To: Clients of URMC Labs

From:

Dwight J. Hardy, PhD
Director, URMC Clinical Microbiology Laboratory
Phone: (585) 275-1408
E-mail: Dwight_Hardy@urmc.rochester.edu

Julietta Fiscella, MD, CPE, FCAP
Director, Dept. Pathology, Cytopathology & Lab Medicine
Clinical Assoc. Professor, Pathology & Lab Medicine
Chair, Quality & Compliance Department, URMC Labs
Strong Health Highland Hospital
Phone: (585) 341-8075
E-mail: Julietta_Fiscella@urmc.rochester.edu

Re: **URMC Labs offers Quantiferon TB Gold in-Tube®**

Date: 3/4/2013

Latent infection with *Mycobacterium tuberculosis* has traditionally been determined by intradermal injection into the forearm of Purified Protein Derivatives (PPD) prepared from a stock strain of *M. tuberculosis*. The skin test, commonly known as the Tuberculin Skin Test (TST), is then read 2 to 3 days later by an experienced health care worker by measuring the area of induration at the injection site. Disadvantages of the TST include strict criteria for proper injection of PPD, variability in assessing the area of induration due to reader subjectivity, the requirement for a follow-up visit within a narrow time period and the cross-reactivity which arises following vaccination with BCG vaccine and/or heavy exposure to environmental *Mycobacterium* species.

Newer *in vitro* assays (generically referred to as Interferon Gamma Release Assays [IGRA]) which utilize patient whole blood, more specific TB-antigens and which do not require a return visit for test interpretation have been recently introduced into the marketplace. One such assay which we offer is the **Quantiferon-TB Gold in-Tube®**; this assay utilizes three special/unique tubes to determine a patient's prior exposure to antigens of *M. tuberculosis*: (1) a tube containing TB-specific antigens (2) a tube containing an environmental antigen [mitogen control] and (3) a tube with no antigen [negative control]. Each of the three tubes must be filled with patient blood and submitted immediately after collection to the laboratory for appropriate incubation and processing. Using an Enzyme Immunoassay (EIA) format, the assay detects gamma interferon which is released following exposure of patient T-cells to specific antigens of *M. tuberculosis*; test results for gamma interferon are reported in IU/ml with an interpretation. Specimens for this test may be collected on any day of the week (Sunday-Saturday) and submitted to the laboratory immediately after collection for testing on Wednesday with results available by 4 p.m.

The Centers for Disease Control recommends IGRA over TST **only** for those patients who have been vaccinated with BCG vaccine or who cannot be relied upon to return for the follow-up visit which is required following intradermal injection of PPD; after consultation with URMC Pulmonary Medicine and Infectious Diseases, we support limited use of this test as recommended by the CDC. It must also be noted that the CDC does not recommend IGRA for children <5 years old, and IGRA may be falsely positive in patients infected with *M. kansasii, M. szulgai* and *M. marinum*.

Out-patients should be referred to one of four URMC Patient Service Centers for specimen collection (see URMC Labs Test Index for further information). For in-patient units and ED, the special collection tubes and instructions for specimen collection can be obtained by requesting PMM #190403 from the following locations: (1) at Strong Memorial Hospital, call Hospital Stores 6th floor Service Center (x5-8211) and (2) at Highland Hospital, call Hospital Stores (x1-6341).

CDC. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection – United States, 2010. MMWR 2010; 59(No. RR-5).