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Instructions for Use

CTA (CYSTINE TRYPTIC AGAR) MEDIA

Cat. no. Y11	CTA Base, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y12	CTA with Dextrose, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y13	CTA with Lactose, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y14	CTA with Maltose, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y15	CTA with Mannitol, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y16	CTA with Sucrose, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y17	CTA with Sorbitol, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y20	CTA with Trehalose, 13x100mm Tube, 3ml Deep	20 tubes/box
Cat. no. Y24	CTA with Salicin, 13x100mm Tube, 3ml Deep	20 tubes/box

INTENDED USE

Hardy Diagnostics CTA Media are recommended for the determination of carbohydrate fermentation by fastidious organisms such as *Neisseria* spp. They are also used for the detection of bacterial motility and serve as a culture media for microorganism maintenance.

SUMMARY

Hardy Diagnostics CTA Media provide a nutritious basal medium composed of casein peptones, cystine, inorganic salts, phenol red, and agar. Necessary nutrients are supplied by the casein peptones and cystine. The inorganic salts serve as a source of essential ions. Phenol red is the pH indicator.

CTA Media supplemented with a 1% concentration of a specific carbohydrate are 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 masking the acid by-products with alkaline by-products with peptone degradation. The acid produced by carbohydrate fermentation causes a decrease in pH, causing 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.

CTA Base (Cat. no. Y11) medium is a carbohydrate-free medium that can be used as a holding medium for fastidious microorganisms at 25ºC.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	20.0gm
Sodium Chloride	5.0gm
L-Cystine	0.5gm
Sodium Sulfite	0.5gm
Phenol Red	17.0mg
Agar	3.5gm

Additionally, CTA Media with carbohydrate contain 10.0gm of the specified carbohydrate.

Final pH 7.5 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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.

PROCEDURE

Specimen Collection: Specimen collection is not applicable since this medium is not intended for primary isolation from clinical specimens. As a general rule, infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, the specimen should be inoculated onto an appropriate transport media and refrigerated until inoculation. Consult listed references for

information on specimen collection.[1-5]

Method of Use:

1. Prior to inoculation, allow the medium to equilibrate to room temperature.

2. Using an inoculating needle, obtain isolated colonies from an 18-24 hour culture. Colonies should be taken from a non-selective primary medium, e.g. Chocolate Agar, (Cat. no. E14).

3. Inoculate the medium by stabbing the center of the medium at least seven times to a depth of 1/4 inch from the bottom of the tube.

4. Inoculate a control tube of CTA Base in parallel with the carbohydrate based media.

5. With caps loose, incubate aerobically at 35ºC. for 24-48 hours.

6. Examine daily for evidence of carbohydrate fermentation. To assist in acid by-product detection, the carbohydrate based media should be compared to the CTA Base control tube.

INTERPRETATION OF RESULTS

A positive carbohydrate fermentation reaction is the development of a yellow color change in the inoculated area (stab line) of the medium.

A negative carbohydrate fermentation reaction is demonstrated by a red-pink or deep red color in the medium. Growth with a deep red to orange color in the medium indicates that the carbohydrate has not been utilized and that peptone degradation has occurred.

Positive motility is denoted when turbidity or cloudy growth extends from the line of inoculation. Growth only along the stab line is indicative of a negative motility test.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

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.

Some strains of gonococci require additional compounds not provided by the CTA Media formulations 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 loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, 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 Base:					
Neisseria meningitidis ATCC® 13090	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
Neisseria gonorrhoeae ATCC® 43069	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Dextrose:					
Neisseria gonorrhoeae ATCC® 43069**	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria meningitidis ATCC® 13090	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Listeria monocytogenes ATCC® 19115	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Lactose:					
Neisseria lactamica ATCC® 23970**	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria gonorrhoeae ATCC® 43069**	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
Moraxella catarrhalis ATCC®25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Maltose:					
Neisseria meningitidis ATCC® 13090**	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Mannitol:					
Enterococcus faecalis ATCC® 29212	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria gonorrhoeae ATCC® 43069	E	24-48hr	35°C	Aerobic	Growth; negative, no color change

Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Mannose:					
Klebsiella pneumoniae ATCC® 13883	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria gonorrhoeae ATCC® 43069	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Salicin:					
Enterococcus faecalis ATCC® 29212	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria gonorrhoeae ATCC® 43069	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Sorbitol:					
Listeria monocytogenes ATCC® 19115**	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA Sucrose:					
Neisseria sicca ATCC® 9913	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Neisseria gonorrhoeae ATCC® 43069**	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change
CTA with Trehalose:					
Klebsiella pneumoniae ATCC® 13883	E	24-48hr	35°C	Aerobic	Growth; positive acid (yellow)
Moraxella catarrhalis ATCC® 25240	E	24-48hr	35°C	Aerobic	Growth; negative, no color change

* 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.

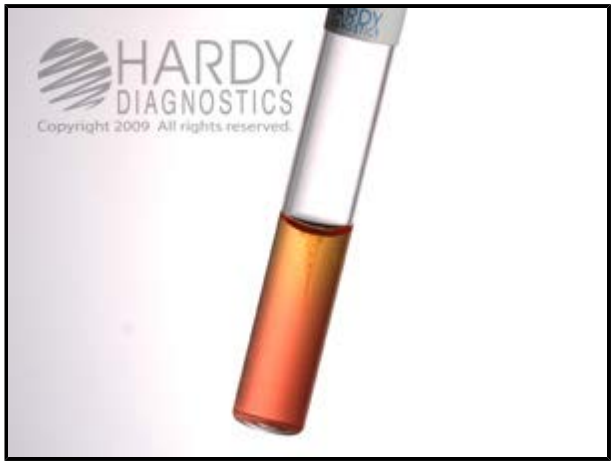
USER QUALITY CONTROL

End users of commercially prepared 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

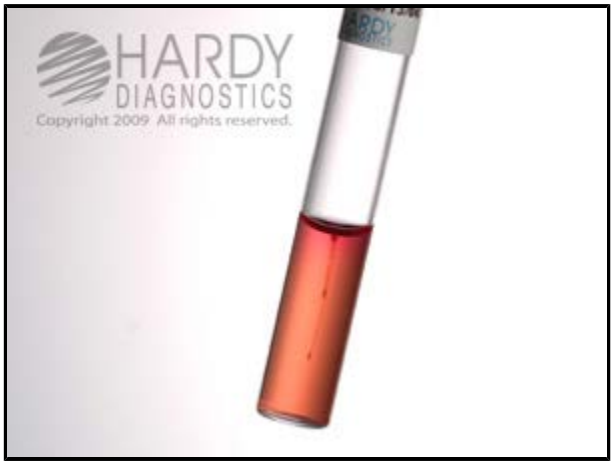
a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

CTA Media should appear clear, and red-pink in color.



Neisseria gonorrhoeae (ATCC® 43069) growing in CTA Media (Cat. no. Y12). Incubated aerobically for 24 hours at 35ºC.



Moraxella catarrhalis (ATCC® 25240) growing in CTA with Dextrose Media (Cat. no. Y12). Incubated aerobically for 24 hours at 35ºC.

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

HDQA 2207F [D]