

Instructions for Use

CRITERION™ SHIGELLA BROTH BASE

Cat. no. C9150	CRITERION™ Shigella Broth Base	120gm
Cat. no. C9151	CRITERION™ Shigella Broth Base	500gm
Cat. no. C9152	CRITERION™ Shigella Broth Base	2kg
Cat. no. C9153	CRITERION™ Shigella Broth Base	10kg
Cat. no. C9154	CRITERION™ Shigella Broth Base	50kg

INTENDED USE

IFU

Hardy Diagnostics CRITERION[™] Shigella Broth Base is intended for us with Novobiocin NaCl supplement (Cat. no. Z915A), for the selective enrichment broth used for the isolation of *Shigella spp*. from food.

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

Shigella are gram negative, rod shaped, enteric bacteria that are well documented as a food pathogen. Upon consumption, many strains are capable of producing Shiga toxin and enterotoxin, which cause a type of dysentary known as shigellosis. Shigella Broth as described in BAM and APHA is used for the isolation and enrichment of *Shigella spp*. from food samples.^(1,2)

The addition of Novobiocin NaCl supplement (Cat. no. Z915A) to the broth during preparation allows for the inhibition of gram-positive organisms while allowing enteric bacteria such as *Shigella* to be selectively enriched.

FORMULA

Gram weight per liter:	31.5gm/L
Tryptone	20.0gm
Sodium Chloride	5.0gm
Glucose	1.0gm
Monopotassium Phosphate	2.0gm
Dipotassium Phosphate	2.0gm
Polysorbate 80	1.5ml

Final pH 7.2 +/- 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 yellowish-beige.

Store the prepared culture media at 2-8°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 "<u>Guidelines for Isolation</u> <u>Precautions</u>" 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 31.4gm 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.

4. Cool to 45-50°C. and, if desired, aseptically add 0.5ml pre-sterilized Novobiocin NaCl supplement (Cat. no. Z915A) into the broth.

5. Mix thoroughly before dispensing desired volume into pre-sterilized containers..

PROCEDURE AND INTERPRETATION OF RESULTS

For the enrichement of *Shigella spp*. from food samples, please consult the listed references.^(1,2)

LIMITATIONS

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, incubators, and Novobiocin NaCl supplement, 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	Kesuns
Shigella flexneri ATCC [®] 12022	J	18-24hr	35°C	Aerobic	Growth
Shigella sonnei ATCC [®] 9290	J	18-24hr	35°C	Aerobic	Growth
Staphylococcus aureus ATCC [®] 25923	J	18-24hr	35°C	Aerobic	Complete Inhibition***

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

***When broth is prepared with the Novobiocin NaCl supplement.

USER 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:

PHYSICAL APPEARANCE

CRITERIONTM Shigella Broth Base powder should appear homogeneous, free-flowing, and light yellow-beige in color. The prepared media should appear transparent and light amber in color.

REFERENCES

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

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

3. Atlas R.M., 2010, Handbook of Microbiological Media 4th Edition, CRC Press, Boca Raton, New York, London, Tokyo

4. Hale T. L., Keusch G. T., 1996, Shigella. In: Barons Medical Microbiology (Barron S et al, Eds.), 4th Ed., Univ of Texas Medical Branch.

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

IFU-10257[A]



1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760 Website: <u>HardyDiagnostics.com</u> <u>Email: TechnicalServices@HardyDiagnostics.com</u> <u>Ordering Information</u>

Distribution Centers: 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.

Copyright© 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207B [D]