

PVA Fixatives (Zn) Formalin (10% and 5%) Buffered Fixatives

INTENDED USE

PVA (Zn) Fixative and Buffered Formalin Fixatives are designed for the collection, transport and preservation of patient specimens for intestinal parasites. These systems are convenient, easy to use and provide reliable results when examination of the specimen may be delayed.

PRINCIPLES

Intestinal parasitic infections are diagnosed and treated upon positive recovery and identification of protozoan trophozoites and/or cysts or helminth eggs and/or larvae. Often, different circumstances prevent immediate examination of intestinal specimens. Therefore, the specimen must be preserved with the appropriate fixative for recovery and recognition of intestinal parasites. Incubation, refrigeration and freezing have been shown to be ineffective for preserving and recovering parasites.

PVA is an excellent preservative and fixative for protozoan trophozoites and cysts. The primary use of PVA-fixed specimens is the permanent stained smear, which may be considered the most important technique for the recovery and identification of intestinal parasites. Due to the unique properties of PVA, permanent stain slides can be prepared immediately or months later.

Formalin fixatives are recommended for collecting and concentrating specimens for examination of eggs, larvae and cysts. Neutralized or buffered formalin was shown more satisfactory for the preservation of cysts. Alpha Tec Systems, Inc. offers both 5% and 10% buffered formalin fixatives. The combined use of PVA and buffered formalin in a two-vial system has been shown to be very effective and beneficial in preserving, recovering and identifying all diagnostic stages of intestinal parasites.

There have been changes in the use of the traditional mercury PVA of Brooke and Goldman to Zinc based PVA Fixative. The substitution of zinc salts for mercuric chloride eliminates the danger of mercuric chloride and allows for easier disposal.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

1. PVA (Zn) and Formalin fixatives are POISONOUS. If ingested, give plenty of milk or water. Contact a physician or poison center immediately.
2. Avoid contact of PVA (Zn) and Formalin with skin, eyes, and clothing. If contacted, wash thoroughly with water. Seek a physician if irritation develops.
3. Avoid contact of PVA (Zn) with any metal.
4. All safety precautions must be taken for handling and processing of stool specimens.

STABILITY AND STORAGE

PVA (Zn) and Formalin Systems are stable to the stated expiration date supplied on the labeling when stored at 15-30°C.

USER QUALITY CONTROL

PVA (Zn) Fixative:

1. Clear and slightly viscous.
2. Should at any time the PVA (Zn) gel or become cloudy, place the vial in a 50°C water bath until liquefied and clear.
3. A light precipitate may form on the bottom with prolonged storage. This will not hinder or affect the performance of the PVA (Zn) fixative.

Buffered Formalin Fixatives:

1. Clear and free of any precipitates.

SPECIMEN COLLECTION AND PREPARATION

1. The patient should be warned against taking any antacids, oily laxatives or antidiarrheal medication unless prescribed by a physician.

2. Radiological examination utilizing bismuth or barium should be avoided.
3. Multiple stool samples should be collected and examined for confirmation of findings.
4. Stool specimens should be passed into dry and clean containers. A bedpan, wax paper, plastic wrap or bag, or a Styrofoam plate can be used. Do not contaminate with urine or water.
5. Slimy, bloody or watery stool, if present, should be selected and placed into the vial. Place enough stool specimen so that the volume reaches the FILL LINE.
6. Carefully break up the specimen. Tighten the cap and shake until it is thoroughly mixed.
7. Label each vial with the appropriate patient information and take the specimen to the laboratory without refrigerating or incubating the sample.
8. The well-mixed specimen collected in the formalin vial must be fixed for a minimum of 2-4 hours to assure adequate fixation of most helminth eggs and protozoan cysts, however the *Ascaris* egg will not be killed in this concentration of formalin and will continue to grow and develop if the specimen is held at room temperature or kept at refrigeration temperatures. Formalin fixed specimens are inadequate and/or ineffective for fixing trophozoites of amoebae or other protozoa, usually rendering them unrecognizable.
9. The well-mixed specimen collected in the PVA (ZN) vial must be fixed for a minimum of 1 hour to assure adequate fixation of the parasitic elements.

PROCEDURE

Materials Provided: PVA (Zn) Fixative, and/or 5% Buffered Formalin, and/or 10% Buffered Formalin.

Materials Not Provided: Transfer Pipettes, Coverslips, Centrifuge, Ethyl Acetate (#0003344), Microscope, Centrifuge Tubes and Caps, Clear Glass Slides, 0.85% Normal Saline, Stain of Choice, Cotton-tipped Applicators, PRS™ Concentration Filters (#0004043).

SPECIMEN PROCESSING

There are many variations of procedures found in all laboratories. Use of Alpha-Tec Systems reagents is not limited to any one procedure, but the following four are recommended to assure a thorough and complete examination.

A. Macroscopic Examination:

1. Stool consistency should be noted and recorded along with any visible irregularities such as worms, mucous, blood or proglottids.

B. Microscopic Examination:

1. Prepare a wet mount by placing a drop of saline or iodine solution onto a clean glass slide.
2. Add enough specimen to make a thin film where newsprint or text may be read through it.
3. Cover with a #2 coverslip and examine using the 10x scanning objective, and then use the 40x objective to observe morphological characteristics.

C. Permanent Slides and Smears:

1. Pour a small amount of PVA fixed specimen onto a paper towel. Allow for three minutes of absorption.
2. Using an applicator, carefully spread a portion of the stool onto a glass slide. Two or more slides are recommended.
3. Dry slides for 3 to 24 hours at 37°C or room temperature.
4. Stain using procedure of choice, but Wheatley's Trichrome Stain (#0003351 and components) is recommended.

D. Concentration Procedures:

Formalin-Ethyl Acetate Sedimentation

NOTE: Diethyl Ether is not recommended due to its volatile nature. Commercially available concentration systems may be utilized. The PRS (Parasite Recovery System #0004043) is a complete and standardized system for concentrating clinical specimens. Refer to directions accompanying each package.

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1. Mix the formalin fixed specimen (or a small sample of fresh unpreserved stool in 10 ml of formalin) until thoroughly suspended.
2. Strain 1 ml of specimen through a PRS filter or a single or double layer of cheesecloth into a 10 ml centrifuge tube.
3. Centrifuge at 500 – 600 xg for 10 minutes. Decant supernatant into a disinfectant.
4. A second washing with 0.85% saline may be desired for a cleaner sediment.
5. Add 1 ml of 10% formalin and mix until sediment is completely suspended and allow to stand for five minutes.
6. Add 1 ml of ethyl acetate or substitute and stopper. Shake vigorously for 30 seconds.
7. Carefully remove stopper and recap tube.
8. Centrifuge at 500 – 600 xg for 10 minutes.
9. Four layers result: A top layer of ethyl acetate or substitute, a second layer of debris, a third layer of formalin, and a bottom layer of sediment (parasites, if present).
10. Decant top three layers slowly while scraping debris from the sides of the tube with an applicator. Use a cotton swab to remove any excess debris.
11. Add a few drops of 10% formalin or 0.85% saline and resuspend sediment using a pipette.
12. Prepare a wet mount using saline or iodine solution and cover with a #2 coverslip.
13. Examine using the 40x objective.
14. If appropriate, prepare a slide for *Cryptosporidium* spp. oocysts.
 - a. Place a small drop of sediment onto a glass slide and spread evenly.
 - b. Allow the sediment to dry completely at 25-37°C.
 - c. Stain using acid-fast method of choice and examine. Cryptosporidium Stain Set (#0003357) is a trouble-free method when used as directed.
 - d. QC1™ Cryptosporidium Control Slides (#0003256) should run concurrent with the patient(s) smear(s) to validate the stain and procedures.

CONSED® SEDIMENTATION PROCEDURE

The use of CONSED Sedimentation Solution has been shown to increase the recovery of all stages of parasites of properly fixed specimens. Refer to the CONSED Directions For Use for complete instructions.

EXPECTED RESULTS

If intestinal parasites are present in the clinical specimen and processed according to the procedures listed in this document, they can be identified from collected specimens using appropriate staining techniques.

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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:

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PRODUCT CODES:

0003101 PVA (Zn) Fixative, 50/Box
0003102 PVA (Zn) Fixative/10% Formalin, 25 Sets/Box
0003105 PVA (Zn)/10% Formalin/ETM, 50 Set/Box
0003107 PVA (Zn) Fixative, 50 Sets/Box
0003110 Microvials PVA (Zn) Fixative/10% Formalin, 50 Sets/Box
0003113 PVA (Zn) Fixative, 1 x 500 ml
0003119 PVA (Zn)/ETM/Collection Cup, 60 Sets/Box
0003335 10% Formalin, Buffered, 50 Sets/Box
0003362 10% Formalin, 50/Box
0003716 PVA (Zn) Fixative, Microvials, 64/Box
0003724 ETM/PVA (Zn) Fixative/10% Formalin, Buffered, 32 Sets/Box
0003805 5% Formalin, 1 x 3.785 L

**PVA Fixatives (Zn)
Formalin (10% and 5%) Buffered Fixatives**

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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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Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenuto sufficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebina zadostuje za <n> testov / Contém quantidade suficiente para <n> testes



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