



MEMORANDUM

To: All Regional Medical Laboratory, Inc. (RML) Clients
From: Regional Medical Laboratory, Inc.
Dr. Gerald Miller, PhD, Clinical Director, RML Immunology and Serology
Patti Loykasek, HTL (ASCP), Manager Immunology and Serology
Date: December 11, 2018
Subject: New QuantiFERON®TB Gold Plus Assay

Regional Medical Laboratory (RML) is pleased to announce the availability of a new QuantiFERON® TB Gold Plus assay for improved detection of present or past Mycobacterium tuberculosis infection, utilizing peripheral blood lymphocytes. This new assay optimizes the tuberculosis (TB) specific antigens that elicit responses from both CD8+ and CD4+ T cells, enabling a more comprehensive assessment of cell-mediated immune response to TB infection.

This test brings several advantages including:

- 1.) Improved sensitivity (94%+) and specificity (97%).
- 2.) Inclusion of Interferon-gamma responses from T cytotoxic lymphocytes (CD8) rather than just T helper lymphocytes (CD4) which is suggested to assist in distinguishing active tuberculosis (TB) from latent tuberculosis infections (LTBI).
- 3.) Ease of collection and transport.

RML will be converting from the QuantiFERON®TB Gold to the new QuantiFERON® TB Gold Plus at the end of 2018. As of January 2, 2019, we will no longer offer QuantiFERON®TB Gold.

There will be no change in CPT code or pricing for the new test. There are no changes to the reference ranges, except for the addition of the TB2 values. Test information can be found below and will also be available on www.rmlonline.com.

TEST NAME	TB GOLD PLUS
TEST CODE	5587326
CPT CODE	86480
LOINC CODES	TB Gold Plus Panel 71775-1 Mitogen minus NIL 71774-4 NIL 71776-9 TB1 minus NIL 64084-7 TB2 minus NIL 88517-8 Interp 71773-6
TAT	4-6 days

The QuantiFERON TB Gold Plus assay is available with 2 methods for specimen collection. The method used will vary based upon proximity to the laboratory.

Option 1: One tube collection – *PREFERRED for clients within close proximity to laboratory*

- Collect whole blood into a single 6 mL lithium-heparin no-gel tube
- A minimum of 4.0 mL whole blood is required
- Specimen must remain at room temperature for a minimum of 15 minutes after collection before being refrigerated
- Transport to RML refrigerated the same day it is collected. Specimen must arrive at RML's testing lab within 48 hours of collection to avoid exceeding stability
- Further specimen preparation steps will be completed by trained staff at RML

Option 2: Four tube collection

*****Do not attempt this collection option prior to being properly trained and approved by RML staff*****

- Collect whole blood into 4 QFT-Plus blood collection tubes
 - Draw/fill tubes in this order:
 - Nil
 - Antigen 1
 - Antigen 2
 - Mitogen
- A minimum of 1.0 mL whole blood per tube is required
- Immediately after filling, gently shake tubes 10 times to coat the inner surface of the tube walls (overly vigorous shaking may lead to aberrant results).
- Transport to RML at room temperature. Specimen must be received in-lab at RML within 16 hours of collection OR incubated at 37° C for 16-24 hours at the client site prior to transport to RML.
- If uncertain of transport time to RML or unable to incubate the specimens at 37° C, please use option 1 above.

For more detailed instructions on blood draw, please visit the Specialized Testing section of www.rmlonline.com. Supplies can be obtained through contacting the RML Materials Management Department.

For further information, contact Dr. Gerald Miller at 918-744-2553 x15543.