IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

NUTRIENT AGAR

Cat. no. L20	Nutrient Agar, 16x100mm Tube, 5.5ml Slant	20 tubes/box
Cat. no. Q65	Nutrient Agar, 20x150mm Tube, 20ml Deep	20 tubes/box
Cat. no. Q84	Nutrient Agar, 20x150mm Tube, 20ml Pour Tube	100 tubes/box
Cat. no. W31	Nutrient Agar, 15x100mm Plate, 26ml (w/o plate label)	10 plates/bag
Cat. no. W51	Nutrient Agar, 15x100mm Plate, 26ml	10 plates/bag
Cat. no. W68	Nutrient Agar 1.5%, 15x100mm Plate, 26ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Nutrient Agar formulations are general purpose growth media recommended for use in the isolation and cultivation of nonfastidious microorganisms.

Cat. no. W31 is not intended to be used for the diagnosis of human disease.

SUMMARY

The American Public Health Association developed Nutrient Agar as a standard culture medium for growing a wide variety of microorganisms used in water, wastewater, food, and dairy testing.[2-4] The medium is still recommended today for the cultivation and maintenance of nonfastidious microorganisms from a broad spectrum of materials.[5,8,9,11-13]

Nutrient Agar is composed of pancreatic digest of gelatin and beef extract, which provide organic nitrogen compounds, long-chained fatty acids, carbohydrates, vitamins, and essential amino acids necessary for cell growth. Agar is the solidifying agent.

Nutrient Agar 1.5% is a modification of traditional Nutrient Agar and has a slightly more alkaline formulation. The medium also contains 0.8% sodium chloride, which helps maintain osmotic balance and protects against cell damage due to lysis.

FORMULA

Ingredients per liter of deionized water:*

Nutrient Agar:	
Pancreatic Digest of Gelatin	5.0gm
Beef Extract	3.0gm
Agar	15.0gm

Final pH 6.8 +/- 0.2 at 25°C.

Nutrient Agar 1.5%:	
Pancreatic Digest of Gelatin	5.0gm
Beef Extract	3.0gm
Sodium Chloride	8.0gm
Agar	15.0gm

Final pH 7.3 +/- 0.2 at 25°C.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store media in plates at 2-8°C. Media in tubes may be stored at 2-30°C. 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 and freezing.

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

For Cat. nos. L20, Q65, Q84, W51, and W68:

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 *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." 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.

For Cat. no. W31:

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.*

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PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection. [1-5,7-9,13] 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.

Method of Use: Inoculate and streak the specimen as soon as possible after collection. If the specimen to be cultured is on a swab, roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop. Incubate tubes or poured plates aerobically at 35-37°C for 18-24 hours. Examine for colonial morphology.

Plates are primarily used for the isolation of pure cultures from specimens containing mixed flora. Tubed media are primarily used for the cultivation and maintenance of pure cultures.

INTERPRETATION OF RESULTS

Consult listed references for the identification of colony morphology and further biochemical tests required for identification.[1-5,7-9,11]

LIMITATIONS

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

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

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus epidermidis ATCC ® 12228	A	18-24hr	35°C	Aerobic	Growth
Escherichia coli ATCC ® 25922	A	18-24hr	35°C	Aerobic	Growth

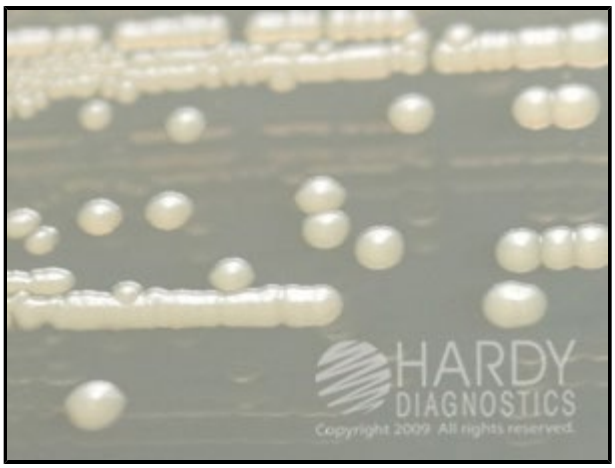
* Refer to the document "Inoculation Procedures for Media QC" for more information.

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 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

Nutrient Agar should appear slightly opalescent, and light amber in color. Nutrient Agar 1.5% should appear clear to slightly opalescent, and light amber in color.



Escherichia coli (ATCC ® 25922) colonies growing on Nutrient Agar (Cat. no. W51). Incubated aerobically for 24 hours at 35°C.

Staphylococcus epidermidis (ATCC ® 12228) colonies growing on Nutrient Agar (Cat no. W51). Incubated aerobically for 24 hours at 35°C.

Uninoculated plate of Nutrient Agar (Cat. no. W51).

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

3. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods,* APHA, Washington, D.C.

4. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater,* APHA, Washington, D.C.

5. Association of Official Analytical Chemists. *Official Methods of Analysis*^{sm}, AOAC, Washington, D.C.

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

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

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

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

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

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

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Ordering Information

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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 2207F [C]