

QFT NEWS

Mar 2009

Welcome to **QFT™ News**
Here you will find
the latest updates on how
QuantiFERON®-TB Gold (QFT) is
“**Changing the way
the world looks at TB**”

Recent Developments

Korean Reimbursement

Cellestis is pleased to announce that the QuantiFERON-TB Gold In-Tube test has been granted a medical reimbursement approval code in Korea. Approval of this reimbursement by the Korean authorities is a strong indication of the growing interest and medical acceptance of QFT in Korea. Cellestis wishes to acknowledge the efforts of **Woongbee Meditech**, our commercial partner in Korea, for their role in achieving QFT's regulatory approval and now reimbursement.



US Navy releases updated TB policy which includes QFT

The US Navy has released their updated TUBERCULOSIS CONTROL PROGRAM instructions (BUMEDINST 6224.8A 12 Feb 2009), which now include QFT as an alternative to the TST. As a result of the new policy, US Navy facilities are permitted to order QFT as a routine assay as defined by their new policy for TB screening and testing. The new Navy policy defines that the following individuals should be tested for TB by either QFT or TST:

1. All Navy and Marine Corps recruits on entry into the naval service.
2. All active duty and reserve personnel during periodic health checks.
3. Civilian mariners are to be screened annually.
4. Individuals at risk of acquiring TB, including those as part of a contact or outbreak investigation or those that may be TB suspects.
5. Prior to boarding a commissioned vessel.
6. Prior to leaving Naval service.

This new recommendation follows that released by the US Army in September 2008.

▷ The US Navy policy statements are available [here](#).

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Technical Training in Southeast Asia

Cellestis recently increased its activities in Southeast Asia. Dr Christian Stoeckigt, Director Global Technical Services, met with customers and commercial partners in Taiwan, Singapore and Indonesia to assess their technical requirements and needs to automate QFT.

Focus Events

Houston QuantiFERON Symposium

Cellestis was pleased to sponsor its first educational symposium for the year, on January 15 2009, within the Texas Medical Center, Houston USA.

The symposium, jointly hosted by Cellestis and The Methodist Hospital Research Institute (TMHRI), focused on tuberculosis screening using QFT. The event enabled independent speakers from different parts of the US to share their experiences first hand with the Houston attendees. The distinguished speaker panel had varied backgrounds representing many years of QFT testing in a research, public health, clinic, occupational health and corporate setting. The keynote speakers included:

- **Masae Kawamura MD**, Director/TB Controller, San Francisco TB Control Section, Department of Public Health, CA.
- **Edward Graviss PhD, MPH**, Director, Molecular Tuberculosis Laboratory, TMHRI, Houston TX.
- **David Marder MD, MPH**, Director, University Health Services, University of Illinois, Chicago IL.
- **Jackie Kinard RN, APN**, United HealthCare, Las Vegas NV.
- **Elizabeth Lawhorn MSN, RN**, US Production Medicine and Occupational Health Coordinator, ExxonMobil Corporation, Houston TX.
- **Richard Dockins MD MPH**, ExxonMobil Corporation Medicine and Occupational Health, Houston TX.

Over 100 attendees, the majority from local Houston hospitals, attended the symposium. Subjects presented included reasons for switching to QFT, benefits over TST, methods of implementation, experiences with the test, long term cost savings as well as concerns and results. Dr Edward Graviss, Director of the TMHRI Molecular Tuberculosis Laboratory expertly chaired the symposium. The TMHRI laboratory is an excellent resource for the QFT test and currently performs testing for local Houston hospitals as well as ExxonMobil (some Houston-based oil companies currently use or plan to adopt QFT to screen their offshore employees). The meeting also included a brief presentation by Quest Laboratories (Houston). Quest has recently rolled out QFT testing in the Houston area and is an excellent channel as a reference laboratory.

The enthusiasm of the attendees indicated there was significant interest and support for bringing QFT onboard as the routine tool for LTBI screening.

▷ View a pdf version of each of the presentations [here](#).

Health Care Worker screening, a focus for Cellestis at the Arab Health Conference in Dubai, United Arab Emirates

Cellestis exhibited at the premier Arab Health Conference and Congress in Dubai this January. This unique forum for medical professionals brought leading researchers, scholars and renowned speakers together.

Dr Albert Nienhaus MD MPH, was the featured presenter in the Microbiology section. His presentation “Screening Health Care Workers for Latent Tuberculosis Infection” covered a wide range of areas including the cost-effectiveness of TB-screening in Healthcare Workers (HCWs) using Interferon-gamma Release Assays.

Speaking to a standing room only audience, Dr Nienhaus discussed the current situation—“The burden of tuberculosis (TB) in Healthcare Workers (HCWs) is still high. Fingerprint studies help to better understand the infectious pathways. Following these studies, chances are 40 to 80% that active TB in a HCW is caused by an infection at the workplace. This emphasises the need for a sophisticated TB screening program for HCWs. With the newly developed and meanwhile extensively evaluated Interferon-gamma Release Assays (IGRAs) new and efficient tests for the diagnosis of latent TB infection (LTBI) are available which can replace the Tuberculin Skin Test (TST). The IGRAs are far more specific than the TST and have at least the same sensitivity. With the IGRAs no second appointment for reading the test is needed and the interpretation of the results does not depend on circumstances like exposure, BCG vaccination, repeated testing, age of the person or country in which the test is performed. The IGRA is endorsed by several national guidelines either in addition to or as replacement of the TST.”

In the course of his presentation, Dr Nienhaus also elaborated on the cost-effectiveness of TB-screening in HCWs using the IGRA and placed special emphasis on migrant healthcare workers. Following the presentation, a question and answer session clearly highlighted the need for the use of IGRAs in HCW screening programs.

Dr Albert Nienhaus MD MPH, Head of the Occupational Health Research Department of the National Accidents and Occupational Disease Insurance for Healthcare and Welfare Workers in Hamburg, Germany (BGW)



Publications Update

Healthcare workers (HCWs) are at significant risk of contracting TB infection from patients. Additionally, if infected, there is considerable risk of them passing on infection to the vulnerable populations they work with. Therefore TB control in healthcare settings usually involves routine screening of the HCWs for latent TB infection (LTBI).

Previously, in spite of its shortcomings, the tuberculin skin test (TST) was the only tool available. In some countries where BCG vaccination has been (or still is) used, the poor specificity of the TST has resulted in screening policies not being followed. Availability of Interferon Gamma Release Assays (IGRAs) such as QuantiFERON-TB Gold and QuantiFERON-TB Gold In-Tube (QFT), now allows a more specific and effective alternative to the TST for diagnosing latent TB infection in HCWs. Key advantages of QFT include a single clinical visit, no interpretation problems or variable cut-off interpretation, fast results within 24 hours, and high specificity with no effect of BCG vaccination. The end result is a more accurate diagnosis with fewer logistical problems, less cost, and overall better compliance in HCW programs. Two recent studies focusing on LTBI screening of HCWs are of major significance in relation to the use and benefits of QFT over TST.

One of the largest studies performed to date is that by Vinton and colleagues in Australia, comparing the efficacy of QFT versus TST for the screening of HCWs in a developed country environment. This study included 481 hospital staff with varied demographics and TB risk factors, of which 358 participants had both TST and QFT results available for comparison. The study correlated positive results to risk factors, such as country of birth, travel to high-risk areas, or high-risk occupation in the HCW setting, as well as BCG vaccination status. A powerful aspect of this study was that it used time of exposure as a continuous variable, a method that matches the reality that risk of TB infection correlates to time of exposure. For example, it was found that QFT positive results strongly relate to how long a person had been a resident in a high-risk country, rather than treating birth in a high risk area as a single risk. As expected, many fewer were positive for QFT (6.6%), while 33% of the Australian HCWs were positive for TST. The authors concluded that a positive QFT result was associated with demographic

and occupational risk factors such as birth in a high prevalence country, or an occupational contact. A positive TST result, on the other hand, was very highly associated with a prior history of BCG vaccination, far more than occupational exposure.

Another HCW screening study performed by Marie de Perio *et al* at the University of Cincinnati analysed the cost effectiveness of QFT and the TST in the LTBI screening of new hires. This used Markov modeling of costs and benefits, to examine the cost-benefits. Results indicated that the QFT test offers superior clinical results and costs less than the TST, regardless of BCG vaccination status. The authors summarised **“Use of the QFT-G and QFT-GIT leads to superior clinical outcomes and lower costs than the TST and should be considered in screening non-BCG vaccinated and BCG-vaccinated new HCWs for LTBI.”***

*QFT-G and QFT-GIT — Author’s terms for QuantiFERON-TB Gold and QuantiFERON-TB Gold In-Tube, respectively.

References

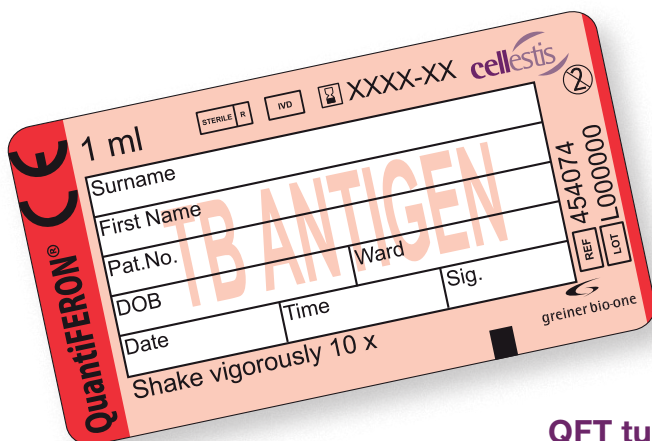
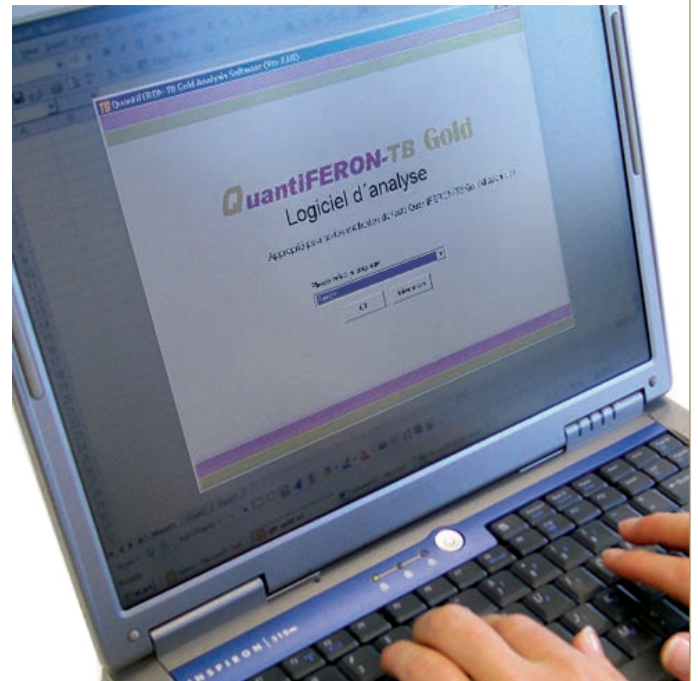
1. Vinton P, Mhrshahi S, Johnson P, Jenkin GA, Jolley D, Biggs BA. Comparison of QuantiFERON-TB Gold In-Tube Test and tuberculin skin test for identification of latent Mycobacterium tuberculosis infection in healthcare staff and association between positive test results and known risk factors for infection. *Infect Control Hosp Epidemiol* 2009; 30:215-21.
2. de Perio MA, Tsevat J, Roselle GA, Kralovic SM, Eckman MH. Cost-effectiveness of interferon gamma release assays vs tuberculin skin tests in health care workers. *Arch Intern Med* 2009; 169:179-87.

Product Release / Update

New multi-language QFT software (v2.60)

Cellestis announces the development of a multi-language version of the QFT software. The new software **version 2.60** is now available for download from the Cellestis website. This version replaces the previous version 2.50.4. For this new release, the user has the option to run the software in English, French, German, Italian and Spanish. The software has a modular set-up so that additional languages can be added easily in the future. Translations into Czech, Greek and Portuguese are planned but not yet implemented. Our goal is to add new languages quarterly and to continuously provide our customers with optimal service and support.

▷ For a link to the new software update, click [here](#).



QFT tube caps and label redesign

The caps and labels of the QFT tubes are in the process of redesign. The new tubes will have a 'screw cap' style for easy handling. The labels will be redesigned with an enhanced colour bar around the edges. This will enable laboratories adding barcode information on top of the existing tube label to clearly continue to identify the TB Antigen, Nil and Mitogen tubes. The added colour bar around the edges makes the identification of the individual tubes easier for lab personnel.

2nd Global Symposium on IGRAs

May 30—June 1 2009 Dubrovnik Croatia

Cellestis is proud to sponsor the 2nd Global Symposium on IGRAs in Dubrovnik from May 30 until June 1, 2009. The focus of this year's symposium is on "Putting Interferon-gamma Release Assays into Practice".

The symposium will present practical experience that has been gained using IGRAs for detecting TB infection, the latest clinical information on IGRAs, new concepts in TB latency and the risk of disease progression. Detailed information can be viewed in the preliminary agenda.

This is an exciting and rapidly developing area which continues to challenge dogmas and opinions on TB epidemiology and current diagnostic practices. As a satellite symposium of the 5th Congress of the European Region of the International Union Against Tuberculosis and Lung Disease (IUATLD), this symposium will be held at the same venue immediately after the Union Meeting.

▷ Register now to secure your place at this exciting forum:
<http://www.igrasymposium.com/agenda.html>

Proudly sponsored by FIND Diagnostics and Cellestis



Upcoming Events

Visit us at these events to find out the latest information about QFT

Deutsche Gesellschaft für Infektiologie Annual Congress	Mar 12–14, 2009	Freiburg, Germany
DGP Congress	Mar 18–21, 2009	Mannheim, Germany
Navy and Marine Corps Public Health Center	Mar 23–24, 2009	Virginia, USA
Gesellschaft für Pädiatrische Pneumologie	Mar 26–28, 2009	Düsseldorf, Germany
59. Wissenschaftlicher Bundeskongress der Ärzte des öffentlichen Gesundheitsdienstes	Apr 7–9, 2009	Bielefeld, Germany
SGP Annual Meeting	Apr 16–17, 2009	Davos, Switzerland
Voorjaarsdagen medische Microbiologie	Apr 20–22, 2009	Ede, Netherlands
7. Nordbayrisches Forum für Betriebsärzte	Apr 23–24, 2009	Erlangen, Germany
CA TB Controllers Association	Apr 30–May 1, 2009	San Francisco, USA
American Thoracic Society	May 15–20, 2009	San Diego, USA
American Society of Microbiology	May 18–20, 2009	Philadelphia, USA
American College Health Association	May 28–29, 2009	San Francisco, USA
Association for Professionals in Infection Control and Epidemiology	Jun 7–9, 2009	Fort Lauderdale, USA
Journées Nationales d'Infectiologie	Jun 10–12, 2009	Lyon, France
ÖPG Jahrestagung 2009	Jun 11–13, 2009	Salzburg, Austria
National TB Contollers Association	Jun 16–18, 2009	Atlanta, USA
International Congress of Chemotherapy and Infection	Jun 18–21, 2009	Toronto, Canada
American Association for Clinical Chemistry	Jul 21–23, 2009	Chicago, USA
Force Health Protection	Aug 19–20, 2009	Albuquerque, USA
ERS Annual Congress	Sep 12–16, 2009	Vienna, Austria
Association of Occupational Health Professionals	Sep 16–19, 2009	Portland, USA
Infectious Disease Society of America	Oct 29–Nov 1, 2009	Philadelphia, USA

Cellestis events can also be accessed online by clicking [here](#).

Message from the CEO

The end of 2008 signalled an important event for Cellestis, the announcement of a profitable half-year and a small dividend for the shareholders who have waited patiently for the last 7 years as we have developed and brought QFT to the world market. It is satisfying to be able to reassure our customers that the company is in a solid position, with a strong balance sheet, and a plan to be your long-term partner in changing the way the world looks at TB. For this result I also thank those early, far-sighted physicians and TB controllers who shared our vision of improving TB control through better diagnosis of TB infection and better tools for stopping TB before it spreads. Without them it would simply have not been possible.

I write these words from Johannesburg, where I have recently had the privilege to speak at a South African conference, sponsored by our partner in South Africa, Pro-Gen Diagnostics, on the role of latent TB treatment in this high burden country. The statistics on TB and HIV co-infection are, in one word, terrifying. Rates of active TB exceed 1% per annum and have doubled, nearly tripled, in the last 10 years, with 30 % of the population HIV infected. The focus of TB control is, of course, on the huge problem of active disease. Even in the middle of this immensely difficult situation, it is recognised that curing TB in those who have already developed symptoms, and are spreading TB infection, is not enough. No war is won simply by treating the wounded. Treating the latently infected offers a chance to at least slow down the cycle of transmission. This is a truly daunting task in South Africa and certainly not one they could universally adopt right now. But QFT can help by identifying who is truly infected and who may benefit most from preventive therapy. Certain groups are critical for any chance to fight the epidemic. Protection of healthcare workers around the world is a goal of Cellestis and nowhere are healthcare workers more at risk and in need of TB protection, than in Africa.

Yours Sincerely,

Tony Radford, CEO

“ I ... thank those early, far-sighted physicians and TB controllers who shared our vision of improving TB control through better diagnosis of TB infection. ”

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