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Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

anaeroGRO™
Pre-Reduced Anaerobic Culture Media

# ANAEROBIC TRANSPORT MEDIA SYSTEMS

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| Cat. no. AG25H | Anaerobic Transport Medium, 15x103mm Tube with Hungate Septum Cap and No Swabs, 7ml | 20 tubes/box |
| Cat. no. S1200 | Starswab™ Anaerobic Transport Medium, Sterile Surgery Pack with Hungate Septum Cap and No Swabs, 7ml | 100 tubes/case |
| Cat. no. S120D | Starswab™ Anaerobic Transport Medium, Sterile Surgery Pack with Two Rayon Swabs and Hungate Septum Cap, 7ml | 100 tubes/case |

## INTENDED USE

Hardy Diagnostics AnaeroGRO™ Anaerobic Transport Medium is recommended for use in maintaining the viability of obligate anaerobic microorganisms, as well as aerobic and facultatively anaerobic bacteria, during transport. Starswab™ Anaerobic Transport Systems are enclosed, self-contained, ready-to-use, sterile surgery packs, available with or without swabs, for maintaining anaerobic transport of clinical specimens.

## SUMMARY

Clinical specimens containing obligate anaerobic bacteria should be protected from the toxic effects of atmospheric oxygen until proper processing in the laboratory can be achieved.[3] Routine use of optimal transport mechanisms, such as reduced or "gassed" collection tubes, is strongly recommended in order to maintain viability of anaerobic microorganisms.[2] Moreover, research shows that the survival of aerobic and facultative microorganisms may also be enhanced when transported using an oxygen-free environment.[5] Studies show that culture viability can be maintained for at least 48 hours at 22-25ºC. (72-77ºC.) using this type of transport system.[11]

AnaeroGRO™ Anaerobic Transport Media Systems contain sodium thioglycollate as a reducing agent. Resazurin is an oxygen indicator that will turn pink if the anaerobic condition within the tubes has been compromised. A pink band (up to 2mm) on the top portion of the medium in an unopened tube is considered acceptable, and may result when the tubes are agitated, such as during shipping and transport. The recessed butyl rubber stopper (Hungate) and screw cap design facilitate the transfer of liquid specimens to the vial through the rubber stopper using a syringe or needle device.

AnaeroGRO™ Anaerobic Transport Media Systems are manufactured for and distributed by Hardy Diagnostics. They are packaged in an oxygen-free, reduced state to prevent the formation of toxic oxidized by-products that may damage obligate anaerobes and inhibit the growth of more fastidious species. Use of AnaeroGRO™ Anaerobic Transport Media Systems facilitate the preservation of obligately anaerobic species cultured from body sites during transport and prior to processing in the laboratory.

## FORMULA

Modified, buffered, semi-solid Cary Blair medium supplemented with L-cysteine and resazurin. The medium is balanced, reduced and non-nutritive and was devised to improve the survival of clinical pathogens during transport without stimulating an over-growth of organisms.[11]

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

## STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC. away from direct light. Media should not be used if there are any signs of deterioration, 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 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.

The plates must be inoculated **immediately** after opening the AnaeroGRO™ pouch. After inoculation, the plates must be placed **immediately** into an anaerobic atmosphere (pouch, jar, or chamber) to ensure optimal growth of anaerobic bacteria.

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 *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.

## PROCEDURE

Information on specimen collection and transport may be found in standard reference materials.[2-10,12]

Peel open the sterile package, if applicable. Remove the swab, if applicable, and collect the specimen. Remove the tube cap and insert the swab into the tube: submerge the swab tip completely into the transport medium and break the scored shaft on the swab. Quickly replace and tighten the cap. Transport media to the laboratory promptly for further processing.

Liquid specimens should be injected directly into the tube through the rubber septum on the Hungate cap. Gently invert the contents of the tube to ensure sample and transport media have been thoroughly combined. Do not shake.

## INTERPRETATION OF RESULTS

Consult standard references for expected results upon culture.[2-10,12]

Refer to the *Wadsworth-KTL Anaerobic Bacteriology Manual* or other texts for more information on identification of anaerobes.[8]

## LIMITATIONS

Clinical specimens should be inoculated to an appropriate anaerobic culture medium upon receipt in the laboratory. After inoculation, specimens should be placed **immediately** into an anaerobic atmosphere (pouch, jar, or chamber) to ensure optimal growth of obligate anaerobic bacteria.

Some microorganisms may survive for a limited time in transport media and should be transported to the laboratory as soon as possible after specimen collection. Avoid extremes in temperature during transport. Specimens with less than 100,000 colony forming units (CFU) per ml may not survive for more than 24 hours.

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 (except Cat. no. S120D), applicator sticks, syringes, needles, forceps, other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

## QUALITY CONTROL

Each lot of AnaeroGRO™ Anaerobic Transport Media Systems is subject to the following Quality Control evaluation as outlined by Starplex Scientific, Inc.:

1. Sterility - Representative samples of each lot are tested for sterility using Fluid Thioglycollate Broth and Tryptic Soy Broth.

2. Performance - Samples of each lot are challenged by standard microorganism inocula and tested for recovery on appropriate plated media according to the CLSI (formerly NCCLS) M40-A document: *Quality Control of Microbiological Transport Systems*; Approved Standard.

3. Physical appearance - Medium level, medium integrity, pink line formation, and label information are some of the physical attributes of the products that are inspected.

4. pH - Each lot of product is checked against the standard pH of 7.25 +/- 0.25.

## 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

AnaeroGRO™ Anaerobic Transport Media Systems should appear clear, 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. Atteberry, H.R., and S.M. Finegold. Combined screw-cap and rubber-stopper closure for Hungate tubes (pre-reduced anaerobically sterilized roll tubes and liquid media). *Appl. Microbiol.*; 18:558-561.

3. Holdeman, L.V., E.P. Cato, and W.E.C. Moore. *Anaerobe Laboratory Manual*, 4th ed. Virginia Polytechnic Institute and State University, Blacksburg, VA.

4. Engelkirk, P.G., J. Duben-Engelkirk, and V.R. Dowell, Jr. *Principles and Practice of Clinical Anaerobic Bacteriology*. Star Publishing Company, Belmont, CA.

5. Finegold, S.M., V.L. Sutter, H.R. Attebery, and J.E. Rosenblatt. Isolation of Anaerobic Bacteria *in Manual of Clinical Microbiology*, 2nd. ed. American Society for Microbiology. Washington, D.C.

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

8. Jousimies-Somer, H.R., S.P. Citron, D. Baron, E.J. Wexler, and H.M. Finegold. *Wadsworth-KTL Anaerobic Bacteriology Manual*. Star Publishing Company, New York, N.Y.

9. Versalovic, J., 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. Starplex Scientific, Inc. internal evaluation.

12. Sutter, V.L., H.R. Attebery, J.E. Rosenblatt, K.S. Bricknell, and S.M. Finegold. *Anaerobic Bacteriology Manual*. Extension Division, University of California, Los Angeles.



This document is provided for general product information only. It does not replace the manufacturer's product insert. Always refer to the actual product insert for procedural use and for the most recent information.

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



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