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30 Nov 2009

Dear QFT Customer:

RE: Quantitative results from QuantiFERON® Gold In-Tube (QFT)

The US Centers for Disease Control and Prevention (CDC) anticipated 2009 update to guidelines for using interferon gamma release assays (IGRAs) is likely to include a statement regarding quantitative results of IGRAs. Specifically, the guidelines may request that both qualitative and quantitative IGRA measurements be reported.

While the FDA-approved QFT [Package Insert](#) (Document number US05990301E, Jan 2009) states that "the magnitude of the measured IFN- γ level cannot be correlated to stage or degree of infection, level of immune responsiveness, or likelihood for progression to active disease," the updated CDC guidelines highlight the concerns of many QFT users regarding the quantification of IFN- γ levels.

Consistent with the new CDC guidelines, Cellestis now recommends that all QFT users provide to physicians the quantitative (i.e. IFN- γ level) as well as qualitative result (i.e. positive, negative, indeterminate) results. The Cellestis-developed and validated QFT Analysis Software program provides both quantitative and qualitative results and is free for QFT customers. To obtain current QFT Analysis Software for your region, please visit www.cellestis.com. Alternatively, if you have questions regarding the technical application of QFT, please contact your local Cellestis representative.

Sincerely,

Dr Jim Rothel

Chief Scientific Officer
Cellestis

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