Diagnostic BioSystems

Instructions For Use KT 001-IFU

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Acid Fast Bacteria (AFB) Stain Kit

Description and Principle

The Acid Fast Bacteria (AFB) Stain Kit is intended for use in the histological visualization of bacteria characterized as "acid-fast". AFB is especially useful detecting mycobacteria such as *Mycobacterium tuberculosis*. Acid-fast organisms take up Carbol Fuchsin and resist decolorization due to high lipid content of the cell wall. Carbol Fuchsin is removed from organisms without a lipoid cell wall by a dilute acid.

Expected Results

Acid Fast Organisms: Background: Bright Red Light Green

Kit Contents	Storage
1. Carbol Fuchsin Solution	15-30°C
2. Acid Alcohol Solution (0.5%)	15-30°C
3. Light Green Solution	15-30°C.

Suggested Controls (not provided)

Tissue or cell smear containing acid-fast organisms

Uses/Limitations

For In-Vitro Diagnostic use only. Do not use if reagents become cloudy or precipitate Do not use past expiration date. Use caution when handling reagents. Non-Sterile Intended for FFPE sections cut at 5-10µm. This procedure has not been optimized for frozen sections. Frozen sections may require protocol modification.

Storage

Store kit and all components at room temperature (15-30°C).

Safety and Precautions

Please see current Safety Data Sheets (SDS) for this product and components GHS classification, pictograms, and full hazard/precautionary statements. If there is any serious incident that has occurred in relation to the device, please contact the manufacturer: Diagnostic

BioSystems Technical Support at (925) 484-3350, extension 2 or

techsupport@dbiosys.com. If required, please report to the Competent Authority of the Member State in which the user and/or patient is established.

Note: Carbol Fuchsin Solution should be filtered when a thick sheen develops on top of solution. To avoid possible contamination, gloves should be worn when performing this procedure. Do not use tap water prior to application of Carbol Fuchsin Solution as it is reported that Acid Fast Bacteria can be found in some systems. Therefore use of distilled water is recommended whenever possible

Procedure

1. Deparaffinize sections if necessary and hydrate to distilled water.

2. Incubate slide in Carbol Fuchsin Solution for 15 minutes.

3. Rinse for 2 minutes in running tap water followed by 2 changes of distilled water.

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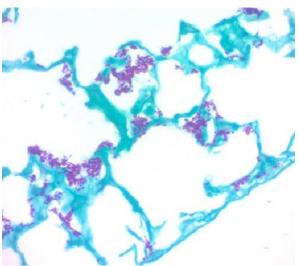
MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland



MedEnvoy Global B.V. Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands

4. Decolorize in Acid Alcohol Solution (0.5%) until sections are a pale pink color.

- 5. Dip slide twice in distilled water to rinse.
- 6. Counterstain in Light Green Solution for 1-2 minutes.



Mycobacterium gordonae artifically introduced in Mouse Lung demonstrated by Acid Fast Bacteria Stain.

7. Rinse in several changes of distilled water.

 $\ensuremath{\mathbf{8}}$. Dehydrate quickly through graded alcohols ending with 2 changes in absolute alcohol.

9. Clear, and mount in synthetic resin.

References

1. Sheenan, D.C., Hrapchak, B.B. Theory and Practice of Histotechnology, 2nd Edition. Battelle Press, Columbus, OH. 2. Carson, F.L., 1996, Histotechnology; A Self-Instructional Text, 2nd Edition. ASCP

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