QIAGEN

QuantiFERON®-TB Gold In-Tube test Sole Source Justification

QuantiFERON technology is a unique approach to disease detection and monitoring – a patented whole blood method for detecting cell mediated immune responses.

QuantiFERON-TB Gold In-Tube (QFT®) is an in vitro diagnostic test using a peptide cocktail simulating ESAT-6, CFP-10, and TB7.7 proteins to stimulate cells in heparinized whole blood. Detection of interferon-gamma by ELISA is used to identify in vitro responses to these peptide antigens that are associated with *Mycobacterium tuberculosis* infection.

The QuantiFERON-TB Gold In-Tube test was developed after extensive pre-clinical and clinical testing within the U.S. and elsewhere, and was approved by the FDA on October 10, 2007 as an indirect test for detection of *M. tuberculosis* infection.

QIAGEN has exclusive rights to the patented QuantiFERON technology and licenses for exclusive use of tuberculosis specific antigens: ESAT-6, CFP-10, and TB 7.7(p4) in the QuantiFERON-TB Gold In-Tube test using whole blood, under US Patent no.5955077, 6290969, and 6291190 respectively.

QIAGEN is the manufacturer of QuantiFERON products. QIAGEN is the sole source supplier of the QuantiFERON-TB Gold In-Tube test to commercial customers in the United States (with the exception of Puerto Rico and the U.S. Virgin Islands) at this time.

FDA approval notes that QFT is an indirect test for *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluation. For up-to-date licensing information and product-specific disclaimers please refer to the package insert, available at **www.QuantiFERON.com** or on request from QIAGEN Technical Services.

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