



PRINCIPLE

ETM® (Enteric Transport Media) Collection/Transport System is designed for collection, transport, and preservation of patient stool specimens for recovery and examination of enteric bacterial pathogens and toxins [Shiga toxins and *Clostridium difficile* A & B].

CLINICAL SIGNIFICANCE

Bacterial intestinal diseases are diagnosed and treated upon positive recovery and isolation of bacterial pathogens. Different circumstances may delay immediate processing of collected specimens. Refrigeration, incubation, or ambient storage of samples until examination does not provide satisfactory recovery of all enteric pathogens. Therefore, the specimen must be preserved to guarantee optimal recovery.

ETM is an isotonic and non-nutritive formulation that prevents overgrowth of commensal flora. The medium is also buffered and a pH indicator is utilized to show any acidic shifts. ETM will assure the user that all specimens will be maintained for enteric pathogen culture for up to 96 hours at room temperature. ETM may be used for the recovery of *C. difficile* Toxin-A testing when receipt of the specimen into the laboratory is expected to be greater than 2 hours after collection. The specimen should be collected and placed into the ETM medium to yield a 1:4 dilution of specimen to fixative and transported to the laboratory at room temperature. Upon receipt in the laboratory, the specimen in ETM should be processed for enteric culture and then held at 2°-8° C until tested for *C. difficile* Toxin-A&B.

SPECIMEN COLLECTION AND PREPARATION

1. Multiple samples should be collected over several days and examined to confirm all findings.
2. Patient specimen should be passed into a dry and clean container. A bedpan, wax paper, plastic wrap or bag, or styrofoam plate can be used. The stool must NOT be contaminated with urine or water.
3. Slimy, bloody, or watery stool, if present, should be selected and placed into the vial. Place enough specimen to reach the FILL LINE.
4. Carefully break up the specimen and swirl the contents until thoroughly mixed using the spork (attached to the cap). Screw on and tighten the cap without further mixing or shaking.
5. Label each vial with appropriate patient information and deliver the specimen to the laboratory without refrigeration or incubation.
6. **FOR IN VITRO DIAGNOSTIC USE ONLY.**

REAGENTS AND MATERIALS

1. **Provided**
 - a. ETM (Enteric Transport Media)
 - b. Patient sets include simple, illustrated, multi-language instructions.
2. **Not Provided**
 - a. Sterile loops or swabs
 - b. Growth media
3. **Storage:** 15°-30° C.
4. **Stability:** ETM has a shelf life of 24 months from the date of manufacture, when stored at 15°-30° C.

CALIBRATION

N/A

QUALITY CONTROL

1. Vials should contain stated volume of clear, red-colored media and be free of precipitates.
2. Any vial with media that is cloudy or yellow should be discarded.
3. The total bacteria population of a normal stool specimen must be within +/-20 CFU (Colony Forming Units/ml) for 96 hours.

PROCEDURE

1. Due to the hazardous nature of patient specimens, all standard laboratory safety procedures should be observed during all phases of examination and subculturing.
2. Wear disposable gloves at all times.
3. Work in biohazard cabinet at all times.
4. Mix specimen well and remove cap.
5. Place the vial on paper towels pre-moistened with a disinfectant.
6. Inoculate appropriate enrichment and/or selective media using a sterile loop or swab. (Good microbiology procedures suggest that bacterial pathogens be processed on both enrichment and selective media.)
7. Replace cap and tighten.
8. Sterilize the vial and all other material before disposal.

CALCULATIONS

N/A



RESULTS

ETM has been shown to be an excellent transport and preservation medium for *Shigella*, *Salmonella*, *Vibrio*, *Yersinia*, enterotoxigenic *Escherichia coli* (ETEC), *E. coli* O157:H7, and *Campylobacter* as well as toxin assays for *C. difficile* and EIA assays for Shiga toxins [*E. coli* O157:H7] with the EHEC assay. From recent studies, ETM with indicator and 0.16% agar, rather than the traditional 5% agar, maintained *Campylobacter* viability for up to 35 days at 4° C and up to 7 days at 25° C. The efficacy of BGS has been demonstrated since its introduction by Teague and Clurman in 1916 and later modified in 1931 by Sachs to support the transport and preservation of *Salmonella* and *Shigella*. However, recent studies have revealed the BGS did not maintain the viability of *Campylobacter jejuni* as long as ETM. For transporting or preserving patient stool specimens until examination for bacteria pathogens, especially *Campylobacter* spp., ETM is recommended.

NOTES

If the contents of the specimen vial exhibit a yellow-colored solution, an acid shift has taken place and a new specimen should be collected.

ETM formulation is based upon the modification of Cary Blair media and is compatible with the functions, uses, and associated procedures designed for modified Cary Blair media.

LIMITATIONS

N/A

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CONTACT

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WARRANTY

Alpha-Tec Systems, Inc. warrants this product 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.










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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 / Gemachtigde 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 / Iakttag försiktighet / Previdno / Atenção
-  Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperature 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 / 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
-  Consult instructions for use / Consulter la notice d'utilisation / Consulte las instrucciones para el uso / Consultare le istruzioni per l'uso / Bitte beachten Sie die Anwendungsvorschriften / Raadpleeg instructies voor gebruik / Konsultera bruksanvisningen innan användning / Glej navodila za uporabo / Consulte instruções para o uso
-  Do not reuse / Ne pas réutiliser / No reutilizar / Non riutilizzare / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize