Intended use

For susceptibility testing of *Mycobacterium tuberculosis* from clinical samples.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / 600ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Asparagine</td>
<td>3.600</td>
</tr>
<tr>
<td>Monopotassium phosphate</td>
<td>2.400</td>
</tr>
<tr>
<td>Magnesium sulphate</td>
<td>0.240</td>
</tr>
<tr>
<td>Magnesium citrate</td>
<td>0.600</td>
</tr>
<tr>
<td>Potato starch, soluble</td>
<td>30.000</td>
</tr>
<tr>
<td>Malachite green</td>
<td>0.400</td>
</tr>
<tr>
<td>Glycerol</td>
<td>12.00 ml</td>
</tr>
<tr>
<td>Whole Egg Emulsion</td>
<td>1000.00 ml</td>
</tr>
<tr>
<td>D-Cycloserine</td>
<td>30 µg/ml</td>
</tr>
</tbody>
</table>

Formula adjusted, standardized to suit performance parameters

**Directions**

Inoculate either the sputum sample previously subjected to decontamination and concentration process or the pure culture of *Mycobacteria* isolated from a clinical sample on the surface of the slants. Incubate the slants at 30-35°C with 5-10% CO2 and examine the slants every week up to 8 weeks.

**Principle And Interpretation**

L.J. Medium is prepared as per the Jensen’s (3) modification of the original formulation of Lowenstein (5). The egg base medium supports a wide variety of *Mycobacteria* and can also be used for niacin testing (1). Glycerol provides fatty acids. Malachite green serves as an inhibitor as well as pH indicator. Formation of blue zones indicates a decrease in pH by Gram-positive contaminants (e.g. *Streptococci*) and yellow zones of dye destruction by Gram-negative bacilli. Proteolytic contaminants cause localized or complete digestion of the medium (6).

**Type of specimen**

Clinical samples - sputum

**Specimen Collection and Handling**

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (2,4). After use, contaminated materials must be sterilized by autoclaving before discarding.

**Warning and Precautions :**

In Vitro diagnostic Use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets

**Limitations :**

Some hospital isolates may require longer incubation periods.

**Performance and Evaluation**

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.
Quality Control

Appearance
Pale bluish green coloured, opaque smooth slant containing w/ D-Cycloserine (30 µg/ml).

Sterility test
Passes release criteria

Cultural response
Cultural characteristics within 10 to 15 days at 35°C, with 5-10% CO2 (further growth may be observed for 2 to 4 weeks)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Colony characteristics</th>
<th>Inoculum</th>
<th>Growth on control</th>
<th>Growth on slant w/ D-Cycloserine (30 µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>M. tuberculosis</em> H37Rv ATCC 25618</td>
<td>Granular, rough, warty, dry friable colonies</td>
<td>Standardized inoculum giving approximately 1000000 cfu/ml</td>
<td>Luxuriant</td>
<td>No growth</td>
</tr>
</tbody>
</table>

Storage and Shelf Life
Store between 2-8°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal
User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,4).

Reference

Revision : 01 / 2019
In vitro diagnostic medical device

CE Marking

Storage temperature

2°C - 8°C

Do not use if package is damaged

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