November 25, 2015 – Northwest Washington, Vancouver and Oregon

**ALERT**

**New rapid PCR test detects Mycobacterium tuberculosis directly from sputum**

**WHAT’S NEW?**
Effective Wed., Dec. 2, 2015, Peacehealth Laboratories will offer a rapid, nucleic acid amplification test by PCR to detect *Mycobacterium tuberculosis* complex (MTB) directly from a sputum specimen (order 58510/ LAB6564 MTB Detection & Rifampin Resistance PCR, Sputum). The Cepheid Xpert MTB/RIF Assay test will simultaneously detect Rifampin (RIF) resistance mutations, when MTB is present in the specimen. This test is FDA cleared to detect MTB DNA using induced or expectorated sputum which is unprocessed (raw) or concentrated as sediment.

**INTENDED USE**
The CDC recommends that nucleic acid amplification testing for MTB be performed on at least one respiratory specimen from patients with a moderate to high suspicion of having pulmonary tuberculosis and for whom the test result would alter case management or tuberculosis control activities.

The MTB/RIF assay is intended for use with specimens from adults with clinical suspicion of tuberculosis and who have received ≤3 days anti-tuberculosis therapy. It is not intended as a test of cure, nor is it FDA authorized for use in pediatric patients.

**AFB Smear and Culture still recommended**
The MTB/RIF assay does not replace the need for conventional testing regardless of the MTB/RIF PCR result. Both a smear with microscopy for acid-fast bacillus (AFB) and Mycobacteria culture are still required because nucleic acid amplification testing will not detect all patients with pulmonary tuberculosis and recovery of the organism is necessary for further characterization and drug susceptibility testing. This testing should optimally be performed on the same specimen.

When multiple tests are ordered and insufficient sputum volume is available for MTB/RIF PCR testing along with culture and smear for AFB, the MTB/PCR test will be prioritized.

**INFECTION PREVENTION**
Hospitalized patients with suspected tuberculosis are maintained in airborne infection isolation according to infection prevention guidelines. The FDA has cleared the Xpert MTB/RIF Assay for an intended use that includes the testing of sputum specimens as an alternative to examination of serial acid-fast stained sputum smears to aid in the decision of whether continued airborne infection isolation is warranted for patients with suspected pulmonary tuberculosis.

The MTB/RIF test should not be used for decisions regarding the need for continued airborne infection isolation if MTB has already been detected by any method (culture or PCR).

Please contact your Infection Prevention department to obtain specific institutional guidelines.

*Continued on next page*
INTERPRETATION
Detection of MTB
A negative MTB result by DNA testing does not rule out the pulmonary tuberculosis and should not be the sole basis for infection prevention practices. The MTB/RIF assay should be performed and interpreted in the context of an AFB smear and culture. The CDC provides guidance for the interpretation of MTB/RIF test results in correlation with the AFB smear results [CDC, MMWR 2009].

Resistance to Rifampin
Specimens in which rifampin resistance is detected will be referred to the state public health laboratory to receive confirmation testing. Rapid confirmation is required as RIF resistance is a predictor of multidrug-resistant tuberculosis since RIF resistance commonly occurs with isoniazid resistance.

QUESTIONS?
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REFERENCES


For complete ordering information, please see next page.
## ORDERING INFORMATION

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<thead>
<tr>
<th>Unit Code</th>
<th>Test</th>
<th>Acceptable Specimens</th>
<th>Volume Required</th>
<th>Transport/Storage</th>
<th>Performing Laboratory</th>
<th>Turnaround Time</th>
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<tbody>
<tr>
<td>58510</td>
<td>NEW! MTB Detection &amp; Rifampin Resistance PCR, Sputum</td>
<td>Sputum</td>
<td>Minimum 1 mL</td>
<td>Refrigerated up to 7 days</td>
<td>PeaceHealth Laboratories: Bellingham Longview Vancouver Springfield</td>
<td>3 hours from receipt in performing laboratory</td>
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<tr>
<td>LAB6564</td>
<td>MTB Detection &amp; Rifampin Resistance PCR, Non-Sputum</td>
<td>Non-sputum respiratory, CSF, body fluids</td>
<td>Minimum 1 mL</td>
<td>Refrigerated up to 7 days</td>
<td>ARUP</td>
<td>1 - 3 days from receipt at ARUP</td>
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<tr>
<td>94250</td>
<td>Acid-Fast Bacilli (AFB) DNA Detection (from tissue)</td>
<td>Tissue or sterile body fluids (non-blood)</td>
<td>1 cc tissue; 1 mL fluid</td>
<td>Frozen</td>
<td>University of Washington Medicine Laboratory</td>
<td>1 - 2 weeks</td>
</tr>
<tr>
<td>LAB7072</td>
<td>Acid-Fast Bacilli (AFB) Culture and Acid-Fast Bacilli Stain</td>
<td>Most specimens. Swabs are discouraged.</td>
<td>See Test Menu (minimum 3 mL sputum)</td>
<td>Refrigerated up to 72 hours</td>
<td>Springfield</td>
<td>Smear result within 24 hrs of receipt in Springfield</td>
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<tr>
<td>94115</td>
<td>Acid-Fast Bacilli (AFB) Smear and Culture, Reflex to MTB by PCR</td>
<td>Discontinued effective Wed., Dec 2, 2015</td>
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