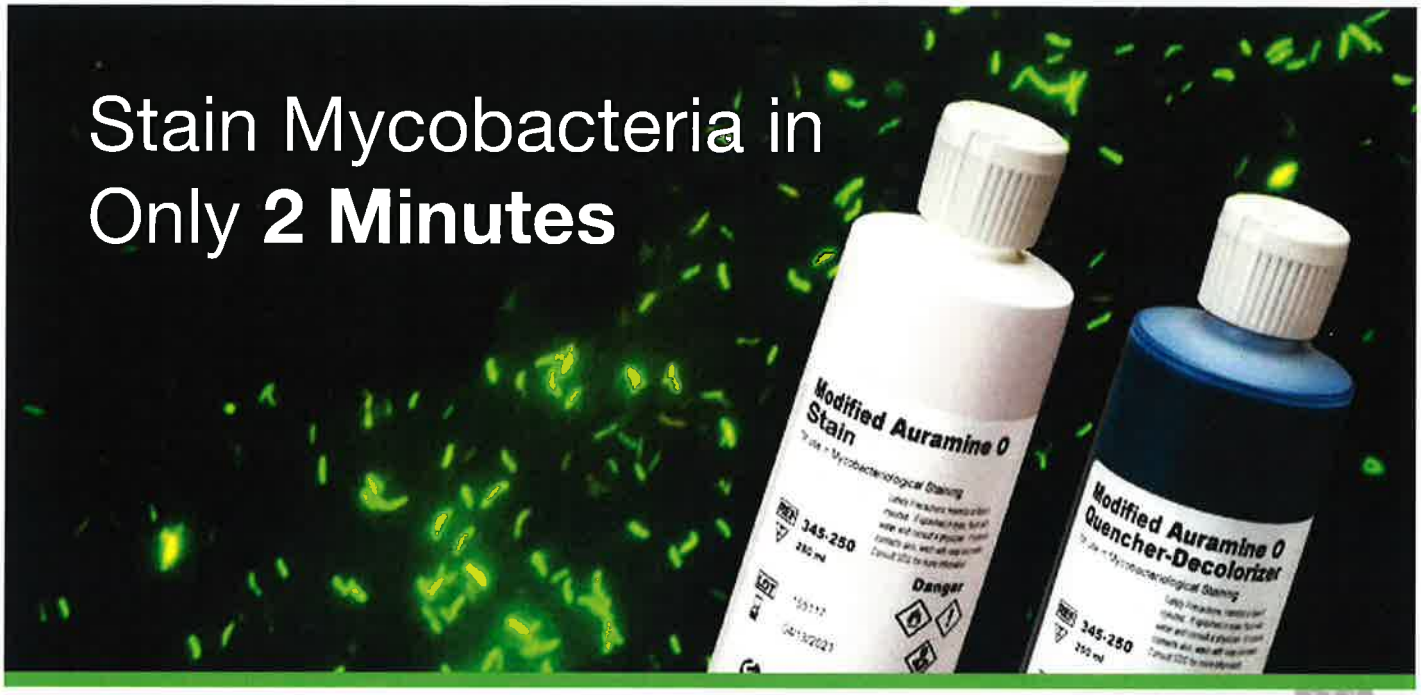

Modified Auramine O

Easier, Quicker Stain

- Saves 30-45 minutes per test
- Simple, 2-step process – no permanganate step

Faster Scan

- Initially scan on lower power, then confirm
- High-contrast fluorescence of organisms
- Less non-specific background fluorescence

Clinically Proven

- Studies by Johns Hopkins & Loyola Medical Center
- Concluded more cost-effective & more efficient mycobacteria staining
- Published in *Journal of Clinical Microbiology*

Other products available at Scientific Device Laboratory

EFFICIENCY-MINDED TB PRODUCTS

- *Acid Fast Control Slides (#351)*
- *Premeasured Digestion/ Decontamination & Sterilized Buffer (#667 & #669)*
- *Easily Scan Printed TB Slides (#041-0120)*
- *Modified Auramine O (#345-250 or #345-04L)*

For more information see the catalog on our website.

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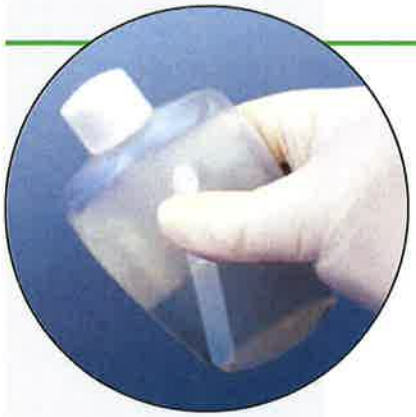
Productive TB Processing



Snap n' Digest

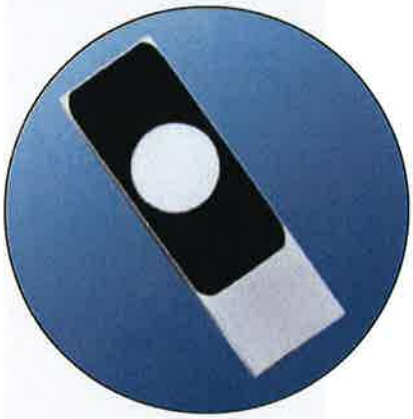
- Simple - One bottle, premeasured, ready-to-use sputum decontamination and digestion system
- Efficient - Compatible with multiple automated TB systems
- Save time and money - No weighing or waste
- Easy to use 4% solution with sealed ampoule of preweighed NALC in safety tube to easily trap & release NALC capsule. (Unbroken capsule stable for 1 year without refrigeration.)
- Control inventory - Each pkg contains 10 bottles & 5 packets of dry TB buffer powder

667 Snap n' Digest 75ml - 10 bottles/pkg
668 Snap n' Digest 150ml - 10 bottles/pkg
6671 Phosphate Buffer Packets 4.2g each - 5 packets/pkg

Sterilized TB Buffer

- Slash autoclave usage with presterilized & ready-to-use pH6.8 buffer
- Improve efficiency with economical 100ml or 500ml bottles with 1-yr expiration.

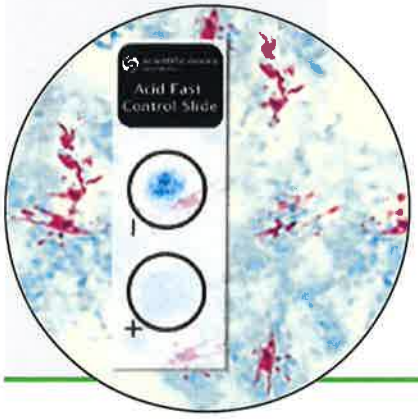
669-100 Sterile Phosphate Buffer - 10 x 100ml bottles/pkg
669-500 Sterile Phosphate Buffer - 1 x 500ml bottle/pkg



Easy Scan Printed TB Slides

- Locate smeared area easily within 20mm well
- Train technicians quickly who have less experience in locating hard to find smears
- Increase contrast with black epoxy background for fluorescent staining

041-0120 Printed TB Slides priced per gross – 5 gross minimum order



Acid Fast Control Slides

- Simulate clinical sputum smear with appropriate background material
- Scan quickly with high organism counts on both positive & negative wells
- Satisfy regulatory requirements with Kinyoun, Modified Auramine O, or other fluorescent stains

350 Acid Fast Stain Control Slides - 10 slides/pkg
351 Acid Fast Stain Control Slides - 50 slides/pkg

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Abstract of paper presented at:
ASM National Meeting, Orlando FL 2006
Poster C-324: ***Evaluation of Four Commercially Available Auramine O Stain Sets***

Schlacks, M.I, Coppernoll, S.2, DeBoo, A.I, Schmidt, AI, Bartnicki, L.', Schreckenberger, P. I and Lipton, S.2, Loyola Medical Center, Maywood, IL; 2 Scientific Device Laboratory, Des Plaines, IL

BACKGROUND: With a dramatic increase of incidence of Mycobacterial disease, it is more important than ever to find rapid methods for identification of the organism. The current fluorescent techniques to identify acid fast organisms in smears take from 20-30 minutes to perform. The purpose of this study was to compare the qualitative intensity of fluorescence and quantitative time of staining of three commercially available Auramine O stain sets with that of a recently introduced rapid method which takes 2 minutes to perform. The four stains used were TB Auramine O Kit (Remel), TB Fluorescent Stain Kit Auramine M (BD), Auramine O Stain Kit (MCC) and the flew Rapid Modified Auramine O (SDL).

METHODS: Four sets of smears were prepared from 185 patient specimens. Each was stained using the four fluorescent techniques outlined in the technical insert provided by each company. The first three commonly used stain sets use a three-step procedure utilizing stain, decolorizer and permanganate. The new Rapid Modified Auramine O procedure differed by utilizing a two-step procedure in which the decolorizer and quenching agent were combined together. The entire smear area of 20mm was scanned by an experienced technologist under low power for any fluorescence. If fluorescence was seen, the objective was switched to oil for organism confirmation. Relative intensity of fluorescence was measured on a scale of 1-4 on all positive smears. Results: A total of 14 (77%) of 18 patient smears were positive using all four stains. The staining intensity was equal for all techniques used. One (0.5%) specimen was positive with MCC stain and SDL Stain only. There was one additional smear that was weakly positive only with the SDL stain. In both these latter cases the clinical diagnosis corresponded with the positive smears. When the cost was compared from the list price of each of the stain sets, the Rapid Modified Auramine O (SDL) was less expensive than the others, especially when considering the technologist staining time. The fluorescent intensity on positive specimens was equivalent.

CONCLUSION: All stain sets tested gave equivalent results. The Rapid Modified Auramine O was less expensive and could be performed in 1/5 of the time required for conventional Auramine staining.

Abstract of paper presented at:
ASM National Meeting, Boston MA 2008
Poster U-083: ***Evaluation of a Rapid, Fluorescent Stain for the Detection of Mycobacteria in Clinical Specimens***

Cindy Hendry, Kim Dionne, Karen Carroll, and Nicole Parrish, The Johns Hopkins Medical Institutions, Baltimore, MD

ABSTRACT: Due to the steady increase in Mycobacterial disease, rapid detection is essential for early diagnosis and treatment of infection. A common method used for screening clinical specimens suspected of containing mycobacteria is microscopic examination of stained smears for the presence of acid-fast bacilli (AFB). We compared two Auramine-O stains: the Remel TB Auramine-O stain (RAO) and the Rapid Modified Auramine-O stain from Scientific Device Laboratory (MAO). The RAO procedure required 8 steps using 3 stains and 22 minutes for completion. The MAO procedure required 6 steps using 2 stains and 2 minutes for completion. Testing included pooled specimens from the following digested/ decontaminated sources: tissue, sputum, bronchial lavage, peritoneal fluid, and (undigested) cerebrospinal fluid. Each source was divided into separate aliquots and inoculated with a dilution series of *Mycobacterium gordonae* to reflect the burden of organism typically seen in clinical samples. 100 duplicate slide sets were prepared according to manufacturer's protocols and divided into sets "A" (RAO-stained) and "B" (MAO-stained). Slides were graded for quantity of organism and brightness of both AFB and background debris. In comparing both methods all slides were positive for AFB with no significant quantification difference in organism between stains. Approximately 40% of the MAO slides were brighter than their paired RAO counterpart. Overall, MAO-stained slides exhibited less background debris staining (4%) versus RAO stained slides (30%). MAO staining required significantly less time (2 min) versus the RAO staining (22 min). Results of this study suggest that the MAO-stain has several favorable characteristics for use in a clinical laboratory setting: it is rapid, provides equivalent AFB quantitation as compared with the RAO stain, but with less non-specific background fluorescence. As such, the MAO stain has the potential to be more cost effective and efficient in presenting presumptive evidence of mycobacteria in clinical specimens.

INTRODUCTION: Rapid diagnosis of mycobacterial infections is essential for initiation of infection control practices when necessary and to provide appropriate antimicrobial therapy. A common method used for screening clinical specimens suspected of containing mycobacteria is microscopic examination of stained smears for the presence of acid-fast bacilli (AFB). Effective time management can be a major factor contributing to the efficiency of mycobacteriology laboratories with high testing volumes. Thus, rapid staining methods for AFB are essential to provide the fastest turn-around-time for reporting results. Additionally, more rapid staining methods will provide for decreased technician time resulting in improvement of overall laboratory performance. In this study, we compared two Auramine-O stains: the Remel TB Auramine-O stain (RAO) and the Rapid Modified Auramine-O stain from Scientific Device Laboratory (MAO).

METHODS:
RAO procedure: 8 steps, 3 stains, total time 22 minutes.
MAO procedure: 6 steps, 2 stains, total time 2 minutes.
Part 1: Testing included pooled specimens from the following digested/ decontaminated sources: tissue, sputum, bronchoalveolar lavage, peritoneal fluid, and (undigested) cerebrospinal fluid. Each source was divided into separate aliquots and inoculated with a dilution series of *Mycobacterium gordonae* to reflect the burden of organism typically seen in clinical samples. In a blind study, 100 duplicate slide sets were prepared according to manufacturer's protocols and divided into sets "A" (ROA-stained) and "B" (MAO-stained). Slides were read and graded independently by multiple qualified technologists and the results compared. Results included both the quantity of organisms observed (1+ to 4+) and brightness (1+ to 4+) of both the AFB and background debris.

Part 2: The same as listed in Part 1 was repeated using additional species (2 strains each) of mycobacteria including *M. tuberculosis, M. avium, M. kansasii, M. lentiflavum, M. abscessus, M. chelonae, M. scrofulaceum, M.neoaurm,* and *M. mucogenicum*. This comparative analysis between the two methods was performed in a blinded manner in which both species identification and dilution number were removed. Slides were graded as outlined above.

TABLE 1.
Comparisons of results from rapid-AO versus standard-AO staining of mycobacterial species in spiked sputum samples.

Species	Stain	AFB quantitation score (avg)	Concordance (%)	Debris brightness score (avg)	Concordance (%)
M. tuberculosis	Standard AO	4+	100	3.2	80
	Rapid AO	4+	100	1.2	80
M. avium	Standard AO	3.2+	80	2.1+	80
	Rapid AO	3+	100	1+	100
M. fortuitum	Standard AO	4+	100	1.4	80
	Rapid AO	4+	100	1.2	80

Technical Insert

CE

Modified Auramine O Stain Set

Manufacturer/Supplier:

Scientific Device Laboratory, 411 Jarvis Avenue, Des Plaines, IL 60018 USA
General and Technical Information Phone Number: 847-803-9495
Website: www.scientificdevice.com

EU Authorized Rep:

mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany
General and Technical Information Phone Number:+49 511 39089530

Intended Use:

The SDL Modified Auramine O Stain Set uses a modified stain and quenching/decolorizing agent to make a rapid (2 minute) two step fluorescent staining procedure for the visualization of *Mycobacteria* organisms in clinical specimens.

Summary and Explanation:

For public health reasons, it is necessary to identify Mycobacterial disease as rapidly as possible.[1] The stains classically used are time consuming and often difficult to read if decolorization is not performed properly. Auramine O and Auramine-Rhodamine stains have been used successfully but have 3 steps with a prolonged staining time. SDL'S Modified Auramine O Stain uses a combination of a quencher/decolorizer to make a rapid (2 minute) two step stain.

Principle of the Procedure:

The SDL Modified Auramine O Stain Set is a two minute two step fluorescent stain that is used to identify *Mycobacteria* species. This stain has been shown to have a specificity of 90%.[2]

Components:

Modified Auramine O Stain Set contains two stains, first the Modified Auramine O Stain (250 ml or 1 gallon) and then a Decolorizer/Quencher (250 ml or 1 gallon).

Warnings:

Do not use product beyond the expiration date. Do not interchange or mix components from different staining sets.

Cultures should be performed for confirmation on positive smears. A negative result does not preclude the presence of Mycobacteria. Avoid wiping slide dry with cloth or paper towels, let slide air dry.

Storage:

Store at room temperature (15°C to 30°)

Procedure:

Preparation of Patient Sputum Smear :

1. Heat fix smear.
2. Apply Auramine O Stain on smear for 1 minute.
3. Rinse with deionized or tap water and drain slide.
4. Apply Decolorizer/Quencher reagent for 1 minute.
5. Rinse with deionized or tap water and drain slide.
6. Allow slide to air dry.
7. Read slide under mercury or halogen light source fluorescent microscope using recommended techniques

Expected Results:

View slides using a fluorescent microscope with a blue barrier filter (390-440µ, blue) as used for Fluorocein isothiocyanate.

Mycobacteria fluoresce green against a dark background. All other organisms will not be visible. A fluorescent bacilli is presumptive identification of *Mycobacteria species*. Cultures should be performed for confirmation. A negative result does not preclude the presence of Mycobacteria.

Quality Control:

Prior to shipping each lot of the Auramine O Stain Set has been quality controlled using an Acid Fast Control Slide. In addition each lot should be quality controlled prior to use with standard laboratory procedures

Limitations:

Some rapid growers do not fluoresce with this stain. Therefore, a Ziehl-Neelsen or Kinyoun stain should be performed on these specimens. The correct timing for stain and decolorizer should be observed. Turbidity of the stain will not affect the results. Smears should be viewed as soon as possible.

Safety:

For *In vitro* diagnostic use. See MSDS for additional information.

These reagents can be harmful or fatal to your health. Use them in a well ventilated area. Use proper gloves when staining. Keep away from flames. Good general microbiology techniques should be followed.

References:

1. Ann. New York Acad. Sci 84,225-238, 1984.
2. Hendry, C *et al. J. Clin. Micro. 47:4, 1206-1208, 2009.*

Related Product Information:

Catalog # 345-250: 250 ml Modified Auramine O Stain & Modified Auramine O Quencher/Decolorizer

Catalog # 345-04L: 4 x 1 liter each/package Modified Auramine O Stain & Modified Auramine O Quencher/Decolorizer

Catalog # 350: Acid Fast Stain Control Slides (10 slides/box)

Catalog # 351: Acid fast stain Control Slides (50 slides/box)

Catalog # 041-0120 Printed TB Slides

Symbol Legend

Catalog Number

In Vitro Diagnostic Medical Device

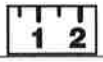

Consult Instructions for Use (IFU)

Temperature Limitations (Storage Temp.)

Batch Code (Lot Number)


Use By (Expiration Date)

Quantity Included



Dimension

Revision History

CR#	Rev
1009-003	00
0410-004	01
0910-002	02
0417-002	03