IFU

Instructions for Use

CRITERION™ UVM MODIFIED LISTERIA ENRICHMENT BROTH

Cat. no. C7240	CRITERION™ UVM Modified Listeria Enrichment Broth	104gm
Cat. no. C7241	CRITERION™ UVM Modified Listeria Enrichment Broth	500gm
Cat. no. C7242	CRITERION™ UVM Modified Listeria Enrichment Broth	2kg
Cat. no. C7243	CRITERION™ UVM Modified Listeria Enrichment Broth	10kg
Cat. no. C7244	CRITERION™ UVM Modified Listeria Enrichment Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ UVM Modified Listeria Enrichment Broth is recommended for the rapid isolation of *Listeria monocytogenes*.

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

Listeria monocytogenes is a widespread problem in public health and food industries. *Listeria monocytogenes* was first described in 1926 by Murray, Webb and Swann, and can cause human illness and death, particularly in immunocompromised individuals and pregnant women.[1,2] The first reported food-borne outbreak of listeriosis was in 1985.[3] The principle route of transmission is via the consumption of foodstuffs contaminated with *Listeria monocytogenes*.[4]

This organism has been isolated from turkey frankfurters, coleslaw, pasteurized milk, Mexican-style cheese, pate, and pickled pork tongue.[5] *Listeria monocytogenes* is present in a wide range of unprocessed foods as well as in soil, sewage, silage, and river water.[6] *Listeria* species can grow over a pH range of 5.0-9.6 and survive in food products with pH levels outside of that range.[7]

UVM Modified Listeria Enrichment Broth is a modification of the formula described by Donnelly and Baigent.[9] It is used for selective enrichment of *Listeria* spp. from food and clinical specimens.

CRITERION™ UVM Modified Listeria Enrichment Broth contains beef extract, yeast extract, pancreatic digest of casein, and peptic digest of animal tissue which provide nitrogen, vitamins and minerals. Sodium chloride is added to maintain osmotic balance and phosphate is added as a buffer. Nalidixic acid inhibits gram-negative organisms and acriflavine hydrochloride inhibits many gram-positive bacteria. Esculin is hydrolyzed by *Listeria* species.

FORMULA

Gram weight per liter:	52.0gm/L
Sodium Chloride	20.0gm
Disodium Phosphate	9.6gm
Pancreatic Digest of Casein	5.0gm
Peptic Digest of Animal Tissue	5.0gm
Beef Extract	5.0gm
Yeast Extract	5.0gm
Monopotassium Phosphate	1.35gm
Esculin	1.0gm
Nalidixic Acid	20.0mg
Acriflavine HCl	12.0mg

Final pH 7.2 +/- 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 beige.

Store the prepared culture media at 2-30ºC.

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 52.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat as necessary to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Cool to 45-50ºC.

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. K96.

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, 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	
Listeria monocytogenes ATCC® 19114	A	18-48hr	35°C	Aerobic	Growth
Staphylococcus aureus ATCC® 29523	B	18-48hr	35°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 25922	B	18-48hr	35°C	Aerobic	Inhibited
Enterococcus faecalis ATCC® 29212	B	18-48hr	35°C	Aerobic	Inhibited

* 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™ UVM Modified Listeria Enrichment Broth powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear very slightly opalescent with a fine precipitate, and amber in color.

REFERENCES

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4. Bremer, P.J., and C.M. Osborne. 1995. Thermal-death times of *Listeria monocytogenes* in green shell mussels (*Perna canaliculus*) prepared for hot smoking. *J. Food Prot.*; 58:604-608.

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12. Hayes, P.S., L.M. Graves, B. Swaminathan, G.W. Ajello, G. B. Marcolm, R.E. Weaver, R. Ransom, K. Deaver, B.D. Plikaytis, A. Schuchat, J.D. Wenger, R.W. Pinner, C.V. Broome, and The *Listeria* Study Group. 1992. Comparison of three selective enrichment methods for the isolation of *Listeria monocytogenes* from naturally contaminated foods. *J. Food Prot.*; 55:952-959.

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

IFU-10286[A]

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

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