PRODUCT INFORMATION AND QUALITY CONTROL SHEET
FLUID THIOGLYCOLLATE MEDIUM

I. INTENDED USE
This media is recommended for sterility testing of biologicals and general cultivation of pathogenic and non-pathogenic species of aerobes and anaerobes.

II. SUMMARY AND EXPLANATION
Fluid Thioglycollate was developed by Brewer (2) and is recommended by the USP (5) for sterility testing of clear fluid biologics. It is a noninhibitory broth that is an excellent supplement or backup for isolation of slow growing or fastidious organisms. It supports good growth of essentially all anaerobes commonly found in clinical specimens.

III. PRINCIPLES OF THE PROCEDURE
Thioglycollate medium supports the growth of a wide variety of fastidious microorganisms. The medium contains Sodium Thioglycollate as a reducing agent and Resazurin as an Eh indicator. A small amount of agar is added to impede diffusion of oxygen.

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

Pancreatic Digest of Casein	15.0g
Yeast Extract	5.0
Dextrose	5.5
L-Cystine	0.5
Sodium Chloride	2.5
Sodium Thioglycollate	0.5
Resazurin	0.001
Agar	0.75

Final pH 7.1 ± 0.2 @ 25^{0}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 2-25^{0}C (36-77^{0}F) away from direct light. 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
The quality of culture results depends primarily on the adequacy and condition of the specimen submitted for examination.

Information on specimen collection can be found in standard reference material on the subject (1). The specimen should be transported to the laboratory without delay and should be protected from excessive heat and cold. If there is to be any delay in culturing, the specimen should be placed in suitable transport medium such as Amies. Specimens should be collected prior to the initiation of antimicrobial therapy. If therapy has been started prior to collection, notice should accompany specimen.

VIII. MATERIALS PROVIDED
Fluid Thioglycollate Media Tubes

IX. MATERIALS REQUIRED BUT NOT PROVIDED
Incubator maintaining 35^{0}C.
Ancillary culture media

X. PROCEDURE
The specimen should be inoculated into a tube of Thioglycollate Medium. Generally other media such as Blood Agar plates should also be inoculated. Incubate at 35 ± 2^{0}C in an aerobic atmosphere for about 4 days, observing daily for growth. If *Actinomyces* is suspected, incubate at least 10 days. If growth occurs, gram stain and subculture onto appropriate plating media. Identification of isolates may be accompanied as directed in standard reference material on the subject (1,3,4).

XI. EXPECTED RESULTS

NCCLS CONTROL ORGANISMS (ATCC STRAINS)

Staphylococcus aureus (25923)	good growth
Clostridium sporogenes (11437)	good growth
Bacteroides fragilis (25285)	good growth

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. Balows, A., et al. 1991. Manual of Clinical Microbiology. 5th ed. ASM. Washington, DC.
2. Brewer, J.H., 1940. J. Amer. Med. Assoc. 115:598
3. Dowell, V.R., and T.M. Hawkins. 1975 Laboratory Methods in Anaerobic Bacteriology. CDC Laboratory Manual. USDHEW. Atlanta.
4. Holderman, L.V. and W.E.C. Moore. 1975. Anaerobic Laboratory Manual. VPI. Blacksburg, VA.
5. U.S. Pharmacopeia. XXII. 1990.

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: 22-35^{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.

HealthLink
3611 St. Johns Bluff Rd. So. Ste. 1
Jacksonville, FL 32224
1-800-638-2625

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