SLO Public Health Laboratory Bulletin

October 2010

Quantiferon Reporting

Since the introduction of Quantiferon testing by the San Luis Obispo Public Health Laboratory in the fall of 2007, a number of reports of investigative studies of the use of the Quantiferon assay have been published in the peer-reviewed scientific literature. Recently the Centers for Disease Control and Prevention (CDC) experts reviewed the literature and published a series of recommendations for use of this assay. Among the principle recommendations is that laboratories report all the quantitative values that are used to determine Mycobacterium tuberculosis (MTB) infection. (MMWR June 25, 2010;59 No. RR-5).

The SLO Public Health Laboratory will initiate reporting of the quantitative values before the end of this calendar year. An example of the reported values, the reference range and the interpretation of these parameters is shown in the following table.

Values	Reference range IU/ml	Interpretation
Nil	≤ 8.0	Background level of interferon; can be elevated due other non-TB infections or conditions to the level where TB antigen stimulus cannot be measured
Mitogen	NA	Unnormalized interferon level due mitogen stimulation of effector T-cells
TB antigen	NA	Unnormalized interferon level due to M. tuberculosis specific antigen stimulation of effector T-cells
Mitogen minus Nil	≥ 0.5	Normalized (Nil value subtracted) interferon levels produced in response to Mitogen
TB-antigen minus Nil		Normalized (Nil value subtracted) interferon levels produced in response to M. tuberculosis specific antigens
	< 0.35	Negative – TB infection unlikely
	0.35-0.59	Borderline result – recommend retesting and clinical evaluation
	≥ 0.6	Positive result – TB infection likely also requires that the value be greater than or equal to 25% of the Nil value

Studies of low positive values have provided evidence that a borderline zone – not cleared by FDA in the Quantiferon package insert- should be established. Beginning with specimens submitted on November 1, 2010 low range values will be reported as “BORDERLINE” with an interpretative statement. As individual patient interferon levels can vary substantially over time <u>in the absence of any recognized stimulus</u>, the interpretative statement will recommend retesting if the clinical picture warrants such action.

Additionally Quantiferon reports for indeterminate results will be expanded to guide health providers: Two interpretative reports will be rendered when (1) a patient has an underlying disease process that results in high Nil interferon values, and (2) a patient sample fails to demonstrate a successful positive control in response to mitogen stimulation of T-cells.

Dr Jim Beebe, the SLO PH laboratory director is available for in-service lectures to interested health care providers on the Quantiferon assay. Call 805-781-5512 or email jbeebe@co.slo.ca.us

What else does a public health laboratory do besides Pertussis Testing?

The SLO Public Health laboratory has begun seasonal influenza surveillance and diagnostic testing. Several specimens have been submitted for Influenza virus by PCR with a single detection of seasonal Influenza A seasonal H3N2 virus. Flu Rapid test positive specimens are being accepted for Influenza PCR testing using the most advanced CDC-developed assay.