IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

TRYPTIC SOY BROTH (TSB), USP

Cat. no. K82	TSB, USP, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. K82BX	TSB, USP, 16x125mm Tube, 10ml	80 tubes *ReadyRack
Cat. no. K83	TSB, USP/EP/JP, 20x125mm Tube, 15ml	20 tubes/box
Cat. no. K182	TSB, USP, 16x125mm Tube with Hungate Septum Cap, 10ml	20 tubes/box
Cat. no. K380	TSB, USP, 20x150mm Tube, 20ml	100 tubes/box
Cat. no. K380BX	TSB, USP, 20x150mm Tube, 20ml	80 tubes *ReadyRack
Cat. no. U38	TSB, USP, 20ml Serum Vial, 20ml	50 vials/box
Cat. no. U42	TSB, USP, 4oz. Glass Bottle, 100ml	20 bottles/box
Cat. no. U44	TSB, USP, 2oz. Glass Bottle, 50ml	24 bottles/box
Cat. no. U46	TSB, USP, 100ml Serum Bottle, 100ml	20 bottles/box
Cat. no. U56	TSB, USP, 100ml Serum Bottle, 100ml, Unlabeled	20 bottles/box
Cat. no. U62	TSB, USP, 500ml Glass Bottle, 500ml	500ml bottle
Cat. no. U65	TSB, USP, 500ml Polycarbonate Bottle, 500ml	500ml bottle
Cat. no. U67	TSB, USP, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
Cat. no. U71	TSB, USP, 180ml Wide Mouth Jar, 100ml	12 jars/box
Cat. no. U80	TSB, USP, 500ml Wide Mouth Polycarbonate Bottle with Cap, 225ml	10 bottles/box
Cat. no. U82	TSB, USP, 20ml Serum Vial, 15ml	50 vials/box
Cat. no. U100	TSB, USP, 100ml Bag, 100ml	10 bags/box
Cat. no. U133	TSB, USP, 180ml Wide Mouth Jar, 90ml	12 jars/box
Cat. no. U141	TSB, USP, 125ml Polycarbonate Bottle with Septum Cap, 100ml	16 bottles/box

Cat. no. U171	TSB, USP, 250ml Square Polycarbonate Bottle, 160ml	12 bottles/box
Cat. no. U223	TSB, USP, 180ml Wide Mouth Jar, 25ml	12 jars/box
Cat. no. U242	TSB, USP, 16oz. Glass Bottle, 400ml	12 bottles/box
Cat. no. U267	TSB, USP, 100ml Serum Bottle, 50ml	20 bottles/box
Cat. no. U274	TSB, USP, 500ml Glass Bottle, 500ml	10 bottles/box
Cat. no. U316	TSB, USP, 8oz. Wide Mouth Jar, 180ml	12 jars/box
Cat. no. U421	TSB, USP, 500ml Glass Bottle with Septum Cap, 300ml	10 bottles/box
Cat. no. U435	TSB, USP, 8oz. Glass Bottle, 200ml	12 bottles/box
Cat. no. U462	TSB, USP, 2oz. Glass Bottle, 40ml	24 bottles/box
Cat. no. U8210	TSB, USP, 20ml Serum Vial, 10ml	50 vials/box

*ReadyRack is a plastic rack designed for cleanroom use and can be rinsed with alcohol.

INTENDED USE

Hardy Diagnostics Tryptic Soy Broth is recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of bacteria and fungi. The *U.S. Pharmacopeia National Formulary* (USP) describes its use for sterility testing.[1]

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Tryptic Soy Broth is widely used for the cultivation of microorganisms from environmental sources; supporting the growth of the majority of bacteria and fungi. Tubes of this medium may be used for preparing dilutions of organism for colony counts and preparation of standard inocula. Tryptic Soy Broth is also recommended for use in sterility testing for the detection of contamination with low incidence fungi and aerobic bacteria.[1]

Tryptic Soy Broth, also known as Soybean-Casein Digest, conforms to the formula given by the U.S. Pharmacopeia.[1] This medium contains digests of soybean meal and casein, which provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of organisms. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is incorporated as an energy source. The dipotassium phosphate is included in the formulation as a buffer to maintain the pH.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	17.0gm
Sodium Chloride	5.0gm

Papaic Digest of Soybean Meal	3.0gm
Dextrose	2.5gm
Dipotassium Phosphate	2.5gm

Final pH 7.3 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25°C. away from direct light. Media should not be used if there are any signs of deterioration (discoloration), contamination, or if the expiration date has passed. Protect from light, excessive heat, moisture, and freezing.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended quality control incubation times.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

PROCEDURE

Specimen Collection: Consult listed references for appropriate methods for the collection of specimens from environmental and industrial sources.[1-3]

Method of Use: Inoculate the medium as soon as possible after the specimen has been collected. Incubate, with caps loosened, in the appropriate atmospheric environment and incubation temperature for 18-24 hours, or up to five days. Refer to listed references of test protocols and additional procedures using this media.

INTERPRETATION OF RESULTS

Consult listed references for interpretation criteria and further biochemical testing of growth in Tryptic Soy Broth.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Venting of closed containers (vials, bottles, tubes, or jars) during incubation is recommended in order to provide satisfactory growth conditions for aerobes. Use of vented needles is strongly encouraged for serum or septum-capped containers during incubation to ensure the growth of obligate aerobes.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538**	J	24-72 hrs	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027**	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633**	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633**	J	24-72 hrs	20-25°C	Aerobic	Growth
Candida albicans ATCC® 10231**	J	3-5 days	20-25°C	Aerobic	Growth

Aspergillus brasiliensis ATCC® 16404**	J	5 days	20-25°C	Aerobic	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

** Tested in accordance with USP <61> and <62>.[6,7]

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

Tryptic Soy Broth (TSB), USP should appear clear, and light amber in color.

REFERENCES

1. *United States Pharmacopoeia and National Formulary* (USP-NF). Rockville, MD: United States Pharmacopeial Convention.

2. U.S. Food and Drug Administration. *Bacteriological Analytical Manual.* Arlington, VA http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm

3. American Public Health Association. *Standard Methods for the Examination of Dairy Products,* APHA, Washington, D.C.

4. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods,* APHA, Washington, D.C.

5. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

6. The Official Compendia of Standards. USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

7. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

8. The Official Compendia of Standards. USP General Chapter <60> Microbiological Examination of Nonsterile Products - Tests for Burkholderia cepacia Complex. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD

ATCC is a registered trademark of the American Type Culture Collection.

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207F [C]