



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 for diagnosis of tuberculosis infection.

Cellestis Limited (Melbourne, Australia) has exclusive rights to the patented QuantiFERON® technology and licenses for exclusive use of tuberculosis specific antigens: ESAT-6, CFP-10 and TB7.7(p4) in the QuantiFERON®-TB Gold In-Tube test, under US Patent no. 5955077, 6290969, and 6291190 respectively.

Cellestis Inc. is the legal manufacturer of QuantiFERON® products, and is a wholly owned subsidiary of Cellestis Limited. Cellestis was acquired by QIAGEN in August 2011, and Cellestis is now a QIAGEN company. As such, QIAGEN Inc. has been assigned the rights of sole source supplier of the QuantiFERON®-TB Gold In-Tube test and other QuantiFERON® products to commercial customers in the United States (with the exception of Puerto Rico, the U.S. Virgin Islands and GSA), effective December 1, 2012.

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 evaluations. 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.

Cellestis, a QIAGEN company

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