



## QUALITY CONTROL PROCEDURES

## I INTRODUCTION

Trichosel™ Broth, Modified, with 5% Horse Serum is used for the isolation and cultivation of *Trichomonas* species.

## II PERFORMANCE TEST PROCEDURE

1. Inoculate representative samples with the cultures listed below.
  - a. For *T. vaginalis*, inoculate direct from a pure stock culture.
  - b. For all other organisms, inoculate 1 µL (0.001 mL) from a 4 – 5 h culture of Trypticase™ Soy Broth (TSB) diluted to yield  $10^6$  –  $10^7$  CFU/mL.
  - c. Incubate at  $35 \pm 2$  °C for 48 h under appropriate atmospheric conditions.
  - d. Include tubes of a previously tested lot of TSB as nonselective controls.
2. Examine tubes for growth of *T. vaginalis*. After 48 h of incubation, prepare a wet mount from the *Trichomonas* tube and examine under low power for the presence of flagellate protozoans. If negative, incubate for an additional 24 h at  $35 \pm 2$  °C and re-examine.

## 3. Expected Results

Organisms	ATCC™	Recovery
<i>Candida albicans</i>	10231	Fair to heavy growth
* <i>Staphylococcus aureus</i>	25923	Inhibition (partial to complete)
* <i>Trichomonas vaginalis</i>	30001	Moderate to heavy growth

\*Recommended organism strain for User Quality Control.

## III ADDITIONAL QUALITY CONTROL

1. Examine tubes as described under "Product Deterioration."
2. Visually examine representative tubes to assure that any existing physical defects will not interfere with use.
3. Determine the pH potentiometrically at room temperature for adherence to the specification of  $6.0 \pm 0.2$ .
4. Incubate uninoculated representative tubes at  $30 - 35$  °C and  $20 - 25$  °C for 72 h and examine for microbial contamination.

## PRODUCT INFORMATION

## IV INTENDED USE

Trichosel Broth, Modified, with 5% Horse Serum is used for the isolation and cultivation of *Trichomonas* species.

## V SUMMARY AND EXPLANATION

BBL Trichosel Broth, Modified, with 5% Horse Serum is a modification of the Simplified Trypticase™ Serum (STS) Medium of Kupferberg et al. for the cultivation of *Trichomonas* spp.<sup>1</sup> The classical formula has been modified by the addition of beef extract, horse serum and an increased amount of yeast extract to improve performance. Chloramphenicol, a relatively stable antibiotic, replaces the penicillin and streptomycin recommended for addition to the STS base.

## VI PRINCIPLES OF THE PROCEDURE

BBL Trichosel Broth, Modified, with 5% Horse Serum contains casein peptone, cysteine, beef extract and yeast extract as sources of amino acids, nitrogen, sulfur, carbon, vitamins and trace ingredients. Maltose is an energy source for the metabolism of microorganisms including *Trichomonas* spp. Chloramphenicol is a broad spectrum antibiotic which inhibits a wide range of gram-positive and gram-negative bacteria. Horse serum contains growth factors required by *Trichomonas* spp.

## VII REAGENTS

## BBL Trichosel Broth, Modified, with 5% Horse Serum

Approximate Formula\* Per Liter Purified Water

Pancreatic Digest of Casein.....	12.0 g	Agar .....	1.0 g
Beef Extract.....	2.0 g	Chloramphenicol.....	0.1 g
Yeast Extract.....	5.0 g	Methylene Blue.....	3.0 mg
L-Cysteine HCl.....	1.0 g	Horse Serum.....	5%
Maltose.....	2.0 g		

\*Adjusted and/or supplemented as required to meet performance criteria.

Warnings and Precautions: For *in vitro* Diagnostic Use.

Tubes with tight caps should be opened carefully to avoid injury due to breakage of glass.

Pathogenic organisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens.

"Standard Precautions"<sup>2-5</sup> and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.

**Storage Instructions:** On receipt, store tubes in the dark at 2 – 8 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed media stored as labelled until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

**Product Deterioration:** Do not use tubes if they show evidence of microbial contamination, discoloration, precipitation, evaporation or other signs of deterioration.

## VIII SPECIMEN COLLECTION AND HANDLING

Specimens suitable for culture may be handled using various techniques. For detailed information, consult appropriate texts.<sup>6,7</sup> Specimens should be obtained before antimicrobial agents have been administered. Provision must be made for prompt delivery to the laboratory.

## IX PROCEDURE

**Material Provided:** BBL Trichosel Broth, Modified, with 5% Horse Serum

**Materials Required But Not Provided:** Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.

**Test Procedure:** Observe aseptic techniques.

Inoculate specimens suspected of containing *Trichomonas* organisms into the broth medium using swabs containing the specimen or by alternative methods, as appropriate. Incubate tubes at 35 ± 2 °C in an aerobic atmosphere. After 48 h and again after 5 days of incubation, prepare a wet mount from the broth and examine microscopically under low power for the presence of flagellate protozoans.

**User Quality Control:** See "Quality Control Procedures."

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

## X RESULTS

If growth of *Trichomonas* spp. has occurred, organisms of typical morphology will be seen in the broth medium when an aliquot is examined microscopically using low power magnification.

## XI LIMITATIONS OF THE PROCEDURE

The agents in selective media may inhibit some strains of the desired species or permit the growth of a species they were designed to inhibit, especially if the species is present in large numbers in the specimen.

## XII PERFORMANCE CHARACTERISTICS

In a study by Dawson et al.,<sup>8</sup> six methods were compared for their ability to detect *Trichomonas vaginalis* in 214 sexually active adolescent females. The six methods used were: **BBL™ Trichosel™** Broth culture, PEM-T™ (HDC Corp.) culture, saline wet mount, acridine orange stain, Diff-Quik™ (Dade) stain and Papanicolaou smears. Of the 214 specimens examined for *T. vaginalis*, 25% were positive by at least one of the methods examined.

The sensitivities and negative predictive values (NPV) for the various methods were:

	Trichosel Culture	PEM-T Culture	Acridine Orange	Diff-Quik	Wet Mount	PAP Smear
<b>Sensitivity</b>	73.1%	40.5%	82.6%	78.3%	61.5%	65.8%
<b>NPV</b>	91.5%	84.1%	94.7%	93.4%	88.0%	86.7%

## XIII AVAILABILITY

### Cat. No. Description

298323 BBL™ Trichosel™ Broth, Modified, with 5% Horse Serum, Pkg. of 10

## XIV REFERENCES

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7. Forbes, B.A., D.F. Sahn, and A.S. Weissfeld. 1998. Bailey & Scott's diagnostic microbiology, 10th ed. Mosby, Inc., St. Louis
8. Dawson, M.S., R. Mraz, B.K. Garner, R. Brookman and H.P. Dalton. 1985. Comparison of diagnostic tests for the detection of *Trichomonas vaginalis* in clinical specimens. Abstr. C-16, p. 302. Abstr. 85th General Meeting of the American Society for Microbiology. 1985.