

Rapid Auramine O Fluorescent Stain Set

INTENDED USE

The Rapid Auramine O Fluorescent Stain Set is recommended for use in qualitative procedures for the fluorescent microscopic detection of mycobacteria.

SUMMARY

One of the earliest methods devised for the detection of the tubercle bacillus is the microscopic staining technique. Mycolic acid within the mycobacteria cell wall interacts with dyes resulting in the characteristics known as "acid-fastness". Acid-fast microscopy is the most rapid, initial step in diagnosis and provides information about the number of acid-fast bacilli present. Hagermann described the use of fluorescent dyes for the detection of acid-fast bacilli in clinical specimens. In 1962, Truant, Brett, and Thomas evaluated the usefulness of a fluorescent staining technique and found it to yield a larger number of positive smears than the conventional fuchsin-stained method. In 1966, Bennedson and Larsen also reported a higher yield of positive smears with a reduced time requirement when using the fluorescent technique.

The fluorochrome dye Auramine O, used in this stain, reacts with the mycolic acids in the acid-fast cell wall of the organism. The combination Rapid Fluorescent Decolorizer/Counterstain renders tissue and debris non-fluorescent, thereby reducing the visibility of artifacts. The cells visualized under ultraviolet light appear bright yellow-green.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

Rapid Auramine O Fluorescent Stain is poisonous and may be harmful or fatal if swallowed. May cause irritation to skin, eyes and respiratory tract. Combustible, keep away from heat and flame. Contains material which may cause cancer based on animal data. Avoid breathing vapor and eye/skin contact. The Rapid Fluorescent Decolorizer/Counterstain may be harmful if swallowed. Avoid eye/skin contact and breathing vapors. Flammable; keep away from heat and flame.

STORAGE

This product is ready for use, and no further preparation is necessary. Store in its original container at 15-30°C until used. Store away from heat and direct sunlight.

USER QUALITY CONTROL

This product should not be used if the color has changed, the expiration date has passed, or there are other signs of deterioration.

SPECIMEN COLLECTION AND PREPARATION

Appropriate specimens for the detection of *Mycobacterium* spp. should be collected according to prescribed standards and delivered to the laboratory in a safe and timely manner. Refer to local procedural guidelines for this information.

PROCEDURE

Materials Provided: Rapid Auramine O Fluorescent Stain, Rapid Fluorescent Decolorizer/Counterstain.

Materials Not Provided: Pipettes, glass slides, fluorescent microscope, immersion oil, deionized or distilled water, Bunsen burner or slide warmer, AFB Stain Control Slide (#0003240).

SPECIMEN PROCESSING

1. Make a thin smear of the specimen over an area of 2-3 sq. cm. Heat-fix by warming on a slide warmer (65-75°C) for 10 minutes, or until the smear is dry. If a Bunsen burner is used, pass the slide slowly 3 times over its cone of heat. Do not scorch.
2. Flood the smear with Rapid Auramine O Fluorescent Stain for 1 minute.
3. Rinse with deionized or distilled water and drain.
4. Decolorize with Rapid Fluorescent Decolorizer/Counterstain for 1 minute.
5. Rinse with deionized or distilled water and allow to air-dry.
6. Examine microscopically using low power (10x – 40x) under a fluorescent microscope and confirm at 100x with oil immersion.
7. A positive fluorescent smear may be re-stained using the conventional Ziehl-Neelsen or Kinyoun procedures.

EXPECTED RESULTS

Positive Reaction: Acid-fast positive organisms fluoresce bright yellow-green against a dark blue/grey background.

Negative Reaction: Nonacid-fast organisms will not fluoresce or may appear a pale grey, quite distinct from the bright acid-fast organisms.

LIMITATIONS OF PROCEDURES

1. Overheating (burning) during fixation should be avoided.
2. Do not stain smears which have only been air-dried. Smears must also be heat-fixed.
3. Smears should not be too thick. After air-drying, examine under a microscope.
4. After staining it is essential that the back surface of the slide is wiped clean.
5. If washing with deionized or distilled water is not done adequately, crystallization of the stain may appear on the slide.
6. A positive staining reaction provides presumptive evidence of the presence of mycobacteria. A negative staining reaction does not indicate that the specimen will be culturally negative; therefore, cultural methods must be employed.
7. Most strains of rapid growers may not appear fluorescent. It is recommended that all negative fluorescent smears be confirmed with Kinyoun Carbofuchsin Stain (#0003524), Ziehl-Neelsen (#0003531), or TB Rapid Stain (#0003445). At least 100 fields should be examined before being reported as negative.
8. Excessive exposure to the counterstain may result in a loss of brilliance of the fluorescing organism.
9. Turbidity may develop in the stain, but it will not interfere with its effectiveness. Shake the bottle before using.
10. Stained smears should be observed within 24 hours of staining because of the possibility of the fluorescence fading.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product has been tested using the QC1™ AFB Quality Control Slide and has been found to yield acceptable stain results. Appropriate testing should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

BIBLIOGRAPHY

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7. Truant, J.P., W.A. Brett, and W. Thomas. 1962. Henry Ford Hosp. Med. Bull. 10:287-296.

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CONTACT

Alpha-Tec Systems, Inc. offers a complete line of reagents, stains, and QC1™ Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing, as well as O&P collection systems and concentration devices for Parasitology. For Technical Assistance, email Technical@AlphaTecSystems.com, and for Customer Service, email Sales@AlphaTecSystems.com, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY

This product is warranted by Alpha-Tec Systems, Inc. to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS

QC1™ is a trademark of Alpha-Tec Systems, Inc., 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA.

PRODUCT CODE

0003570 Rapid Auramine O Fluorescent Stain Set, 1 set, 2 x 250 ml



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GLOSSARY OF SYMBOLS



Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote



Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog number / Het aantal van de catalogus / Kataloška številka / Número de catálogo



In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro



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