IFU

Instructions for Use

CRITERION™ HALF FRASER BROTH BASE

Cat. no. C8040	CRITERION™ Half Fraser Broth Base	110gm
Cat. no. C8041	CRITERION™ Half Fraser Broth Base	500gm
Cat. no. C8042	CRITERION™ Half Fraser Broth Base	2kg
Cat. no. C8043	CRITERION™ Half Fraser Broth Base	10kg
Cat. no. C8044	CRITERION™ Half Fraser Broth Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Half Fraser Broth Base is used with Fraser Broth Supplement for the selective enrichment and detection of *Listeria* spp. The medium is also used in conjunction with Fraser Broth Supplement for the rapid detection of *Listeria* from food and environmental samples.

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

First described by Murray, Webb and Swann, *Listeria monocytogenes* is a widespread problem in public health and the food industries.[3,8] This organism can cause human illness and death, particularly in immunocompromised individuals and pregnant women. The first reported food-borne outbreak of listeriosis was in 1985. Since then, microbiological and epidemiological evidence from both sporadic and epidemic cases of listeriosis has shown that the principal route of transmission is via the consumption of foodstuffs contaminated with *Listeria monocytogenes*.[1,4]

Implicated vehicles of transmission include turkey frankfurters, coleslaw, pasteurized milk. Mexican-style and other soft cheeses, pate' and pickled pork tongue. The organism has been isolated from commercial dairy and other food processing plants. It is ubiquitous in nature, being present in a wide range of unprocessed foods and in soil, sewage, silage and river water. *Listeria* species grow over a pH range of 5.0-9.6 and survive in food products with pH levels outside these parameters.[1]

Half Fraser Broth Base is a modification of Fraser Broth Base in which the nalidixic acid and acriflavine concentrations have been reduced to 10.0mg/L and 12.5mg/L respectively, in accordance with AFNOR guidelines.[10] It contains pancreatic digest of casein, proteose peptone, and yeast extract as nitrogen, vitamin, and mineral sources. Differentiation is aided by including ferric ammonium citrate in the final medium. Since all *Listeria* species hydrolyze esculin, the addition of ferric ions to the medium will detect the reaction. Ferric ions, combined with esculetin, produce a dark brown to black color change in the medium surrounding the colonies.

Selectivity is provided by the presence of lithium chloride, nalidixic acid, and acriflavine in the formula. The high salt tolerance of *Listeria* is used as a means to inhibit growth of enterococci.

FORMULA

Gram weight per liter:	55.0gm/L
Sodium Chloride	20.0gm
Disodium Phosphate	9.6gm
Proteose Peptone	5.0gm
Pancreatic Digest of Casein	5.0gm
Beef Extract	5.0gm
Yeast Extract	5.0gm
Lithium Chloride	3.0gm
Monopotassium Phosphate	1.35gm
Esculin	1.0gm
Acriflavine Hydrochloride	12.5mg
Nalidixic Acid	10.0mg

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 light beige.

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 55.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat while stirring to dissolve completely. Avoid overheating.

3. Distribute and autoclave at 121ºC. for 15 minutes.

4. Cool to room temperature. Aseptically add enrichment, 10ml of a filter sterilized 5% aqueous solution of ferric ammonium citrate (Fraser Broth Supplement, Cat. no. Z210).

5. Dispense as desired into sterile containers.

PROCEDURE AND INTERPRETATION OF RESULTS

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

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.

Since the nutritional requirements of organisms vary, some strains of *Listeria* may be encountered that fail to grow or grow poorly on this medium.

CRITERION™ Half Fraser Broth Base is a partially selective medium. Growth of some contaminating strains will be markedly but not totally inhibited.

Poor growth and a weak esculin reaction may be seen after 40 hours incubation for some enterococci.

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, Fraser Broth Supplement (Cat. no. Z210), 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					Growth; positive esculin

E. coli 19114	A	24-48hr	35°C	Aerobic	reaction (blackening)
Enterococcus faecalis *E. coli* 29212	B	24-48hr	35°C	Aerobic	Partial to complete inhibition
Escherichia coli *E. coli* 25922	B	24-48hr	35°C	Aerobic	Partial to complete inhibition

* 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™ Half Fraser Broth Base powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear to slightly opalescent, with a fine precipitate, and medium amber in color.

REFERENCES

1. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

2. International Dairy Federation. 1990. Milk and milk products - detection of *Listeria monocytogenes*. IDF Provisional International Standard No. 143. International Dairy Federation, Brussels.

3. Murray, E.G, et al. 1926. A disease of rabbits characterized by large mononuclear leucocytosis caused by a hitherto undescribed bacillus *Bacterium monocytogenes*. *J. Path. Bact.*; 19:407-439.

4. Monk, J.D, et al. Irradiation inactivation of *Listeria monocytogenes* and *Staphylococcus aureus* in law and high-fat frozen and refrigerated ground beef. *J. Food Prot.*; 57:769-772.

5. Wehr, H.M. 1987. *Listeria monocytogenes* - a current dilemma Special Report. *J. Assoc. Anal. Chem.*; 80:769-7762.

6. Grau, F.H., et al. 1995. Occurrence, numbers, and growth of *Listeria monocytogenes* on some vacuum-packaged processed meats. *J. Food Prot.*; 55:4-4.

7. Kramer, P.A., et al. 1969. Media selective for *Listeria monocytogenes*. *J. Appl. Bacteriology*; 32:381-394.

8. Lovett, J.D., et al. 1987. *Listeria monocytogenes*. *J. Food Prot.*; 50:188-192.

9. Lee, W.H., et al. 1994. Laboratory Communication No. 57 (revised February 8, 1994), U.S.D.A., F.S.I.S. Microbiology Division, Bethesda, MD.

10. L'association franciase de normalisation (AFNOR). Food Microbiology - Detection of *Listeria monocytogenes* - Routine Method, V 08-055. AFNOR, Paris, France, 1993.

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

HDQA 2207B [D]