


remel

Schaudinn's Fixative w/o Acetic Acid

INTENDED USE

Remel Schaudinn's Fixative is recommended for use in qualitative procedures for fixation of protozoan trophozoites and cysts in fresh stool specimens or samples from the intestinal mucosal surfaces. Permanent stains, such as trichrome and iron-hematoxylin, can be performed from Schaudinn's-fixed specimens.

SUMMARY AND EXPLANATION

The detection and correct identification of intestinal protozoa is frequently dependent on the examination of a permanently stained smear as smaller protozoans are often missed with only the direct smear and concentration methods. Wheatley used Schaudinn's Fixative as the initial step in his permanent staining procedure.^{1,2}

PRINCIPLE

Schaudinn's Fixative adheres the fecal material to the slide and maintains the staining integrity of protozoan trophozoites and cysts found in specimens.¹

REAGENTS (CLASSICAL FORMULA)*

Mercuric Chloride (Saturated aqueous solution):
(CAS 7487-97-7).....600.0 ml
Ethanol 95% (CAS 64-17-5)300.0 ml

*Adjusted as required to meet performance standards.

PRECAUTIONS

DANGER! Flammable. Toxic and may be fatal if swallowed. Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed. Cannot be made non-poisonous. Can cause birth defects. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Refer to Material Safety Data Sheet for more information.

This product is For *In Vitro* Diagnostic Use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and test materials 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 overheat.

PRODUCT DETERIORATION

This product should not be used if (1) the appearance has changed from clear and colorless, (2) the expiration date has passed, or (3) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, TRANSPORT

Refer to collection instruction sheet included with this product. Consult appropriate references when necessary.^{3,4}

1. Substances and medications, such as mineral oil, barium, bismuth, antibiotics, antimalarials, and nonabsorbable antidiarrheal preparations interfere with the detection of intestinal protozoa. Intestinal protozoa may be undetectable for one to several weeks after administration of any of these substances. Specimen collection should be performed after seven days in the case of antibiotics or barium.
2. A series of three specimens is considered a minimum for an adequate examination. Stool specimens should be collected every other day or within a time frame of no more than 10 days. If a series of 6 specimens is ordered, they should be submitted within a 14 day period.
3. Specimens should not be contaminated with water or urine. Water may contain free-living organisms that can be mistaken for human parasites and urine may destroy motile organisms.

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Paper towels or other absorbent material, (2) Applicator sticks, plain and cotton-tipped, (3) Disposable glass or plastic pipettes, (4) Incubator, slide warmer, (5) Wheatley Trichrome Stain (REF 40217) or iron-hematoxylin stain reagents, (6) Coplin jars, staining rack, forceps, (7) Glass microscope slides, coverslips, mounting medium, (8) Microscope with calibrated ocular micrometer, immersion oil, (9) Glacial acetic acid, (10) 0.85% Saline.

PROCEDURE

Specimens should be considered potentially infectious and handled accordingly.

Reagent Preparation:

Immediately before use add 5 ml of glacial acetic acid to 100 ml of Schaudinn's Fixative in a Coplin jar. This mixture is stable for two weeks.

Slide Preparation:

1. Using an applicator stick make a thin, even smear of the specimen by streaking the material back and forth on the slide. If necessary, dilute the specimen with physiological saline (0.85%). The material should be spread thin enough that newsprint can be read through the smear.
2. Immediately immerse the slide in Schaudinn's Fixative. Smears must not dry prior to fixation. Allow slides to fix for a minimum of 30 minutes; overnight fixation is preferred. Slides may be left in fixative for up to a week, if necessary. Allow slides to dry before staining.
3. Remove the slide from Schaudinn's fixative and place in 70% ethanol for 5 minutes, prior to staining.
4. Proceed with trichrome or iron-hematoxylin stain according to established laboratory procedures.

NOTE: A thin, even smear is essential for good preparations. Smears that are too thick stain poorly and will be too dense to examine adequately. Thin smears destain too rapidly, and unless organisms are numerous, they may be missed or require prolonged examination to be found.

QUALITY CONTROL

All lot numbers of Schaudinn's Fixative have been tested using the following quality control organism and have been found to be acceptable. Testing of control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
<i>Trichomonas vaginalis</i> ATCC® 30001	1 hour @ Room Temperature	Well fixed smear, typical morphology observed

LIMITATIONS

1. Results obtained will largely depend on proper and adequate specimen collection and fixation. Improperly fixed specimens will result in protozoan forms that are non-staining or predominantly red.
2. Smears that are inadequately dried on the slide may flake off or peel. Slides used for staining should be free of grease.²
3. Prepared slides can be stored in Schaudinn's Fixative for up to a week without distortion of protozoan organisms.⁴

4. *Entamoeba coli* cysts are difficult to fix properly and may be difficult to identify on the stained slide. For this reason, it is possible to have fixatives that meet quality control criteria and yet, do not always yield good morphology for this particular organism. Use of a longer fixation time (60 minutes) sometimes produces better morphology after staining.




BIBLIOGRAPHY

1. Melvin, D.M. and M.M. Brooke. 1982. Laboratory Procedures for the Diagnosis of Intestinal Parasites. 3rd ed. U.S. Dept. H.H.S., CDC, Atlanta, GA.
2. Clinical and Laboratory Standards Institute (CLSI)/NCCLS. 2005. Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline, 2nd ed. M28-A2. CLSI, Wayne, PA.
3. Koneman, E.W., S.D. Allen, W.M. Janda, P.C. Schreckenberger, and W.C. Winn, Jr. 1997. Color Atlas and Textbook of Diagnostic Microbiology. 5th ed. Lippincott Williams & Wilkins, Philadelphia, PA.
4. Isenberg, H.D. 2004. Clinical Microbiology Procedures Handbook. 2nd ed., Vol. 2. ASM Press, Washington, D.C.

PACKAGING

REF 40035, Schaudinn's Fixative..... 250 ml/Btl
REF 40036, Schaudinn's Fixative..... 500 ml/Btl

Symbol Legend

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

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CAS (Chemical Abstracts Service Registry No.)

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