

Copan

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Transsystem™

Instructions for Use

CE 0123

Copan Transystem™ Instructions for use

Copan Swab Applicators - Technical Notes

Technical Note: Copan swab applicators are manufactured using natural fibers that have not be treated with chemical additives, whitening agents or bleaches as these substances can compromise the viability of microorganisms and performance of the product. Because Copan use natural fibers the appearance of the swab tip can be slightly yellow, this is perfectly normal and has no affect, whatsoever, on product performance or patient safety.

Sodium Thioglycollate - Technical Note

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.

Amies Agar Gel Medium Without Charcoal - Amies Agar Gel Medium With Charcoal

REF. NUMBER*	TRANSPORT MEDIUM	APPLICATOR SWAB TYPE	INTENDED USE/SAMPLING SITE**
108C.USE / 108C	amies agar gel without charcoal	regular single plastic applicator	mouth, throat, vagina, wounds
109C.USE	amies agar gel without charcoal	regular single wooden applicator	mouth, throat, vagina, wounds
110C.USE / 110C	amies agar gel without charcoal	minitip aluminium wire	eye, ENT, urogenital, pediatric
114C.USE / 114C	amies agar gel with charcoal	regular single plastic applicator	mouth, throat, vagina, wounds
115C.USE	amies agar gel with charcoal	regular single wooden applicator	mouth, throat, vagina, wounds
116C.USE / 116C	amies agar gel with charcoal	minitip aluminium wire	eye, ENT, urogenital, pediatric
124C.USE	amies agar gel without charcoal	minitip soft aluminium wire	eye, ENT, urogenital, pediatric
125C.USE	amies agar gel with charcoal	minitip soft aluminium wire	eye, ENT, urogenital, pediatric
128C	amies agar gel without charcoal	minitip paper applicator	eye, ENT, urogenital, pediatric
134C.USE	amies agar gel without charcoal	two regular plastic applicators	mouth, throat, vagina, wounds
136C.USE	amies agar gel with charcoal	two regular plastic applicators	mouth, throat, vagina, wounds
190C.USE	amies agar gel without charcoal	minitip twisted wire	eye, ENT, urogenital, pediatric, np
192C.USE	amies agar gel with charcoal	minitip twisted wire	eye, ENT, urogenital, pediatric, np
408C	amies agar gel without charcoal	regular single plastic applicator	mouth, throat, vagina, wounds
414C	amies agar gel with charcoal	regular single plastic applicator	mouth, throat, vagina, wounds
434C	amies agar gel with charcoal	two regular plastic applicators	mouth, throat, vagina, wounds
1E023S	amies agar gel without charcoal	regular single plastic applicator b. cap	mouth, throat, vagina, wounds

* Only Copan codes are listed here. For custom codes please refer to Copan Italia sales office.

** this is just a suggested table. Please refer to your GLP procedures to choose the most appropriate device for the specific sampling site.

INTENDED USE

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

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 Transystem™. Each 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 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 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: Cumitech 9², 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. Nitrogen gas is flushed into the transport tube during media filling and capping process. 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	3.0 g
Potassium Chloride	0.2 g
Calcium Chloride	0.1 g
Magnesium Chloride	0.1 g
Monopotassium Phosphate	0.2 g

Disodium Phosphate	1.15 g
Sodium Thioglycollate	1.0 g
Bacteriological Agar	7.5 g
Distilled Water	1 liter

Amies Agar Gel Transport Medium With Charcoal

Sodium Chloride	3.0 g
Potassium Chloride	0.2 g
Calcium Chloride	0.1 g
Magnesium Chloride	0.1 g
Monopotassium Phosphate	0.2 g

Disodium Phosphate	1.15 g
Sodium Thioglycollate	1.0 g
Charcoal	10.0 g
Bacteriological Agar	7.5 g
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.

Copan swab applicators are manufactured using natural fibers that have not been treated with chemical additives, whitening agents or bleaches as these substances can compromise the viability of microorganisms and performance of the product. Because Copan uses natural fibers the appearance of the swab tip can be slightly yellow, this is perfectly normal and has no effect, whatsoever, on product performance or patient safety.

PRECAUTIONS

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. For In Vitro Diagnostic Use.
3. Copan 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.
4. 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.
5. 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.
6. Directions for use must be followed carefully. The manufacturer can not be held responsible for any unauthorized or unqualified use of the product.
7. 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.
8. Observe aseptic techniques when using the product.
9. 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.
10. 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.
11. The product must be used as directed it must not be subjected to any additional chemical or physical sterilization or microcidal or microstatic processes prior to use as this will compromise the performance and function of the product.

STORAGE AND STABILITY

Store 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.

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. If product is stored incorrectly it can compromise the performance and invalidate the product specifications and performance claims.

MATERIALS SUPPLIED

Different packaging units are available for specific customized codes. Typically 50 units of sterile Transystem™ are contained in a metallic foil pack; alternatively, from 100 to 150 units of sterile Transystem™ are contained into a carton box. Each individual swab pouch contains an applicator and a plastic tube containing transport medium. For additional information about customized codes please refer to Copan Italia sales office.

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.

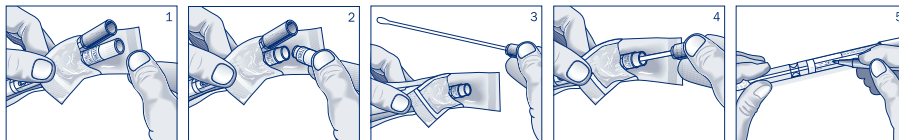
DIRECTIONS FOR USE

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

1. Peel open the Transystem™ sterile pouch at the point marked "Peel Here".
2. Remove cap from transport tube.
3. 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.
4. Place applicator swab in transport tube and replace cap firmly to completely seal.

5. Record patient's name and information on tube label.
6. 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 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 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 Transystem™ Amies Medium transport swabs are able to maintain the viability of clinically important aerobic and anaerobic bacteria for 24 hours⁵⁻¹⁵.

LIMITATIONS

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 media, staining reagents, immersion oil, glass slides and specimens themselves sometimes contain dead organisms visible upon Gram staining. Copan Transystem™ is not validated for environmental sampling and sterility test.

PERFORMANCE CHARACTERISTICS

Recovery studies were performed using Copan 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.

Optimal product performances are achieved by Transystem™ packed in a barrier plastic peel pouch plus aluminium foil envelope.

Please refer to symbol table at the end of the instructions for use

Italiano

Istruzioni per l'uso

USO PREVISTO

I dispositivi COPAN Transystem™ sono dei sistemi sterili e pronti all'uso, previsti per il prelievo, il trasporto e il mantenimento di campioni clinici per l'esame batteriologico.

CODICE*	TERRENO DI TRASPORTO	TIPOLOGIA DI TAMPONE	USO PREVISTO/SITO DI PRELIEVO**
108C.USE / 108C	amies agar gel senza carbone	Tampone di plastica regular singolo	bocca, gola, vagina, ferite
109C.USE	amies agar gel senza carbone	Tampone di legno regular singolo	bocca, gola, vagina, ferite
110C.USE / 110C	amies agar gel senza carbone	Tampone minitip in alluminio	occhio, ORL, urogenitale, pediatrico
114C.USE / 114C	amies agar gel con carbone	Tampone di plastica regular singolo	bocca, gola, vagina, ferite
115C.USE	amies agar gel con carbone	Tampone di legno regular singolo	bocca, gola, vagina, ferite
116C.USE / 116C	amies agar gel con carbone	Tampone minitip in alluminio	occhio, ORL, urogenitale, pediatrico
124C.USE	amies agar gel senza carbone	Tampone minitip in alluminio soft	occhio, ORL, urogenitale, pediatrico