

Venturi Transystem

AMIES TRANSPORT SWAB SYSTEM

Quantity: 50 pieces per pack / 500 pieces per case

PRODUCT INFORMATION & HOW TO USE SWAB GUIDE

Copan Venturi Transystem (Amies Transport Swab System)

Amies Agar Gel Medium Without Charcoal

Amies Agar Gel Medium With Charcoal

Intended Use

Copan Venturi Transystem are sterile ready-to-use systems intended for the collection, transport, and preservation of clinical specimens for bacteriological examinations.

Description of Applicator Stick	Intended use / sampling sites
Regular single plastic	Mouth, throat, vagina and wounds
Dual plastic	Mouth, throat, vagina and wounds
Minitip narrow paper shaft	Pediatric
Minitip narrow plastic shaft	Eye, ENT, nasopharynx, urogenital and pediatric
Aluminum wire	Eye, ENT, nasopharynx, urogenital and pediatric
Flexible twisted aluminum wire	Nasopharynx

Summary and Principles

One of the routine procedures in the diagnosis of bacterial infections involves the collection and safe transportation of a clinical specimen from the patient to the laboratory. This can be accomplished using the Copan Venturi Transystem. Each Venturi Transystem unit comprises a sterile peel pouch containing a swab applicator used to collect the sample and a tube containing transport medium into which the swab applicator is placed after sampling.

Copan Venturi Transystem is available with a range of different transport media. Amies Medium Without Charcoal and Amies Medium With Charcoal are non-nutritious, buffered with phosphate, and provide a reduced environment, due to their formulation with sodium thioglycollate¹. Organisms in the sample material are protected from drying by moisture in the transport medium. The medium is designed to maintain the viability of organisms during transit to the laboratory. Survival of fastidious bacteria such as *Neisseria gonorrhoeae* can be prolonged due to the presence of charcoal in Amies Medium With Charcoal.

The Venturi Transystem is available with different applicator shafts which facilitate the collection of specimens from various sites of the patient as described in the table above. For specific recommendations about collection of specimens for microbiology analysis and primary isolation techniques, consult the following references: Cumitech⁹, Manual of Clinical Microbiology³ and the Clinical Microbiology Procedures Handbook⁴.

The transport tube has an hour glass shaped construction designed to keep the 6cm deep agar gel medium column intact. The tube construction reduces the surface area for diffusion of air into the column of agar. During final packaging of the swab and tube, air is removed from the pouch by vacuum and nitrogen gas is flushed inside. Venturi Transystem pouches are made of a plastic film which retards the penetration of atmospheric air into the product. In addition to this, Venturi Transystem pouches are packed in an outer metallic foil pack which provides further barrier to the penetration of atmospheric oxygen. Plastic film pouch and metallic foil pack minimize the oxidation effect and evaporation of water from the product to enhance product stability.

Once a swab sample is collected it should be placed in the tube of medium and transported to the laboratory as soon as possible and cultured onto appropriate primary isolation medium (Blood Agar, Laked Blood Agar, MacConkey etc.)

Reagents

The nominal formula for each medium is as follows:

Amies Agar Gel Transport Medium Without Charcoal

Sodium Chloride	3.0g
Potassium Chloride	0.2g
Calcium Chloride	0.1g
Magnesium Chloride	0.1g
Monopotassium Phosphate	0.2g
Disodium Phosphate	1.15g
Sodium Thioglycollate	1.0g
Bacteriological Agar	7.5g
Distilled Water	1 liter

Amies Agar Gel Transport Medium With Charcoal

Sodium Chloride	3.0g
Potassium Chloride	0.2g
Calcium Chloride	0.1g
Magnesium Chloride	0.1g
Monopotassium Phosphate	0.2g
Disodium Phosphate	1.15g
Sodium Thioglycollate	1.0g
Charcoal	10.0g
Bacteriological Agar	7.5g
Distilled Water	1 liter

Technical Notes

Amies medium formula contains Sodium Thioglycollate, an important component for the performance of the product and the maintenance of organism viability. Sodium thioglycollate has a natural sulfur-like odor. It may be possible to detect this sulfur odor momentarily when first opening the swab peel pouch. This odor is a perfectly normal and completely harmless characteristic. From time to time the medium containing tube may demonstrate some yellow coloration to varying degrees. This coloration is natural and a well-known phenomenon

associated with the medical grade polypropylene used and the process of ionizing irradiation and has no adverse effect on the quality or performance of the product.

Precautions

- Do Not Freeze – store in a cool dry place
- For In Vitro Diagnostic Use.
- Copan Venturi Transystem is certified as a Class IIa device under the classification terms of the European Medical Device Directive EC 93/42. In particular, the swab applicator is qualified for short transient contact with the patient in order to collect a specimen. This short contact is made with the patient's external surfaces or internal surfaces via normal body orifices such as the nose, throat or vagina or via surgical wounds.
- When collecting swab samples from patients, care should be taken not to use excessive force or pressure which may result in breakage of the swab shaft.
- The fiber attachment to the applicator stick is qualified to withstand short transient contact with the patient in order to collect the sample; prolonged contact must be avoided as this may result in the detachment of fiber.
- Directions for use must be followed carefully. The manufacturer can not be held responsible for any unauthorized or unqualified use of the product.
- When the swab sample is cultured in the laboratory, if the procedure necessitates that the applicator(s) be placed in a tube of culture broth, great care should be taken in detaching the applicator stick from the cap to eliminate any risk of splashes or aerosols. If it is necessary to cut the applicator stick, sterile scissors should be used to facilitate a safe and clean break.
- Observe aseptic techniques when using the product.
- It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens should be handled with the appropriate precautions.
After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.
- Swab sample processing should be performed inside a protective safety cabinet or protective hood. Protective laboratory clothing and eyeglasses should be worn at all times when processing culture swab samples.
- The product must be used as directed it must not be subjected to any additional chemical or physical sterilization or micro-cidal or micro-static processes prior to use as this will compromise the performance and function of the product.

Sodium Thioglycollate – Technical Note

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Storage and Stability

Store Venturi Transystem at 5 – 25°C. Do not freeze or overheat. Do not use after the expiration date which is clearly printed on the outer box, each pack of swabs, each individual sterile swab pouch and the specimen transport tube label. If product is stored incorrectly it can

compromise the performance and invalidate the product specifications and performance claims.

Product Deterioration

The contents of unopened or undamaged units are guaranteed sterile. Do not use if they show evidence of damage, dehydration or contamination. Do not use if expiration date has passed.

Materials Supplied

Fifty (50) units of sterile Venturi Transystem contained in a metallic foil pack. Each individual swab pouch contains an applicator and a plastic tube containing transport medium.

Materials Required But Not Supplied

Appropriate materials for isolating, differentiating and culturing aerobic and anaerobic bacteria. These materials include culture media plates or tubes, and incubation systems, gas jars or anaerobic workstations.

Directions for Use

The directions for use are printed on each Venturi Transystem unit along with descriptive diagrams. Directions for use are summarized as follows:

- a. Peel open the Venturi Transystem sterile pouch at the point marked "Peel Here".
- b. Remove cap from transport tube.
- c. Remove applicator swab and collect specimen. During specimen collection, the applicator tip should only touch the area where the infection is suspected to minimize potential contamination.
- d. Place applicator swab in transport tube and replace cap firmly to completely seal.
- e. Record patient's name and information on tube label.
- f. Send specimen to the laboratory for immediate analysis.

Precaution - When collecting swab samples from patients, care should be taken not to use excessive force or pressure which may result in breakage of the swab shaft.

Quality Assurance

All raw materials, swab components and batches of finished product are subjected to rigorous quality control. As part of these test procedures, a panel of control organisms is used to test the performance of Venturi Transystem. Certificates of sterility and quality assurance, which describe some of the QC procedures, are available on request from Copan. For those laboratories wishing to test the performance of transport swabs a simple test protocol is described in the Quality Control section in Clinical Microbiology Procedures Handbook⁴.

Results

The survival of bacteria in a transport medium depends on many factors. These include the type of bacteria, duration of transport, storage temperature, concentration of bacteria in the sample and formulation of the transport medium. Copan Venturi Transystem will maintain viability of many microorganisms for 24 to 48 hours. For fastidious bacteria, such as

Neisseria gonorrhoeae, *Streptococcus pneumoniae* and anaerobes, swab specimens should be plated directly onto culture medium or transported immediately to the laboratory and cultured within 24 hours. Published studies have demonstrated that Copan Venturi Transystem Amies Medium transport swabs are able to maintain the viability of clinically important aerobic and anaerobic bacteria for 24 hours⁵⁻¹⁵.

Limitations

Venturi Transystem Amies Medium Without Charcoal and Amies Medium With Charcoal are intended for the collection and transport of bacteriological samples only. Preferred samples for anaerobic investigations are: tissue samples obtained during surgical procedures, biopsies from tissue or bone, fluid, pus or aspirates collected using a syringe. For detailed information and recommendations for transporting fluid and tissue specimens for anaerobic culture refer to specific publications^{3,4,16}. Samples containing viruses or chlamydia should be collected and transported using alternative specific transport systems.

Transport gel media constituents, staining reagents, immersion oil, glass slides and specimen themselves may sometimes contain non viable organisms visible upon gram staining.

Performance Characteristics

Recovery studies were performed using Copan Venturi Transystem Amies Medium Without Charcoal and Amies Medium With Charcoal products with a variety of aerobic and anaerobic organisms. Swabs were dosed with inoculum and inserted into the transport tube containing medium. The tubes were stored at room temperature prior to subculturing onto appropriate media.

Aerobic organisms evaluated were *Escherichia coli* (NCTC 9001 and ATCC 25922), *Haemophilus influenzae* (ATCC 10211), *Neisseria gonorrhoeae* (ATCC 43069), *Neisseria meningitidis* (NCTC 10025 and ATCC 13090), *Pseudomonas aeruginosa* (NCTC 9332 and ATCC 27853), *Staphylococcus aureus* (NCTC 5532 and ATCC 25923) and *Streptococcus pyogenes* (ATCC 19615). Anaerobic organisms evaluated were *Bacteroides fragilis* (ATCC 25285), *Bacteroides levii* (ATCC 29147), *Bacteroides thetaiotaomicron* (ATCC 29741), *Bacteroides vulgatus* (ATCC 8482), *Clostridium difficile* (ATCC 9689), *Clostridium perfringens* (ATCC 13124), *Clostridium sporogenes* (ATCC 3584), *Clostridium tertium* (ATCC 19405), *Fusobacterium necrophorum* (ATCC 25286), *Fusobacterium nucleatum* (ATCC 25586), *Peptostreptococcus anaerobius* (ATCC 27337), *Peptostreptococcus magnus* (ATCC 29328), *Porphyromonas gingivalis* (ATCC 33277), *Prevotella melaninogenica* (ATCC 25845), and *Propionibacterium acnes* (ATCC 6919). All organisms tested remained viable for more than 24 hours when maintained at room temperature.

References

1. Amies C.R. A modified formula for the preparation of Stuart's medium. Canadian Journal of Public Health, July 1967. Vol. 58, 296 - 300.
2. Isenberg H. D., Schoenkencht F.D. and Von Graeventiz A. Cumitech 9, Collection and processing of bacteriological specimens. Coordinating editor, S. J. Rubin. American Society for Microbiology, Washington, DC, 1979.

3. Balows A., Hausler, Jr. W. J., Herrmann K.L., Isenberg H. D., Shadomy H.J. Manual of Clinical Microbiology. Fifth Edition. American Society for Microbiology, Washington DC, 1991.
4. Isenberg H. D. (Editor in Chief). Clinical Microbiology Procedures Handbook. American Society for Microbiology, Washington DC, 1992.
5. Zavala M. K., Citron D. M., Goldstein E. J. C. Evaluation of a novel specimen transport system for anaerobic bacteria. Clinical Infectious Diseases, 1997; Vol. 25 (Suppl 2): S132 – 3.
6. Perry J.L. Assessment of swab transport systems for aerobic and anaerobic organism recovery. Journal of Clinical Microbiology, May 1997. Vol. 35, 1269 – 1271.
7. Van Horn K., Tóth C. and Wegienek J. Viability of aerobic microorganisms in four swab systems. Poster Session 249/C Abstract C-436. 98th General Meeting of American Society for Microbiology, Atlanta, GA, May 1998.
8. Van Horn K., Tóth C. and Warren K. Comparison of Copan Amies agar swab and BBL Port-a-cul swab for recovery of anaerobic bacteria. Poster Session 249/C Abstract C-437. 98th General Meeting of American Society for Microbiology, Atlanta, GA, May 1998.
9. Arbique J.C, Forward K. R., and Le Blanc J. Evaluation of four commercial transport media for the survival of Neisseria gonorrhoeae. Diagnostic Microbiology and Infectious Disease, 2000 Vol. 26, 163-168.
10. Van Horn K., Warren K., and Tóth C. Comparison of four swab systems for the recovery of anaerobic bacteria. Abstract C-32. 99th General Meeting of American Society for Microbiology, Chicago, IL, May 1999.
11. Olsen C. C., Schwebke J. R., Benjamin W. H., Beverly A., and Waites K. B. Comparison of direct inoculation and Copan transport systems for the isolation of Neisseria gonorrhoeae from endocervical specimens. Journal of Clinical Microbiology Vol. 37, No. 11, Nov. 1999, p. 3583 – 3585.
12. Citron D. M., Warren Y. A., Hudspeth M. K. and Goldstein E. J. C. Survival of aerobic and anaerobic bacteria in purulent clinical specimens maintained in Copan Venturi Transystem and Becton Dickinson Port-a-Cul transport systems. Journal of Clinical Microbiology Vol. 38, No. 2. Feb. 2000, p. 892-894.
13. Thompson D. S., French S. A. Comparison of commercial Amies transport systems with in-house Amies medium for recovery of Neisseria gonorrhoeae. Journal of Clinical Microbiology Vol. 37, No. 9. Sept. 1999, p. 3020-3021.
14. Hetchler C., Brown C., and Galbraith J. Comparison of 3 Amies Gel transport systems for the recovery of 12 clinically significant organisms. Abstract C-152. 100th General Meeting of American Society for Microbiology, Los Angeles, CA, May 2000.
15. Hindiyeh M., Acevedo V., Croft A., and Carroll K. Comparison of the new Starplex StarSwab II and the new Copan Vi-Pak Amies Agar Gel collection and transport swabs with BBL Port-a-Cul for the maintenance of anaerobic and fastidious aerobic organisms. Abstract C-154. 100th General Meeting of American Society for Microbiology, Los Angeles, CA, May 2000.
16. Summanen P., Baron E.J., Citron D. M., Strong C.A., Wexler H.M. and Finegold S. M. Wadsworth Anaerobic Bacteriology Manual. Fifth Edition. Star Publishing Company, Belmont, CA, 1993.

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