Intended Use:
Recommended for cultivation of *Mycobacterium tuberculosis* from clinical samples.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>HiVeg™ peptone No. 3</td>
<td>4.000</td>
</tr>
<tr>
<td>Yeast extract</td>
<td>2.000</td>
</tr>
<tr>
<td>Disodium hydrogen phosphate</td>
<td>2.500</td>
</tr>
<tr>
<td>Monopotassium phosphate</td>
<td>1.000</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>1.500</td>
</tr>
<tr>
<td>Magnesium sulphate</td>
<td>0.600</td>
</tr>
<tr>
<td>Polysorbate 80 (Tween 80)</td>
<td>0.500</td>
</tr>
<tr>
<td>Final pH (at 25°C)</td>
<td>7.0±0.2</td>
</tr>
</tbody>
</table>

**Formula adjusted, standardized to suit performance parameters**

**Directions**
Suspend 12.1 grams in 1000 ml purified /distilled water, which if desired contains 5 ml glycerol (tested to be non-inhibitory to typical cultures). Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-55°C and enrich with dextrose to a final concentration of 0.5% and either bovine albumin fraction-V or serum as desired.

**Principle And Interpretation**
TB Broth media are based on the medium formulated by Dubos and Davis (1) and are used as liquid media for the cultivation of *Mycobacterium tuberculosis*. This medium provides dispersed growth of tubercle bacilli which is free of excessive clumps and so it can be used to prepare a uniform suspension of Mycobacteria. The medium can be used without additives and supplements; however, sterile dextrose and sterile serum can be added for the enrichment. Glycerol addition helps in the cultivation of *Mycobacterium tuberculosis* though some bovine strains are inhibited by it. TB HiVeg™ Broth Base is same as TB Broth Base except that the animal based peptones are completely replaced with vegetable peptones.

HiVeg™ peptone No. 3 and yeast extract provide nitrogenous and carbonaceous nutrients, long chain amino acids and peptides, vitamin B complex and other essential nutrients. The medium is well buffered by phosphates. The salts present in the medium supply ions required for the mycobacterial metabolism. Sodium citrate inhibits gram-positive organisms and coliforms. Polysorbate 80, an oleic acid ester provides essential fatty acids for the replication of Mycobacteria.

**Type of specimen**
Clinical samples - Sputum sample

**Specimen Collection and Handling**
For clinical samples follow appropriate techniques for handling specimens as per established guidelines (2,3). 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 :**
1. Further biochemical and serological tests must be carried out for further identification.

**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
Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium
Yellow coloured clear solution without any precipitate.

Reaction
Reaction of 1.21% w/v aqueous solution at 25°C. pH : 7.0±0.2

pH
6.80-7.20

Cultural Response
Cultural characteristics observed after an incubation at 35-37°C for 2-4 weeks.

Organism | Inoculum (CFU) | Growth
--- | --- | ---
*Mycobacterium kansasii* ATCC 12478 | 50-100 | luxuriant
*Mycobacterium smegmatis* ATCC 14468 | 50-100 | luxuriant
*M. tuberculosis H37RV* (25618) | 50-100 | luxuriant

Storage and Shelf Life
Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle inorder to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use. 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 (2,3).

Reference

Revision : 02 / 2019

Please refer disclaimer Overleaf.
Technical Data

In vitro diagnostic medical device

CE Marking

Storage temperature

10°C

Do not use if package is damaged

HiMedia Laboratories Pvt. Limited,
23 Vadhani Industrial Estate,
LBS Marg, Mumbai-86, MS, India

CE Partner 4U, Esdoornlaan 13, 3951 DB Maarn The Netherlands,
www.cepartner4u.eu

Disclaimer:

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.