IFU

Instructions for Use

CRITERION™ TETRATHIONATE BROTH BASE

Cat. no. C7060	CRITERION™ Tetrathionate Broth Base	92.5gm
Cat. no. C7061	CRITERION™ Tetrathionate Broth Base	500gm
Cat. no. C7062	CRITERION™ Tetrathionate Broth Base	2kg
Cat. no. C7063	CRITERION™ Tetrathionate Broth Base	10kg
Cat. no. C7064	CRITERION™ Tetrathionate Broth Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Tetrathionate Broth Base, with the addition of Iodine-Iodide Solution (Cat. no. Z129), is a selective enrichment medium for *Salmonella* spp., used for microbiological testing of foods such as, raw milk or other highly contaminated samples or specimens.[14,15]

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

Muller first described use of Tetrathionate Broth for the cultivation and enrichment of *Salmonella* spp. Later modifications of the formula were done by Kauffman, Schaeffer, and Knox, et al.[12] Knox found Tetrathionate Broth to be inhibitory to commensal organisms while promoting growth of Salmonellae.[13]

CRITERION™ Tetrathionate Broth Base contains bile salts which act as a selective agent that inhibits gram-positive organisms and coliforms. Tetrathionate is formed with the addition of the Iodine-Iodide Solution (Cat. no. Z129) to the Tetrathionate Broth just prior to inoculation.[5] Proteose peptone acts as a nutritive base. The tetrathionate together with the sodium thiosulfate, iodide, and calcium carbonate, all work as selective agents to commensal fecal flora, but the most important of these is tetrathionate. *Salmonella* species that are capable of reducing tetrathionate will proliferate in this medium.[16]

CRITERION™ Tetrathionate Broth Base conforms to the formulation recommended by the American Public Health Association (APHA), the Food and Drug Administration (FDA), and The United States Pharmacopeia (USP).[8-11]

FORMULA

Gram weight per liter:	46.0gm/L
Sodium Thiosulfate	30.0gm
Calcium Carbonate	10.0gm

Proteose Peptone	5.0gm
Bile Salts	1.0gm

Final pH 8.4 +/- 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 white.

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 46.0gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat as necessary to dissolve completely.

3. Do not autoclave.

4. Cool to 45-50ºC.

5. Aseptically dispense 10ml per sterile tube.

6. Refrigerate until use.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, refer to the prepared media Instructions for Use (IFU) for Cat. No. K65.

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.

The recovery of many *Salmonella* spp. is greatly jeopardized if stool specimens remain unpreserved for more than three hours before processing. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport medium and refrigerated until further testing.

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, Iodine-Iodide Solution (Cat. no. Z129), 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	
Salmonella enterica ATCC® 14028	I	18-24hr	35°C	Aerobic	Growth on HE or XLD upon subculture
Escherichia coli ATCC® 25922	I	18-24hr	35°C	Aerobic	Partial to complete inhibition on HE or XLD upon subculture

* 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™ Tetrathionate Broth Base powder should appear homogeneous, free-flowing, and white in color. The prepared media should appear clear, with a precipitate, and milky white in color. Iodine-Iodide Solution (Cat. no. Z129)

should appear dark amber to brown in color.

REFERENCES

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

HDQA 2207B [D]