Tuberculosis Second Line Kit (Total 10 slants)  

SL024  

Containing eight antitubercular agent (Kanamycin, Amikacin, Ethionamide, D-Cycloserine, Clarithromycin, Ciprofloxacin, p-Amino salicylic acid, Rifabutin) + 2 controls.

**Composition**  
Proprietary

**Directions**  
Follow good laboratory procedures when working with *Mycobacteria* cultures and specimens. Perform all work in Biological safety cabinet. For inoculations use calibrated loop or micropipette. Ensure that all the specimen and used slants are immersed in suitable disinfectant or preferably 2% gluteraldehyde for minimum two hours before disposal. The Drug Susceptibility Test is carried out for 1) Either sputum sample previously subjected to decontamination and concentration process. Inoculate 10µ of the processed specimen on slants. OR 2) Pure culture of *Mycobacteria* isolated from a clinical sample.

**Preparation of inoculum:**  
Take a loopful aseptically from the *M. tuberculosis* growth, primarily isolated on L. J. medium slant. Suspend the sample in 1.0ml of sterile distilled water in a screw capped bottle. (Recommended to use glass beads of 3.0mm diameter for better homogenization and declumping of cells). Further homogenize the mixture on a vortex mixture up to 10 minutes. Keep standing for 10 minutes before opening the bottle. Adjust opacity of suspension to match McFarland 0.5 standard with saline giving approximately 1.5x 10^8 cfu/ml. Dilute this suspension to 1:10000.

**Principle And Interpretation**  
Based on invivro correlation between the clinical response to antimicrobial agent and the result of invivro susceptibility testing kit (SL023) helps in diagnosing the sensitivity pattern of *M. tuberculosis* affected patient and accordingly provide treatment, drug therapy for the patients.

Primary drug resistance for *M. tuberculosis* is defined as resistance to an antimicrobial drug in an organism isolated from a patient who has not previously received antituberculosis therapy. Therefore drug resistance applies to previously untreated patients who are found to have drug resistant organisms presumably because they have been infects from an outside source of resistant *M. tuberculosis*. Acquired (or secondary) drug resistance is due to importantly because of non-adherence in drug taking.

*Mycobacteria* susceptibility test can be inoculated either directly from digested and concentrated smear positive sputum (direct test) or from a pure culture of *Mycobacteria* isolated from a clinical specimen (indirect test). The direct test is usually done only on specimens showing *Mycobacteria* on smear and give the best results when large no. of *Mycobacteria* are present. The advantage of the direct test is that a much earlier report of susceptibility studies (3 to 4 weeks) can be made than with indirect test which may take up to 5 to 7 weeks, but can be frequently be complicated by over growth with other bacteria that have survived the decontamination procedure.

**Quality Control**  
**Appearance**  
Pale bluish green coloured, smooth slants containing eight antitubercular drugs(Kanamycin, Amikacin, Ethionamide, D-Cycloserine, Clarithromycin, Ciprofloxacin, p-Amino Salicylic acid, Rifabutin)and two controls.

**Sterility test**  
Passes release criteria

**Cultural response**  
Cultural response observed after an incubation at 35-37°C under 5-10% CO2 for 2-4 weeks(further growth may be observed for 6-8 weeks)
<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum</th>
<th>Growth on control slants</th>
<th>Colony characteristics on control slants</th>
<th>Growth on slant w/antibiotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. tuberculosis H37Rv ATCC 25618</td>
<td>Standardized inoculum giving approximately 1000000 cfu/ml</td>
<td>Luxuriant</td>
<td>Granular, rough dry, friable colonies</td>
<td>Inhibited</td>
</tr>
</tbody>
</table>

**Storage and Shelf Life**
Store between 2-8°C. Use before expiry date on the label.

**Reference**
9. Lorian, V. 2005, Antibiotics in Laboratory Medicine, 5th edition, Lippincott Williams & wilkins, USA.

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