CRITERION™ UREA AGAR BASE CONCENTRATE

Cat. no. C7230	CRITERION™ Urea Agar Base Concentrate	54gm
Cat. no. C7231	CRITERION™ Urea Agar Base Concentrate	500gm
Cat. no. C7232	CRITERION™ Urea Agar Base Concentrate	2kg
Cat. no. C7233	CRITERION™ Urea Agar Base Concentrate	10kg

INTENDED USE

Hardy Diagnostics CRITERION™ Urea Agar Base Concentrate is recommended for use in the detection of urea hydrolysis in gram-negative organisms.

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

Urea Agar was developed by Christensen in 1946 for the differentiation of enteric bacilli, as an improvement over the broth method used at that time.[3] Urea Agar is used to differentiate between rapidly positive *Proteus* species and other slower urea positive members of the *Enterobacteriaceae*. This medium may also be used in the detection of ureaseactivity in other gram-negative organisms, such as *Pseudomonas*, *Pasteurella*, and *Brucella*.[5] Webb et al. also reported that Urea Agar is useful in differentiating *Cryptococcus* from other yeast species.[9]

CRITERION™ Urea Agar Base Concentrate contains urea as a source of nitrogen for the production of urease and phenol red as the pH indicator. Organisms capable of hydrolyzing urea form ammonia as a by product, thus turning the medium alkaline. The pH indicator turns from pale yellow to pink-red in color under these conditions. The reduced buffer content and peptone in this medium promote rapid growth and a faster reaction time for many members of the *Enterobacteriaceae*. Dextrose is included in the formulation to stimulate urease activity in organisms that hydrolyze urea slowly and to exclude false-negativereactions. *Proteus* species rapidly hydrolyze urea and a positive reaction is usually seen within one to six hours. Other organisms may require a 24 to 48 hour, or longer, incubation time.

CRITERION™ Urea Agar Base Concentrate is a 10X concentrate for the preparation of Christiansen's medium and requires the supplementation of bacteriological grade agar (Cat. no. C5000) for the preparation of solid media.

FORMULA*

Gram weight per liter:	29.0gm/L
Urea	20.0gm

Sodium Chloride	5.0gm
Gelatin Peptone	1.0gm
Dextrose	1.0gm
Disodium Phosphate	0.1gm
Monopotassium Phosphate	0.09gm
Phenol Red	0.012gm

Final pH 6.8 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

Supplement	
Composition per liter:	
Agar, Bacteriological Grade	15.0gm/L

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 orange or light pink.

Store the prepared culture media at 2-8ºC.

The expiration dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 29gm of the Urea Agar Base Concentrate dehydrated culture media in 100ml of distilled or deionized water. Stir to mix thoroughly. Sterilize by filtration using a 0.2 micron filter.

2. Suspend 15gm of bacteriological grade agar (Cat. no. C5000) in 900ml of distilled or deionized water.

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

4. Cool the agar solution to 45 to 50ºC and aseptically add 100ml of the sterile Urea Agar Base Concentrate.

5. Mix thoroughly and dispense aseptically into sterile tubes.

6. Cool tubed medium in a slanted position so deep butts are formed.

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. L65.

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.

To facilitate growth and the urea hydrolysis reaction, do not use inoculum from a broth suspension.

Due to nutritional variation, some strains may grow poorly or fail to grow on this medium.

Urea Agar relies upon the pH indicator to detect an alkaline reaction such as the hydrolysis of urea. After prolonged incubation times, a false-positive alkaline reaction may be seen due to the hydrolysis of peptones and the release of amino acid residues. To rule out this occurrence, check the test with a control (an uninoculated tube of Urea Agar along with the inoculated tube) during prolonged incubation.

To detect *Proteus* species, the Urea Agar slants may be examined within six hours of inoculation.

Urea Agar should not be used to determine the quantitative rate of urease activity, as organisms vary in their capability and rate of hydrolysis.

Failure to incubate this medium with loose caps may cause erroneous results.

Do not heat the Urea Agar slants, as urea decomposes very readily when heated.

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, innoculation loops, 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 Certificates of Analysis (CofA). The following organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Proteus mirabilis ATCC ® 12453	E	18-24hr	35°C	Aerobic	Positive: Growth; pink color change
Escherichia coli ATCC ® 25922	E	18-24hr	35°C	Aerobic	Negative: Growth; yellow color or no color change

* 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 certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Urea Agar Base Concentrate powder should appear homogeneous, free-flowing, and light orange to light pink in color. The prepared medium should appear opalescent, and light to medium yellow-orange in color.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

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

3. Christensen, W.B. 1946. Urea decomposition as a means of differentiating *Proteus* and paracolon cultures from each other and from *Salmonella* and *Shigella* types. *J. Bacteriol*. 52:461.

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

5. King, E.O. 1960. *The Identification of Unusual Pathogenic Gram Negative Bacteria*, U.S.D.H.E.W., CDC, Atlanta, GA.

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

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

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

9. Webb, C.D., et al. 1973. *Identification of Yeasts, U.S.D.H.E.W*., CDC, Atlanta, GA.

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

HDQA 2207B [C]