

Instructions for Use

CRITERION™ TRYPTIC SOY BROTH #2 (TSB)

Cat. no. C9140	CRITERION™ Tryptic Soy Broth #2	61gm
Cat. no. C9141	CRITERION™ Tryptic Soy Broth #2	500gm
Cat. no. C9142	CRITERION™ Tryptic Soy Broth #2	2kg
Cat. no. C9143	CRITERION™ Tryptic Soy Broth #2	10kg

INTENDED USE

Hardy Diagnostics CRITERION™ Tryptic Soy Broth #2 is recommended for use as a general purpose medium for the isolation and cultivation of a wide variety of microorganisms.

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

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.^(8,9)

Tryptic Soy Broth, also known as Soybean-Casein Digest Medium, conforms to the formula given by the U.S. Pharmacopeia.⁽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. Sodium chloride is added to maintain the osmotic equilibrium. Dextrose is incorporated as an energy source. Dipotassium phosphate is included in the formulation as a buffer to maintain pH. The peptones used in Tryptic Soy Broth #2 are distinct from those used in conventional Tryptic Soy Broth. This is a non-irradiated product and requires sterilization by autoclaving prior to use.

FORMULA*

Gram weight per liter:	30.0gm/L
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

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original light beige.

Store the prepared culture media at 2-30°C.

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 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." 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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 30.5gm of the dehydrated culture media in 1 liter of distilled or deionized water.
2. Heat to boiling and mix to dissolve completely.
3. Sterilize in the autoclave at 121°C. for 15 minutes.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. no. K89 or K82 (for USP).⁽¹⁻⁹⁾

LIMITATIONS

This product must be sterilized by autoclaving and not by cold filtration.

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

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Refer to the document "[Limitations of Procedures and Warranty](#)" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, and incubators, etc., 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	
<i>Candida albicans</i> ** ATCC® 10231	J	1-3 days	30-35°C	Aerobic	Growth
<i>Bacillus subtilis</i> ** ATCC® 6633	J	1-3 days	35°C	Aerobic	Growth
<i>Staphylococcus aureus</i> ATCC® 25923	A	24-48hr	35°C	Aerobic	Growth
<i>Staphylococcus aureus</i> ** ATCC® 6538	J	1-3 days	35°C	Aerobic	Growth
<i>Pseudomonas aeruginosa</i> ** ATCC® 9027	J	1-3 days	35°C	Aerobic	Growth
<i>Escherichia coli</i> ATCC® 25922	A	24-48hr	35°C	Aerobic	Growth
<i>Escherichia coli</i> ** ATCC® 8739	J	1-3 days	35°C	Aerobic	Growth
<i>Salmonella enterica</i> ** ATCC® 14028	J	1-3 days	35°C	Aerobic	Growth

* Refer to the document "[Inoculation Procedures for Media QC](#)" for more information.

USER QUALITY CONTROL

Users of dehydrated 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. In addition, refer to the following document "[Finished Product Quality Control Procedures](#)," for more information on QC or see the reference(s) for more specific information.

** Tested in accordance with USP <61> and <62>. ^(8,9)

PHYSICAL APPEARANCE

CRITERION™ Tryptic Soy Broth powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear translucent, and light amber in color.

REFERENCES

1. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA.
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>.
2. Marshall, R.T., (ed.). 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.
3. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.
4. Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington, D.C.
5. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.
6. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.
7. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.
8. 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.
9. 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.

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

IFU-10274[B]



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

HDQA 2207B [D]