Alberta Public Laboratories (APL)

Laboratory Bulletin

Date: **May 6, 2019**
To: **TB Physicians, Infectious Diseases Physicians and Medical Officers of Health**
From: **Alberta Public Laboratories (APL) - ProvLab**
Re: **Changes in the Quantiferon (QFT) Assay (interferon gamma release assay)**

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Key Message:

- **Effective May 1, 2019, the QFT assay will be changing from a 3 tube assay to a 4 tube assay**. Therefore, 4 tubes will now be required (1.0 mL of blood in each) for each patient.
- Of the 4 tubes, there are two (2) tubes that contain TB antigens. TB1 tube (green) measures interferon gamma released by CD4+ cells. TB2 tube (yellow) measures interferon gamma released by both CD4+ and CD8+ cells. Measurement of interferon gamma from both CD4+ and CD8+ cells enhances the overall sensitivity of the QFT assay.
- QFT patient reports will have the interferon gamma concentrations for BOTH tubes AND a POSITIVE or NEGATIVE or INDETERMINATE result stated depending on the amount of interferon gamma detected.
- The tubes required (Figure 1, displayed below) for the new assay are “high altitude” tubes meaning that the vacuum draw of blood is faster than the previous 3 tube assay (QFT Gold). This will lessen the time required to collect blood from the patient.

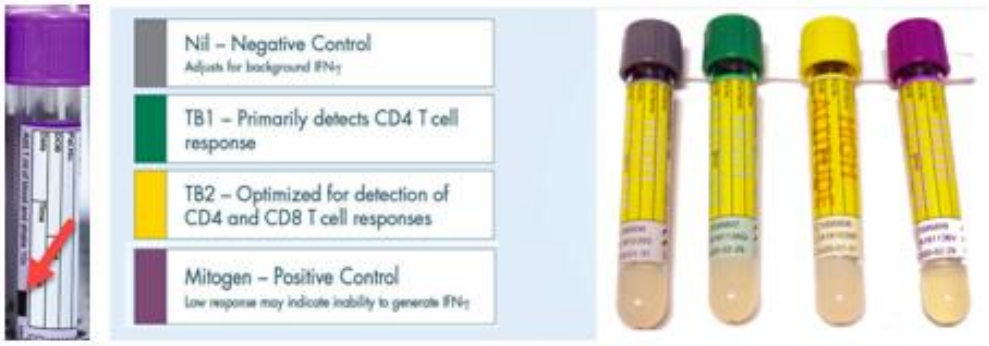

Figure 1: QuantiFERON-TB Gold Plus tubes, requiring exactly 1.0 mL of blood, fill to **black line** (see red arrow).

Why this is important:

- Four (4) tubes of blood (1.0 mL each) now need to be collected.
- QFT testing will now produce two (2) interferon gamma result values on patient reports where previously it was only one (1).
- High altitude tubes (required for QFT testing) have a higher vacuum and must be carefully filled to the line.
- Effective May 1, 2019, the laboratory will only accept the 4 tube assay due to a laboratory information system (LIS) hard changeover.

Background:

- The previous QFT assay required 3.0 mL of blood collected into 3 separate tubes (1.0 mL each). Tube 1 (grey) was the "nil" tube (no antigen), tube 2 (purple) was the mitogen tube (used to make sure a patient produced interferon gamma), and tube 3 (TB: green) contained TB antigens designed to stimulate patient CD4+ cells (helper T cells) that had previously been sensitized to tuberculosis and therefore would produce interferon gamma. The new assay has changed to include a FOURTH tube (TB2: yellow) that now contains TB antigens designed to stimulate BOTH CD4+ (helper T cells) and CD8+ cells (cytotoxic T cells). This new assay is called "QFT Plus". Therefore, results are obtained for interferon gamma released from both CD4+ cells and CD8+ cells (TB1 and TB2 tubes). The nil and mitogen tubes remain the same. Patient reports will have both interferon gamma values indicated (from TB1 and TB2 tubes) as well as a result interpretation (i.e., positive, negative or indeterminate).

Action Required:

- **Change in tubes required for QFT:** QFT now requires a total of four (4) tubes of blood (1.0 mL of blood x 4 tubes) to be drawn.
- **Collection Hard Stop: Four (4) tubes are now required for testing. Effective April 30th, start the collection of the 4 tubes for the new QFT Plus assay.**
- **Discard old tubes:** discard unused QFT Gold collection tubes (3 tube assay) after May 1, 2019.
- **Order new tubes:** new QFT Plus collection tubes are available for order by emailing: PRL.VirologySrTech-Edmonton@albertapubliclabs.ca
- **Review the QFT Plus collection requirements in the ProvLab Guide to Lab Services (GLS):** https://www.albertahealthservices.ca/webapps/labservices/indexProvLab.asp
- **Note the change in QFT Plus reporting:** QFT Plus patient reports will now have two (2) interferon gamma values and not just one (1) as previous. There will still be interpretations provided as previous

Inquiries and feedback may be directed to:

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This bulletin has been reviewed and approved by:

Dr. Graham Tipples, Medical Scientific Director, ProvLab.