IFU

Instructions for Use

CRITERION™ XLD AGAR

Cat. no. C7320	CRITERION™ XLD Agar	114gm
Cat. no. C7321	CRITERION™ XLD Agar	500gm
Cat. no. C7322	CRITERION™ XLD Agar	2kg
Cat. no. C7323	CRITERION™ XLD Agar	10kg
Cat. no. C7324	CRITERION™ XLD Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ XLD Agar is recommended for use as a selective and differential medium for the isolation of gram-negative enteric bacilli such as *Salmonella* and *Shigella*.

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

Xylose-Lysine-Deoxycholate (XLD) Agar was developed by Taylor for the differentiation, isolation, and identification of enteric pathogens, and to support the growth of more fastidious enteric organisms.[5] XLD Agar was especially designed to allow the growth of *Shigella* species, and is a proven medium for the isolation of this organism. It has also been found to be an excellent medium for isolating *Salmonella* species as well.

The selective agent in XLD Agar is sodium deoxycholate, which inhibits the growth of gram-positive organisms. The carbohydrate source is xylose which is fermented by most enterics except for *Shigella* species, and these colonies appear red on this medium as a result. A second differential mechanism for *Salmonella* is employed by the addition of lysine. Lysine decarboxylation reverts the pH of the medium to an alkaline condition. To avoid this reversal to a *Shigella* reaction, lactose and sucrose are added in excess. The addition of sodium thiosulfate and ferric ammonium citrate as a sulfur source and indicator, respectively, allows hydrogen sulfide forming organisms to produce colonies with black centers, under alkaline conditions. Organisms which ferment xylose, are lysine- decarboxylase-negative, and do not ferment lactose or sucrose cause an acid pH in the medium, and form yellow colonies. Examples of such organisms are *Citrobacter* spp., *Proteus* spp., and *Escherichia coli* .

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	3.0gm
Sodium Deoxycholate	2.5gm
Ferric Ammonium Citrate	0.8gm
Phenol Red	0.08gm
Agar	15.0gm

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.

2. Heat to boiling and mix to dissolve completely. Avoid overheating.

3. Cool to 45-50ºC. and dispense as desired.

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. G65.

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.

As some species of *Salmonella* may form red colonies without a black center, which resemble *Shigella* colonies. In addition, a few species of *Shigella* ferment lactose, and *Salmonella* that fail to decarboxylate lysine would not be detected on this medium.

Red, false-positive colonies may occur with some *Proteus* and *Pseudomonas* spp.

Processing delays of over 2-3 hours of unpreserved stool specimens greatly jeopardizes the recovery of many enteric pathogens, as these organisms are very susceptible to the acidic changes that occur with a temperature drop of the feces.

Longer incubation may result in false-positive results.

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; red colonies with black centers
Shigella flexneri ATCC® 12022	A	18-24hr	35°C	Aerobic	Growth; red to pink colonies
Enterococcus faecalis ATCC® 29212	B	18-24hr	35°C	Aerobic	Partial to complete inhibition; clear, pinpoint colonies
Escherichia coli					Partially inhibited; yellow to

ATCC® 25922	B	18-24hr	35°C	Aerobic	yellow-red 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™ XLD Agar powder should appear homogeneous, free-flowing, pink in color. The prepared media should appear clear, and red in color.

REFERENCES

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

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

3. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria,* Vol. I. Williams & Wilkins, Baltimore, MD.

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

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

8. Atlas, R.M. 1997. *Handbook of Microbiological Media*, 2nd ed. CRC Press, Boca Raton, FL.

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

HDQA 2207B [D]