



Technical Alert

QuantiFeron IGRA Demonstrates Uncertainty Around the Cutoff

TO: Medical Staff and Clients

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SUBJECT: **QuantiFeron may show elevated TB antigen values resulting in potential false positive**

The QuantiFeron Gold Plus (test code 6373) interferon gamma release assay (IGRA) measures the release of gamma interferon from lymphocytes following exposure to two TB-specific antigens: ESAT-6 and CFP-10 proteins. The assay includes mitogenic stimulation to assess the ability of those lymphocytes to respond, and a “nil” tube that is devoid of stimulation. A value greater than 0.35 in either antigenic response, once background is subtracted out, differentiates positive from negative.

According to the manufacturer’s data, there is variation around that cutoff, which is not addressed in reporting. Brown J, et al. (Eur Respir J 2017) reported that there was uncertainty between values 0.2 and 0.7, and that repeating the test changed the result 35% of the time. They proposed an equivocal interpretation for those values in this range, which could impact about 8% of samples tested.

In response to client concerns of unexpected positive results, DLS audited positive cases from employee health clients, and observed values in this range of uncertainty behaved as reported by Brown and colleagues.

Effective immediately, values that fall into this gray area will be reported as “Equivocal,” and released with this results comment:

“The patient’s result falls within a statistical range of uncertainty around the cutoff (Brown J, et al. Eur Respir J 2017). Recommend repeat collection/testing OR consider skin testing as an alternative.”

If a repeat collection yields a similar, equivocal result, skin testing may be the best alternative.

Because “Equivocal” is not a reportable result included in the manufacturer’s FDA-approval, we will be issuing these results as “No Charge” items.

Please refer any questions to Jantzen Lim at 589-5265, Dr. Wes Kim at 589-5131, Dr. Chris Whelen at 589-5242, or DLS Client Services at 589-5101.

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