IFU

Instructions for Use

GROUP A BETA STREP AGAR

Cat. no. A72	Group A Beta Strep Agar, 15x100mm Plate, 17ml	10 plates/bag
Cat. no. GA72	Group A Beta Strep Agar, 15x100mm Plate, Reduced Stacking Ring, 17ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Group A Beta Strep Agar is an enriched media for the selective isolation of group A streptococci (*Streptococcus pyogenes*) from clinical specimens, especially from respiratory specimens.

SUMMARY

Group A Beta Strep Agar is a selective media for isolation of group A streptococci (GAS) from respiratory sources. Group A streptococci are virulent pathogens and timely detection, reporting and antibiotic treatment decreases the risk of non-suppurative sequela.

The recovery of group A beta-hemolytic streptococci from throat swabs is a widely applied and well-accepted method. However, problems can occur with routine cultures because over growth of normal upper respiratory tract flora will obscure the presence of GAS and result infalse-negative results. Additionally, delays in reporting can be caused by attempting to re-isolate the organism. Other formulations using selective agents resulted in inhibition and slow growth rate of the group A streptococci. By utilizing a nutritive growth medium as the base, inhibitory effects of the selective agents on group A streptococci are almost entirely eliminated.

Tryptic Soy Agar is the basal medium for Selective Strep Agar. Organic nitrogen, particularly amino acids and long-chained peptides are supplied by the combination of casein and soy peptones. This combination renders the medium highly nutritious. Osmotic equilibriumis maintained by sodium chloride. Sheep blood (5%) has been added to facilitate growth and to detect hemolytic activity. Selective agents are added to inhibit most other normal respiratory flora including *Neisseria* spp., most Enterobacteriaceae, diptheroids, *Pseudomonas* species, and *Streptococcus mitis*. *Streptococcus pneumoniae* and streptococci groups C, F, and G are also inhibited.

FORMULA

Ingredients per liter of deionized water:*

Casein Peptone	15.0gm
Soy Peptone	5.0gm
Sodium Chloride	5.0gm
Selective Agents	35.5mg
Sheep Blood	50.0ml
Agar	15.0gm

Final pH 7.3 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as needed to meet performance requirements.

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), hemolysis, 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 form excessive heat and cold. If there is to be a delay in processing, 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. Inoculate media with specimen and streak for isolation using four quadrant technique. For testing an isolated organism, touch the top of a colony with a sterile wire loop and streak for isolation. Stab the medium several times with the inoculating loop in the area of heavy inoculation in order to create anaerobic conditions to stimulate maximum expression of beta-hemolysis. Incubate aerobically at 35ºC. for 24-48 hours. Plates may also be incubated in 5-10% CO_2 or anaerobically for better development of hemolytic reactions. Examine plate for growth and typical colony morphology and hemolysis.

INTERPRETATION OF RESULTS

Typical colonies of group A streptococci appear small, white, and convex surrounded by a zone of beta-hemolysis after 24-48 hours of incubation. Refer to listed references for more information.[1,2]

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.

Unless a provision is made to reduce oxygen tension, approximately 2% of group A streptococci may be missed if incubated aerobically. It is recommended that several stabs be made into the medium upon inoculation.[1] Incubation in increased CO_2 or anaerobically is recommended.

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 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	
Streptococcus pyogenes ATCC® 19615	A	24hr	35°C	CO_2**	Growth with beta-hemolysis
Streptococcus mitis ATCC® 6249	B	24hr	35°C	CO_2**	Partial to complete inhibition
Escherichia coli ATCC® 25922	B	24hr	35°C	CO_2**	Partial to complete inhibition
Staphylococcus epidermidis ATCC® 12228	B	24hr	35°C	CO_2**	Partial to complete inhibition

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

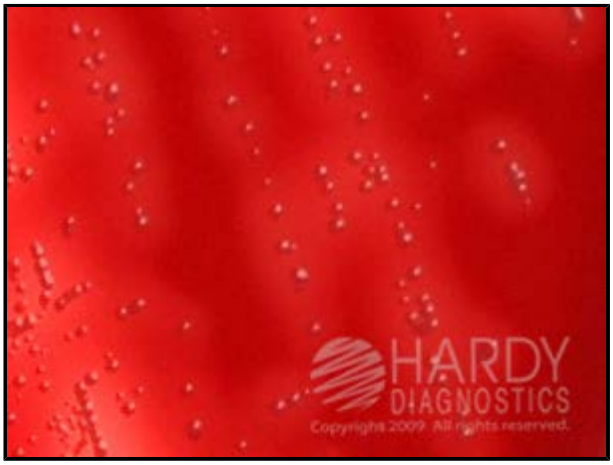
** Atmosphere of incubation is enriched with 5-10% CO_2

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

Group A Beta Strep Agar should appear opaque, and cherry red in color.



Streptococcus pyogenes (ATCC® 19615) colonies growing on Group A Beta Strep Agar (Cat. no. A72). Incubated in CO_2 for 24 hours at 35ºC.

Escherichia coli (ATCC® 25922) growth inhibited on Group A Beta Strep Agar (Cat. no. A72). Incubated aerobically for 24 hours at 35ºC.

REFERENCES

1. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

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

3. 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.

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

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

IFU-10458[D]

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.

HDQA 2207F [D]