

In Focus: A New Era for QuantiFERON®-TB Gold (QFT®)



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In Focus: A New Era for QFT

Cellestis and its QuantiFERON®-TB Gold (QFT®) assay have been “measuring the other side of immunity” for over 10 years. QFT uniquely measures the cell mediated immune response to TB. As of August 29, 2011, the sample and assay technology company, QIAGEN, took the reins of Cellestis and QuantiFERON platform technology. In this issue, we describe how QFT will grow under the QIAGEN name and continue to change the way we look at – and fight – TB.

Introducing... *Cellestis, a QIAGEN Company*

Over the last decade, Cellestis has been developing and providing diagnostic tests that measure immune function for diseases with an unmet medical need. Through the establishment of its QuantiFERON platform technology and, in particular, its QFT assay, Cellestis has helped shape the way tuberculosis (TB) is detected around the world.

Cellestis’ vision and core values of innovation, quality, medical responsibility, customer satisfaction, and service have been keys to its success and central to QFT’s success as well. These are major reasons why QIAGEN, the leading provider of sample and assay technologies, acquired Cellestis. The company formerly known as Cellestis is now officially known as *Cellestis, a QIAGEN Company*.



Figure 1. Cellestis and QIAGEN will be working together to help change the way we look at - and fight - TB.

Who is QIAGEN?

With more than 3,600 employees in over 35 locations worldwide, QIAGEN is a global leader in sample and assay technologies used in many laboratory and clinical situations. QIAGEN’s sample technologies are used to isolate DNA, RNA, and proteins from biological samples, whereas the assay technologies are then used to make specific target biomolecules, such as the DNA of a specific virus, visible for subsequent analysis.

QIAGEN supports molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers whose applications range from forensics, animal and food testing, and pharmaceutical process control to molecular and companion diagnostics for infectious and other diseases. In particular, QIAGEN’s *digene* HPV Test is regarded as a “gold standard” in testing for high-risk types of human papillomavirus (HPV), the primary cause of cervical cancer. This test is one of more than 500 consumable products and automated solutions that QIAGEN provides.

Why Cellestis & QuantiFERON?

Cellestis’ success as a company and its QuantiFERON technology and products were central to QIAGEN’s acquisition. In addition to complementary product portfolios, both companies share a similar value system with elements such as quality, service and support at the forefront.

Less prominent in the traditionally TB-focused QuantiFERON News, but a major focus for QIAGEN, is QuantiFERON®-CMV (QF-CMV), a blood test for monitoring the immune system response to cytomegalovirus infection and disease. QF-CMV is complementary to QIAGEN profiling tests, including the *artus*® CMV real-time PCR test. Common assay

processing and detection technologies between Cellestis and QIAGEN also ensure that development or new applications for QuantiFERON continues in the future.

How might the change from Cellestis to QIAGEN affect QFT customers?

The merger of Cellestis and QuantiFERON technology into QIAGEN will occur over some time, with visible changes occurring throughout 2012.

One of the first changes you may notice online, and in promotional materials, is the name change to "Cellestis, a QIAGEN Company." QFT promotional materials will take on the QIAGEN look and feel, commencing with this newsletter. The websites www.Cellestis.com and www.QuantiFERON.com will also be merged onto one global home page, so all information for QuantiFERON products is accessible. The list of labs offering QFT that was originally on www.QuantiFERON.com will soon be found on the links showing *Find QFT in Your Area* and under the *Contact Us* tab. Also, the new email domain "@qiagen.com" will begin to replace "@cellestis.com" emails, so please ensure your email program settings will allow emails from the "@qiagen.com" domain to your inbox.

Further shifts in company branding, products, and packaging will also begin to appear. By

nature, product transitions will take much longer to complete, and timing may be different from country to country, as changes are dependent on local regulatory requirements. Your local QuantiFERON representative will inform you of upcoming changes that may affect you.

Generally speaking, however, for most of 2012 your current Cellestis contact persons, the appearance of QFT products will remain as before. QuantiFERON products will continue to be sold through the Cellestis sales force. The QuantiFERON technical support and customer service will also be enhanced.

One project within the QuantiFERON team is to merge QuantiFERON support into QIAGEN's broad network. Simply having QIAGEN's geographical reach will provide more opportunities for QFT service and support to customers around the world. In this way, the combination of QIAGEN and Cellestis may for some customers create significant advantages in terms of convenience, cost-efficiency, and continued quality.

Please let your local QuantiFERON representative know if you have any concerns or questions during this transition period. Cellestis, a QIAGEN Company, aims to provide the highest quality service and support throughout the merger and beyond.



Figure 2. Cellestis will be updating all sales and technical material, as well as packaging, in the near future. Please contact your local sales representative if you have any questions.

3rd Global Symposium on IGRAs, Hawaii, Jan 2012

Cellestis funded through an educational grant the 3rd Global IGRA Symposium in January, presented by the University of California, San Diego. Over 100 clinicians, researchers, laboratory professionals, and industry representatives attended the symposium. After previous successful symposia in Vancouver (2006) and Croatia (2009), secluded Waikoloa, Hawaii, provided the backdrop for exciting discussions and debates on the latest clinical research and opinion on TB and IGRAs.

One of the most discussed topics at the conference included IGRA screening and surveillance in healthcare workers. Several studies, many from large healthcare facilities, demonstrated excellent negative predictive

value of IGRAs for pre-employment screening in this group – even in the face of co-morbidities. Furthermore, the vast majority of the healthcare workers studied were IGRA-negative, indicating that a relatively small percentage of healthcare workers were IGRA-positive and required further clinical investigation. Another benefit mentioned was that healthcare workers is that the screening process can be completed in one visit.

The symposium presentations have been posted on UCSD's CME website (<http://cme.ucsd.edu/igras/syllabus.html>), and these topics will also be highlighted in future Cellestis materials.



Figure 3. The 3rd Global Symposium on IGRAs 2012 was sponsored by Cellestis.

Continuing Medical Education (CME) Program Launch:

“Tuberculosis Testing in the 21st Century: The Role of Interferon-Gamma Release Assays”

Cellestis has funded through an educational grant a Cleveland Clinic Foundation CME activity entitled, “Tuberculosis Testing in the 21st Century: The Role of Interferon-Gamma Release Assays.” To view the available sessions please visit <http://www.clevelandclinicmeded.com/online/tb-testing>.

The educational activities follow the launch at the American College of Rheumatology meeting last November of a long-term initiative to promote and support TB screening for patients with rheumatoid arthritis prior to commencing tumor necrosis factor-alpha (TNF- α) inhibitor therapy. A new Clinical Review investigating the clinical evidence for QFT use in these patients has been released. You can find the Clinical Review and other new materials on www.cellestis.com/TBandTNF that have been developed with the new QIAGEN look.

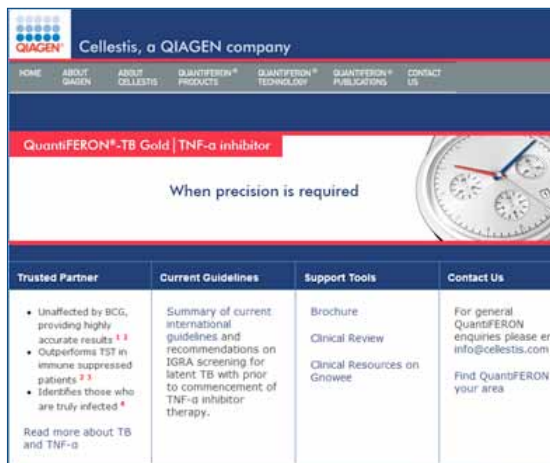


Figure 4. A new web page has been launched in conjunction with the TB and TNF initiative. Visit www.cellestis.com/TBandTNF to find out more.

Event Updates

World TB Day – March 24, 2012

World TB Day is designed to build public awareness that TB remains an epidemic in many parts of the world and causes the deaths of several million people each year. The day commemorates when Dr Robert Koch announced that he had discovered the cause of TB in 1882. At the time of Koch’s announcement, TB was rampant and causing many deaths worldwide. Koch’s discovery enabled progress toward diagnosing and curing TB.

The WHO’s Stop TB Partnership has created a new series of posters that are available in many languages for download [here](http://www.mystoptb.org) to help you and your team support World TB Day. In addition, on a new interactive website, www.mystoptb.org, you can make your own poster and add a message about what you expect to change about TB in your lifetime.

The QuantiFERON team is proud to support World TB Day through engagement in local TB-related activities like the Stop TB Trot in Denver, Colorado, on March 25, 2012. For a full listing of all QuantiFERON events in your region, please visit the [Events Calendar](#).

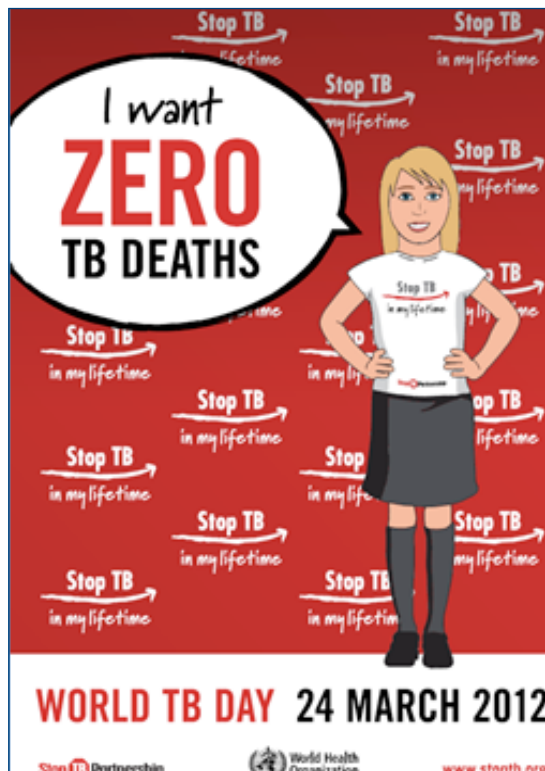


Figure 5. WHO’s Stop TB Partnership has created a new series of posters. Visit www.mystoptb.org to find out more.

Publications Update: What's new in Gnowee?

Gnowee is your complete QuantiFERON-TB Gold library where you can find complementary clinical abstracts, guidelines, presentations, and more.

Register online now at www.gnowee.net.

Journal Article	PubMed ID #
Welch RJ, et al. Anti-tuberculosis IgG antibodies as a marker of active Mycobacterium tuberculosis disease. Clin Vaccine Immunol. 2012 Feb 1. [Epub ahead of print]	22301692
Legesse M, et al. Association of the level of IFN- γ produced by T cells in response to Mycobacterium tuberculosis-specific antigens with the size of skin test indurations among individuals with latent tuberculosis in a highly tuberculosis-endemic setting. Int Immunol. 2012 Feb;24(2):71-8. Epub 2012 Jan 31.	22298884
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Minguez S, et al. Interferon-gamma release assays in the detection of latent tuberculosis infection in patients with inflammatory arthritis scheduled for anti-tumour necrosis factor treatment. Clin Rheumatol. 2012 Jan 21. [Epub ahead of print]	22271230
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Publications Update: What's new in Gnowee? continued

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