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 ± 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 ± 2 °C and re-examine.
3. Expected Results

<table>
<thead>
<tr>
<th>Organisms</th>
<th>ATCC™</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candida albicans</td>
<td>10231</td>
<td>Fair to heavy growth</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>25923</td>
<td>Inhibition (partial to complete)</td>
</tr>
<tr>
<td><em>Trichomonas vaginalis</em></td>
<td>30001</td>
<td>Moderate to heavy growth</td>
</tr>
</tbody>
</table>

*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 ± 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. 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                          |
| Beef Extract....................................................................| 2.0 g                           |
| Yeast Extract..........................................................| 5.0 g                           |
| L-Cysteine HCl.........................................................| 1.0 g                           |
| Maltose..........................................................................| 2.0 g                           |
| Agar...............................................................................| 1.0 g                           |
| Chloramphenicol.........................................................| 0.1 g                           |
| Methylene Blue................................................................| 3.0 mg                          |
| Horse Serum....................................................................| 5%                              |

*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” 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. 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., 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 Papanicolau 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:

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Sensitivity (%</th>
<th>NPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichosel Culture</td>
<td>73.1</td>
<td></td>
</tr>
<tr>
<td>PEM-T Culture</td>
<td>40.5</td>
<td></td>
</tr>
<tr>
<td>Acridine Orange</td>
<td>82.6</td>
<td></td>
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<tr>
<td>Diff-Quik</td>
<td>78.3</td>
<td></td>
</tr>
<tr>
<td>Wet Mount</td>
<td>61.5</td>
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</tr>
<tr>
<td>PAP Smear</td>
<td>65.8</td>
<td></td>
</tr>
</tbody>
</table>

XIII AVAILABILITY
Cat. No.  Description
298323    *BBL™ Trichosel™* Broth, Modified, with 5% Horse Serum, Pkg. of 10

XIV REFERENCES

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