IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CRITERION™ CYSTINE TRYPTIC AGAR (CTA)

Cat. no. C5510	CRITERION™ Cystine Tryptic Agar (CTA)	59gm
Cat. no. C5511	CRITERION™ Cystine Tryptic Agar (CTA)	500gm
Cat. no. C5512	CRITERION™ Cystine Tryptic Agar (CTA)	2kg
Cat. no. C5513	CRITERION™ Cystine Tryptic Agar (CTA)	10kg
Cat. no. C5514	CRITERION™ Cystine Tryptic Agar (CTA)	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Cystine Tryptic Agar (CTA) is recommended for the determination of carbohydrate fermentation by fastidious microorganisms, such as *Neisseria* spp. It is also used for the detection of bacterial motility and the base can serve as a holding medium for the maintenance of fastidious microorganisms.

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

In general, Cystine Tryptic Agar (CTA) provides a nutritious basal medium composed of casein peptones, cystine, inorganic salts, phenol red, and agar. The inorganic salts serve as a source of essential ions. Phenol red is the pH color indicator.

CRITERION™ Cystine Tryptic Agar (CTA) supplemented with a 1% concentration of a specific carbohydrate is used to detect fermentation reactions. The 1% concentration is recommended to decrease the possibility of reversal reactions. Reversion occurs when the carbohydrate is depleted, thereby resulting in the masking of acid by alkaline by-products from peptone degradation. The acid produced by carbohydrate consumption causes a decrease in pH resulting in a color shift in the medium from red-pink to yellow.

The addition of agar to the medium allows for the detection of motility along the stab line of inoculation. Motile organisms extend from the stab line and produce turbidity or cloudiness throughout the medium. Non-motile organisms grow only along the stab line and leave the surrounding medium clear.

CRITERION™ Cystine Tryptic Agar (CTA) can also be made carbohydrate-free and used as a holding medium for fastidious microorganisms at 25ºC.

FORMULA*

Gram weight per liter:	29.5gm/L
Pancreatic Digest of Casein	20.0gm

Sodium Chloride	5.0gm
L-Cystine	0.5gm
Sodium Sulfite	0.5gm
Phenol Red	0.017gm
Agar	3.5gm

Final pH 7.3 +/- 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 29.5gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat with frequent agitation to boiling for one minute to dissolve completely.

3. If desired, add 5-10gm (0.5-1.0%) of carbohydrate to the medium before autoclaving. Stir to mix thoroughly. Adjust the pH if necessary. (Note: Some carbohydrates are degraded by heat and should be added as described in step 4.)

4. Pour the desired volume of media into appropriately sized tubes and sterilize in the autoclave at 118ºC. for 12

minutes. As an alternative, dissolve medium in 900ml of water, autoclave, and aseptically add 100ml of sterile 5-10% carbohydrate solution.

5. Cool tubes in the upright position.

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. Y11.

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.

Only small amounts of acid may be produced by *Neisseria* spp., as the organisms utilize carbohydrates oxidatively.

Aerobic incubation is necessary, as incubation in CO_2 may lead to erroneous results.

Lack of sufficient inoculum may lead to erroneous results.

Do not inoculate to the bottom of the tube; improper inoculation may lead to weak acid reactions, thus creating difficulty in test interpretation.

Peptone utilization results in the production of alkaline by-products. Prolonged incubation may result in a reversion reaction where alkaline by-products mask the acid by-products formed from carbohydrate utilization.

Because some strains of meningococci, primarily sulfonamide-resistant strains, do not produce acid from maltose, repeated subcultures to non-inhibitory media may be required to restore their maltose utilizing capability.

Rare strains of gonococci require additional compounds not provided by the CTA Media formulation and will, therefore, not grow on CTA Media.

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	
CTA Dextrose :**					

Listeria monocytogenes ATCC® 7644	E	18-48hr	15-30°C	Aerobic	Growth; motility (+), acid (+)
Neisseria gonorrhoeae ATCC® 43069	E	18-48hr	35°C	Aerobic	Growth; motility (-), acid (+)
Neisseria meningitidis ATCC® 13090	E	18-48hr	35°C	Aerobic	Growth; motility (-), acid (+)
Branhamella (*Moraxella*) *catarrhalis* ATCC® 25240	E	18-48hr	35°C	Aerobic	Growth; motility (-), acid (-)

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

** Expected results when product is prepared with 1% glucose.

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™ Cystine Tryptic Agar powder should appear homogeneous, free-flowing, and pink in color. The prepared media should appear clear, and red-pink 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. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

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

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

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

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IFU-10142[B]

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

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