers a number of advantages compared with the TST, including increased specificity in persons who have had a BCG vaccination, and elimination of the need for a second visit to read the TST. Providers and facilities providing TB testing should determine if QFT-Gold will replace the TST or will be used to confirm positive TST results. Considerations include cost, feasibility, TST reading rates, and availability of the test. Maximum benefit from QFT-Gold is likely to be realized in BCG-vaccinated individuals, populations with poor adherence rates to TST reading, and in settings where quality assurance and training of skin testing is poor or lacking. Local TB control programs can be contacted to provide consultation to clinicians and facilities regarding the implementation of the QFT-Gold test.

As with the TST, the sensitivity of the QFT-Gold may be decreased in immunocompromised persons and infants (< 1 year of age), but further research is needed (3, 4, 5, 6, 7). In high risk situations (e.g. contact investigations, infants or clinical suspicion of disease), neither a negative TST nor a negative QFT-Gold excludes the presence of TB infection or disease. The use of both tests may be appropriate in particular circumstances, but the results should be interpreted in the context of the individual case and with expert consultation when appropriate. QFT-GOLD will likely prove most useful in asymptomatic, non-immunocompromised risk groups with low risk for progression to active disease, where specificity is more important than sensitivity. Because there are few studies directly comparing the QFT-Gold and the TST in children, caution should be exercised, especially in high risk situations.

CAUTION: Neither the TST nor the QFT-Gold can exclude the diagnosis active TB when there is a high level of clinical suspicion for that diagnosis (e.g. symptoms and radiographic findings typical of TB). Additional diagnostic studies (e.g. sputum for AFB smear and culture, induced sputum, bronchoscopy, tissue biopsy) should be performed promptly as indicated (1, 2). When the level of clinical suspicion for active TB is high, TB treatment should be initiated while the results of diagnostic studies are pending, even if both the TST and QFT-Gold are negative.

References:

- (1) CDC. Guidelines for Using the QuantiFERON®-TB Gold Test for Detecting *M. tb*. Infection, United States. MMWR, 2005; 54 (RR-15):49.
- (2) [Dewan PK](#), [Grinsdale J](#), [Kawamura LM.](#), Low Sensitivity of a Whole-Blood Interferon- γ Release Assay for Detection of Active TB. Clin Infect Dis, 2007; 44:69 and accompanying editorial pages 74-77

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- (3) Luetkemeyer AF, Charlebois ED, Flores LL, Bangsberg DR, Deeks SG, Martin JN, Havlir DV. Comparison of an Interferon- γ Release Assay to TST in HIV-Infected Individuals. Am J Respir Crit Care Med, 2007; 175:737
- (4) Brock I, Ruhwald M, Lundgren B, Westh H, Mathiesen LR, Ravn P. Latent Tuberculosis in HIV positive, diagnosed by the M. tb. Specific Interferon- γ test. Respir Res, 2006; 7:56
- (5) Connell T, et al. Early Detection of Perinatal TB Using a Whole Blood Interferon- γ Release Assay. Clinical Infect Dis, 2006; 42:e82-e85
- (6) Connell TG, et al. Performance of a Whole Blood Interferon- γ Assay in Detecting Latent Infection with M. tb. in Children. Thorax, 2006; 61:616
- (7) Dogra S, et al Comparison of a Whole Blood Interferon- γ assay with TST for the Detection of TB Infection in Hospitalized Children in Rural India. J Infect, 2007; 54:267
- (8) Menzies D, Pai M, Comstock G. Meta-analysis: New Tests for the Diagnosis of Latent Tuberculosis Infection: Areas of Uncertainty and Recommendations for Research. Ann Int Med, 2007; 340-354

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