Cellestis GmbH
QIAGEN Strasse 1
40724 Hilden

www.cellestis.com

XX September 2012

Re: Notification of market withdrawal of QuantiFERON®-TB Gold TB-Antigen blood collection tubes – Lot # A111103N and Lot # A111103M (High Altitude)

Dear Valued Customer;

Cellestis, a QIAGEN company, wishes to advise a voluntary market withdrawal of QuantiFERON-TB Gold TB-Antigen collection tubes – Lot # A111103N and Lot # A111103M (High Altitude). These tubes were distributed in Europe from the 3rd of February 2012 to the 16th of July 2012, and are included in the following Cellestis products, with the Lot numbers listed below:

Product Number	Product Description	Lot number
0590-0201	QFT Gold Tubes	059060641
0590-0501	QFT Gold Tubes High Altitude (HA)	059060661
0597-0101	QFT Gold Single Patient Pack HA	059570991, 059771101
0597-0201	QFT Gold Single Patient Pack	059770911, 059770951, 059770961, 059771061

Use of these products should be discontinued and any product sequestered such that it cannot be used or distributed.

Following a product enquiry, reporting a higher than expected rate of QFT positive results from Lot # A111103N, Cellestis initiated an investigation into the situation and confirmed the findings with the identification of 4 positive results from 17 persons who tested negative using several other lots of tubes. Cellestis conducted a review of our manufacturing process and identified the potential contamination of Lot #A111103M (High Altitude) and a portion of tubes from Lot # A111103N.

The same testing has confirmed that other Lots of TB-antigen tubes perform as expected, with no evidence of aberrant results. Importantly, negative QFT results generated using the affected tubes are valid.

Cellestis has subsequently implemented corrective measures to prevent a repeat occurrence of this situation.

Customers are advised that if unexpected positive results have been obtained using these tubes, results should be considered in light of all clinical information. Patient retesting, using a different Lot of QFT TB-Antigen tubes, should be considered. If and when a retest is required, Cellestis will provide replacement materials.

We remind our customers that diagnosing or excluding tuberculosis disease, and assessing the probability of LTBI, requires a combination of epidemiological, historical, medical, and diagnostic findings that should be taken into account when interpreting QFT results.

Cellestis apologizes for any inconvenience this market withdrawal has caused. Please do not hesitate to contact your local QuantiFERON sales representative or customer service representative should you have any questions or concerns.

Yours Sincerely,

Mark Boyle

Vice President, Head of Clinical Sales
& Market Development, QuantiFERON

Kevin Liddle, PhD

Director of Quality & Regulatory Affairs