

## PRODUCT INFORMATION AND QUALITY CONTROL SHEET

### TODD HEWITT BROTH w/ GENTAMYCIN & NALADIXIC ACID

#### I. INTENDED USE

This medium is for the selective isolation of group B streptococci.

#### II. SUMMARY AND EXPLANATION

Group B streptococci are frequent pathogens in serious neonatal infections<sup>1,5</sup>. Most infants who become infected during the first few days of life acquire the organism from the maternal genital tract<sup>1,5</sup>. It has been suggested by some that cervico-vaginal cultures be performed and those found to be group B streptococci carriers receive antibiotic prophylaxis as a means of preventing neonatal infection<sup>5,6</sup>.

#### III. PRINCIPLES OF THE PROCEDURE

Infusion from Beef Heart and peptone provides the nitrogen, vitamins and amino acids. Dextrose is the carbon source, and a stimulant for hemolysin production<sup>7</sup>. Disodium Phosphate and Sodium Carbonate act as buffers to aid in neutralizing acid production from dextrose fermentation, and protect hemolysin from inactivation<sup>7</sup>. Sodium Chloride maintains the osmotic balance of the medium.

#### IV. TYPICAL FORMULA AND APPEARANCE

Appearance = Light amber, clear to very slightly opalescent.  
(Approximate formula\* per liter of processed water)

Beef heart, infusion	3.1g
Peptone	20.0
Dextrose	2.0
Sodium Chloride	2.0
Disodium phosphate	2.5
Sodium carbonate	2.5
Gentamycin	8.0 mg
Nalidixic acid	15.0 mg

Final pH 7.8 ± 0.2 @ 25°C

\*adjusted and/or supplemented to meet performance criteria.

#### V. PRECAUTIONS

This product is for *IN VITRO* diagnostic use only. Culture specimens may contain microorganisms which can be potentially infectious to the user. Strict adherence to aseptic techniques and established precautions against microbiological hazards should be followed throughout the procedure. Carefully dispose of all items which contact patient specimens or isolated bacteria.

#### VI. STORAGE/SHELF LIFE

Media should be stored at 2-8°C (36-46°F). DO NOT FREEZE OR EXPOSE TO HIGH TEMPERATURES. Allow unopened tubes to warm to room temperature prior to inoculation. Prior to and during inoculation procedures, tubes should be handled in a manner that minimizes product exposure to the environment. Product that has exceeded the assigned expiration date noted on the label should not be used.

Do not use tubes that exhibit evidence of discoloration, microbial contamination or any other signs of deterioration.

#### VII. SPECIMEN COLLECTION

Information on specimen collection may be found in standard references on the subject. Vaginal cultures are obtained at bedside; swab cultures are inoculated into tubes of Todd-Hewitt Broth w/Gentamycin & Nalidixic acid, transported to the laboratory and incubated overnight at 35°C<sup>2</sup>. Cultures are then streaked onto blood agar, incubated and examined for beta hemolytic colonies. These colonies are then identified by conventional methods<sup>3,4</sup>.

#### VIII. MATERIALS PROVIDED

Todd Hewitt Broth w/Gentamycin & Nalidixic Acid Tubes

#### IX. MATERIALS REQUIRED BUT NOT PROVIDED

Incubator maintaining 35°C.  
Ancillary culture media

#### X. PROCEDURE

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#### XI. EXPECTED RESULTS

##### NCCLS CONTROL ORGANISMS (ATCC STRAINS)

<i>Streptococcus agalactiae</i> (ATCC 12386)	Growth
<i>Staphylococcus aureus</i> (ATCC 25923)	Inhibited
<i>E. coli</i> (ATCC 25922)	Inhibited

#### XII. LIMITATIONS

The ability to detect microorganisms by culture techniques can be affected by the following factors: improper specimen collection, storage and inoculation, initiation of anti-infective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media.

#### XIII. REFERENCES

1. Baker, C.J., et al. 1973. *J. Pediatr.* 82:724-729.
2. Baker, C.J., D.J. Clark, and F.F. Barrett. 1973. *Appl. Microbiol.* 26:884-85.
3. Balows, A., et al. 1991. *Manual of Clinical Microbiology*. 5<sup>th</sup> ed. ASM. Washington, DC.
4. Facklam, R.R. *Isolation and Identification of Streptococci II. Extraction and Serological Identification*. CDC Laboratory Manual. U.S.D.H.E.W. CDC, Atlanta.
5. Franciosi, R.A., et al. 1973. *J. Pediatr.* 82:707-718.
6. McCracken, G.H., Jr. 1973. *J. Pediatr.* 82:603-706.
7. MacFadin, J.D. 1985. *Media for isolation-cultivation-identification-maintenance medical bacteria*, p. 772-775. Vol. 1. Williams & Wilkins, Baltimore, MD.
8. Todd, E.W. and L.F. Hewitt. 1932. *J. Pathol. Bacteriol.* 35:973.
9. Updyke, E. and M.I. Nickle. 1954. *Appl. Microbiol.* 2:117.

### USER QUALITY ASSURANCE/ QUALITY CONTROL PROCEDURES AND INFORMATION

HealthLink recommends that the following quality assurance and quality control procedures be performed on each batch of product.

#### I. QUALITY ASSURANCE

The following quality assurance procedures must be performed to assure the product will perform according to its intended use within the assigned expiry date:

1. Daily, document that product storage refrigerator maintains temperature within the recommended range: 2-8°C.
2. Daily, document that laboratory incubator maintains temperature within the recommended range: 22-35°C.

## **II. QUALITY CONTROL**

The following incoming inspection procedures must be performed for each batch (batch = same lot, same shipment) of culture media received in the laboratory:

Inspect tubes according to instructions contained in Section VI: STORAGE/SHELF LIFE.

Note: Notify Technical Service immediately if media does not meet the inspection criteria.

## **TECHNICAL SERVICE**

HealthLink provides a toll free technical service line (1-800-638-2625) to assist with product usage. To have technical questions answered, please call between the hours of 9:00 am to 5:00 pm EST.

### **HealthLink**

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