

Press Release

New CDC Guidelines Prefer Use of Blood Tests, including QuantiFERON[®]-TB, to Diagnose Tuberculosis Infection in Certain Populations

TB Remains a Major Public Health Threat in Both Developing and Developed Countries

Valencia, CA, 24 June, 2010 – Today the United States (U.S.) Centers for Disease Control and Prevention (CDC) issued new and important guidelines on the detection of *Mycobacterium tuberculosis* infections, the causative agent of tuberculosis (TB). In these landmark guidelines, CDC advises that Interferon Gamma Release Assay (IGRA) blood tests are now preferred over the 100+-year-old tuberculin skin test (TST) for diagnosing TB infection in certain populations, including people who typically do not return for the necessary reading of TST results, and those who have received Bacille Calmette-Guérin (BCG) as a vaccine or for cancer therapy. Typically the TST or IGRAs, such as QuantiFERON[®]-TB Gold (QFT), manufactured by Cellestis Limited, should be used as aids to diagnose infection with *M. tuberculosis*.¹

“In the U.S., up to 14 million Americans may be infected with TB bacteria and are at risk of developing full-blown, highly contagious TB. With these sobering numbers, complacency about TB’s public health impact is not an option,” said Antonino Catanzaro, M.D., professor of medicine, University of California San Diego, and Non-Executive Independent Director, Cellestis Limited. “These guidelines encapsulate the enormous body of clinical evidence on the performance of the QFT test and reflect the significant benefits this test is bringing to TB control worldwide.”

The CDC report, “Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection — United States, 2010” along with a companion implementation guide, appears in the June 25, 2010, Volume 59, No. RR-5 issue of the CDC’s Morbidity & Mortality Weekly Report (MMWR). TST’s drawbacks – which include a higher risk for false positives, especially in people who have been BCG-vaccinated; irritating TB-extract that must be injected under the skin; and the need for a second doctor’s visit – were evaluated by the CDC and factored into their recommendations.

Approximately one person dies of TB every 17 seconds.² Each infected person represents a potential yet preventable future outbreak. Convenient and trustworthy testing for TB infection is vital in order to efficiently identify the appropriate persons for treatment and thereby prevent its spread.

The populations specified by CDC in these guidelines, represent a majority of those being screened for TB infection. “With a specificity of more than 99 percent, QFT virtually eliminates false positive results and is simple to administer,” said Tony Radford, chief executive officer, Cellestis Limited. “With more than 400 peer-reviewed, published clinical studies, QFT is a modern, scientifically–validated solution for reliable diagnosis of TB infection, and offers significant economic and public health advantages.”

Specific highlights from the recommendations with regards to IGRAs include:

- IGRAs are preferred over the TST for testing persons who have received BCG (as a vaccine or for cancer therapy).
- IGRAs are preferred over the TST for diagnosing TB infection for persons from groups that historically have low rates of returning to have TSTs read.
- IGRAs may be used in place of (not in addition to) TST in all situations in which CDC recommends testing, and is considered acceptable medical and public health practice.
- IGRAs may be used in place of TST (without preference) to test recent contacts of persons with infectious tuberculosis.
- IGRAs may be used in place of TST (without preference) for periodic screening to address occupational exposure to TB.
- A TST is preferred for testing children aged <5 years. Use of an IGRA in conjunction with TST has been advocated by some experts to increase diagnostic sensitivity in this age group. Recommendations regarding use of IGRAs in children have also been published by the American Academy of Pediatrics.

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.³ 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.⁴

According to the World Health Organization, about one person dies of TB every 17 seconds, causing nearly 2 million deaths annually.⁴ 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. and through Quest Diagnostics, Inc. 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 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 and www.TackleTB.com.

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References

¹ CDC MMWR. [June 25, 2010, Vol.59. No RR-5]

² CDC Tuberculosis Data and Statistics <http://www.cdc.gov/tb/statistics/default.htm>. Accessed 2/25/10.

³ CDC TB Basic Facts <http://www.cdc.gov/tb/topic/basics/default.htm>. Accessed 2/24/10.

⁴ World Health Organization. Tuberculosis Infection and Transmission <http://www.who.int/mediacentre/factsheets/fs104/en/index.html>. Accessed 3/1/10.