

**Collection/Transport Systems
Clean Vial****INTENDED USE**

Clean Vials are designed for the collection and transport of patient fecal specimens. Systems are convenient, easy to use and produce reliable results when properly used.

SUMMARY

Intestinal parasitic infections are diagnosed and treated upon positive recovery and identification of protozoa and helminths.

All unpreserved specimens should be collected in close proximity to the laboratory and examined without much delay. Exposure to air and temperature decreases the viability of protozoa quickly. The unpreserved specimen allows tests for occult blood, fat content, electrolytes, pH, bacteria cultures, amoeba cultures as well as direct parasitic examination.

FOR IN VITRO DIAGNOSTIC USE ONLY**STABILITY AND STORAGE**

Keep from direct heat. Store at 15-30°C.

USER QUALITY CONTROL

Vials should be clean and free of any debris.

PROCEDURE

Materials Provided: Empty vial with no preservative or fixative.

Materials Not Provided: Glass slides, Centrifuge, Coverslips, Stain of Choice, Normal Saline, Centrifuge Tubes, Microscope, Culture Media, Concentration Reagents.

SPECIMEN COLLECTION

1. The patient should be instructed not to take any antacids, oily laxatives, or antidiarrheal medication unless directly prescribed by a physician.
2. Multiple samples should be collected and examined to confirm all findings.
3. Patient specimens should be passed into dry, clean container. A bed pan, wax paper, plastic wrap or bag, or styrofoam plate can be used. The specimen must NOT be contaminated with water or urine.
4. Slimy, bloody, or watery stool, if present, should be selected and placed into the vial. Place enough specimen into the vial to reach the FILL LINE.
5. Label each vial with appropriate patient information and deliver the specimen to the laboratory.

SPECIMEN PROCESSING**Microscopic Examination:**

1. Unpreserved "Fresh" Specimen
 - a. Place a drop of saline or iodine onto a glass slide.
 - b. Mix a small portion of sample on the slide.
 - c. Cover with a #2 coverslip (22 x 40 mm) and examine using 40x objective.

Other Diagnostic Tests:

1. **Permanent Stain Smears**
 - a. Must be used with PROTO-FIX® (#0004600) or PVA (Zn) Fixative (#0003113).
 - b. Stain using Wheatley's Trichrome Stain (#0003351) or iron hematoxylin.
 - c. CELL-BOND® Slides, Mayer's Albumin (#0003355) or Slide Coating Solution (#0004120) may be used to increase adherence of the specimen to the slide.
2. **Concentration Techniques**
 - a. Specimen must be placed in PROTO-FIX, 5% or 10% Formalin, or SAF, and then the Formalin-Ethyl Acetate or CONSED® Sedimentation procedure may be performed.

3. Bacterial Cultures

- a. Samples may be screened for enteric pathogens by inoculating appropriate selective/differential and enrichment media.
- b. It is recommended that a fresh specimen be preserved in ETM® (Enteric Transport Media) for anaerobic culture for *C. difficile* toxin assays.

4. Fat Content

- a. The Sudan Black Stain can be used for determining fat content.

5. Leukocytes

- a. Wright's Stain is used for WBC determination.

BIBLIOGRAPHY

1. Eisenberg, H.D., et al., 1979. "Cumitech 9- Collection and Processing of Bacterial Specimens". AMERICAN SOCIETY FOR MICROBIOLOGY, Washington D.C.
2. Lennette, E.H., et al., 1980. MANUAL OF CLINICAL MICROBIOLOGY, ASM, Washington, D.C., 3RD Edition, pp.669-687.
3. Melvin, D.M. and M.M. Brooke, 1980. LABORATORY PROCEDURES FOR THE DIAGNOSIS OF INTESTINAL PARASITES. U.S. Department of H.E.W., 79:8282, CDC, Atlanta, pp.23-65.

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 CODE:

0003366 Clean Collection Vials, 50/Box
0003371 ETM/Clean, 25 Sets/Box
0003712 SAF/ETM/Clean Microvials, 32 Sets/Box
0003725 ETM/Clean Microvials, 50 Sets/Box
0004604 PROTO-FIX/Clean Vials, 25 Sets/Box



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GLOSSARY OF SYMBOLS

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

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

IVD 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

EC REP Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Germachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeo Autorizado



Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada



Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante



Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / laktag försiktighet / Previdno / Atenção



Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperatura comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas



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



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