

Instructions For Use IFU-046

SSK-FITES

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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

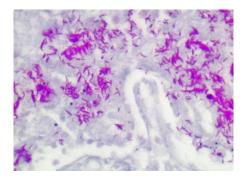
Use caution when handling

reagents. Non-Sterile.

Results: Lepra bacillus: Red

Nocardia: Red Background: Blue **Control Tissue:**

Any well fixed paraffin embedded tissue.



Kit Contents:

<u>ltem #</u>	<u>Kit Contents</u>	<u>Volume</u>	<u>Storage</u>
SSC-XPO125	Xylene-Peanut Oil Solution	125 ml	18-25°C
SSC-CFZ125	Carbol Fuchsin Solution	125 ml	18-25°C
SSC-AAM500	Acid Alcohol Solution (1%)	500 ml	18-25°C
SSC-MBS125	Methylene Blue Solution	125 ml	18-25°C

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. Control Slides Available. Catalog: CS-FITE/25, Fite, 25/pack



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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.
- 13. Mount in synthetic resin.

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.
- 13. Mount in synthetic resin.



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References:

- 1. Echeverri, C., et al. Fite Stain Positivity in Rhodococcus equi: Yet Another Acid-Fast Organism in Respiratory Cytology A Case Report. Diagnostic Cytopathology; April 2001, Volume 24, Issue 4, pages 244-246.
- 2. Crowder, C., Taylor, HW., Modified Fite Stain for Demonstration of Mycobacterium Species in Tissue Sections; Journal of Histotechnology; 1996, Volume 19; 2: pages 133-134.
- 3. Mallory, Pathological Technique; page 275.



Approved By:

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

Kit Lot Number:				Kit Component	Lot #
Kit Expiration Date:				Xylene-Peanut Oil Sol.	
Date Tested:			Carbol Fuchsin Solution		
Control Tissue (#)			Acid Alcohol Sol (1%)		
Approved for Use: Y/N			Methylene Blue Solution		
Date put into use:					
If not approved,					
corrective actions	-				
taken:					
Approved by:					
Replacement	Replacement	Lot #	Accepted	Comments	
Component if used	Date		Y/N		
Xylene-Peanut Oil Sol.					
Carbol Fuchsin Sol.					
Acid Alcohol Sol. (1%)					
Methylene Blue Sol.	·				

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.