



## Press Release

### **CELLESTIS RESPONDS TO WORLD HEALTH ORGANIZATION GUIDANCE ON USE OF BLOOD TESTS FOR ACTIVE TUBERCULOSIS**

*Blood Tests Still Necessary for Latent Disease; WHO Guidance is Not Applicable to QuantiFERON-TB Gold (QFT), Used to Test for Latent TB*

**MELBOURNE, AUSTRALIA, July 25, 2011** – A new policy recommendation released on 20 July by the World Health Organization (WHO) warns against the use of serological (blood) tests to diagnose active tuberculosis (TB). Serological tests measure antibodies to TB in serum and are different to QuantiFERON, which measures responses of white blood cells to TB specific proteins.

Active tuberculosis occurs when the TB organism has overcome the body's immune defences and proliferates to cause clinical symptoms. According to WHO, TB takes one life every 17 seconds globally.<sup>1</sup> People with active disease often shed live TB bacteria and infect others. A person who is infected with the bacteria that causes TB, but who shows no symptoms and is not sick with the disease, is said to have latent TB infection (LTBI).<sup>2</sup> People with LTBI are at risk of developing active TB, particularly if their immune system becomes depressed<sup>2</sup>.

QFT is intended as an aid to the diagnosis of TB infection, both active and latent, and does not discriminate between the two conditions. Cellestis Limited, manufacturer of QuantiFERON<sup>®</sup>-TB Gold (QFT), has become aware that some media reports have caused confusion around the WHO announcement. The press release from WHO clearly notes that it refers to serological (antibody-based) blood tests for active TB, and their comments do not apply to Interferon-Gamma Release Assays (IGRAs) for diagnosing latent TB. This has been confirmed by direct correspondence by WHO to Cellestis.

"QuantiFERON-TB was developed in response to the poor quality of previous tests such as those referred by WHO. We thoroughly agree with the comments of WHO regarding serological tests for active TB," said Dr Jim Rothel, Chief Scientific Officer of Cellestis. "It is imperative to recognize that TB is still one of the world's deadliest diseases. We are confident that QFT has the ability to help reduce the future healthcare burden of TB, and potentially help to lower healthcare costs related to TB and reduce the risk of epidemics."

QFT is well-regarded by the public health and infectious disease communities, and evidence of its clinical effectiveness and utility in tuberculosis management have been supported over the years in more than 600 peer-reviewed studies published in prestigious medical journals throughout the world.<sup>3,4,5,6</sup>

#### **About QuantiFERON<sup>®</sup>-TB Gold (QFT)**

QuantiFERON<sup>®</sup>-TB Gold (QFT) is a whole blood test that accurately identifies people infected with *Mycobacterium tuberculosis*, the causative agent of Tuberculosis (TB). As a modern alternative to the 110 year old Tuberculin Skin Test (TST), also known as the Mantoux, QFT offers unmatched specificity, high sensitivity and simplicity. QFT enables focused TB therapy by providing clinicians with an accurate, reliable and convenient TB diagnostic tool. QFT is unaffected by previous BCG vaccination and most other environmental mycobacteria. Unlike the TST, it requires only one patient visit, is a controlled laboratory test and provides an objective, reproducible result that is unaffected by subjective interpretation.

QFT is available for use in all clinical settings in which TST is commonly used. Examples include contact tracing, regular employee testing, for example for health care workers, as well as screening programs for prisoners and immigrants. QFT's application in the screening of immunosuppressed patients prior to anti-TNF-alpha therapy initiation and in patients with HIV, cancer or organ transplants offers distinct advantages over the TST.

QFT is sold directly in the U.S. by Cellestis Inc. and through Quest Diagnostics, Inc., LabCorp, and other commercial laboratories. In Europe QFT is provided by Cellestis GmbH (Germany); and in Australia/New Zealand by Cellestis International Pty. Ltd. (Australia). QFT is also available through Cellestis Commercial Partners in Japan, Europe, the Middle East, Africa, South America and Asia.

### **About Cellestis Limited**

Cellestis Limited, a listed Australian biotechnology company founded in 2000 in Melbourne, Australia, develops and manufactures the QuantiFERON-TB Gold (QFT) test, a breakthrough blood test for the detection and control of tuberculosis. The QuantiFERON technology is a patented method for detecting cell mediated immune (CMI) responses of T-cell lymphocytes using whole blood samples. In comparison to existing methods of measuring CMI, this unique technology provides accuracy and sensitivity along with major savings in operator time, labor and reagents. Using its patented QuantiFERON technology, Cellestis develops diagnostics tests that measure immune function for diseases with an unmet medical need.

Cellestis is proud to be exploring opportunities to enhance the global effort to eliminate TB. Cellestis is an industry partner of FIND (the Foundation for Innovative New Diagnostics) and the Stop-TB Partnership.

For more information, please visit [www.Cellestis.com](http://www.Cellestis.com) and [www.TackleTB.com](http://www.TackleTB.com).

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### **REFERENCES**

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<sup>3</sup> Diel R, Loddenkemper R, Niemann S, Meywald-Walter K, Nienhaus A. "Negative and positive predictive value of a whole-blood IGRA for developing active TB – an update." *Am J Respir Crit Care Med* (2008).

<sup>4</sup> Diel et al. "Evidence-based comparison of commercial interferon-gamma release assays for detecting active TB: a metaanalysis." *Chest* (2010) 137: 952 – 968.

<sup>5</sup> Anderson P, Munk ME, Pollock JM, Doherty TM. "Specific immune-based diagnosis of TB." *Lancet* (2000) 356: 1099 – 1104.

<sup>6</sup> Higuchi K, Harada N, Mori T, Sekiya Y. "Use of QuantiFERON®-TB Gold to investigate tuberculosis contacts in a high school." *Respirology* (2007) 12: 88 – 92.