Two-hour detection of MTB and resistance to rifampicin.

**Xpert® MTB/RIF**

Go from test and wait to test and treat.
"It’s basically a development that the world has been waiting for, for literally decades. It’s something that has the potential of truly revolutionizing the way we deal with TB today.”

Dr. Mario Raviglione
Director, Stop TB Department, WHO
As stated in the TB diagnostics conference call hosted by Advocacy to Control TB Internationally on December 7, 2010

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**The Need**

**Current Testing Methodologies Are Too Slow**

According to the World Health Organization (WHO), *Mycobacterium tuberculosis* (MTB) is considered to be vastly under diagnosed today, despite approximately 500,000 new active cases reported in the WHO European region during 2007. This is a direct result of current MTB testing methods requiring weeks to deliver a definitive result, which can lead to patients being left untreated or placed on ineffective therapies. These patients may continue to spread MTB to others in the community, increasing the disease burden.

**Drug Resistant Strains**

With the worldwide re-emergence of TB, multi-drug resistant (MDR) and extensively drug resistant (XDR) strains have become an even greater threat. According to the WHO Global Tuberculosis Control Report 2009, there may be more than 500,000 cases of MDR-TB worldwide. Current testing for drug resistance can take more than 4 weeks, leading to higher mortality and the further spread of MDR strains.

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**The Solution**

**Xpert® MTB/RIF**

- Simultaneous detection of both MTB and rifampicin resistance, a surrogate marker for MDR strains
- Unprecedented sensitivity for detecting MTB — even in smear negative, culture positive specimens
- Results in two hours; requires no instrumentation other than the GeneXpert® System
- On-demand results enable physicians to treat rapidly and effectively

WHO’s endorsement of the Xpert MTB/RIF test, which is a fully automated NAAT (nucleic acid amplification test) follows 18 months of rigorous assessment of its field effectiveness in the early diagnosis of TB, as well as multidrug-resistant TB (MDR-TB) and TB complicated by HIV infection, which are more difficult to diagnose.

As printed in the December 8, 2010 FIND and WHO joint press release
**Sensitive**

- Hemi-nested PCR increases sensitivity
- Highly sensitive for confirmation of both smear positive and smear negative samples
- Robust sonication/mechanical DNA extraction procedure
- Internal extraction control assures extraction performance

**Efficient**

- Rapid, on-demand results mean that infected patients can quickly be placed in isolation and appropriate treatment started early
- Rapid detection of rifampicin-resistance not only guides individual patient therapy but aids with infection control and public health activities as well

### XPERT® MTB/RIF ASSAY VERSUS AFB AND CULTURE STATUS - SINGLE SPITUM PER PATIENT

<table>
<thead>
<tr>
<th>AFB-</th>
<th>AFB+</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTB DETECTED</td>
<td>122</td>
</tr>
<tr>
<td>MTB NOT DETECTED</td>
<td>45</td>
</tr>
</tbody>
</table>

**OVERALL SENSITIVITY CULTURE POSITIVE: 92.1%**

Sensitivity AFB+/Culture+: 97.9%
Sensitivity AFB-/Culture+: 73.1%
Specificity: 99.0%

### XPERT® MTB/RIF ASSAY VERSUS AFB AND CULTURE STATUS - THREE SPUTUMS PER PATIENT

<table>
<thead>
<tr>
<th>AFB-</th>
<th>AFB+</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTB DETECTED</td>
<td>153</td>
</tr>
<tr>
<td>MTB NOT DETECTED</td>
<td>17</td>
</tr>
</tbody>
</table>

**OVERALL SENSITIVITY CULTURE POSITIVE: 96.2%**

Sensitivity AFB+/Culture+: 97.9%
Sensitivity AFB-/Culture+: 90.0%
Specificity: 99.5%

### XPERT® MTB/RIF ASSAY COMPARSED TO DRUG SUSCEPTIBILITY TESTING FOR RIFAMPICIN (RIF)

**Sensitivity:** 97.2%
**Specificity:** 95.3%
**PPV:** 99.0%
**NPV:** 98.3%

<table>
<thead>
<tr>
<th>DST</th>
<th>RIF Resistant</th>
<th>RIF Sensitive</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIF Resistance DETECTED</td>
<td>141</td>
<td>7</td>
</tr>
<tr>
<td>RIF Resistance NOT DETECTED</td>
<td>4</td>
<td>415</td>
</tr>
</tbody>
</table>
A better way.

Why wait... and potentially have to delay start of treatment or isolation of the patient? Within only 2 hours, the Xpert® MTB/RIF will help you make the right decision.

Immediate benefits:

**IMPROVED MEDICAL VALUE**
- Better and earlier diagnosis
- Early choice of appropriate treatment
- Reduced cross-infection cases
- Decreased length of stay
- Reduced deaths

**REDUCED EXPENSE**
- Antibiotics
- Isolation
- Blocked bed

**WORKFLOW:**

3 Easy Steps

Total hands-on time: 2 Minutes

1. Pour Sample Reagent into sample tube. Incubate for 15 minutes at room temperature. (Acceptable sample types: unprocessed sputum or sediment from concentrated specimen.)
2. Pipette diluted sample into cartridge.
3. Insert Cartridge and start assay.

ORDERING INFORMATION

Xpert® MTB/RIF (10 Cartridges with Sample Reagent) ............................... Catalog No. GXMTB/RIF-10

References:

**Advantage: Test and Treat**

**DIMINISHING MEDICAL VALUE**

**INCREASING EXPENSE**

**TIME TO RESULT**

**HOURS**

24

12

0

**Batch PCR**

**MEDICAL VALUE**

**EXPENSE**

**CULTURE**

**Pipette diluted sample into cartridge.**

**Insert Cartridge and start assay.**

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