

Instructions for Use

HardyCHROM™ GROUP A STREP AGAR

Cat. no. G337	HardyCHROM TM Group A Strep Agar, 15x100mm Plate, 18ml	10 plates/bag
---------------	-------------------------------------------------------------------	---------------

INTENDED USE

Hardy Diagnostics HardyCHROMTM Group A Strep Agar is a chromogenic medium recommended for the selective cultivation and differential isolation of Group A *Streptococcus* (*S. pyogenes*) from specimens based on colony color.

SUMMARY

Group A streptococci (GAS) are virulent pathogens that may cause infections such as strep throat (pharyngitis), scarlet fever, or impetigo. Timely detection, reporting, and antibiotic treatment decrease the risk of nonsuppurative sequelae. In addition, throat cultures are necessary to confirm bacterial pharyngitis by group A beta-hemolytic streptococci prior to antibiotic therapy. However, there may be problems detecting these strains as overgrowth of normal upper respiratory tract flora can obscure the presence of GAS and cause false-negative results. Additionally, delays in reporting can be compounded by attempting to re-isolate the organism.

Formulations using selective agents have been known to inhibit the growth of certain fastidious strains and causea slow recovery rate of GAS from patient cultures. Utilizing a nutritive basal medium may limit the inhibitoryeffects of selective agents. Chromogens added to the nutritive base also help differentiate the target organism and provide early presumptive identification and differentiation of GAS isolates.

HardyCHROMTM Group A Strep Agar contains organic nitrogen, particularly amino acids and long-chain polypeptides, from peptones and yeast extract. These, along with additional growth factors, render the medium highly nutritious and help to counteract selective agents added to inhibit unwanted flora. Carbohydrates are added to provide a source of energy and osmotic equilibrium is maintained by the addition of salts. Lastly, a unique chromogenic mixture aids by creating a color reaction in target strains to differentiate GAS isolates from other species that may be present in the sample.

FORMULA

Ingredients per liter of deionized water:*

Peptones	18.0g
Salts	8.0g
Yeast Extract	4.0g
Growth Factors	3.0g
Carbohydrate	3.0g
Selective Agents	2.2g

Chromogenic Mixture	1.7g
Agar	13.0g

Final pH 7.3 +/- 0.2 at 25°C.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-8°C 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: Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If a delay in processing is unavoidable, specimens should be inoculated into an appropriate transport media and refrigerated until inoculation.

Method of Use: Prior to inoculation, the medium should be brought to room temperature and the surface of the agar should be dry.

- 1. Inoculate the surface of the medium with the specimen and streak for isolation using the four quadrant technique. For testing a pure isolate, touch the top of a colony with a sterile wire loop and streak for isolation.
- 2. Incubate plates in an enhanced 5-10% CO₂ environment at 35°C for 24 hours. A CO₂ environment can be achieved using a CO₂ incubator or by using a sealed jar such as <u>Cat. no. 16000</u> in conjunction with a CO₂ generating sachet, <u>Cat. no. CD025A</u>. For incubating only a small number of plates (one to four 15x100mm plates), a pouch, sealing bar, and gas generating system can also be used, such as <u>Cat. no. AG020C</u>, <u>Cat. no. AN005C</u>, and <u>Cat. no. CD020C</u> to create an enriched CO₂ environment.

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

3. After incubation, examine plates for growth, typical colony morphology, and a red, red-brown, or red-orange colony pigment.

INTERPRETATION OF RESULTS

Typical colonies of group A streptococci (GAS) appear as small convex and red, red-brown, or red-orange colonies after 24 hours incubation. Non-GAS isolates should appear as blue, clear, or white colonies. Confirm colonies using latex agglutination (Cat. no. PL030HD) or other confirmatory method.

LIMITATIONS

Unless a provision is made to reduce oxygen tension, approximately 2% of group A streptococci may be missed if incubated aerobically. Aerobic incubation may also interfere with proper colony color development. Incubation in increased CO_2 is recommended.

If further biochemical or confirmatory testing involves a colorimetric reaction, it is recommended users validate the test method if using a colony direct from HardyCHROMTM Group A Strep Agar, or subculture an isolated colony to a non-selective plate to ensure chromogens from the medium do not interfere with the results of the test.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, incubators, 2.5L gas jar (<u>Cat. no. 16000</u>), 2.5L CO₂ sachet (<u>Cat. no. CD025A</u>), CO₂ pouch (<u>Cat. no. AM005C</u>), pouch sealing bars (<u>Cat. no. AN005C</u>), or pouch CO₂ sachet (<u>Cat. no. CD020C</u>), etc., as well as serological and biochemical reagents (<u>Cat. no. PL030HD</u>), are not provided.

QUALITY CONTROL

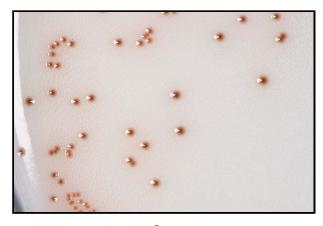
Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	Results
Streptococcus pyogenes ATCC® 19615	A	24hr	35°C	CO ₂ **	Growth; red-brown colonies
Streptococcus pyogenes ATCC® 12384	A	24hr	35°C	CO ₂ **	Growth; red to red-orange colonies
Streptococcus salivarius ATCC® 13419	В	24hr	35°C	CO ₂ **	Variable growth; blue colonies
Streptococcus oralis ATCC® 6249	В	24hr	35°C	CO ₂ **	Partial to complete inhibition; if growth, colonies should appear white or blue in color
Escherichia coli ATCC® 25922	В	24hr	35°C	CO ₂ **	Inhibited
Candida albicans ATCC® 10231	В	24hr	35°C	CO ₂ **	Inhibited

^{**} Atmosphere of incubation is enriched with 5-10% CO₂.

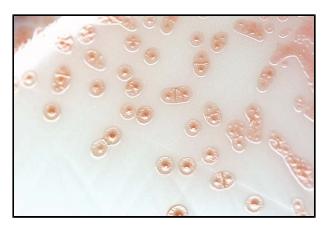
USER QUALITY CONTROL

PHYSICAL APPEARANCE

HardyCHROMTM Group A Strep Agar should appear opaque and white to off-white in color.



Streptococcus pyogenes (ATCC[®]19615) red-brown colonies growing on HardyCHROMTM Group A Strep Agar (Cat. no. G337). Incubated in CO₂ for 24 hours at 35°C.



Streptococcus pyogenes (clinical strain) red-orange colonies growing on HardyCHROMTM Group A Strep Agar (Cat. no. G337). Incubated in $\rm CO_2$ for 24 hours at 35°C.

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. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI formerly NCCLS), Wayne, PA.
- 3. Tille, P.M., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
- 4. Jorgensen et al. Manual of Clinical Microbiology. American Society for Microbiology, Washington, D.C.
- 5. Centers for Medicare & Medicaid Services (CMS). Individualized Quality Control Plan (IOCP).

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

IFU-000787[E]



1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658

Fax: (805) 346-2760 Website: <u>HardyDiagnostics.com</u>

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.