FACT SHEET

QuantiFERON®-TB Gold In-Tube Test Test 7700

Test Description:
QuantiFERON ®-TB Gold In-Tube test is a whole blood assay for the detection of latent and active tuberculosis. This test offers unmatched specificity and simplicity by using modern genomic technology to provide a result unaffected by subjective interpretation, previous BCG vaccination, and cross-reactivity with most other mycobacteria. QuantiFERON ®-TB Gold is highly specific and a positive test result is strongly predictive of true infection with *Mycobacterium tuberculosis*. QuantiFERON ®-TB Gold is an indirect test for *Mycobacterium tuberculosis* and is intended for use with risk assessment, radiography and other medical and diagnostic evaluations.

Blood samples are mixed with antigens (substances that can produce an immune response) and controls. For QFT-G, the antigens include mixtures of synthetic peptides representing two *M. tuberculosis* proteins, ESAT-6 and CFP-10. After incubation of the blood with antigens for 16-24 hours, the amount of interferon-gamma (IFN-gamma) is measured. If the patient is infected with *M. tuberculosis*, their white blood cells will release IFN-gamma in response to contact with the TB antigens.

- Eliminates false positive outcomes due to bacilli Calmette-Guerin (BCG) vaccination and most non-tuberculosis mycobacteria.
- Unlike the tuberculin skin testing, it requires only one patient visit for a blood draw. Tuberculin skin tests require 2 visits.
- Results can be available within 24 hours.
- The CDC has published Interferon Gamma Release Assay guidance (MMWR June , 2010) indicating the QuantiFERON test should be used in most situations where the traditional tuberculin skin test (TST) has been used.
- Blood samples must be protected from temperature extremes and be processed within 16 hours after collection while white cells are still viable.

Sensitivity: 81-88%
Specificity: 95-99% Infections cuased by M.kansasii, M szulgai or M. marinum are likely to result in a positive Quantiferon test

Specimen:
Special three tube collection kit (1 mL whole blood per tube). Kits provided by the Public Health Laboratory. Blood collection set must be received by the laboratory in 16 hrs or less.

CPT CODE : 86480

San Luis Obispo County Public Health Laboratory

Phone: (805) 781-5507 Fax: (805) 781-1023 www.sloPublicHealth.org/lab
2191 Johnson Ave., San Luis Obispo, CA 93401
Laboratory Hours: Monday – Friday, 8:00am – 5:00pm

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LITERATURE SUMMARY

Quantiferon Values and Treatment

Summary – Seven studies reported an aggregate of 674 active patients of which 566 (83.9%) had positive QFT before treatment, and 347 (51.5%)after treatment for a reversion rate of 38.7%.

Patient number (n)	Baseline Before Rx n QFT+ (%)	Post Rx n QFT+ (%)	Rx in months	Reversion Rate	Ref
60	53 (88.3%)	38 (61.6%)	6	28.3%	1
275	212 (80.4%)	110 (51.8**%**)	6	48.5%	2
36	25 (69.4%)	21 (48.8%)	Not reported	16.0%	3
149	133 (89.0%)	108 **(81.0%)**	6-9	18.7%	4
76	72 (94.7%)	36 (47.9%)	6	50%	5
38	38 (100%)	11 (29.0%)	6	71%	6
40	33 (83%)	23 (58%)	6	25%	7
Total= 674	566 (83.9%)	347 (51.5%)		Avg 38.7	

References:

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2. Chee,C., KhinMar, K., Gan, S., Barkham, T., Koh, C., Shen,L and Wang, Y. Tuberculosis treatment effect on T-cell interferon-γ responses to Mycobacterium tuberculosis-specific antigens. Eur Respir J 36:355-361, 2010.
3. Domínguez J, De Souza-Galvao M, Ruiz-Manzano J, Latorre I, Prat C, et al. 2009. T-cell responses to the Mycobacterium tuberculosis-specific antigens in active tuberculosis patients at the beginning, during, and after antituberculosis treatment. Diagn Microbiol Infect Dis 63: 43–51. 2009.
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6. Sauzullo, I, Mengoni, F., Lichtner, M., Massetti, A., Rossi,R., Iannetta, M., Marocco,R, DelBorgo, C, Soscia F,Vullo V, Mastroianni CM. In vivo and in vitro effects of antituberculosis treatment on mycobacterial interferon-gamma T cell response. PloS One 2009;4. e5187.
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LITERATURE SUMMARY

Quantiferon Values and TST boosting

Summary lists the percent of patients who exhibit a boosted Quantiferon value after a tuberculin skin test is placed.

Patient category	Days post TST					Ref
	3	7	28	42	84-90	
TSTor IGRA negative patients						
TST-negative	0/15 (0%)					2
IGRA-negative		2/16(**12.5**%)				1
QFT/TST-negative			5/33(**15**%)			5
QFT-negative				3/9 (**33**%)		4
TST-negative					10/35(**29**%)	3
TSTor IGRA Positive patients						
Cured TB 4/5QFT pos	4/5 (**80**%)					2
TST pos 17/46 QFT+	18/46 (**39**%)					2
IGRA-pos		5/8 (**62.5**%)				1
QFTpos/TST neg					8/12(**67**%)	3

References

1. Van Zyl-Smit RN et al. Within-subject variability and boosting of T-cell interferon-γ responses after tuberculin skin testing. Amer J Resp Crit Care Med 180:49-58, 2009.
2. Leyten, EMS et al. Effect of tuberculin skin testing on a Mycobacterium tuberculosis-specific interferon-γ assay. Eur Respir J 29:1212-1216, 2007
3. Nguyen,M et al. Quantiferon-TB predicts tuberculin skin test boosting in US foreign born. Int J Tuberc Lung Dis 9:985-991, 2005.
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