QUALITY CONTROL PROCEDURES

I INTRODUCTION
Serum Tellurite Agar is a selective and differential medium primarily used for the isolation of members of the genus Corynebacterium and in the diagnosis of diphtheria.

II PERFORMANCE TEST PROCEDURE
1. Inoculate representative samples with the cultures listed below.
   a. Streak the plates for isolation. Use an 18- to 24-h broth culture of Escherichia coli diluted to yield 10^4–10^5 CFU/plate. For the remaining organisms, use 18- to 24-h broth cultures diluted to yield 10^3–10^4 CFU/plate.
   b. Incubate plates at 35 ± 2°C in an aerobic atmosphere.
   c. Include Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) plates as nonselective controls for all organisms.
2. Examine plates after 18–24 and 48–72 h for amount of growth, colony size, pigmentation and selectivity.
3. Expected Results

<table>
<thead>
<tr>
<th>Organisms</th>
<th>ATCC™</th>
<th>Recovery</th>
<th>Colony Color</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Corynebacterium diphtheriae</em></td>
<td>9675</td>
<td>Moderate to heavy growth</td>
<td>Gray to black colonies, some with dark centers</td>
</tr>
<tr>
<td>Corynebacterium diphtheriae</td>
<td>51696</td>
<td>Moderate to heavy growth</td>
<td>Gray to black colonies, some with dark centers</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>25922</td>
<td>Partial inhibition</td>
<td>(trace growth acceptable)</td>
</tr>
</tbody>
</table>

*Recommended organism strain for User Quality Control.

III ADDITIONAL QUALITY CONTROL
1. Examine plates as described under "Product Deterioration."
2. Visually examine representative plates 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 7.5 ± 0.2.
4. Note the firmness of plates during the inoculation procedure.
5. Incubate uninoculated representative plates at 35 ± 2°C for 72 h and examine for microbial contamination.

PRODUCT INFORMATION

IV INTENDED USE
Serum Tellurite Agar is used for isolation of members of the genus Corynebacterium, particularly in the laboratory diagnosis of diphtheria.

V SUMMARY AND EXPLANATION
Serum Tellurite Agar, which contains lamb serum and potassium tellurite, was developed for use in the examination of nose, throat and vaginal cultures for isolation of Corynebacterium species.1

VI PRINCIPLES OF THE PROCEDURE
The nutrients in Serum Tellurite Agar are supplied by Proteose Peptone No. 3, which provides growth factors such as nitrogen, carbon, sulfur, and trace ingredients. Sodium chloride provides essential electrolytes. Potassium tellurite is inhibitory for a variety of microorganisms; however, corynebacteria are resistant to tellurite and produce characteristic gray to black colonies on media containing tellurite.2 Lamb serum contains growth factors required by Corynebacterium species.

VII REAGENTS

Serum Tellurite Agar

Approximate Formula* Per Liter Purified Water

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteose Peptone No. 3</td>
<td>20.0 g</td>
</tr>
<tr>
<td>Lamb Serum</td>
<td>50.0 mL</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>5.0 g</td>
</tr>
<tr>
<td>Potassium Tellurite Solution, 1%</td>
<td>10.0 mL</td>
</tr>
<tr>
<td>Agar</td>
<td>20.0 g</td>
</tr>
</tbody>
</table>

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

Warnings and Precautions: For in vitro Diagnostic Use.
If excessive moisture is observed, invert bottom over an off-set lid and allow to air dry in order to prevent formation of a seal between the top and bottom of the plate during incubation.
Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. *Standard Precautions*3-6 and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. After use, prepared plates, specimen containers and other contaminated materials must be sterilized by autoclaving before discarding.
Storage Instructions: On receipt, store plates in the dark at 2–8°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Prepared plates stored in their original sleeve wrapping at 2–8°C 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 plates if they show evidence of microbial contamination, discoloration, drying 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.7,8 Specimens should be obtained before antimicrobial agents have been administered. Provision must be made for prompt delivery to the laboratory.
IX  PROCEDURE
Material Provided: Serum Tellurite Agar
Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required.
Test Procedure: The agar surface should be smooth and moist, but without excessive moisture. Streak the specimen as soon as possible after it is received in the laboratory. The streak plate is used primarily to isolate pure cultures from specimens containing mixed flora. Alternatively, if material is being cultured directly from a swab, roll the swab over a small area of the surface at the edge and streak from this inoculated area. Incubate plates 24–48 h at 35 ± 2°C in an aerobic atmosphere.
User Quality Control: See “Quality Control Procedures.”

X  RESULTS
After incubation, most plates will show an area of mass or confluent growth. Because the streaking procedure is, in effect, a "dilution" technique, diminishing numbers of microorganisms are deposited on the streaked areas. Consequently, one or more of these areas should exhibit isolated colonies of the organisms contained in the specimen. Better isolation is obtained due to the inhibitory action of the medium.

Typical colonial morphology on Serum Tellurite Agar is as follows:
- Corynebacteria: Gray, dark centers, smooth to rough, flat
- Streptococci: Small, white to gray
- Staphylococci: Large, white to gray
- Micrococci: Large, white to gray, rough
- Candida: Small, white to gray
- Listeria monocytogenes: Gray
- Gram-negative bacteria: No growth to trace growth

For additional information, consult the text.9

XI  LIMITATIONS OF THE PROCEDURE
Organisms other than Corynebacterium diphtheriae; i.e., Staphylococcus spp., may reduce tellurite and produce black colonies on Serum Tellurite Agar. Some diagnostic tests may be performed with the primary plate. However, a pure culture is recommended for biochemical tests and other identification procedures. Consult appropriate texts for detailed information and recommended procedures.7-9 A single medium is rarely adequate for detecting all organisms of potential significance in a specimen. Cultures of specimens grown on selective media should, therefore, be compared with specimens cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

XII  PERFORMANCE CHARACTERISTICS
Prior to release, all lots of Serum Tellurite Agar are tested for performance characteristics. Representative samples of the lot are tested with cell suspensions of C. diphtheriae ATCC 9675 and ATCC 51696, and E. coli ATCC 25922, inoculated by streaking the surface of the medium with saline suspensions diluted to yield 1 x 10^3 to 1 x 10^4 CFU/plate for C. diphtheriae and 1 x 10^1 to 1 x 10^2 CFU/plate for E. coli. After incubation at 35–37°C for 48 h in an aerobic environment, typical gray to black-colored colonies and moderate to heavy growth are observed with C. diphtheriae. No growth to trace growth is observed with E. coli.

XIII  AVAILABILITY
Cat. No. 221183
BB™ Serum Tellurite Agar, Pkg. of 20 plates

XIV  REFERENCES