IFU

Instructions for Use

CRITERION™ XLT-4 AGAR BASE

Cat. no. C8030	CRITERION™ XLT-4 Agar Base	114gm
Cat. no. C8031	CRITERION™ XLT-4 Agar Base	500gm
Cat. no. C8032	CRITERION™ XLT-4 Agar Base	2kg
Cat. no. C8033	CRITERION™ XLT-4 Agar Base	10kg
Cat. no. C8034	CRITERION™ XLT-4 Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ XLT-4 Agar Base is a highly selective plating medium for the detection and isolation of non- *typhi Salmonella* species.

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

Numerous media have been developed for the isolation and differentiation of enteric bacteria, most designed to recover a broad spectrum of enteric pathogens. Subsequently, overgrowth of inconsequential bacteria can be a problem, when recovery of a specific species is desired. This is true of *Salmonella* isolation media where *Proteus Providencia*, and *Pseudomonas* can interfere with the desired results.

Xylose-Lysine-Desoxycholate (XLD) media was developed as a selective and differential media for the isolation of gram-negative enteric pathogens. The sodium deoxycholate found in the XLD media is replaced by Tergitol 4 in Xylose-Lysine-Tergitol 4 (XLT-4) Agar. This addition makes XLT-4 more highly selective for *Salmonella* than its predecessor.[1-3]

Proteose Peptone No.3 in XLT-4 Agar provides a source of complex nitrogen compounds. Yeast extract is added to supply vitamins and co-factors. Differentiation on this medium is based on xylose, lactose, sucrose, lysine decarboxylation, and hydrogen sulfide production. The pH shifts in the medium due to the fermentation and decarboxylation reactions are visualized by the addition of phenol red. The Tergitol 4 in the XLT-4 Agar inhibits all gram-positive bacteria and molds, and inhibits the growth of numerous gram-negative bacteria including *Proteus*, *Providencia* and *Pseudomonas* species.[1-3] This attribute makes XLT-4 Agar excellent for the isolation and detection of non- *typhi Salmonella*.

FORMULA

Gram weight per liter:	57.0gm/L
Lactose	7.5gm

Sucrose	7.5gm
Sodium Thiosulfate	6.8gm
Sodium Chloride	5.0gm
L-Lysine	5.0gm
Xylose	3.75gm
Yeast Extract	3.6gm
Proteose Peptone No. 3	1.6gm
Ferric Ammonium Citrate	0.8gm
Phenol Red	80.0mg
Agar	16.0gm

Final pH 7.4 +/- 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 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 57.0gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Add 4.6ml of XLT-4 Agar Supplement.

3. Heat to boiling to dissolve completely. Do Not Overheat.

4. **Do not autoclave.**

5. Cool to 45-50ºC. in a waterbath.

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. G165.

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.

Rare strains of *Salmonella* do not produce H_2S and will not appear black on XLT-4 Agar. However, these colonies will be pink to pinkish yellow, which differentiates them from the bright yellow colonies of non- *Salmonella* species.

XLT-4 Agar is used to aid in the isolation and differentiation of *Salmonella* species. Additional biochemical and serological tests are required for complete identification. See listed references for more information.[1-4]

Some strains of *Salmonella* may fail to grow, or grow poorly on this medium due to nutritional variances.

Non-*Salmonella* strains that are not completely inhibited on XLT-4 Agar may be encountered, and must be differentiated from *Salmonella*. Consult listed references for more information.[1-4]

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	
Salmonella enterica ATCC® 14028**	A	18-24hr	35°C	Aerobic	Growth; yellow to red colonies with black centers
Escherichia coli					Partial to complete inhibition;

ATCC® 25922**	B	18-24hr	35°C	Aerobic	yellow colonies
Proteus mirabilis ATCC® 12453	B	18-24hr	35°C	Aerobic	Inhibited
Staphylococcus aureus ATCC® 25923**	B	18-24hr	35°C	Aerobic	Inhibited

* Refer to the document "Inoculation Procedures for Media QC" for more information.

** Recommended QC strains for User Quality Control according to the CLSI document M22 when applicable.

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™ XLT-4 Agar Base powder should appear homogeneous, free-flowing, and pink in color. The prepared media should appear slightly opalescent, and red in color.

REFERENCES

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

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

3. Miller, R.G., et al. 1992. Xylose-Lysine-Tergitol 4: An improved selective agar medium for the isolation of *Salmonella*. *Poultry Science*; 71:398.

4. Miller, R.G., et al. 1991. Xylose-Lysine-Tergitol 4: An improved selective agar medium for the isolation of *Salmonella*. *Poultry Science*; 70:2429-2432.

5. Andrews, W.H., et al. 1995. *Salmonella*. In *Bacteriological Analytical Manual*, 8th ed. AOAC International, Gaithersburg, MD.

6. Vanderzant, C. and D.F. Splittstoesser (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. American Public Health Association, Washington, D.C.

7. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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

HDQA 2207B [D]