



F.A.S.T. AFB Control Slides

Instruction Manual



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F.A.S.T. AFB Control Slides

Intended Use

For use as a quality control of acid fast staining and smear examination procedures

Summary and Principles

Adequate quality control is critical for evaluation of the efficacy of the diagnostic systems employed in clinical laboratories. For acid fast bacilli (AFB) based diagnostic procedures, microscope slide preparations with confirmed AFB are critical for challenging the staining procedures and reagents, instrumentation, and technician's suitability to perform the test.

The QBC *F.A.S.T.* Quality Control Slides are designed to meet the needs of proper acid fast microscopy quality control. Each slide contains two circles which define a smear of non-viable, fixed organisms. The positive (+) control circle contains a non-viable smear of *Mycobacterium tuberculosis*. The negative (-) control circle contains a non-viable smear of *Escherichia coli*. Positive and negative control organisms are contained in a background with a distribution designed to simulate a patient specimen, which provides enhanced quality control function.

Acid fast bacilli, such as *Mycobacterium tuberculosis*, contain mycolic acid, which makes them recalcitrant to decolorization with acidic solvents following staining with dyes such as carbol fuchsin and Auramine O. In contrast, non-acid fast bacilli, such as

Eschrechia coli, will not retain stains following decolorization with acidic solvents. Therefore, when stained utilizing acid fast staining protocols, the positive control well should contain organisms that retain stain following decolorization and that contrast against the background. This will provide a means to help ensure staining and microscopy systems are functioning. The negative control well should exhibit only background staining characteristics and thus provide a means to identify sources of false positive reading such as system contamination or examination error.

Contents

Contents of this package include the following items:

5 QBC *F.A.S.T.* Quality Control Slides

Each QBC *F.A.S.T.* Quality Control Slide contains:

- Positive control smear of fixed, non-viable *Mycobacterium tuberculosis*
- Negative control smear of fixed, non-viable *Escherichia coli*

1 Package insert

Warnings and Precautions

For in vitro diagnostic use

Patient smears should be prepared on blank slides to ensure that cross-contamination does not occur.

The control organisms have been chemically inactivated and air-dried on the slide. However, all slides should be handled as if they have infectious material. Follow proper established laboratory procedure in handling and disposing of infectious material.

This product is designed to aid in the detection of acid fast bacilli. Sputum smear microscopy and the procedures involved with sample preparation and processing for AFB detection should be performed only by those trained in the techniques involved as well as general laboratory practices and procedures.

Caution: This product is made with glass. Handle with care.

Storage Instructions

Store at 15-25°C. Do not freeze or expose to excess heat. Do not use beyond expiration date.

Materials Required But Not Provided

Acid-fast stain reagents and/or fluorescent stain reagents, conventional microscope and/or fluorescent microscope assembly. If fluorescence reagents are used, fluorescent microscope must be equipped with the proper filter sets that will allow excitation of the dye and capture of fluorescence (e.g., for Auramine O-Excitation filter: 435 - 480 nm; Emission filter: 510 - 600 nm).

Instructions for Use

Slides should be stained with reagents to be used for patient specimen examination. The technician performing patient specimen staining should perform the control slide staining using specimen staining procedures. Both positive and negative smears should be examined by laboratory technicians performing patient specimen diagnosis. QC should be performed routinely and in accordance with governing regulations. Results should be documented.

QC Slides are for single use only.

Test Procedure

1. Stain the QBC *F.A.S.T.* Quality Control Slide along with the test slide, using a fluorescent or acid-fast stain kit according to your laboratory's recommended procedure.
2. Keep slides well separated during the staining procedure to avoid cross-contaminating carry over of stain reagents from slide to slide.
3. Read the stained slide with a microscope appropriate for the type of stain and record the results.

Expected Results

When using Ziehl-Neelsen or Kinyoun staining methods, the mycobacteria should stain red to pink with the background staining blue or green depending on the counterstain used. For fluorescence staining procedures, the mycobacteria should fluoresce bright green or golden orange depending on the staining procedure. The negative control should exhibit the background staining characteristics.

If expected results are not obtained, investigate cause of failure, which may include failure of reagents, instrument, and operators. If control failure is suspected, use another means to test system such as patient specimen (known positive or negative). Do not report patient results until system failure is corrected.

Limitations

When used for fluorescence staining procedures, fluorescence of smears will wane over time. Therefore, stained slides should be examined as soon as possible.

References

The QBC *F.A.S.T.* AFB Control Slides are an integral part of overall acid fast microscopy quality assurance. For addition guidance on quality assurance for the mycobacteriology lab, the following resources are available:

1. Essential Procedures for Clinical Microbiology. (1998) American Society of Microbiology. Washington, D.C.
2. Laboratory Diagnosis of Tuberculosis by Sputum Microscopy. (2005) Institute of Medical and Veterinary Science. Adelaide, Australia
3. Manual of Clinical Microbiology. (2007) Volumes 1 and 2. 9th Edition. American Society of Microbiology. Washington, D.C.

Ordering Information

QBC *F.A.S.T.* AFB Control Slides,
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Manufacturer



Authorized Representative in the European Community



Use By



Catalog Number



In Vitro Diagnostic Medical Device



Temperature Limitation



Batch Code (Lot)



Consult Instructions for Use



Single Use Only



Control