remel

QC-Slide[™] AFB Stain Control

INTENDED USE

Remel QC-Slide™ AFB Stain Control is a specifically designed, unstained, ready-to-use microscope slide. It is intended to be part of a quality control program to monitor microbiological acid-fast stains and staining techniques used in acid-fast stain procedures.

PRINCIPLE

Clinical laboratory regulatory agencies and Good Laboratory Practice regulations require quality control programs. The performance of equipment, reagents, methods, and techniques must be monitored and documented. QC-Slide™ AFB Stain Control is a control slide for use with microbiological acid-fast stains.

Each QC-Slide™ AFB Stain Control contains one circle with a simulated sputum containing *Mycobacterium tuberculosis* and one circle with an acid-fast negative organism. The smear is heat-fixed and ready for staining.

PRECAUTIONS

This product is For Laboratory Use only and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological and sharps hazards by properly sterilizing and disposing of specimens, containers, microscope slides, and media after use. Directions should be read and followed carefully.

STORAGE

Store product in its original container at room temperature until used. Do not freeze or expose to excess heat. Protect from light.

PROCEDURE

QC-Slide $^{\text{TM}}$ AFB Stain Control may be stained with the following carbolfuchsin or fluorescent staining procedures:

Kinyoun Carbolfuchsin Method:

- 1. Place QC-Slide™ AFB Stain Control on a staining rack in a sink.
- Flood with TB Kinyoun Carbolfuchsin (REF R40204) and stain for 5 minutes. Rinse with water and drain.
- Decolorize with TB Decolorizer (3% Acid Alcohol) (REF R40206) for 3 minutes. Rinse with water and drain.
- 4. Repeat decolorization step (step 4) for 1-2 minutes or until no red stain appears. Rinse with water and drain.
- Flood with either, TB Methylene Blue (REF R40210), TB Malachite Green (REF R40208), or TB Brilliant Green (REF R40200) and stain for 3-4 minutes. Rinse with water and drain.
- 6. Allow slide to air-dry. Do not blot.
- 7. Examine under oil immersion (1000 X).

Ziehl-Neelsen Carbolfuchsin Method:

- Place QC-Slide™ AFB Stain Control on a staining rack in a sink.
- Flood with TB Ziehl-Neelsen Carbolfuchsin (REF R40202) and steam gently for 1 minute using a Bunsen burner flame below the rack or a slide warmer. Do not allow the slides to boil or dry out.
- Allow stain to remain on the slide for an additional 4-5 minutes without heat. Rinse with water and drain.
- Flood with TB Decolorizer (3% Acid Alcohol) (REF R40206) for 3 minutes. Rinse with water and drain.
- Flood with TB Methylene Blue counterstain (REF R40210) for 1 minute. Rinse with water and drain.
- 6. Allow slide to air-dry. Do not blot.
- 7. Examine under oil immersion (1000 X).

Auramine O Fluorescent Method:

- Flood QC-Slide™ AFB Stain Control with TB Auramine O (REF R40186) and stain for 15 minutes. Rinse with water and drain.
- Flood with TB Decolorizer (Truant-Moore) (REF R40207) for 2-3 minutes. Rinse with water and drain.
- Flood slide with TB Potassium Permanganate counterstain (REF R40192) and stain for 2-4 minutes, no longer. Rinse with water and drain. Allow slide to air dry. Do not blot.

- Examine with a fluorescent microscope using a 25 X or 40 X objective (a total magnification of 250 X or 400 X).
- 5. Confirm under oil immersion at a magnification of 450 X or 1000 X.

INTERPRETATION

Kinyoun and Ziehl-Neelsen Methods:

Positive Control - Mycobacteria appear red, small, slightly curved, possibly beaded or banded, with tapered ends. The specimen/background stains blue or green depending

on the counterstain used.

Negative Control - Nonacid-fast organisms stain blue or green depending

on the counterstain used.

Auramine O Fluorescent Method:

Positive Control - Mycobacteria fluoresce a bright yellow-green against a dark background. The specimen/background

fluoresces pale yellow.

Negative Control - Nonacid-fast organisms will not fluoresce or may appear pale yellow, quite distinct from the bright yellow acid-fast organisms.

QUALITY CONTROL

All lot numbers of QC-Slide™ AFB Stain Control have been analyzed to verify contents. Quality control testing should be performed in accordance with established laboratory procedures. If aberrant quality control results are noted, test results should not be reported.

LIMITATIONS

- Extended exposure to counterstain may result in loss of brilliance in fluorescent stain techniques.
- Fluorochrome-stained smears may lose fluorescence with time. Examine smears within 24 hours of staining.⁵
- The acid-fast stain is not specific for mycobacteria. Other microorganisms, such as Nocardia, Rhodococcus, Legionella, Cryptosporidium, Isospora and other microsporidia, may stain acidfast.⁶
- Rinse water containing chlorine may interfere with fluorescence. In such instances, use demineralized water to rinse smear.⁵

BIBLIOGRAPHY

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PACKAGING

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
[]i	Consult Instructions for Use (IFU)
A	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
\square	Use By (Expiration Date)

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