



***TransPorter***<sup>®</sup>

**PRODUCT INSERT &  
HOW TO USE SWAB GUIDE**

**Healthlink TransPorter®**

**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 *
4111	Stuart Agar Gel Without Charcoal	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
4113	Stuart Agar Gel Without Charcoal	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
4029	Stuart Liquid	Minitip Soft Aluminium Wire	Eye, Ent, Urogenital, Pediatric
4132	Cary Blair Agar Gel	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
4138	Amies Liquid	Two Regular Plastic Applicators	Mouth, Throat, Vagina, Wounds
4138Q	Amies Liquid	Two Regular Plastic Applicators, polyester tip	Mouth, Throat, Vagina, Wounds
4019	Stuart Liquid	Two Regular Plastic Applicators	Mouth, Throat, Vagina, Wounds
4139Q	Stuart Liquid	Two Regular Plastic Applicators, polyester tip	Mouth, Throat, Vagina, Wounds
4140	Amies Liquid	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
4140Q	Amies Liquid	Regular Single Plastic Applicator, polyester tip	Mouth, Throat, Vagina, Wounds
4432	Stuart Liquid	Regular Single Plastic Applicator	Mouth, Throat, Vagina, Wounds
4142	Amies Liquid	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
4143	Stuart Liquid	Minitip Aluminium Wire	Eye, Ent, Urogenital, Pediatric
4191	Amies Liquid	Minitip Flexible Twisted Wire	Eye, Ent, Urogenital, Pediatric
4195	Stuart Liquid	Minitip Flexible Twisted Wire	Eye, Ent, Urogenital, Pediatric

\*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**

Healthlink TransPorter® 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 Healthlink TransPorter®. Each TransPorter® 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. Healthlink TransPorter® 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 TransPorter® 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 6 cm 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. TransPorter® 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:

<b>Liquid Stuart Transport Medium</b>		<b>Cary-Blair Agar Gel Transport Medium</b>	
Sodium Glycerophosphate	10.0g	Disodium Hydrogen Phosphate	1.1 g
Calcium Chloride	0.1g	Sodium Thioglycollate	1.5g
Mercaptoacetic Acid	1.0 ml	Sodium Chloride	5.0g
Distilled Water	1 liter	Calcium Chloride	0.09g
<b>Liquid Amies Transport Medium</b>		Bacteriological Agar	5.6g
Sodium Chloride	3.0g	Distilled Water	1 liter
Potassium Chloride	0.2g	<b>Stuart Agar Gel Transport Medium</b>	
Calcium Chloride	0.1g	Sodium Glycerophosphate	10.0g
Magnesium Chloride	0.1g	Calcium Chloride	0.1g
Monopotassium Phosphate	0.2g	Mercaptoacetic Acid	1.0 ml
Disodium Phosphate	1.15g	Bacteriological Agar	7.5g
Sodium Thioglycollate	1.0g	Distilled Water	1 liter
Distilled Water	1 liter		

**TECHNICAL NOTES**

TransPorter® 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.

TransPorter® 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 TransPorter® 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. 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.
4. 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.
5. Directions for use must be followed carefully. The manufacturer can not be held responsible for any unauthorized or unqualified use of the product.
6. 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.
7. Observe aseptic techniques when using the product.
8. 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.
9. 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.
10. 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.
11. 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 TransPorter® 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 TransPorter® product or independently validate and qualify the use of the TransPorter® with said test kit or assay.

**STORAGE AND STABILITY**

Store TransPorter® 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**

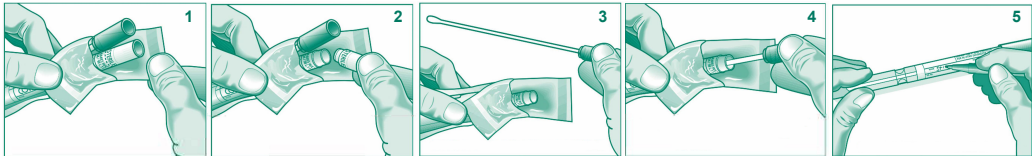
Typically 50 units of sterile TransPorter® are contained in a metallic foil pack. Each individual swab pouch contains an applicator and a plastic tube containing transport medium.

**MATERIALS REQUIRED BUT NOT SUPPLIED**

Appropriate materials for isolating, differentiating and culturing 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 TransPorter® unit along with descriptive diagrams. Directions for use are summarized as follows:



1. Peel open the TransPorter® 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 TransPorter®. 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 Handbook11.

**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 Healthlink TransPorter® with Liquid Stuart and Liquid Amies Transport Medium will maintain the viability of a range of aerobic bacteria for 24 hours13-20.

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 days6. 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 temperature7. 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 days8. The medium of Cary-Blair is also recommended for transporting specimens suspected of containing Campylobacter jejuni12.

**LIMITATIONS**

Healthlink TransPorter® 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. Healthlink TransPorter® is not validated for environmental sampling and sterility test.













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



**INDEX OF SYMBOLS**

Symbol	Meaning
	Manufacturer
	In vitro diagnostic device
	Sterilized using irradiation
	Do not reuse
	Catalogue number
	Temperature limitation
	Use by date
	Consult Instructions for Use
	Peel
	Batch code (Lot)
	Contains sufficient for <n> tests
	Do not use if package is damaged
<b>Rx Only</b>	Prescription Device Labeling Statement



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