IFU

Instructions for Use

CRITERION™ M BRILLIANT GREEN BROTH

Cat. no. C7940	CRITERION™ m Brilliant Green Broth	152gm
Cat. no. C7941	CRITERION™ m Brilliant Green Broth	500gm
Cat. no. C7942	CRITERION™ m Brilliant Green Broth	2kg
Cat. no. C7943	CRITERION™ m Brilliant Green Broth	10kg
Cat. no. C7944	CRITERION™ m Brilliant Green Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ m Brilliant Green Broth is for the selective and differential isolation of *Salmonella* spp. from water by membrane filtration.

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

The *Salmonella* species are responsible for multiple types of clinical infection including gastroenteritis, bacteremia or septicemia, enteric fever, and a carrier state where a formerly infected person can excrete the bacteria up to one year following the withdrawal of symptoms.[1,2] These organisms are common in the environment, though much less frequent than coliforms, and small concentrations can be found in most surface waters.[3] This may require testing of larger amounts of water and the use of multiple enrichment and isolation medias in order to recover all the *Salmonella* serotypes.[3]

Kristensen et al., in 1925, first described use of Brilliant Green Agar as a primary plating medium for the isolation of *Salmonella* spp.[4] The original formula was altered by Kauffmann ten years later.[5] Hardy Diagnostics CRITERION™ m Brilliant Green Broth is a modification of Kauffmann's Brilliant Green Agar in which the agar has been removed and the remaining ingredients have been increased.

The current formulation incorporates phenol red as the pH indicator of carbohydrate fermentation and brilliant green as an inhibitory agent that acts against gram-positive organisms and gram-negative bacilli. Peptones provide a source of carbon, nitrogen, vitamins and minerals. Yeast extract supplies complex B vitamins, trace elements and amino acids that help stimulate bacterial growth. The carbohydrates available for bacterial growth are lactose and sucrose while sodium chloride is added to ensure proper osmotic pressure.

FORMULA*

Gram weight per liter:	76.0gm/L
Proteose Peptone No. 3	20.0gm

Lactose	20.0gm
Sucrose	20.0gm
Sodium Chloride	10.0gm
Yeast Extract	6.0gm
Phenol Red	0.16gm
Brilliant Green	0.025gm

Final pH 6.9 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. 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 pink.

Store the prepared culture media at 2-8ºC.

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 76gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling while stirring to dissolve completely.

3. DO NOT AUTOCLAVE.

4. Cool to room temperature. Dispense 2ml aliquots onto sterile absorbent pads.

5. Use prepared media within twenty-four hours.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.

LIMITATIONS

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.

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Sterilize all biohazard waste before disposal.

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

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

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as membrane filters, absorbent pads, forceps, swabs, loops, autoclaves, incinerators, incubators, serological and biochemical reagents, 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	
Salmonella enteritidis ATCC® 13076	MF	18-24hr	35°C	Aerobic	Growth; pink to red colonies
Salmonella enterica ATCC® 14028	MF	18-24hr	35°C	Aerobic	Growth; pink to red colonies
Escherichia coli ATCC® 25922	MF	18-24hr	35°C	Aerobic	Partial inhibition; yellow colonies

* 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.

PHYSICAL APPEARANCE

CRITERION™ m Brilliant Green Broth powder should appear homogeneous, free-flowing, and pink in color. The prepared media should appear slightly opalescent, and greenish-red in color.

REFERENCES

1. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology,* J.B. Lippincott Company, Philadelphia, PA.

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

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

4. Kristensen, M., Lester, V. and Jurgens, A. (1925) Use of trypsinised casein, brom-thymol blue, brom-cresol purple, and brilliant green for bacteriological nutrient media. *British Journal of Experimental Pathology*; 6:291-299.

5. Kauffman, F. 1935. Weitere Erfahrungen mit den kombiniereten Anreicherungsverfahren fur Salmonella bazillen. *Zeitschrift fur Hygiene und Infektionskrankheit*; 117:26-32.

6. 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.

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

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

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

HDQA 2207B [D]