

Copan

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# Transsystem™

## Instructions for Use

CE 0123

## Copan Transystem™ Liquid Stuart Medium, Liquid Amies Medium, Cary-Blair Agar Gel Medium and Stuart Agar Gel Medium

REF. NUMBER*	TRANSPORT MEDIUM	APPLICATOR SWAB TYPE	INTENDED USE/SAMPLING SITE **
111C.USE / 111C	Stuart Agar Gel Without Charcoal	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
113C.USE	Stuart Agar Gel Without Charcoal	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
117C.USE / 117C	Stuart Agar Gel With Charcoal	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
119C.USE	Stuart Agar Gel With Charcoal	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
126C.USE	Amies Liquid	Minitip Soft Aluminium Wire	Eye, Ent, Urogenital, Pediatric
132C.USE / 132C	Cary Blair Agar Gel	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
138C.USE	Amies Liquid	Two Regular Plastic Applicators	Mouth, Throat, Vagina, Wounds
139C.USE	Stuart Liquid	Two Regular Plastic Applicators	Mouth, Throat, Vagina, Wounds
140C.USE	Amies Liquid	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
141C.USE	Stuart Liquid	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
142C.USE	Amies Liquid	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
143C.USE	Stuart Liquid	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
191C.USE	Amies Liquid	Minitip Flexible Twisted Wire	Eye, Ent, Urogenital, Pediatric

\* 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: Liquid Stuart, Liquid Amies, Cary-Blair Agar Gel and Stuart Agar Gel Medium. These transport medium are non-nutritious, buffered with phosphate, and provide a reduced environment, due to their formulation with sodium thioglycollate or thioglycollic acid (mercaptoacetic acid)<sup>1,2,3,4,5</sup>. Cary-Blair Transport Medium is specifically recommended for the collection and transport of fecal and rectal swab samples for the investigation of enteric pathogenic bacteria<sup>6,7,8</sup>. 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. 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.)

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 9<sup>9</sup>, Manual of Clinical Microbiology<sup>10</sup> and the Clinical Microbiology Procedures Handbook<sup>11</sup>.

The transport tube has an hour glass shaped construction which serves two functions; in the case of agar gel medium it helps to keep the 6cm deep agar gel medium column intact and in the case of liquid medium products it helps to contain the sponge reservoir in position at the bottom of the tube. Transystem™ are individually packed in plastic film pouches and in an outer metallic foil Vi-Pak. The plastic film pouch and metallic foil pack help to minimize the oxidation of medium and evaporation of water from the product during its shelf life.

## REAGENTS

The nominal formula for each medium is as follows:

### Liquid Stuart Transport Medium

Sodium Glycerophosphate	10.0 g
Calcium Chloride	0.1 g
Mercaptoacetic Acid	1.0 ml
Distilled Water	1 liter

### Liquid Amies Transport Medium

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
Distilled Water	1 liter

### Cary-Blair Agar Gel Transport Medium

Disodium Hydrogen Phosphate	1.1 g
Sodium Thioglycollate	1.5 g
Sodium Chloride	5.0 g
Calcium Chloride	0.09 g
Bacteriological Agar	5.6 g
Distilled Water	1 liter

### Stuart Agar Gel Transport Medium

Sodium Glycerophosphate	10.0 g
Calcium Chloride	0.1 g
Mercaptoacetic Acid	1.0 ml
Bacteriological Agar	7.5 g
Distilled Water	1 liter

### Stuart Agar Gel Transport Medium with Charcoal

Sodium Glycerophosphate	10.0 g
Calcium Chloride	0.1 g
Mercaptoacetic Acid	1.0 ml
Bacteriological Agar	7.5 g
Charcoal	10.0 g
Distilled water	1 liter

## TECHNICAL NOTES

Copan swabs media contain 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 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.

## 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 micro-static processes prior to use as this will compromise the performance and function of the product.
12. Certain fiber swabs and transport medium are known to interfere or be incompatible with certain diagnostic test kits and assays. If the intention is to use any part of a Venturi Transystem™ product with a third party test kit or assay then the user or manufacturer of such third party test kits or assays must verify acceptability of the Copan product or independently validate and qualify the use of the Transystem™ with said test kit or assay.

## 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. 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

Different packaging units are available for specific customized codes.

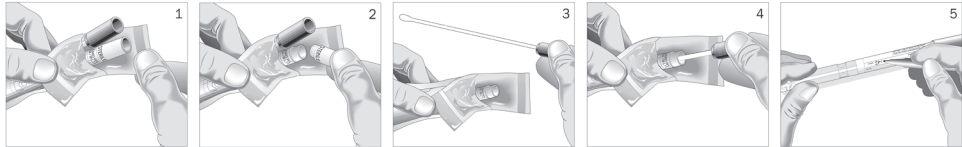
Typically 50 units of sterile Transystem™ are contained in a metallic foil pack; alternatively from 100 to 150 units of sterile Transystem™ are contained into a carton box. Each individual swab pouch contains an applicator and a plastic tube containing transport medium. For additional information about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

#### MATERIALS REQUIRED BUT NOT SUPPLIED

Appropriate materials for isolating, differentiating and culturing bacteria. These materials include culture media plates or tubes, and incubation systems, gas jars or 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 by Copan. 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 or downloaded from our website by registered users. 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 Handbook<sup>11</sup>.

#### 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. Specimens should be transported directly to the laboratory and cultured within 24 hours. Published studies have demonstrated that Copan Transystem™ with Liquid Stuart and Liquid Amies Transport Medium will maintain the viability of a range of aerobic bacteria for 24 hours<sup>13-20</sup>.

Cary and Blair reported in field studies with clinical specimens that *Salmonella* and *Shigella* could be recovered after storage at room temperature for as long as 49 days. In a similar field trial, nonagglutinable *Vibrio cholerae* strains, Heiberg group III and IV, were isolated after 22 days<sup>9</sup>. In survey of 162 routine fecal specimens collected in Cary-Blair Medium, strains of *Shigella* were recoverable for as long as 49 days at room temperature<sup>7</sup>. *Salmonella* continued to be isolated in spite of the presences of *Proteus* and *Pseudomonas aeruginosa* for at least 45 days. In other specimens, not containing these contaminants, *Salmonella* were isolated for as long as 62 days. *Shigella sonnei* was recovered for up to 34 days from a portion of the bowel placed in the transport medium. Using Cary-Blair Medium, Neuman et. al., reported that *Vibrio parahaemolyticus* survives for 35 days<sup>8</sup>. The medium of Cary-Blair is also recommended for transporting specimens suspected of containing *Campylobacter jejuni*<sup>12</sup>. Optimal product performances are achieved by Transystem™ packed in a barrier plastic peel pouch plus aluminium foil envelope.

#### LIMITATIONS

Copan Transystem™ Liquid Stuart Medium, Liquid Amies Medium, Cary-Blair Agar Gel Medium and Stuart Agar Gel Medium are intended for the collection and transport of aerobic bacteriological samples only. Samples containing viruses, chlamydia or anaerobic bacteria 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.

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