Fite's Stain Kit (For Leprosy and Nocardia)

Description: The Fite’s Stain Kit (For Leprosy and Nocardia) is intended for use in the histological visualization of mycobacterium Lepra bacillus and Nocardia. This kit may be used on formalin-fixed, paraffin-embedded or frozen sections.

Uses/Limitations: Not to be taken internally. For In-Vitro Diagnostic use only. Histological applications. Do not use past expiration date. Use caution when handling reagents. Non-Sterile.

Control Tissue: Any well fixed paraffin embedded tissue.

Results: Lepra bacillus: Red
Nocardia: Red
Background: Blue

Kit Contents:

<table>
<thead>
<tr>
<th>Item #</th>
<th>Kit Contents</th>
<th>Volume</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSC-XPO125</td>
<td>Xylene-Peanut Oil Solution</td>
<td>125 ml</td>
<td>18-25°C</td>
</tr>
<tr>
<td>SSC-CFZ125</td>
<td>Carbol Fuchsin Solution</td>
<td>125 ml</td>
<td>18-25°C</td>
</tr>
<tr>
<td>SSC-AAM500</td>
<td>Acid Alcohol Solution (1%)</td>
<td>500 ml</td>
<td>18-25°C</td>
</tr>
<tr>
<td>SSC-MBS125</td>
<td>Methylene Blue Solution</td>
<td>125 ml</td>
<td>18-25°C</td>
</tr>
</tbody>
</table>

Precautions: Keep away from open flame. Avoid contact with skin and eyes. Harmful if swallowed. Follow all Federal, State, and local regulations regarding disposal. Use in chemical fume hood whenever possible.

For information regarding ordering individual components, please contact us at: 800-442-3573.
Lepra bacillus Procedure (Standard):
1. Deparaffinize sections in 2 changes of Xylene-Peanut Oil Solution for 12 minutes each.
2. Air dry slide for 15 minutes “without” removing oil film covering tissue section. Remaining film prevents de-staining of Lepra bacillus during differentiation.
3. Rinse slide in several changes of distilled water.
4. Incubate slide in Carbol Fuchsin Solution for 15 minutes.
5. Rinse slide in several changes of distilled water.
6. Differentiate section in Acid Alcohol Solution (1%) until background is pink.
7. Rinse slide in distilled water and check by microscope for correct differentiation.
8. Rinse in running tap water for 1 minute followed by 1 rinse in distilled water.
9. Dip slide 2-3 times in Methylene Blue Solution.
10. Dip slide quickly in distilled water and check by microscope for correct staining.
11. Air dry slide at room temperature.
12. Dip slide several times in Xylene or Xylene Substitute.

Nocardia Procedure:
Preparation of Reagents Prior to Beginning:
1. Prepare Diluted Acid Alcohol Solution by mixing 25ml of Acid Alcohol Solution (1%) with 25ml of Distilled Water.

Procedure:
1. Deparaffinize sections in 2 changes of Xylene-Peanut Oil Solution for 12 minutes each.
2. Air dry slide for 15 minutes “without” removing oil film covering tissue section. Remaining film prevents de-staining of Lepra bacillus during differentiation.
3. Rinse slide in several changes of distilled water.
4. Incubate slide in Carbol Fuchsin Solution for 15 minutes.
5. Rinse slide in several changes of distilled water.
6. Dip slide 2-3 times in Diluted Acid Alcohol Solution.
7. Rinse slide in distilled water and check by microscope for correct differentiation. Avoid decolorizing the Nocardia organism.
8. Rinse in running tap water for 1 minute followed by 1 rinse in distilled water.
9. Dip slide 2-3 times in Methylene Blue Solution.
10. Dip slide quickly in distilled water and check by microscope for correct staining.
11. Air dry slide at room temperature.
12. Dip slide several times in Xylene or Xylene Substitute.
References:


Lot-to-Lot Validation Form  
Fite’s Stain Kit Catalog: SSK-FITES

<table>
<thead>
<tr>
<th>Kit Lot Number:</th>
<th>Kit Component</th>
<th>Lot #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Xylene-Peanut Oil Sol.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carbol Fuchsin Solution</td>
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<tr>
<td></td>
<td>Acid Alcohol Sol (1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methylene Blue Solution</td>
<td></td>
</tr>
</tbody>
</table>

Kit Expiration Date: ________________  
Date Tested: ________________  
Control Tissue (#): ________________  
Approved for Use: Y/N  
Date put into use: ________________  
If not approved, corrective actions taken: ________________  
Approved by: ________________

<table>
<thead>
<tr>
<th>Replacement Component if used</th>
<th>Replacement Date</th>
<th>Lot #</th>
<th>Accepted Y/N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Approved By: ________________

StatLab is providing this form to assist with reagent lot validation as stated in CLIA’88 Standard 493.1256-For reagent(s), the laboratory must do the following: Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, stains, and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, if applicable.