



Cellestis Inc.
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Re: QuantiFERON®-TB Gold In-Tube test Sole Source

To Whom It May Concern:

The purpose of this document is to verify that Cellestis Inc. (Valencia, CA) is the sole source supplier in the United States (with the exception of Puerto Rico and the U.S. Virgin Islands) of the QuantiFERON®-TB Gold In-Tube test and other QuantiFERON®-TB test products.

Cellestis Inc. is a U.S. registered company, and the wholly owned subsidiary of Cellestis Limited (Melbourne, Australia).

Cellestis Limited has exclusive rights to the patented QuantiFERON® technology. This patent is licensed from CSIRO (Australia) and is valid in the U.S. until 2011 under US Patent no. 5334504. In addition, Cellestis Limited has licenses for exclusive use of tuberculosis specific antigens: ESAT-6, CFP-10 and TB7.7(p4) in the QuantiFERON®-TB Gold In-Tube test, under US Patent no. 5955077 (valid until 2015), 6290969 (valid until 2017), and 6291190 (valid until 2019); respectively.

The Cellestis group has developed the QuantiFERON®-TB Gold In-Tube test kit after extensive pre-clinical and clinical testing within the U.S. and elsewhere.

QuantiFERON®-TB Gold In-Tube was approved by the FDA on October 10, 2007 for diagnosis of tuberculosis infection, replacing the previously approved QuantiFERON®-TB Gold and QuantiFERON®-TB tests.

As a consequence, Cellestis Inc. is the sole source supplier of QuantiFERON®-TB Gold In-Tube, QuantiFERON®-TB Gold and other QuantiFERON® test products within the United States (except Puerto Rico and U.S. Virgin Islands).

Sincerely,

Mark Boyle
President, Cellestis Inc.

