Maintain *Mycobacterium tuberculosis* (MTb) viability while liquefying and decontaminating sputum samples during transport

OMNiGene®-SPUTUM is a non-toxic and highly stable reagent that liquefies and decontaminates sputum samples at the point-of-collection or in the lab. MTb viability is maintained for 8 days at ambient temperatures ranging from 4°C to 40°C. Optimized samples are compatible with all routine TB tests, enable cost-effective sample transport, and simplify laboratory workflows while eliminating the need for NaOH/NALC.

### Stabilize, liquefy, decontaminate and transport samples with OMNiGene-SPUTUM for high quality results

- **Stabilize**
- **Transport**
- **Batch**
- **Concentrate**
- **Analyze**

### Optimize high quality samples

- Stabilize, liquefy and decontaminate sample at point-of-collection
- Eliminate samples lost due to putrefaction

### Scale

- Eliminate cost and complexity of cold chain shipping
- Collect and transport more samples at lower cost

### Simplify

- Simplify processing and batching sputum in the lab
- Eliminate cost and time of NaOH/NALC
- Minimize contamination and cross contamination

### Maximize centralized testing

- Optimize sample for all diagnostic algorithms
- Enable differential diagnostic testing

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**For In Vitro Diagnostic Use**

OM-SPD DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada  K2V 1C2
Subsidiary of OraSure Technologies, Inc.

Toll-free (North America): 1.866.813.6354
Tel.: +1.613.723.5757  •  Fax: +1.613.723.5057
www.dnagenotek.com
info@dnagenotek.com

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OMNIgene•SPUTUM improves detection of MTb positive samples in MGIT culture, reduces culture contamination rates and allows for long-term holds at room temperature.

**Methods:** Sputum samples (n = 15) were collected and split manually into 3 aliquots. One aliquot was immediately treated with OMNIgene•SPUTUM and held for 15 minutes at room temperature. A second aliquot was immediately treated with NaOH/NALC and held for 15 minutes at room temperature. The third aliquot was immediately treated with OMNIgene•SPUTUM and held for 3 days at room temperature. At the end of the designated hold time, sediments were formed by centrifugation. Sediments were evaluated by smear microscopy, Cepheid GeneXpert and MGIT culture. For all samples, smear and GeneXpert were comparable, with minor variations attributable to manual splitting of sputum samples prior to liquefaction (data available upon request).

**Table 1: Product comparison: sample optimization, sputum transport and overall ease-of-use**

<table>
<thead>
<tr>
<th>Product attributes</th>
<th>OMNIgene•SPUTUM</th>
<th>NaOH/NALC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintains MTb viability</td>
<td>8 days</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>1 year</td>
<td>12-18 hours</td>
</tr>
<tr>
<td>Bulk reagent</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Off-the-shelf reagent</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Non-toxic</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Does not require quality control</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Stabilizes sample at point-of-collection</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>liquefies and decontaminates</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Stabilizes DNA for differential diagnostic testing</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Easy-to-use</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Transport at ambient temperature</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Simplifies laboratory workflows</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Improves laboratory worker safety</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Reduces routine laboratory workload</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

OMNIgene•SPUTUM is compatible with the following sputum types: expectorated, induced, aspirated, bronchial lavages and washes.

Figure 1: Performance comparison of OMNIgene•SPUTUM and NaOH/NALC in MGIT culture

There is a growing need to dramatically expand and strengthen TB laboratory services, including increasing access to high quality microscopy, culture, drug susceptibility testing (DST) and new diagnostics.”

Stop TB Partnership, Global Laboratory Initiative

OMNIgene•SPUTUM is available in multiple size formats (250 mL and 1L).
Some DNA Genotek products may not be available in all geographic regions.
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**Superior samples • Proven performance**

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PD-BR-00195 Issue 4/2018-10
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