

Press Release

Blood Tests Demonstrate Superior Accuracy in Diagnosing Tuberculosis, Finds *CHEST* Meta-Analysis

Meta-analysis supports advances in Tuberculosis diagnostics compared to 100+-year-old skin test

Valencia, CA, April 6, 2010 – New data from a meta-analysis of existing literature published today in *CHEST*, the official journal of the American College of Chest Physicians, demonstrate that Interferon Gamma Release Assays (IGRAs) are superior to the previous standard in diagnostics, the 100+-year-old tuberculin skin test (TST), for detecting confirmed active Tuberculosis (TB) disease. This was especially true when the IGRAs, both QuantiFERON[®]-TB Gold (QFT), which is manufactured by Cellestis Limited, as well as the T-SPOT[®]-TB (T-Spot), were administered in developed countries.¹

In the United States (U.S.), TB remains a public health threat, with as many as 14 million Americans infected with TB bacteria.² At any given time, members from this large pool of infected people can develop full-blown, highly contagious TB. This new meta-analysis provides further evidence supporting a new, scientifically-proven standard for detecting tuberculosis infection.

“Tuberculosis remains a global public health threat and as such, should be regarded with a corresponding level of urgency,” said lead study author Roland Diel, MD, MPH, Assistant Professor, Department of Pulmonary Medicine, Medical School (MHH) Hannover. “The study results support IGRAs as modern advances in diagnosing a very old disease that is just as significant today as it was in the 1700s.”

The authors critically reviewed and analyzed 124 studies investigating the commercial QFT and T-Spot blood tests and TST for sensitivity (the percentage of infected persons who return a positive test result) in confirmed active TB cases and specificity (the percentage of uninfected persons who return a negative test result) in individuals with no risk factors for infection. Researchers found that the newer blood tests provide significant improvements in sensitivity over TST. The authors reviewed studies from developed countries and found the TST had only 71.5 percent sensitivity compared with QFT at 84.5 percent and the T-Spot at 88.5 percent.

In a country with a relatively low rate of TB disease, such as the U.S., specificity is more important because poor specificity leads to greater numbers of false positives. QFT is highly specific at 99.2 percent versus 86.3 percent for T-Spot. By comparison, TST specificity may be as low as 59 percent in persons who are BCG-vaccinated and only 97 percent in non-vaccinated populations.³ To highlight the importance of specificity in low prevalence settings, in testing 1,000 persons without TB, the TST would return between 30 and 410 false-positives, T-Spot would return 157 false-positive test results; QFT only eight.

“In addition to aiding the prevention of future outbreaks, improved tuberculosis diagnostics reduce the costs associated with TB control,” said Tony Radford, Chief Executive Officer, Cellestis Limited. “With QFT virtually eliminating false-positive readings that are common with TST, TB control and treatment can now be more accurately targeted to those persons who truly are infected, minimizing unnecessary further testing and treatment.”

Additional Meta-Analysis Results

This new analysis was conducted to establish performance benchmarks, and to this end, only took into account work based on accepted “gold standards” of diagnostic confirmation of active TB disease. The analysis highlights an added benefit that IGRAs offer over TST -- built-in control for measuring immune status of persons tested. This reduces the risk of false-negative results in those with compromised immune systems. IGRAs flag such individuals with a result of “Indeterminate”. The pooled rate for all populations of indeterminate results was low, 2.1 percent for the QFT and 3.8 percent for T-Spot.¹

About Tuberculosis

Tuberculosis (TB) is a contagious disease caused by a bacterium called *Mycobacterium tuberculosis*. TB bacteria usually attack the lungs, but can affect any part of the body such as the kidney, spine, and brain. If not treated properly, TB can be fatal.⁴ TB bacteria is spread through the air when a person with TB disease of the lungs or throat coughs, sneezes, speaks, or sings, which may lead people in close proximity to become infected.^{5,6}

According to the World Health Organization, about one person dies of TB every 17 seconds, causing nearly 2 million deaths annually.⁵ TB continues to be a contagious scourge in developing countries, and with the world shrinking rapidly due to global migration, it is a major public health threat in developed nations as well, including the United States. Each infected person represents a potential yet preventable future outbreak. Convenient and trustworthy testing for TB infection is necessary in order to quickly identify the appropriate persons for treatment and thereby prevent its spread.

About QuantiFERON[®]-TB Gold (QFT)

QuantiFERON[®]-TB Gold (QFT) is a simple 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. Results can be available within 24 hours.

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; in Europe by Cellestis GmbH (Germany); and in Australia and Asia by Cellestis International Pty. Ltd. (Australia). QFT is also available through Cellestis Commercial Partners in Japan, Europe, the Middle East and other countries around the world.

About Cellestis Limited

Cellestis Limited, a listed Australian biotechnology company founded in 2000 in Melbourne, Australia, develops and manufactures the QuantiFERON-TB Gold In-Tube (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.

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References

1 Diel, R et al. Evidence based comparison of commercial interferon-gamma release assays for detecting active tuberculosis -- a meta-analysis. *CHEST*. [INSERT PUBLICATION DATE].

² Bennett DE, Courval JM, Onorato IM, et al. Prevalence of Tuberculosis Infection in the United States Population: The National Health and Nutrition Examination Survey, 1999--2000 *Am J Respir Crit Care Med*, vol 177, pp. 348-355. 2008.

³ Pai *et al*, *Annals Int Med*, 2008.

⁴ CDC TB Basic Facts <http://www.cdc.gov/tb/topic/basics/default.htm>. Accessed 2/24/10.

⁵ CDC TB Basic Facts <http://www.cdc.gov/tb/topic/basics/default.htm>. Accessed 2/24/10.

⁶ World Health Organization. Tuberculosis Infection and Transmission <http://www.who.int/mediacentre/factsheets/fs104/en/index.html>. Accessed 3/1/10.