IFU

Instructions for Use

STARCH AGAR

Cat. no. G294	Starch Agar, 15x100mm Plate, 18ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Starch Agar is used in determining starch hydrolysis by microorganisms.

SUMMARY

Many bacteria produce extracellular enzymes used to catalyze chemical reactions outside of the cell. In this manner, nutrient sources, such as starch, that are too large to be absorbed through the cell membrane can be broken down into smaller molecules and transported into the cell via diffusion.

The base medium of Starch Agar is Nutrient Agar, to which soluble starch has been added. Beef extract and pancreatic digest of gelatin provide nitrogen, vitamins, carbon and amino acids. Agar is the solidifying agent and starch is the carbohydrate. When starch is present, it forms a complex with Gram's iodine to yield a blue color. Organisms capable of hydrolyzing starch through amylase production will produce a clearing zone around the inoculum while the remaining medium is blue.

FORMULA

Ingredients per liter of deionized water:*

Potato Starch	10.0gm
Pancreatic Digest of Gelatin	5.0gm
Beef Extract	3.0gm
Agar	15.0gm

Final pH 6.8 +/- 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: Specimens should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is a delay in processing, specimens should be inoculated into an appropriate transport medium and refrigerated until inoculation. Consult listed references for more information.[2-5,7]

Method of Use:

1. Allow the plate to warm to room temperature prior to use.

2. Inoculate the medium with an 18-24 hour old isolated colony of the test organism using a single heavy streak or a spot inoculum of approximately 5mm diameter.

3. Incubate plates at 35ºC. for 24-48 hours in an aerobic atmosphere.

4. Following incubation, flood the streak or spot growth with Gram's iodine (Cat. no. I008N) to fully cover the inoculum and neighboring agar. Note: Iodine reacts with starch to form a dark blue-colored complex.

INTERPRETATION OF RESULTS

Any zone of clearing surrounding growth of the culture after the addition of Gram's iodine is positive for starch hydrolysis due to the production of amylase, an extracellular enzyme. Cultures negative for starch hydrolysis would lack a clearing zone.

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.

Colonies cannot be subcultured from the medium after the addition of Gram's iodine due to the oxidative nature of the reagent and the resulting cell death.

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, applicator sticks, other culture media, incinerators, Gram's iodine (Cat. no. I008N), 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	
Bacillus subtilis ATCC® 6633**	E	24-48hr	35°C	Aerobic	Growth; colorless zone demonstrating positive starch hydrolysis
Escherichia coli ATCC® 25922**	E	24-48hr	35°C	Aerobic	Growth; no colorless zone demonstrating negative starch hydrolysis

* 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

Starch Agar should appear slightly hazy, and colorless.

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.

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

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

HDQA 2207F [D]