PRODUCT INFORMATION AND QUALITY CONTROL SHEET

SALT BROTH

I. INTENDED USE
Salt Broth is used to differentiate enterococcal group D from nonenterococcal group D streptococcci.

II. SUMMARY AND EXPLANATION
Culture media containing 6.5% NaCl (i.e., Salt Broth) are used to identify the enterococci by determining the salt tolerance of bile-esculin positive streptococci. A positive bile-esculin test and growth in 6.5% NaCl broth confirm the presence of enterococci.

III. PRINCIPLES OF THE PROCEDURE
The enterococcal species (*S. faecalis, S. faecium, S. durans, and S. avium*) are easily differentiated from the nonenterococcal species (*S. bovis and S. equinus*) by the 6.5% NaCl tolerance test.[1] Growth within 48 hours indicates that the strain is salt tolerant, i.e., positive and it can be identified as an enterococcus if it is also bile esculin positive or if it is serologically group D.[2]

IV. TYPICAL FORMULA AND APPEARANCE
Appearance = Light amber, clear to very slightly opalescent
(Approximate formula* per liter of processed water)

Pancreatic Digest of Casein	17.0 g
Enzymatic Digest of Soybean Meal	3.0
Dextrose	2.5
Sodium Chloride	5.0
Dipotassium phosphate	2.5

*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^{0}C (36-46^{0}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 drying, discoloration, microbial contamination or any other signs of deterioration.

VII. SPECIMEN COLLECTION
The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination.
Proper specimen collection techniques must be followed to ensure the most accurate culture results. Sterile swabs and collection containers should be used. Tubes should be inoculated promptly after specimen collection. If a delay in inoculation is unavoidable, transport medium should be employed. Specimens should be collected prior to the initiation of antimicrobial therapy.
Detailed information on proper specimen collection may be obtained from microbiology reference materials.

VIII. MATERIALS PROVIDED
Salt Broth Tubes (10 ea / box)

IX. MATERIALS REQUIRED BUT NOT PROVIDED
Incubator maintaining 33-37^{0}C.
Ancillary culture media, reagents and laboratory equipment as required.

X. PROCEDURE
Inoculate the medium with two to three colonies into a tube of the medium. Incubate the tubes with loose caps for up to 48 hours at 35 ± 2^{0}C in an aerobic atmosphere.

XI. EXPECTED RESULTS

NCCLS CONTROL ORGANISMS (ATCC STRAINS)

Streptococcus faecalis (ATCC 29212)	Growth with blackening around colonies
Streptococcus pyogenes (ATCC 19615)	Inhibition (partial to complete) no blackening

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 antiinfective 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. Facklam et al. 1985. *In* Lennette, Balows, Hausler and Shadomy (ed.), Manual of clinical microbiology, 4th ed. ASM, Washington, D.C.

2. Lennette, Balows, Hausler and Shadomy (ed.), Manual of clinical microbiology, 4th ed. ASM, Washington, D.C., p. 168.

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^{0}C.

2. Daily, document that laboratory incubator maintains temperature within the recommended range: 35-37^{0}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.

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