# PRODUCT INFORMATION AND QUALITY CONTROL SHEET
# TRYPTIC SOY BROTH (TSB)

**I. INTENDED USE**
TSB is a general purpose enrichment broth for the isolation and cultivation of a wide variety of microorganisms. Tryptic Soy Broth conforms with the formula specified in the US Pharmacopeia XXIII (USP)[1] for sterility testing of pharmaceutical products, biologics and devices.

**II. SUMMARY AND EXPLANATION**
Tryptic Soy Broth is a nutritious medium that will support the growth of a wide variety of fastidious and non-fastidious microorganisms. Because of its growth promotion, TSB is also recommended for use in the Kirby-Bauer method for antimicrobial susceptibility testing as described in the National Committee for Clinical Laboratory Standards (NCCLS).[2]

**III. PRINCIPLES OF THE PROCEDURE**
Enzymatic digests of casein and soybean meal provide amino acids and other complex nitrogenous substances. Dextrose is an energy source. Sodium chloride maintains the osmotic equilibrium. Dibasic potassium phosphate acts as a buffer to control pH.

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

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

Final pH 7.3 ± 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. 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**
Obtain and process specimens according to the techniques and procedures established by laboratory policy.

**VIII. MATERIALS PROVIDED**
Tryptic Soy Broth Tubes

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

**X. PROCEDURE**
Information on specimen collection may be found in standard references on the subject (3,4). The specimen should be transported to the laboratory without delay and protected from excessive heat and cold. If there is to be any delay in culturing, a swab inoculated with the specimen should be placed in a suitable transport medium such as Amies. Specimens should be collected before the initiation of antimicrobial therapy.

The specimen to be cultivated should be inoculated into TSB. The tubes should be incubated at 35$^0$C for at least 24 hours and examined for growth. If growth occurs, the medium should be gram stained and subcultured to appropriate agar media. Identification of isolates may be accomplished as directed in standard references. (3,4) Tubes showing no growth should be incubated at least three days before discarding as negative.

**XI. EXPECTED RESULTS**
NCCLS CONTROL ORGANISMS (ATCC STRAINS)

| | |
|---|---|
| *Bacillus subtilis* (ATCC 6633) | Growth |
| *Candida albicans* (ATCC 10231) | Growth |
| *Micrococcus luteus* (ATCC 9341) | Growth |
| *Streptococcus pneumoniae* (ATCC 6305) | 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. United States Pharmacopeial Convention. 1995. The United States Pharmacopeia, 23rd ed. The United States Pharmacopeial Convention, Rockville, MD.
2. National Committee for Clinical Laboratory Standards. 1993. Performance standards for antimicrobial disk susceptibility tests, M2-A5, vol. 13, no. 24. National Committee for Clinical Laboratory Standards, Villanova, PA.
3. Balows, A. et al. 1991. Manual of Clinical Microbiology. 5th ed. ASM. Washington, DC.
4. Koneman, E.W. et al. 1988. Color Atlas and Textbook of Diagnostic Microbiology. 3rd ed. J.B. Lippincott, Philadelphia.

## 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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Product No. 1785 - 2 ml
1759 - 3 ml
1787 - 5 ml
1764 - 8 ml
1789 - 10 ml
1786 - 21 ml
1688 - 100 ml
1689 - 200 ml

Rev. No. New