Dear Valued Partner:

Solstas Lab Partners® is pleased to announce the availability of the QuantiFERON®-TB Gold Interferon Gamma Release Assay (IGRA) for the detection of *Mycobacterium tuberculosis* (MTB) reactivity. The test will be performed at the Greensboro, N.C., reference laboratory and reported within 3 days of specimen receipt. We are pleased to offer this advanced test for MTB exposure screening that provides an alternative to the conventional purified protein (PPD) skin test.

The QuantiFERON-TB Gold test for MTB reactivity is one of only two tests currently cleared by the FDA that measures the release of interferon gamma in response to incubation with MTB antigens. It is cleared for testing of symptomatic and asymptomatic patients with latent TB infection.

The test involves drawing three, one (1) mL tubes of whole blood from a patient. One tube contains the purified TB antigen, one is the negative control and one tube contains a non-specific stimulus (mitogen) that tests for the response of the patient’s immune system to a non-specific stimulus. The levels of Interferon Gamma released in response to each of these tubes is compared to the negative control to determine if the patient has a significantly increased release of Interferon Gamma in response to the specific MTB antigen.

Although traditionally the Tuberculin Skin Test (TST/Mantoux) has been used to screen for MTB, there are several advantages to using an IGRA such as the QuantiFERON®-TB Gold test (1). These include:

- Patients are not injected with a purified MTB protein (PPD) which avoids the possibility of a severe reaction to the TST.
- Improved patient compliance. No return visit is required to interpret the skin test.
- Automated colorimetric results as compared to subjective interpretation for the TST and provider office staff training is no longer required for interpretation of the TST.
- The TB Gold test is the preferred method for people who have received a BCG vaccine.
- The TB Gold test involves only drawing blood from a patient, so it may be used in cases where subjecting a patient to a TB skin test may be contraindicated, such as children, patients who are immunocompromised, or on corticosteroids, or who have auto-immune diseases such as rheumatoid arthritis (3,6).
- If necessary, the TB Gold test can be repeated easily, since it only requires whole blood drawn from the patient, and the patient has not been previously or recently exposed to PPD, which could affect interpretation of the TB skin test.
- Improved sensitivity and specificity of the TB Gold Test compared to the TST (2). The sensitivity is approximately 92% in individuals with active disease and the specificity is >99% in low risk individuals as compared to a sensitivity and specificity of 72% and 78% respectively of the TST (4,5,6,7).
<table>
<thead>
<tr>
<th>Test Name</th>
<th>Ordering Mnemonics</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>Reference Range</th>
<th>NC Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>QuantiFERON – TB Gold</td>
<td>TB GOLD QUANTIFERON</td>
<td>85619</td>
<td>86480</td>
<td>Negative: M. tuberculosis (TB) infection not likely.</td>
<td>$85.20</td>
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</tbody>
</table>

**Specimen Collection:** Samples should be collected Monday – Friday only. Collect specimens using the special QuantiFERON® - TB Gold IT blood collection kits which include the following tubes: Nil Control (Grey cap with white ring), TB Antigen (Red cap with white ring), Mitogen Control (Purple cap with white ring). Each tube must be filled with 1 mL of blood (to the black line on the tube).

VERY IMPORTANT: mix the tubes by SHAKING (10 times or about 5 seconds) just firmly enough to ensure the entire inner surface of the tube has been coated with blood. A special QuantiFERON® - TB Gold Collection procedure is available. Please have phlebotomists read this procedure to ensure proper collection and handling. Special collection kits may be ordered with your regular supply order.

**Shipping Temperature:** Room Temperature – Ship IMMEDIATELY (SAME DAY). Specimens must be received by the lab and placed in an incubator within 16 hours of collection.

**Interpretation of Results:** *Qualitative results* – Results are reported as “Positive”, “Negative”, or “Indeterminate”.

If you have any questions, please call your dedicated Solstas Client Relationship Specialist directly, or contact our Client Services team at 1-888-664-7601. Thank you for choosing Solstas Lab Partners to serve the needs of you and your patients.

Janice J. Hessling, M.D., Ph.D  
Corporate Medical Director

**References**


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