Xpert® MTB/RIF
The World Standard in TB Diagnostics

IS YOUR LAB STUCK IN THE LAST CENTURY?
Traditional MTB diagnostic methods require weeks to deliver a definitive result. First generation NAAT diagnostic tests have been available for the last 20 years. Those solutions rely on antiquated technology that requires highly skilled technicians, increased labor and optimized batching to maintain operational efficiency.

THE NEW WORLD STANDARD
Xpert® MTB/RIF, on-demand molecular testing — an ideal solution.
- Cleared by FDA as an alternative to serial AFB smears as an aid in respiratory isolation decision
- On-demand capability with result turn-around time in <2 hours
- Simultaneous detection of both MTB and rifampin resistance mutations, which are markers for the MDR-TB strain
- On-demand patient management by differentiating MTB vs. nontuberculous mycobacteria

PERFORMANCE*
Xpert MTB/RIF Performance vs. MTB Culture

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Smear Positive</th>
<th>Smear Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>93.8%</td>
<td>99.7%</td>
<td>76.1%</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.7%</td>
<td>98.5%</td>
<td>98.8%</td>
</tr>
</tbody>
</table>

Xpert MTB/RIF Negative vs. Smear and Culture Positive

<table>
<thead>
<tr>
<th>Xpert Negative</th>
<th>Smear Positive</th>
<th>Total Xpert Negative</th>
<th>Probability of Culture Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>One Xpert</td>
<td>2</td>
<td>775</td>
<td>99.7% (773/775)</td>
</tr>
<tr>
<td>Two Xperts</td>
<td>0</td>
<td>772</td>
<td>100% (772/772)</td>
</tr>
</tbody>
</table>

* Source: Cepheid Xpert MTB/RIF (GXMTB/RIF-US-10) Package Insert, 301-1404, Rev. B, Table 3, 4, 13, and 15

Reference:
WORKFLOW:
3 EASY STEPS
Total hands-on time: <1 Minute

1. Pour Sample Reagent into sample tube. Incubate for 15 minutes at room temperature.

2. Pipette liquefied/decontaminated sample into cartridge.

3. Insert cartridge and start test.

Xpert® MTB/RIF is a qualitative real-time PCR test for automated detection of *Mycobacterium tuberculosis* complex DNA and rifampin-resistance associated mutations of the *rpoB* gene.

CATALOG INFORMATION

Xpert MTB/RIF (10 tests) ................................................................. GXMTB/RIF-US-10

2015 Medicare National Limitation Amount*

<table>
<thead>
<tr>
<th>Test</th>
<th>CPT Code</th>
<th>Medicare National Limitation Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert MTB/RIF</td>
<td>M. tuberculoisor complex (87556)</td>
<td>$47.76</td>
</tr>
<tr>
<td></td>
<td>Rifampin-resistance associated mutation (87798)</td>
<td>$47.76</td>
</tr>
</tbody>
</table>

* 2015 Medicare National Limit Amount. Refer to http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html for state-specific payment rates. Effective April 1, 2013 and while sequestration is in effect, all CMS payments for services will be reduced by 2%. The rates above do not reflect this reduction (see: http://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf).

DISCLAIMER: The reimbursement information that we provide is to help laboratory personnel understand and comply with billing and reimbursement requirements that may apply to Cepheid products. It is your responsibility to check with your billing office and/or payers in your area to verify correct coding. It is the ordering provider’s responsibility to determine medical necessity and the proper site for delivery of any services. Use of the codes presented here does not guarantee coverage or payment for specific targets or at any specific level, as reimbursement policies are subject to changing laws, regulations, rules and policies. Policies may vary widely from insurer to insurer, and often reflect different patient conditions.

For In Vitro Diagnostic Use.

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