IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

TRYPTIC SOY BROTH (TSB)

Cat. no. K85	TSB, Filtered, 13x100mm Tube, 1ml	20 tubes/box
Cat. no. K88	TSB, 16x100mm Tube, 9ml	20 tubes/box
Cat. no. K89	TSB, 13x100mm Tube, 5ml	20 tubes/box
Cat. no. K285	TSB, Filtered, 13x100mm Tube, 2ml	20 tubes/box
Cat. no. R30	TSB, 13x100mm Tube, 5ml	20 tubes/box
Cat. no. R31	TSB, 13x100mm Tube, 2ml	20 tubes/box
Cat. no. R36	TSB, 13x100mm Tube, 1ml	20 tubes/box
Cat. no. R41	TSB, 13x100mm Tube, 3ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Tryptic Soy Broth (TSB) is recommended for use as a general growth medium for the cultivation and detection of a wide variety of bacteria, yeast, and other fungi. It is the recommended medium for use in antibiotic susceptibility testing and disk diffusion testing.[5]

SUMMARY

Tryptic Soy Broth is widely used for the isolation of bacteria from clinical specimens, supporting the growth of the majority of pathogenic bacteria. It is also frequently used in blood culture work. Tubes of this medium may be used for preparing dilutions of organism for colony counts, preparation of standard inocula, and antibiotic sensitivity testing for both fastidious and non-fastidious microorganisms. Tryptic Soy Broth is also recommended for use in sterility testing for the detection of contamination with low incidence fungi and aerobic bacteria.[14]

Tryptic Soy Broth, also known as Soybean-Casein Digest, conforms to the formula given by the U.S. Pharmacopeia.[14] It was originally developed for testing the sensitivity of pneumococci and other microorganisms to sulfonamides without adding blood or serum to the medium.[1] Hamilton and Spink in the early 1950's, reported the use of Tryptic Soy Broth as suitable for the growth of aerobic and facultative microorganisms including *Brucella* species.[7,13] Later, Garrison and Hedgecock both demonstrated the use of this medium to promote the growth of pathogenic fungi.[6,8]

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, including most pathogenic bacteria. 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.

Product K85, TSB Filtered 1ml, and K285, TSB Filtered 2ml, are filtered using a 0.2 micron filter to remove non-viable organisms and is recommended for preparing suspensions of organisms for staining.

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 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC (2-8ºC for Cat. no. K85 and Cat. no. R36) away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date 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 incubation times as stated below.

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

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 M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

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

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection.[2-4,9] Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport media and refrigerated until inoculation.

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 seven days. Refer to the current CLSI (formerly NCCLS) guidelines for sensitivity testing protocols, and other listed references for additional procedures using this media.[2-4,9,11,14]

INTERPRETATION OF RESULTS

Consult listed references for interpretation criteria and further biochemical testing of growth in Tryptic Soy Broth.[2-4,9,11,14]

LIMITATIONS

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

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 Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Tryptic Soy Broth: Cat. Nos. K85, K88, K285, R30, R31, R36, and R41					
Staphylococcus aureus ATCC® 25923	A	1-3 days	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922	A	1-3 days	35°C	Aerobic	Growth
Tryptic Soy Broth: Cat. No. K89					
Staphylococcus aureus ATCC® 25923	A	1-3 days	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922	A	1-3 days	35°C	Aerobic	Growth
Candida krusei ATCC® 14243	J	1-5 days	35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	1-3 days	35°C	Aerobic	Growth

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

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 certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

Note: K85 and K285 are filtered using a 0.2 micron filter to remove non-viable organisms and is recommended for preparing suspensions of organisms for staining.

PHYSICAL APPEARANCE

Tryptic Soy Broth should appear clear, and light amber in color.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

4. Bauer, A.W., W.M.M. Kirby, et al. 1966. *Am. J. Clin. Pathol.*; 45:493-496.

5. Garrison, L.G. 1961. Studies of the respiratory activity of *Histoplasma capsulatum. J. Infect. Disease*; 108:120-124.

6. Hamilton, P.K. 1954. *Am. J. of Clin. Pathol.*; 24:580.

7. Hedgecock, L.W. 1971. Effect of vaccines prepared from *Histoplasma capsulatum* and other yeasts on experimental tuberculosis, *J. Bact.*; 82:115-123.

8. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

9. McCullough, N.B. 1949. Laboratory tests in the diagnosis of Brucellosis, *Am. J. of Public Health*; 39:866.

10. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

11. *Performance Standards for Antimicrobial Disk Susceptibility Tests*, 6th ed., M2-A11, Vol. 33, No. 1. 2013. Clinical Laboratory Standards Institute (CLSI - formerly NCCLS), Villanova, PA.

12. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

13. Spink, W.W. 1952. *Am. J. of Clin. Pathol.*; 22:201.

14. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, Rockville, MD.

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

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