

Instructions for Use

AFB SMEAR FIX

Cat. no. Z56	AFB Smear Fix	15ml
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INTENDED USE

Hardy Diagnostics AFB Smear Fix is designed to assist in acid-fast staining of positive mycobacteria cultures from the 12B culture vials used in Becton Dickinson's BACTEC™ Automated Culture System.

SUMMARY

The acid-fast stain is an important confirmation of the presence of mycobacteria. Thus, it is recommended that an acid-fast stain be performed on positive cultures detected in 12B media vials cultured in Becton Dickinson's BACTEC™ Automated Culture System once the culture reaches a GI of 100 or more. The 12B medium is very low in protein, thus the smear may not adhere to the slide well. Becton Dickinson recommends a smear fixative containing 20% phenolized rabbit or other animal serum be used to adhere the culture to the slide before staining. ⁽⁴⁾ Once the culture has been fixed to the slide, staining with the Ziehl-Neelsen (ZN) acid-fast stain or fluorochrome stain may be performed using traditional procedures.

REAGENT FORMULA

AFB Smear Fix is 20% phenolized rabbit serum solution with thimerosol.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30°C. away from direct light. Product should not be used if there are any signs of contamination, deterioration, or if the expiration date has passed.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "[Storage](#)" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "[Guidelines for Isolation](#)"

[Precautions](#)" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections*.

Sterilize all biohazard waste before disposal.

Refer to the document "[Precautions When Using Media](#)" for more information.

PROCEDURE

Place a small drop of AFB Smear Fix on a clean slide. Do not let it dry. Place 1 to 2 large drops of sample from the BACTEC™ 12B vial on top of the drop of the AFB Smear Fix. Mix the two solutions well, and spread over an area of 1½ x 1cm. Let the smear completely air dry. Heat fix the smear by passing the slide over a flame a few times, or use an electric warmer at 65-75°C. for 2-12 hours.

Stain the smear with the Ziehl-Neelsen method, or fluorochrome stain, following instructions located in the appropriate texts. ^(1,2)

INTERPRETATION OF RESULTS

Examine the preparation under low magnification to locate the bacteria. Switch to oil immersion for detailed observation of characteristic morphology of the bacteria. Consult appropriate references for diagnostic features of mycobacteria isolated from clinical specimens.

Consult listed reference for more information regarding culturing, fixing, staining and interpretation of positive cultures. ⁽⁴⁾

LIMITATIONS

The use of fluorochrome staining instead of the Ziehl-Neelsen acid-fast stain will not show bacterial morphology as clearly as that obtained from the Ziehl-Neelsen method.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, microscopes, incinerators, incubators, pasteur pipets, glass microscope slides, slide warmers, bunsen burners and stains, etc., are not provided.

QUALITY CONTROL

USER QUALITY CONTROL

Inspect for signs of deterioration or contamination.

PHYSICAL APPEARANCE

AFB Smear Fix should appear clear, and light amber in color.



AFB Smear Fix (Cat. no. Z56).

REFERENCES

1. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.
2. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.
3. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.
4. BACTEC™ Manual; Section II & VIII - AFB Smear and Ziehl-Neelsen Stains. 1988. Becton Dickinson Microbiology Systems, Cockesville, MD.

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