IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

TRYPTONE GLUCOSE EXTRACT (TGE) AGAR

Cat. no. G115	Tryptone Glucose Extract Agar, 15x100mm Plate, 18ml	10 plates/bag

INTENDED USE

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

This product is not intended to be used for the diagnosis of human disease.

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]

Hardy Diagnostics 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

Ingredients per liter of deionized water:*

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

Final pH 7.0 +/- 0.3 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 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.

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection and processing of food, dairy, water samples, and other materials of sanitary significance.[1-8,10,11]

Prior to inoculation, warm prepared media to room temperature.

Spread Plate Method:

1. Prepare serial dilutions in sterile diluent to obtain 30-300 CFU per plate.

2. Aseptically inoculate agar surface with 0.1ml of a well mixed diluted sample.

3. Using a sterile spreader device, distribute the inoculum evenly over the agar surface.

4. Incubate plates aerobically for 48 +/- 2.0 hours at 35ºC.

INTERPRETATION OF RESULTS

Following incubation, examine the plates for growth. Count the number of colonies and express in number of colony forming units (CFU) per gram or milliliter of sample; take into account the dilution factor. If duplicate plates were set-up, express the average for the two plates in terms of the number of microorganisms per gram or milliliter of sample. Consult listed references for additional information on interpretation and enumeration of microbial growth on this medium.[3,4,6-11]

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.

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, swabs, pipettes, applicator sticks, spreaders, other culture media, 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	
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

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.

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* , 21st ed. 2005. APHA, Washington, D.C.

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

8. *Association of Official Analytical Chemists* . 1990. *Official Methods of Analysis* , 15th ed. AOAC, Washington, D.C.

9. The Official Compendia of Standards. 2008. *USP27-NF22* . United States Pharmacopeial Convention, Rockville, MD.

10. American Public Health Association. *Standard Methods for the Examination of Dairy Products* , APHA, Washington, D.C.

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

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

ATCC is a registered trademark of the American Type Culture Collection.

IFU-10826[A]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
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.

Copyright© 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207D [D]