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Instructions for Use

CRITERION™ TRYPTONE GLUCOSE EXTRACT (TGE) AGAR

Cat. no. C7160	CRITERION™ Tryptone Glucose Extract Agar	48gm
Cat. no. C7161	CRITERION™ Tryptone Glucose Extract Agar	500gm
Cat. no. C7162	CRITERION™ Tryptone Glucose Extract Agar	2kg
Cat. no. C7163	CRITERION™ Tryptone Glucose Extract Agar	10kg
Cat. no. C7164	CRITERION™ Tryptone Glucose Extract Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Tryptone Glucose Extract Agar is recommended for the cultivation and enumeration of microorganisms found in food, water, and dairy products.

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 1910, The American Public Health Association (APHA) issued its first publication entitled " *Standard Methods of Milk Analysis*," which recommended the use of Standard Nutrient Agar for estimating bacterial counts in milk and dairy products.[12] In 1935, Bower and Hucker outlined the composition of a medium for the bacteriological analysis of milk, and reported higher plate counts and larger colony sizes from routine milk grading laboratories.[1,2] Consequently, many researchers compared the performance of this medium, Tryptone Glucose Skim Milk Agar, to the more commonly used Nutrient Agar for estimating bacteria in milk samples and other dairy products.

In 1948, the American Public Health Association (APHA) adopted Tryptone Glucose Extract Agar for use in testing milk and dairy products; for many years, this medium became the standard for testing dairy and water products when supplemented with milk.[4] Tryptone Glucose Extract Agar is currently recommended by the *Compendium of Methods for the Microbiological Examination of Foods* for performing the heterotrophic plate count when testing bottled water.[5]

CRITERION™ Tryptone Glucose Extract Agar is a non-selective medium containing pancreatic digest of casein, beef extract, and glucose, which provide vital amino acids, nitrogen, carbon compounds, carbohydrates, essential minerals, and trace substances to promote the growth of a variety of microorganisms. Agar is the solidifying agent.

FORMULA*

Gram weight per liter:	24.0gm/L

Pancreatic Digest of Casein	5.0gm
Beef Extract	3.0gm
Glucose	1.0gm
Agar	15.0gm

Final pH 7.0 +/- 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 light beige.

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 24.0gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling to dissolve completely.

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

4. Cool to 45-50ºC. and aseptically dispense into sterile containers.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.

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.

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, pipettes, sterile diluent, spreaders, tubes, petri dishes, 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	
Escherichia coli ATCC® 25922	J	24-48hr	35°C	Aerobic	Growth
Staphylococcus aureus ATCC® 25923	J	24-48hr	35°C	Aerobic	Growth

* 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™ Tryptone Glucose Extract Agar powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear clear to slightly opalescent, and light to medium amber in color.

REFERENCES

1. Bowers and Hucker. 1935. The composition of media for the bacteriological analysis of milk. *Tech Bull*. N.Y. State Agr. Expt. Sta. No. 228.

2. Bowers and Hucker. 1936. Further studies of the composition of media for the bacteriological analysis of milk. *Am. J. of Public Health*. Vol. 26.

3. *Standard Methods of Milk Analysis*, 6th ed. 1934.

4. *Standard Methods for the Examination of Dairy Products*. APHA, New York, N.Y.

5. Kim and Feng. 2001. *In* Downes and Ito (ed.), *Compendium of Methods for the Microbiological Examination of Foods*, 4th ed. 1992. APHA, Washington, D.C.

6. *Standard Methods for the Examination of Water and Waste Water*. APHA, Washington, D.C.

7. Association of Official Agricultural Chemists, 10th ed. p. 737; 1965.

8. *Association of Official Analytical Chemists*. *Official Methods of Analysis*, AOAC, Washington, D.C.

9. The Official Compendia of Standards. *USP27-NF22*. United States Pharmacopeial Convention, Rockville, MD.

10. *Standard Methods for the Examination of Dairy Products*, 16th ed. 1992. APHA, Washington, D.C.

11. U.S. Food and Drug Administration. *Bacteriological Analytical Manual*. AOAC, Arlington, VA. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

12. Am. J. Pub. Hyg. 1910. 6:315-345.

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

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

HDQA 2207B [D]