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Instructions for Use

CAMPYGEN™ AND ANAEROGEN™ GAS GENERATING SYSTEMS

Cat. no. AN25US	AnaeroGen™ (for 2.5L jar)	10 sachets/box
Cat. no. AN35US	AnaeroGen™ (for 3.5L jar)	10 sachets/box
Cat. no. CN025A	CampyGen™ (for 2.5L jar)	10 sachets/box
Cat. no. CN035A	CampyGen™ (for 3.5L jar)	10 sachets/box

INTENDED USE

Oxoid CampyGen™ and AnaeroGen™ are self-contained gas generating systems that are used in closed environmental chambers to rapidly generate microaerophilic and anaerobic atmospheres, respectively. CampyGen™ is recommended for use in producing microaerophilic conditions which are essential for the isolation and growth of *Campylobacter* while AnaeroGen™ is recommended for establishing an oxygen depleted environment essential for obligate anaerobic microorganisms.

SUMMARY

Nutrients, moisture, pH, temperature, and atmosphere are all factors which are important in the growth of microorganisms. CampyGen™ and AnaeroGen™ are gas generating systems that establish the necessary environments for organisms that require reduced and depleted oxygen concentration. The generators produce microaerophilic and anaerobic atmospheres without the need for catalyst or the addition of water. Each generator is activated immediately upon removal from the mylar pouch.

When placed in a sealed jar, both gas generating sachets produce carbon dioxide simultaneous to rapidly absorbing the atmospheric oxygen in the jar. The AnaeroGen™ sachet will reduce the oxygen level in the jar to below 1% within 30 minutes and results in 9-13% carbon dioxide. The CampyGen™ sachet produces 5% O_2, 10% CO_2, and 85% N_2. Unlike other gas generating systems, CampyGen™ and AnaeroGen™ do not produce hydrogen gas, thereby eliminating the chance of explosion.

The active component within each gas generating paper cachet is ascorbic acid. Although the reaction of ascorbic acid with oxygen is exothermic, the temperature of the paper sachet will not exceed 65ºC.

FORMULA

Ascorbic acid is the reactive component within each paper sachet.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25ºC. Products should not be used if there are any signs of deterioration (tears), or if the expiration date has passed. Protect from excessive heat 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 quality control incubation times as stated below.

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 avoid exposure to oxygen and 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 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: Consult listed references for information on proper specimen collection.[2-5]

Method of Use:

1. Place the inoculated media plates in the appropriate jar. It is recommended that disposable plastic petri dishes of the vented variety be used in order to aid in the transfer of gas between the interior and exterior of the plates.

2. Tear open the foil pouch at the indicated tear-nick and remove the paper sachet from within.

3. Immediately place the paper sachet in the plate carrier clip within the jar. It is recommended that an Anaerobic Indicator Strip (Cat. no. BR55) be used with the AnaeroGen™ gas generator. The indicator strip should be placed in the jar and used as a visual check that the anaerobic conditions have been achieved and maintained. The indicator strip will turn pink upon exposure to air and will become colorless once oxygen is depleted in the sealed jar.
Note: Indicator Strip must be placed in the jar and the lid immediately attached without delay, in order for the strips to perform properly.

Note: Upon exposure to air, the paper sachet will become warm to the touch.

4. Seal the jar lid immediately.

Note: Do not exceed one minute from the time taken between opening the foil sachet and sealing the jar. Extended exposure to air results in loss of reactivity and microaerophilic/anaerobic conditions may not be achieved in the jar.

5. Remove the plates after the appropriate incubation period and examine for growth and typical colonial morphology.

If further incubation is required then a fresh sachet must be used following steps 2-5 above.

6. Discard exhausted sachets with the appropriate laboratory waste.

Note: Upon removal of the AnaeroGen™ after incubation, the paper sachet will retain a small amount of reactivity and will warm up. The sachets should therefore be allowed to cool to room temperature before disposing.

INTERPRETATION OF RESULTS

Consult listed references for the identification of colony morphology and further biochemical tests required for identification.[2-5]

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.

It is essential that the gas generating paper sachet be placed and sealed in the jar within one minute of its removal from the outer foil sachet. Extended exposure to air will result in loss of reactivity and full microaerophilic/anaerobic conditions may not be achieved.

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, slides, staining supplies, microscopes, incinerators, incubation jars, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

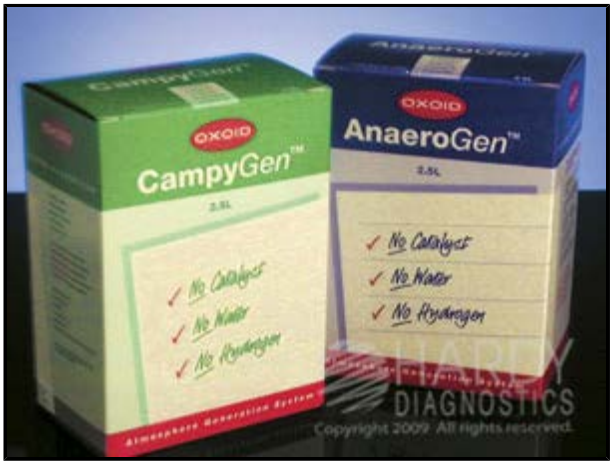
Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	**Reaction**
CampyGen™:	
Campylobacter jejuni ATCC® 33291	Growth
AnaeroGen™:	
Clostridium perfringens ATCC® 13124	Growth

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

PHYSICAL APPEARANCE

CampyGen™ and AnaeroGen™ should appear as white paper sachets individually packaged within a foil pouch.



CampyGen™ and AnaeroGen™ Gas Generating Systems.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3A; Quality Control and Quality Assurance Practices in Clinical Microbiology* , 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. 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. Van Horn, K.G., et al. 1997. *Journal of Clinical Microbiology* ; Vol. 35, No. 8, p. 2170-2173. American Society for Microbiology.

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 most recent product information.

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

HDQA 2207A [D]