

## 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](http://www.Cellestis.com) and [www.QuantiFERON.com](http://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](http://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.

## 3<sup>rd</sup> Global Symposium on IGRAs, Hawaii, Jan 2012

Cellestis funded through an educational grant the 3<sup>rd</sup> 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- $\alpha$ ) 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](http://www.cellestis.com/TBandTNF) that have been developed with the new QIAGEN look.

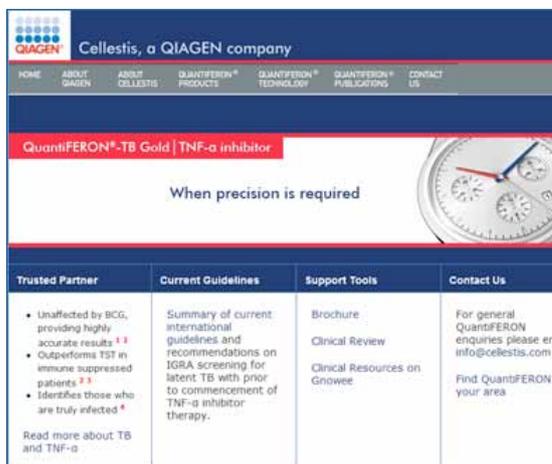


Figure 4. A new web page has been launched in conjunction with the TB and TNF initiative. Visit [www.cellestis.com/TBandTNF](http://www.cellestis.com/TBandTNF) to find out more.

## 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](http://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](#).

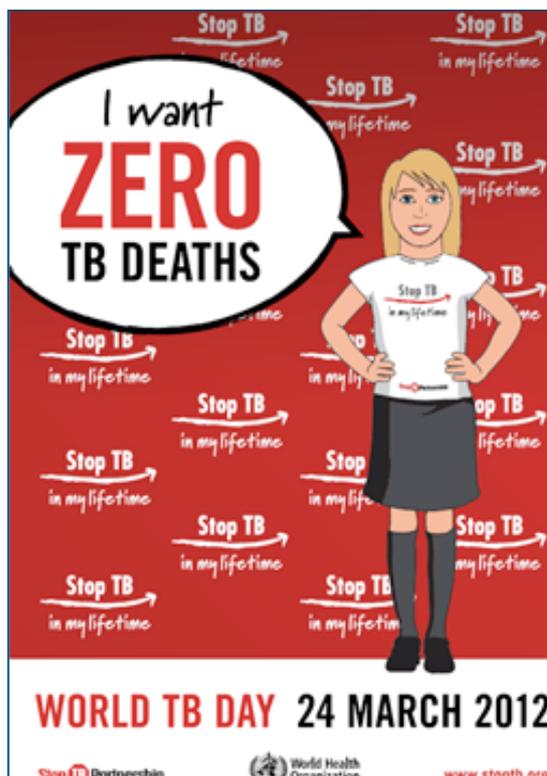


Figure 5. WHO’s Stop TB Partnership has created a new series of posters. Visit [www.mystoptb.org](http://www.mystoptb.org) to find out more.

## 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](http://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- $\gamma$ 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
Shahidi N, et al. Performance of interferon-gamma release assays in patients with inflammatory bowel disease: A systematic review and meta-analysis. Inflamm Bowel Dis. 2012 Jan 31. doi: 10.1002/ibd.22901. [Epub ahead of print]	22294550
O'Donnell MR, et al. Acceptance of interferon-gamma release assay by a high-risk urban cohort. Int J Tuberc Lung Dis. 2011 Oct;15(10):1334-9.	22283891
Skogstrand K, et al. Antigen-induced cytokine and chemokine release test for tuberculosis infection using adsorption of stimulated whole blood on filter paper and multiplex analysis. Scand J Clin Lab Invest. 2012 Jan 27. [Epub ahead of print]	22283828
Casas S, et al. Comparison of the 2-step tuberculin skin test and the QuantiFERON-TB Gold In-Tube Test for the screening of tuberculosis infection before liver transplantation. Liver Transpl. 2011 Oct;17(10):1205-11.	22279622
Thibeault C, et al. A case of active tuberculosis in a cabin crew: the results of contact tracing. Aviat Space Environ Med. 2012 Jan;83(1):61-3.	22272519
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
Fong KS, et al. Challenges of Interferon-gamma Release Assay Conversions in Serial Testing of Health Care Workers in a Tuberculosis Control Program. Chest. 2012 Jan 19. [Epub ahead of print]	22267680
Noorbakhsh S, et al. Evaluation of an interferon-gamma release assay in young contacts of active tuberculosis cases. East Mediterr Health J. 2011 Sep;17(9):714-8.	22259925
Mariette X, et al. Influence of replacing tuberculin skin test with ex vivo interferon $\gamma$ release assays on decision to administer prophylactic antituberculosis antibiotics before anti-TNF therapy. Ann Rheum Dis. 2012 Jan 17. [Epub ahead of print]	22258485
Abu-Taleb AM, et al. Interferon-gamma release assay for detection of latent tuberculosis infection in casual and close contacts of tuberculosis cases. East Mediterr Health J. 2011 Oct;17(10):749-53.	22256408
Ikeue T, et al. [Development of cervical tuberculous lymphadenitis in a patient with Crohn's disease receiving infliximab despite of chemoprophylaxis with isoniazid]. [Article in Japanese] Ikeue T, Nakagawa A, Furuta K, Morita K, Sugita T, Nishiyama H.	22250467
Komukai J, et al. [Comparative performance of tuberculin skin test and QuantiFERON TB-gold in contact investigations for tuberculosis]. [Article in Japanese] Kekkaku. 2011 Nov;86(11):847-56.	22250463
Molicotti P, et al. Performance of QuantiFERON TB in a student population at low risk of tuberculosis. J Infect Dev Ctries. 2012 Jan 12;6(1):100-1.	22240439
Taki-Eddin L & Monem F. Utility of an interferon-gamma release assay as a potential diagnostic aid for active pulmonary tuberculosis. J Infect Dev Ctries. 2012 Jan 12;6(1):67-72.	22240431
Hsia EC, et al. Interferon-gamma release assay versus tuberculin skin test across RA, PsA, and AS patients prior to treatment with golimumab, a human anti-TNF antibody. Arthritis Rheum. 2012 Jan 11. doi: 10.1002/art.34382. [Epub ahead of print]	22238071
Rafiza S & Rampal KG. Serial testing of Malaysian health care workers with QuantiFERON®-TB Gold In-Tube. Int J Tuberc Lung Dis. 2012 Feb;16(2):163-8.	22236915
De Nardo P, et al. Total hip replacement infected with Mycobacterium tuberculosis complicated by Addison disease and psoas muscle abscess: a case report. J Med Case Reports. 2012 Jan 10;6(1):3.	22233936
Imai T, et al. A case of IgG4-related tubulointerstitial nephritis with left hydronephrosis after a remission of urinary tract tuberculosis. Rheumatol Int. 2012 Jan 5. [Epub ahead of print]	22218636

Journal Article	PubMed ID #
Uetsuki H, et al. [A case with hepatitis and interstitial pneumonitis caused by intravesical bacillus Calmette-Guérin (BCG) instillation]. [Article in Japanese] <i>Nihon Hinyokika Gakkai Zasshi</i> . 2011 Sep;102(5):691-5.	22191278
Saleh MA, et al. The use of adenosine deaminase measurements and QuantiFERON in the rapid diagnosis of tuberculous peritonitis. <i>J Med Microbiol</i> . 2011 Dec 15. [Epub ahead of print]	22174374
Mancuso JD, et al. Discordance Among Commercially-Available Diagnostics for Latent Tuberculosis Infection. <i>Am J Respir Crit Care Med</i> . 2011 Dec 8. [Epub ahead of print]	22161162
Maden E, et al. Evaluation of performance of quantiferon assay and tuberculin skin test in end stage renal disease patients receiving hemodialysis. <i>New Microbiol</i> . 2011 Oct;34(4):351-6. Epub 2011 Oct 31.	22143808
Yilmaz N, et al. Comparison of Quantiferon-TB Gold Test and Tuberculin Skin Test for the identification of Latent Mycobacterium Tuberculosis infection in Lupus patients. <i>Lupus</i> . 2011 Dec 2. [Epub ahead of print]	22140142
Jung JY, et al. Questionable role of interferon- $\gamma$ assays for smear-negative pulmonary TB in immunocompromised patients. <i>J Infect</i> . 2012 Feb;64(2):188-96. Epub 2011 Nov 18.	22120597
Banach DB & Harris TG. Indeterminate QuantiFERON®-TB Gold results in a public health clinic setting. <i>Int J Tuberc Lung Dis</i> . 2011 Dec;15(12):1623-30.	22118169
Grinsdale JA, et al. Programmatic impact of using QuantiFERON®-TB Gold in routine contact investigation activities. <i>Int J Tuberc Lung Dis</i> . 2011 Dec;15(12):1614-20.	22118167
Gupta D, et al. Interferon gamma release assay (QuantiFERON-TB Gold In Tube) in patients of sarcoidosis from a population with high prevalence of tuberculosis infection. <i>Sarcoidosis Vasc Diffuse Lung Dis</i> . 2011 Oct;28(2):95-101.	22117500
Matsuyama T, et al. [A case of pulmonary tuberculous initially diagnosed as sarcoidosis because of necrotizing granuloma]. [Article in Japanese] <i>Nihon Kokyuki Gakkai Zasshi</i> . 2011 Oct;49(10):775-9.	22117317
Alsleben N, et al. Interferon-gamma inducible protein 10 as a biomarker for active tuberculosis and latent tuberculosis infection in children: A case-control study. <i>Scand J Infect Dis</i> . 2011 Nov 21. [Epub ahead of print]	22103555
Chiacchio T, et al. Higher frequency of T-cell response to M. tuberculosis latency antigen Rv2628 at the site of active tuberculosis disease than in peripheral blood. <i>PLoS One</i> . 2011;6(11):e27539. Epub 2011 Nov 10.	22102905
González-Salazar F, et al. Snapshot of Quantiferon TB gold testing in Northern Mexico. <i>Tuberculosis (Edinb)</i> . 2011 Dec;91 Suppl 1:S34-7. Epub 2011 Nov 17.	22099419
Hanta I, et al. Detection of latent tuberculosis infection in rheumatologic diseases before anti-TNF therapy: tuberculin skin test versus IFN- $\gamma$ assay. <i>Rheumatol Int</i> . 2011 Nov 18. [Epub ahead of print]	22095393
Moon HW, et al. Latent tuberculosis infection screening for laboratory personnel using interferon- $\gamma$ release assay and tuberculin skin test in Korea: an intermediate incidence setting. <i>J Clin Lab Anal</i> . 2011 Nov;25(6):382-8. doi: 10.1002/jcla.20479.	22086790
Talebi-Taher M, et al. Comparing the performance of QuantiFERON-TB Gold and Mantoux test in detecting latent tuberculosis infection among Iranian health care workers. <i>Int J Occup Med Environ Health</i> . 2011 Dec;24(4):359-66. Epub 2011 Nov 16.	22086450
Sun L, et al. Interferon gamma release assay in diagnosis of pediatric tuberculosis: a meta-analysis. <i>FEMS Immunol Med Microbiol</i> . 2011 Nov;63(2):165-73. doi: 10.1111/j.1574-695X.2011.00838.x.	22077219
De Perio MA, et al. The effectiveness of using interferon-gamma release assays in screening immigration employees for latent tuberculosis infection. <i>Int J Occup Environ Health</i> . 2011 Oct-Dec;17(4):322-7.	22069930
Chen J, et al. Interferon-gamma release assays for the diagnosis of active tuberculosis in HIV-infected patients: a systematic review and meta-analysis. <i>PLoS One</i> . 2011;6(11):e26827. Epub 2011 Nov 1.	22069472
Shah M, et al. Longitudinal analysis of QuantiFERON-TB Gold In-Tube in children with adult household tuberculosis contact in South Africa: a prospective cohort study. <i>PLoS One</i> . 2011;6(10):e26787. Epub 2011 Oct 31.	22066009
Gray J, et al. Identification of False-Positive QuantiFERON-TB Gold In-Tube Assays by Repeat Testing in HIV-Infected Patients at Low Risk for Tuberculosis. <i>Clin Infect Dis</i> . 2012 Feb;54(3):e20-3. Epub 2011 Nov 4.	22057704
Kuś J, et al. [Prevalence of latent infection with Mycobacterium tuberculosis in Mazovia Region using interferon gamma release assay after stimulation with specific antigens ESAT-6 and CFP-10]. [Article in Polish] <i>Pneumonol Alergol Pol</i> . 2011;79(6):407-18.	22028119
Metcalfe JZ, et al. Interferon- $\gamma$ release assays for active pulmonary tuberculosis diagnosis in adults in low- and middle-income countries: systematic review and meta-analysis. <i>J Infect Dis</i> . 2011 Nov 15;204 Suppl 4:S1120-9.	21996694
Chen DY, et al. Biphasic emergence of active tuberculosis in rheumatoid arthritis patients receiving TNF $\alpha$ inhibitors: the utility of IFN $\gamma$ assay. <i>Ann Rheum Dis</i> . 2012 Feb;71(2):231-7. Epub 2011 Oct 21.	22021896

## Publications Update: What's new in Gnowee? continued

Journal Article	PubMed ID #
Yano S. Tuberculous hilar lymphadenopathy progressing after isoniazid administration. J Infect Chemother. 2011 Oct 22. [Epub ahead of print]	22020629
Kim KH, et al. Serial interferon-gamma release assays for the diagnosis of latent tuberculosis infection in patients treated with immunosuppressive agents. Korean J Lab Med. 2011 Oct;31(4):271-8. Epub 2011 Oct 3.	22016681
Trauer JM, et al. Feasibility of latent tuberculosis infection diagnosis by interferon- $\gamma$ release assay remote from testing facilities. Commun Dis Intell. 2011 Jun;35(2):168-71.	22010510
Nienhaus A, et al. [The prevalence of latent tuberculosis infections among health-care workers--a three-country comparison]. Pneumologie. 2011 Dec;65(12):726-9. Epub 2011 Oct 17. [Article in German]	22006409
Kabeer BS, et al. Comparison of interferon gamma-inducible protein-10 and interferon gamma-based QuantiFERON TB Gold assays with tuberculin skin test in HIV-infected subjects. Diagn Microbiol Infect Dis. 2011 Nov;71(3):236-43.	21996360
Vassilopoulos D, et al. Comparison of two gamma interferon release assays and tuberculin skin testing for tuberculosis screening in a cohort of patients with rheumatic diseases starting anti-tumor necrosis factor therapy. Clin Vaccine Immunol. 2011 Dec;18(12):2102-8. Epub 2011 Oct 12.	21994356
Song S, et al. Performance of confirmatory interferon-gamma release assay in school tuberculosis outbreaks. Chest. 2011 Oct 6. [Epub ahead of print]	21980060
Stavri HR, et al. Prospective Comparison of Two Brands of Tuberculin Skin Tests and QuantiFERON-TB Gold in-tube Assay Performances for Tuberculosis Infection in Hospitalized Children. Maedica (Buchar). 2010 Dec;5(4):271-6.	21977169
Yassin MA, et al. Can interferon-gamma or interferon-gamma-induced-protein-10 differentiate tuberculosis infection and disease in children of high endemic areas? PLoS One. 2011;6(9):e23733. Epub 2011 Sep 23.	21966356
Kakkar F, et al. Tuberculosis in children: New diagnostic blood tests. [Article in English, French] Paediatr Child Health. 2010 Oct;15(8):529-38	21966239
Ringrose JS, et al. Detecting latent tuberculosis infection during anti-tumor necrosis factor therapy. Clin Exp Rheumatol. 2011 Sep-Oct;29(5):790-4. Epub 2011 Oct 31.	21961892
Nienhaus A, et al. Systematic review of cost and cost-effectiveness of different TB-screening strategies. BMC Health Serv Res. 2011 Sep 30;11:247.	21961888

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