Package insert and How to use guide

Copan Liquid Amies Elution Swab (ESwab®) Collection and Transport System
Product Insert & How to Use Guide

See the glossary of symbols at the end of the package insert

INTENDED USE
Copan Liquid Amies Elution Swab (ESwab®) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the collection site to the testing laboratory. In the laboratory, ESwab® specimens are processed using standard clinical laboratory operating procedures for bacterial culture.

SUMMARY AND PRINCIPLES
One of the routine procedures in the diagnosis of bacteriological infections involves the collection and safe transportation of swab samples. This can be accomplished using the Copan Liquid Amies Elution Swab (ESwab®) Collection and Transport System. Copan ESwab® incorporates a modified Liquid Amies transporting medium, which can sustain the viability of a plurality of organisms that include clinically important aerobes, anaerobes and fastidious bacteria such as *Neisseria gonorrhoeae* during transit to the testing laboratory. The ESwab® transport medium is a maintenance medium comprising inorganic phosphate buffer, calcium and magnesium salts, and sodium chloride with a reduced environment due to the presence of sodium thioglycollate (1).

Copan ESwab® consists of a sterile package containing two components: a pre-labeled polypropylene screw-cap tube with conical shaped bottom filled with 1 ml of Liquid Amies transport medium and a specimen collection swab which have a tip flocked with soft nylon fiber of regular size. This type of swab is intended for the collection of samples for example from nostril, throat, vagina, rectum or wounds .

Once a swab sample is collected, it should be placed immediately into the ESwab® transport tube, where it comes into contact with the transport medium. Swab specimens for bacterial investigations collected using ESwab® should be transported directly to the laboratory, preferably within 2 hours of collection (2, 3, 4) to maintain optimum organism viability. If immediate delivery or processing is delayed, then specimens should be refrigerated at 4 – 8ºC or stored at room temperature (20 – 25°C) and processed within 48 hours except for *Neisseria gonorrhoeae* cultures which should be processed within 24 hours. Independent scientific studies on swab transport systems have shown that, for certain bacteria, viability is superior at refrigerated temperatures compared with room temperature (12 – 16).

REAGENTS
Copan ESwab® incorporates a modified Liquid Amies medium.

ESwab® MEDIUM FORMULATION
Sodium chloride
Potassium chloride
Calcium chloride
Magnesium chloride
Monopotassium phosphate
Disodium phosphate
Sodium thioglycollate
Distilled water

TECHNICAL NOTE
The modified Liquid Amies Medium in ESwab® transport tubes can have a cloudy appearance. This is normal and is due to the presence of salts in the medium formulation.

SODIUM THIOGLYCOLLATE – TECHNICAL NOTE
ESwab® 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 odor momentarily when first opening the ESwab® peel-pouch. This odor is a perfectly normal and completely harmless characteristic.

PRECAUTIONS
1. This product is For *In Vitro* Diagnostic Use.
2. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.
3. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Sterilize all biohazard waste including specimens, containers and media after their use. Observe other CDC Biosafety Level 2 recommendations (34, 35, 36, 37).
4. Directions should be read and followed carefully.

STORAGE
This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 5 – 25°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile collection unit and the specimen transport tube label.

PRODUCT DETERIORATION
Copan ESwab® should not be used if (1) there is evidence of damage or contamination of the product, (2) there is evidence of leakage, (3) the expiration date has passed, (4) the swab package is open, or (5) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION
Specimens collected for bacteriological investigations, which comprise the isolation of aerobes, anaerobes and fastidious bacteria such as *Neisseria gonorrhoeae* should be collected and handled following published manuals and guidelines (2, 3, 18, 19, 20, 21, 22, 23).

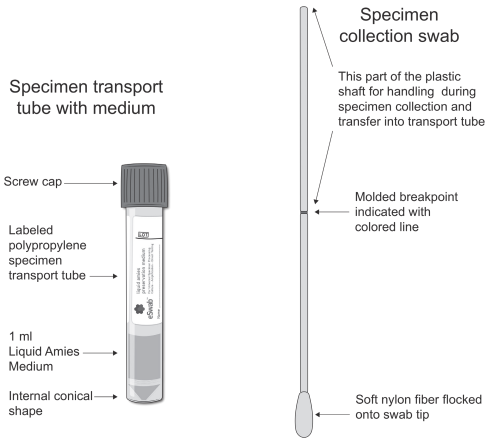
To maintain optimum organism viability, transport specimens collected using ESwab® directly to the laboratory, preferably within 2 hours of collection (2, 3, 4). If

immediate delivery or processing is delayed, then specimens should be refrigerated at 4 – 8ºC or stored at room temperature (20 – 25°C) and processed within 48 hours except for *Neisseria gonorrhoeae* cultures, which should be processed within 24 hours.

Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations (19, 22, 23). Shipping of specimens within medical institutions should comply with internal guidelines of the institution. All specimens should be processed as soon as they are received in the laboratory.

MATERIALS SUPPLIED
Fifty (50) ESwab® collection units are contained in a shelf pack and 10 x 50 or 6 x 50 units are contained in a box. Each collection unit consists of a sterile package containing two components: a pre-labeled polypropylene screw-cap tube with conical shaped bottom filled with 1 ml of Liquid Amies transport medium and one or more specimen collection swabs which have a tip flocked with soft nylon fiber (see Fig 1). The regular size flocked nylon swab applicator is intended for the collection of samples from the nostril, throat, vagina or wounds.

Fig 1. ESwab® Collection Unit Components



All collection swabs provided with ESwab® have a molded breakpoint in the shaft of the applicator, which is highlighted with a colored indication line marked on the shaft of the applicator. After the sample is collected from the patient, the molded breakpoint facilitates easy breakage of the swab applicator into the ESwab® tube of transport medium.

MATERIALS REQUIRED BUT NOT SUPPLIED
Appropriate materials for isolating and culturing aerobes, anaerobes and fastidious bacteria. These materials include culture media plates or tubes and incubation systems, gas jars or anaerobic workstations. Refer to laboratory reference manuals for recommended protocols for culture and identification techniques for aerobes, anaerobes and fastidious bacteria from clinical swab samples (17, 18, 21, 22).

DIRECTIONS FOR USE
Copan ESwab® Collection and Transport System is available in product configurations indicated in the table below.

Table 1

Catalog No.	Copan ESwab® Product Descriptions	Pack Size	Sampling Sites¥
480CFA	Sterile single use sample collection pack containing: - Polypropylene tube filled with 1ml of Liquid Amies Medium with purple screw-cap without capture cap. - One regular size applicator swab with flocked nylon fiber tip.	50 units per shelf pack 10x50 units per box	Nostril,throat, vagina,rectum and wounds

¥ These are just suggestions. Perfomance testing was not conducted using human specimens. Please refer to your internal procedures to choose the most appropriate device for the specific sampling site. Educational material related to sample collection could be available on Copan website.
Performance testing with Copan ESwab® was conducted using laboratory strains spiked onto a swab following the test protocols described in Clinical Laboratory Standards Institute M40-A2 Approved Standard (4).

Specimen Collection
Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals (2, 17, 18, 20, 21, 22).

Do not use the ESwab® medium for pre-moistening or pre-wetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.

1. Open the ESwab® sample collection pouch and remove the tube and swab.
2. Collect the sample from the patient.
3. Unscrew and remove the cap from ESwab® tube making sure not to spill the medium.
4. Break the swab off into the tube as follows:
   - With the other hand grasp the swab shaft at the very end with the thumb and first finger.
   - Lean the part of the shaft with the breaking point against the rim of the tube.
   - Bend the swab shaft at a 180 degrees angle to break it off at the colored ink breakpoint mark. If needed, gently rotate the swab shaft to complete the breakage and take away the upper part of the swab shaft.
   - Discard the broken handle part of the swab shaft into an approved medical waste disposal container.
5. Replace cap on the tube and secure tightly.
6. Write patient information on the tube label or apply patient identification label. Send the sample to the test laboratory.

Fig. 2 Specimen Collection

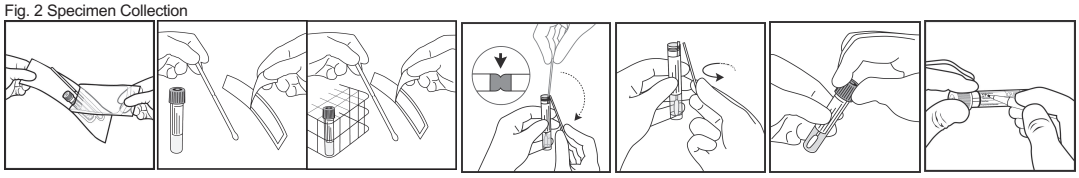
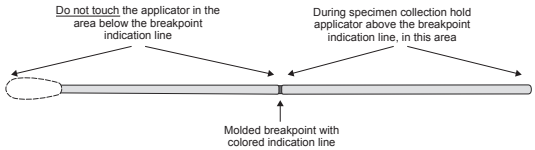


Fig 3. Collection swab showing breakpoint indication line and area for holding the applicator



NOTE: Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft. Swab shafts often exhibit diameter changes to facilitate different sampling requirements. Swab shafts may also have a molded breakpoint designed for intentional breakage of the swab into the transport tube. In all circumstances when collecting swabs samples from patients, do not use excessive force, pressure or bending of the swab as this may result in accidental breakage of the swab shaft.

The operator must only handle the part of the swab applicator shaft above the breakpoint indication line as shown in Fig 3. After the swab sample is taken from the patient, the swab applicator shaft is broken off at the colored breakpoint indication line into the ESwab® tube of transport medium. The operator then discards the handle part of the swab into an approved medical waste disposal container. The tube's screw cap is then replaced and secured tightly.

Plating ESwab® Specimen Cultures in the Laboratory

ESwab® samples should be processed for bacteriological culture using recommended culture media and laboratory techniques which will depend on the specimen type and the organism under investigation. For recommended culture media and techniques for the isolation and identification of bacteria from clinical swab specimens refer to published microbiology manuals and guidelines (17, 18, 21, 24, 25).
Culture investigations of swab specimens for the presence of aerobic bacteria, anaerobic bacteria and fastidious bacteria such as *Neisseria gonorrhoeae* routinely involve the use of solid agar culture medium in Petri dish plates. The procedure for inoculation of ESwab® samples onto solid agar in Petri dishes is as follows.

Note: Wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe other CDC Biosafety Level 2 recommendations (34, 35, 36, 37).

1. Vigorously shake the ESwab® tube containing the swab sample between the thumb and forefinger for 5 seconds or mix the tube using a vortex mixer for 5 seconds to release the sample from the swab tip and evenly disperse and suspend the patient specimen in the liquid transport medium.
2. Unscrew the ESwab® cap and remove the swab.
3. Transfer 10 - 100 µl volumes of the suspension onto each culture plate using a volumetric pipetor and sterile pipet tips (see Fig.4)
4. If it is necessary to culture the swab specimen onto a second culture media plate, return the ESwab® applicator to the transport medium tube for two seconds to absorb and recharge the applicator tip with transport medium/patient sample suspension then repeat Step No. 3.

NOTE : the swab can be re-insert inside of its tube ,but should be plated not more than 60 minutes after the second repetition .

Standard laboratory techniques should then be used to streak the primary inoculum of patient sample across the surface of the culture plate (see Fig 5).
Depending on the streaking pattern to apply, the type of investigation, the agar plate diameter, different volumes of ESwab® can be plated.
For example, for culture investigations that require the seeding of the whole 90 mm agar plate, 100 µL should be pipetted in the center of the plate and then spread.
For culture investigations that require the seeding of the first quadrant to obtain isolated colonies onto 90 mm agar plates, 10-100 µL should be pipetted onto the plate and then streaked.

Fig . Procedures for inoculation of ESwab® specimens onto solid agar in Petri dishes using pipettor and sterile pipet tips to inoculate 10- 100 µl of specimen

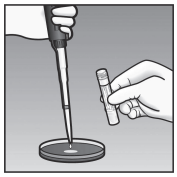
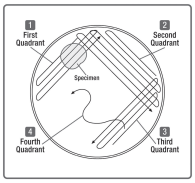


Fig 5. Procedure for streaking ESwab® specimens on agar Petri dishes for primary isolation (33)



Seed a primary inoculum of ESwab® specimen onto the surface of an appropriate agar culture plate in the first quadrant.

Use a sterile bacteriology loop to streak the primary inoculum across the surface of the second, third and fourth quadrants of the agar culture plate.

Preparation of Gram Stain Smears of ESwab® Specimens

Laboratory analysis of clinical swab samples collected from certain sites on the patient can routinely include microscopic examination of stained preparations ("direct Smears") using the Gram stain procedure. This can provide valuable information to physicians who are managing patients with infectious diseases (26). There are many instances in which a Gram stain can assist in making a diagnosis; for example, with swabs taken from the endocervix or male urethra to investigate suspected *Neisseria gonorrhoeae* infections or vaginal swabs to diagnose bacterial vaginosis (27, 28, 29, 30, 31, 39). The Gram stain can also help to judge specimen quality and contribute to the selection of culture media especially with mixed flora (32).
Microscope slides of patient specimens transported in Copan ESwab® transport system can be prepared for Gram stain analysis, as described below, by sampling an aliquot of vortexed suspension of the swab (21, 32). Sample transported in ESwab® elution medium represents a homogeneous suspension in liquid phase. It can be uniformly smeared allowing clear and easy reading.

Note: Wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe other CDC Biosafety Level 2 recommendations (34, 35, 36, 37).

1. Take a clean glass microscope slide, place it on a flat surface and inscribe an area using a diamond-tipped or similar glass marker to identify the location of the specimen inoculum. Note: a slide with a pre-marked 20 mm well can be used.
2. Vortex mix the ESwab® tube containing the swab sample for 5 seconds to release the sample from the swab tip and evenly disperse and suspend the patient specimen in the Liquid Amies transport medium.
3. Unscrew the ESwab® cap and using a sterile pipet, transfer 1 – 2 drops of Liquid Amies sample suspension to the inscribed area on the glass slide. Note: about 30µl would be a suitable amount of liquid for a pre-marked 20 mm diameter well slide.
   In case of bloody or thicker specimens particular care should be taken to thinly spread the sample on the slide. Bacteria are difficult to detect if the sample shows many red cells and debris.
4. Allow the specimen on the slide to air dry at room temperature or place the slide in an electric slide warmer or incubator set at a temperature not exceeding 42°C.
5. Fix smears using methanol. Methanol fixation is recommended as it prevents lysis of Red Blood Cells, avoids damage to all host cells and results in a cleaner background (21, 26, 32).
6. Follow published laboratory reference manuals and guidelines for performing the Gram stain. If commercial Gram stain reagents are used, it is important to comply with instructions in the manufacturer's product insert for performance test procedure.

For further information or guidance on the preparation of specimen slides for microscopic analysis, for information on Gram staining procedures and the interpretation and reporting of microscopic analysis, consult published laboratory reference manuals (20, 24, 25, 26, 32).

QUALITY CONTROL

ESwab® Liquid Amies transport medium is tested for pH and bio-burden using Gram stain microscopic examination to ensure acceptable levels as defined in Clinical Laboratory Standards Institute M40-A2 (4). The ESwab® is quality control tested for ability to maintain viable bacteria for specified time points with a panel of aerobes, anaerobes and fastidious bacteria. Procedures for quality control of bacteriology transport devices are described in Clinical Laboratory Standards Institute M40-A2 and other publications (4, 10, 12, 14, 15, 40, 41).

LIMITATIONS

1. In the laboratory, wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe other CDC Biosafety Level 2 recommendations (34, 35, 36, 37) when handling or analyzing patient samples.
2. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection (2, 3, 17, 18, 20, 21, 24).
3. ESwab® is intended for use as a collection and transport medium for aerobes, anaerobes and fastidious bacteria such as *Neisseria gonorrhoeae*.
4. ESwab® Collection and Transport System is intended to be used with the medium tubes and swabs provided in the unit. The use of tubes of medium or swabs from any other source are not qualified for use with ESwab® and could affect the performance of the product and laboratory test results.

WARNINGS

1. Do not re-sterilize unused swabs.
2. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
3. Do not re-pack.
4. Not suitable to collect and transport microorganisms other than aerobes, anaerobes and fastidious bacteria.
5. Not suitable for any other application than intended use.
6. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
7. Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is broken).
8. Do not use excessive force or pressure when collecting swab samples from patients as this may result in breakage of the swab shaft.
9. Applicator swab is qualified as Class IIa Medical Device according to European Medical Device Directive 93/42/EEC - Surgically Invasive Transient Use.
   Class IIa means swabs can be used for sampling body surfaces, body orifices (e.g., nostril, throat and vagina) and deep invasive surgical wounds.
10. Do not ingest the medium.
11. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.

12. To be handled by trained personnel only.
13. It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste. Observe CDC Biosafety Level 2 recommendations (34, 35, 36, 37).
14. Do not use the ESwab® medium for pre-moistening or pre-wetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.

RESULTS
Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

PERFORMANCE CHARACTERISTICS
In the routine clinical laboratory, the Roll-Plate Method is the primary means of inoculating swab transport devices onto plated media. A limitation of the Roll-Plate Method (4) for bacterial viability performance testing is that it is not a quantitative method; it is, at best, a semi-quantitative approximation. On the other hand, quantitative viability performance methods such as the Swab Elution Method (4) do not reflect the standard protocol used in most clinical laboratories. Whereas the Swab Elution Method allows a quantitative measurement of the ability of a transport system to maintain viable organisms, the Roll-Plate technique takes into consideration some mechanical variables of the direct swabbing action that exist in the clinical laboratory, and which can influence the release of the sample onto culture plates. Because of this, both methods of performing viability studies were used to determine the performance characteristics of the Copan ESwab® Collection and Transport System.
The test procedures employed for determining bacterial viability performance were based upon the quality control methods described in Clinical Laboratory Standards Institute M40-A2 (4, 10, 12, 14, 15, 40, 41). The test organisms utilized in this study were those specifically prescribed in M40-A2 for establishing performance claims and quality control of swab transport systems and include a representative panel of aerobes, anaerobes and fastidious bacteria. An additional group of organisms not required or specified by M40-A2 were tested in order to provide further information on the survival of specific bacteria. Bacterial viability studies were performed on the Copan ESwab® at two different ranges of temperature, 4 – 8 °C and 20 – 25°C, corresponding to refrigerator and room temperature, respectively. Swabs accompanying each transport system were inoculated in triplicate with 100µl of specific concentrations of organism suspension. Swabs were then placed in their respective transport medium tubes and were held for 0 hrs, 24 hrs and 48 hrs. At the appropriate time intervals, each swab was processed according to the Roll-Plate or Swab Elution Method.

Organisms evaluated were divided into three main groups (see note below):

1. Aerobes and Facultative Anaerobes:
   Pseudomonas aeruginosa ATCC® BAA-427, *Streptococcus pyogenes* ATCC® 19615, *Streptococcus pneumoniae* ATCC® 6305, *Haemophilus influenzae* ATCC® 10211.
2. Anaerobes:
   Bacteroides fragilis ATCC® 25285, *Peptostreptococcus anaerobius* ATCC® 27337, *Fusobacterium nucleatum* ATCC® 25586, *Propionibacterium acnes* ATCC® 6919, *Prevotella melaninogenica* ATCC® 25845.
3. Fastidious Bacteria:
   Neisseria gonorrhoeae ATCC® 43069.

Additional organisms evaluated:
Enterococcus faecalis (Vancomycin resistant Enterococcus VRE) ATCC® 51299,*Staphylococcus aureus* (Methicillin resistant *Staphylococcus aureus* MRSA) ATCC® 43300, *Streptococcus agalactiae* (Group B Streptococcus) ATCC® 13813, *Clostridium perfringens* ATCC® 13124, *Clostridium sporogenes* ATCC® 3584, *Fusobacterium necrophorum* ATCC® 25286, *Peptococcus magnus* ATCC® 29328.

NOTE
For product performance claims and viability performance testing, bacteria are categorized into three groups as described in Clinical Laboratory Standards Institute M40-A2 (4) according to their growth responses to atmospheric oxygen:

1. Aerobes and Facultative Anaerobes
   Aerobic bacteria require air or free oxygen to live. Facultative anaerobes are bacteria that can survive in either the presence or absence of oxygen. Many aerobic bacteria are facultative anaerobes meaning they are able to grow and survive in the absence of oxygen. For this reason, the aerobic group includes the description facultative anaerobes
2. Anaerobes
   Anaerobic bacteria do not require air or free oxygen to live. This category includes obligate anaerobes that can only live in the absence of oxygen.
3. Fastidious Bacteria.
   Fastidious bacteria have complicated or exacting growth requirements and this group is represented by the bacterium Neisseria gonorrhoeae.

The results for the bacterial strains tested using the ESwab® System are shown in the tables below.

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
ROLL-PLATE METHOD, 4-8°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	ESwab® Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Interpretation
Pseudomonas aeruginosa ATCC BAA-427	diluted $10^{-3.5}$	5051	261.7	210.7	59.3	Acceptable Recovery
		5052	258.3	206.3	54.7	Acceptable Recovery
		5055	268.0	203.3	56.7	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 10^{-3}	5051	292.7	142.0	49.0	Acceptable Recovery
		5052	283.6	138.3	49.3	Acceptable Recovery
		5055	285.6	145.3	48.0	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted $10^{-1.5}$	5051	193.3	60.7	29.7	Acceptable Recovery
		5052	194.7	61.7	32.3	Acceptable Recovery
		5055	196.7	64.0	35.0	Acceptable Recovery

Haemophilus influenzae ATCC 10211	diluted $10^{-3.5}$	5051	277.7	121.0	27.3	Acceptable Recovery
		5052	267.7	111.3	19.7	Acceptable Recovery
		5055	260.7	101.3	17.3	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 10^{-3}	5051	288.3	93.7	54.0	Acceptable Recovery
		5052	278.3	83.7	44.0	Acceptable Recovery
		5055	272.7	74.3	29.7	Acceptable Recovery
Peptostreptococcus naerobius ATCC 27337	diluted $10^{-2.5}$	5051	286.7	180.3	22.7	Acceptable Recovery
		5052	290.0	182.7	21.3	Acceptable Recovery
		5055	284.3	187.3	23.3	Acceptable Recovery
Fusobacterium nucleatum ATCC 25586	diluted $10^{-1.5}$	5051	272.0	110.0	19.0	Acceptable Recovery
		5052	275.0	102.0	16.7	Acceptable Recovery
		5055	272.0	111.0	22.0	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 10^{-3}	5051	290.7	156.7	48.7	Acceptable Recovery
		5052	288.3	151.3	40.7	Acceptable Recovery
		5055	290.7	154.7	47.0	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted $10^{-2.5}$	5051	292.3	169.3	29.3	Acceptable Recovery
		5052	288.0	168.3	31.0	Acceptable Recovery
		5055	292.7	169.7	29.7	Acceptable Recovery
Neisseria gonorrhoeae ATCC 43069	diluted 10^{-3}	5051	234.7	19.7		Acceptable Recovery
		5052	244.7	24.3		Acceptable Recovery
		5055	246.3	23.7		Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted $10^{-3.5}$	5051	240.0	109.3	41.3	Acceptable Recovery
		5052	230.0	101.7	37.3	Acceptable Recovery
		5055	247.7	102.3	41.0	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted $10^{-3.5}$	5051	238.0	98.0	50.3	Acceptable Recovery
		5052	238.7	98.7	49.0	Acceptable Recovery
		5055	236.3	96.3	48.0	Acceptable Recovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted $10^{-3.5}$	5051	290.0	116.7	56.3	Acceptable Recovery
		5052	292.3	116.7	58.3	Acceptable Recovery
		5055	291.0	116.3	56.7	Acceptable Recovery
Clostridium perfringens ATCC 13124	diluted $10^{-3.5}$	5051	283.3	162.0	48.7	Acceptable Recovery
		5052	279.3	152.0	41.7	Acceptable Recovery
		5055	273.3	145.3	44.0	Acceptable Recovery
Clostridium sporogenes ATCC 3584	diluted $10^{-3.5}$	5051	248.3	100.3	43.7	Acceptable Recovery
		5052	247.0	94.7	38.3	Acceptable Recovery
		5055	238.3	91.3	33.7	Acceptable Recovery
Fusobacterium necrophorum ATCC 25286	diluted $10^{-2.5}$	5051	288.0	146.7	51.3	Acceptable Recovery
		5052	278.0	136.7	41.3	Acceptable Recovery
		5055	274.7	132.7	47.7	Acceptable Recovery
Peptococcus magnus ATCC 29328	diluted $10^{-2.5}$	5051	284.3	153.7	42.3	Acceptable Recovery
		5052	288.0	152.3	43.3	Acceptable Recovery
		5055	274.3	144.3	34.0	Acceptable Recovery

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
ROLL-PLATE METHOD, 20-25°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	ESwab® Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Interpretation
Pseudomonas aeruginosa ATCC BAA-427	diluted $10^{-3.5}$	5051	261.7	190.0	51.7	Acceptable Recovery
		5052	258.3	178.0	44.7	Acceptable Recovery
		5055	268.0	192.3	49.0	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 10^{-3}	5051	292.7	108.0	33.0	Acceptable Recovery
		5052	283.6	115.7	33.0	Acceptable Recovery
		5055	285.6	109.7	31.0	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted $10^{-1.5}$	5051	193.3	56.0	23.0	Acceptable Recovery
		5052	194.7	54.7	21.7	Acceptable Recovery
		5055	196.7	58.7	22.0	Acceptable Recovery
Haemophilus influenzae ATCC 10211	diluted $10^{-3.5}$	5051	277.7	113.3	19.3	Acceptable Recovery
		5052	267.7	98.3	17.0	Acceptable Recovery
		5055	260.7	88.3	11.0	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 10^{-3}	5051	288.3	76.3	40.7	Acceptable Recovery
		5052	278.3	67.7	32.7	Acceptable Recovery
		5055	272.7	60.7	26.7	Acceptable Recovery
Peptostreptococcus anaerobius ATCC 27337	diluted $10^{-2.5}$	5051	286.7	164.0	14.3	Acceptable Recovery
		5052	290.0	154.0	14.0	Acceptable Recovery
		5055	284.3	164.0	15.7	Acceptable Recovery

Fusobacterium nucleatum ATCC 25586	diluted $10^{-1.5}$	5051	272.0	86.3	17.3	Acceptable Recovery
		5052	275.0	78.0	12.7	Acceptable Recovery
		5055	272.0	76.3	17.3	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 10^{-3}	5051	290.7	107.3	36.0	Acceptable Recovery
		5052	288.3	97.3	28.3	Acceptable Recovery
		5055	290.7	105.3	34.7	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted $10^{-2.5}$	5051	292.3	92.3	16.7	Acceptable Recovery
		5052	288.0	93.3	15.0	Acceptable Recovery
		5055	292.7	92.3	17.3	Acceptable Recovery
Neisseria gonorrhoeae ATCC 43069	diluted 10^{-3}	5051	234.7	13.7		Acceptable Recovery
		5052	244.7	15.7		Acceptable Recovery
		5055	246.3	18.0		Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted $10^{-3.5}$	5051	240.0	93.7	32.7	Acceptable Recovery
		5052	230.0	89.0	27.7	Acceptable Recovery
		5055	247.7	86.0	29.3	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted $10^{-3.5}$	5051	238.0	74.3	44.0	Acceptable Recovery
		5052	238.7	73.3	42.7	Acceptable Recovery
		5055	236.3	76.3	42.3	Acceptable Recovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted $10^{-3.5}$	5051	290.0	88.0	47.7	Acceptable Recovery
		5052	292.3	87.0	46.0	Acceptable Recovery
		5055	291.0	86.3	46.3	Acceptable Recovery
Clostridium perfringens ATCC 13124	diluted $10^{-3.5}$	5051	283.3	110.7	37.0	Acceptable Recovery
		5052	279.3	99.7	32.0	Acceptable Recovery
		5055	273.3	92.0	32.0	Acceptable Recovery
Clostridium sporogenes ATCC 3584	diluted $10^{-3.5}$	5051	248.3	91.3	36.0	Acceptable Recovery
		5052	247.0	86.3	31.7	Acceptable Recovery
		5055	238.3	73.3	29.0	Acceptable Recovery
Fusobacterium necrophorum ATCC 25286	diluted $10^{-2.5}$	5051	288.0	107.3	40.3	Acceptable Recovery
		5052	278.0	97.3	30.3	Acceptable Recovery
		5055	274.7	97.0	33.7	Acceptable Recovery
Peptococcus magnus ATCC 29328	diluted $10^{-2.5}$	5051	284.3	107.3	31.3	Acceptable Recovery
		5052	288.0	106.7	31.0	Acceptable Recovery
		5055	274.3	97.3	24.3	Acceptable Recovery

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
SWAB ELUTION METHOD, 4-8°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	ESwab® Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Log_{10} decline	Interpretation
Pseudomonas aeruginosa ATCC BAA-427	diluted 1:10	5051	1.4×10^6	1.1×10^6	2.7×10^5	-0.71	Acceptable Recovery
		5052	1.4×10^6	1.0×10^6	2.6×10^5	-0.73	Acceptable Recovery
		5055	1.5×10^6	9.7×10^5	2.6×10^5	-0.76	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 1:10	5051	6.0×10^5	2.9×10^5	6.0×10^4	-1.00	Acceptable Recovery
		5052	6.0×10^5	2.9×10^5	6.5×10^4	-0.97	Acceptable Recovery
		5055	6.1×10^5	3.0×10^5	6.8×10^4	-0.95	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	5051	1.8×10^6	6.0×10^5	2.0×10^5	-0.95	Acceptable Recovery
		5052	1.8×10^6	6.9×10^5	2.0×10^5	-0.95	Acceptable Recovery
		5055	1.8×10^6	6.4×10^5	1.9×10^5	-0.98	Acceptable Recovery
Haemophilus influenzae ATCC 10211	diluted 1:10	5051	3.9×10^6	9.6×10^5	3.9×10^5	-1.00	Acceptable Recovery
		5052	3.8×10^6	9.9×10^5	3.6×10^5	-1.02	Acceptable Recovery
		5055	3.7×10^6	8.9×10^5	2.8×10^5	-1.12	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 1:10	5051	8.6×10^5	3.7×10^5	1.5×10^5	-0.76	Acceptable Recovery
		5052	8.4×10^5	3.5×10^5	1.4×10^5	-0.78	Acceptable Recovery
		5055	8.2×10^5	3.3×10^5	1.3×10^5	-0.80	Acceptable Recovery
Peptostreptococcus anaerobius ATCC 27337	diluted 1:10	5051	1.6×10^6	9.7×10^5	1.2×10^5	-1.12	Acceptable Recovery
		5052	$1.7x\ 10^6$	9.6×10^5	1.1×10^5	-1.16	Acceptable Recovery
		5055	1.7×10^6	9.5×10^5	1.1×10^5	-1.19	Acceptable Recovery
Fusobacterium nucleatum ATCC 25586	diluted 1:10	5051	2.4×10^6	7.0×10^5	1.8×10^5	-1.12	Acceptable Recovery
		5052	2.4×10^6	6.9×10^5	1.8×10^5	-1.12	Acceptable Recovery
		5055	2.4×10^6	6.8×10^5	1.9×10^5	-1.10	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 1:10	5051	3.8×10^6	1.9×10^6	6.9×10^5	-0.74	Acceptable Recovery
		5052	3.7×10^6	1.8×10^6	6.0×10^5	-0.79	Acceptable Recovery
		5055	3.7×10^6	1.8×10^6	5.9×10^5	-0.80	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted 1:10	5051	3.1×10^6	9.3×10^5	2.7×10^5	-1.06	Acceptable Recovery
		5052	3.0×10^6	9.3×10^5	2.7×10^5	-1.05	Acceptable Recovery
		5055	3.2×10^6	9.3×10^5	2.6×10^5	-1.09	Acceptable Recovery

Neisseria gonorrhoeae ATCC 43069	diluted 1:10	5051	3.6×10^6	2.8×10^5		-1.11	Acceptable Recovery
		5052	3.5×10^6	2.7×10^5		-1.11	Acceptable Recovery
		5055	3.4×10^6	2.5×10^5		-1.13	Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted 1:10	5051	1.4×10^6	8.4×10^5	2.5×10^5	-0.75	Acceptable Recovery
		5052	1.4×10^6	8.2×10^5	2.5×10^5	-0.75	Acceptable Recovery
		5055	1.4×10^6	8.5×10^5	2.6×10^5	-0.73	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	5051	9.9×10^5	7.7×10^5	1.9×10^5	-0.72	Acceptable Recovery
		5052	9.8×10^5	7.6×10^5	1.8×10^5	-0.73	Acceptable Recovery
		5055	1.0×10^6	7.6×10^5	2.0×10^5	-0.70	AcceptableRecovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted 1:10	5051	5.5×10^6	3.4×10^6	8.1×10^5	-0.83	AcceptableRecovery
		5052	5.6×10^6	3.6×10^6	8.0×10^5	-0.85	AcceptableRecovery
		5055	5.4×10^6	3.4×10^6	7.8×10^5	-0.84	AcceptableRecovery
Clostridium perfringens ATCC 13124	diluted 1:10	5051	2.3×10^6	1.3×10^6	3.9×10^5	-0.77	AcceptableRecovery
		5052	2.3×10^6	1.2×10^6	3.6×10^5	-0.81	AcceptableRecovery
		5055	2.2×10^6	1.2×10^6	3.2×10^5	-0.84	AcceptableRecovery
Clostridium sporogenes ATCC 3584	diluted 1:10	5051	6.5×10^5	3.0×10^5	1.2×10^5	-0.73	AcceptableRecovery
		5052	6.4×10^5	4.0×10^5	1.2×10^5	-0.73	AcceptableRecovery
		5055	6.4×10^5	2.9×10^5	1.1×10^5	-0.76	AcceptableRecovery
Fusobacterium necrophorum ATCC 25286	diluted 1:10	5051	9.6×10^5	4.2×10^5	1.7×10^5	-0.75	AcceptableRecovery
		5052	9.7×10^5	4.3×10^5	1.8×10^5	-0.73	AcceptableRecovery
		5055	9.4×10^5	4.1×10^5	1.6×10^5	-0.77	AcceptableRecovery
Peptococcus magnus ATCC 29328	diluted 1:10	5051	4.9×10^6	2.9×10^6	8.6×10^5	-0.76	AcceptableRecovery
		5052	4.9×10^6	2.8×10^6	8.7×10^5	-0.75	AcceptableRecovery
		5055	4.8×10^6	2.8×10^6	7.9×10^5	-0.78	AcceptableRecovery

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY STUDIES
SWAB ELUTION METHOD, 20-25°C

Organism	Dilution: 0.5 McFarland bacterial suspension with saline	ESwab® Lot Number	Average of CFUs recovered at time 0 hrs	Average of CFUs recovered at time 24 hrs	Average of CFUs recovered at time 48 hrs	Log_{10} decline	Interpretation
Pseudomonas aeruginosa ATCC BAA-427	diluted 1:10	5051	1.4×10^6	9.8×10^5	2.7×10^5	-0.71	Acceptable Recovery
		5052	1.4×10^6	9.6×10^5	2.5×10^5	-0.75	Acceptable Recovery
		5055	1.5×10^6	9.8×10^5	2.3×10^5	-0.81	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 1:10	5051	6.0×10^5	2.6×10^5	4.5×10^4	-1.12	Acceptable Recovery
		5052	6.0×10^5	2.5×10^5	4.1×10^4	-1.17	Acceptable Recovery
		5055	6.1×10^5	2.5×10^5	4.2×10^4	-1.16	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	5051	1.8×10^6	4.4×10^5	1.6×10^5	-1.05	Acceptable Recovery
		5052	1.8×10^6	4.7×10^5	1.5×10^5	-1.08	Acceptable Recovery
		5055	1.8×10^6	4.7×10^5	1.5×10^5	-1.08	Acceptable Recovery
Haemophilus influenzae ATCC 10211	diluted 1:10	5051	3.9×10^6	8.2×10^5	3.2×10^5	-1.09	Acceptable Recovery
		5052	3.8×10^6	8.2×10^5	2.9×10^5	-1.12	Acceptable Recovery
		5055	3.7×10^6	7.2×10^5	2.2×10^5	-1.23	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 1:10	5051	8.6×10^5	3.8×10^5	1.2×10^5	-0.86	Acceptable Recovery
		5052	8.4×10^5	3.7×10^5	1.2×10^5	-0.85	Acceptable Recovery
		5055	8.2×10^5	3.5×10^5	1.0×10^5	-0.91	Acceptable Recovery
Peptostreptococcus anaerobius ATCC 27337	diluted 1:10	5051	1.6×10^6	8.5×10^5	1.1×10^5	-1.16	Acceptable Recovery
		5052	1.7×10^6	8.5×10^5	9.9×10^4	-1.23	Acceptable Recovery
		5055	1.7×10^6	8.3×10^5	9.8×10^4	-1.24	Acceptable Recovery
Fusobacterium nucleatum ATCC 25586	diluted 1:10	5051	2.4×10^6	6.6×10^5	1.6×10^5	-1.18	Acceptable Recovery
		5052	2.4×10^6	6.4×10^5	1.6×10^5	-1.18	Acceptable Recovery
		5055	2.4×10^6	6.5×10^5	1.7×10^5	-1.15	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 1:10	5051	3.8×10^6	1.3×10^6	4.3×10^5	-0.95	Acceptable Recovery
		5052	3.7×10^6	1.2×10^6	3.3×10^5	-1.05	Acceptable Recovery
		5055	3.7×10^6	1.2×10^6	3.4×10^5	-1.04	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted 1:10	5051	3.1×10^6	5.9×10^5	2.1×10^5	-1.17	Acceptable Recovery
		5052	3.0×10^6	5.9×10^5	2.1×10^5	-1.15	Acceptable Recovery
		5055	3.2×10^6	6.0×10^5	2.1×10^5	-1.18	Acceptable Recovery
Neisseria gonorrhoeae ATCC 43069	diluted 1:10	5051	3.6×10^6	2.2×10^5		-1.21	Acceptable Recovery
		5052	3.5×10^6	2.1×10^5		-1.22	Acceptable Recovery
		5055	3.4×10^6	1.9×10^5		-1.25	Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted 1:10	5051	1.4×10^6	7.6×10^5	2.1×10^5	-0.82	Acceptable Recovery
		5052	1.4×10^6	7.5×10^5	2.0×10^5	-0.85	Acceptable Recovery
		5055	1.4×10^6	7.5×10^5	1.9×10^5	-0.87	Acceptable Recovery

Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	5051	9.9×10^5	6.9×10^5	1.1×10^5	-0.95	Acceptable Recovery
		5052	9.8×10^5	6.5×10^5	1.2×10^5	-0.91	Acceptable Recovery
		5055	1.0×10^6	6.6×10^5	1.2×10^5	-0.92	Acceptable Recovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted 1:10	5051	5.5×10^6	3.4×10^6	5.4×10^5	-1.01	Acceptable Recovery
		5052	5.6×10^6	3.3×10^6	5.4×10^5	-1.02	Acceptable Recovery
		5055	5.4×10^6	3.6×10^6	5.5×10^5	-0.99	Acceptable Recovery
Clostridium perfringens ATCC 13124	diluted 1:10	5051	2.3×10^6	1.0×10^6	3.3×10^5	-0.84	Acceptable Recovery
		5052	2.3×10^6	9.3×10^5	2.9×10^5	-0.90	Acceptable Recovery
		5055	2.2×10^6	9.3×10^5	2.5×10^5	-0.94	Acceptable Recovery
Clostridium sporogenes ATCC 3584	diluted 1:10	5051	6.5×10^5	2.7×10^5	1.1×10^5	-0.77	Acceptable Recovery
		5052	6.4×10^5	2.6×10^5	9.9×10^4	-0.81	Acceptable Recovery
		5055	6.4×10^5	2.6×10^5	1.0×10^5	-0.81	Acceptable Recovery
Fusobacterium necrophorum ATCC 25286	diluted 1:10	5051	9.6×10^5	2.7×10^5	1.3×10^5	-0.87	Acceptable Recovery
		5052	9.7×10^5	2.6×10^5	1.2×10^5	-0.91	Acceptable Recovery
		5055	9.4×10^5	2.6×10^5	1.4×10^5	-0.83	Acceptable Recovery
Peptococcus magnus ATCC 29328	diluted 1:10	5051	4.9×10^6	2.8×10^6	6.9×10^5	-0.85	Acceptable Recovery
		5052	4.9×10^6	2.7×10^6	5.3×10^5	-0.97	Acceptable Recovery
		5055	4.8×10^6	2.6×10^6	5.7×10^5	-0.93	Acceptable Recovery

In accordance with Clinical Laboratory Standards Institute M40-A2, with the exception of *Neisseria gonorrhoeae*, viability performance is measured for each test organism at the 48 hrs time point and compared with the acceptance criteria. Viability performance is measured for *Neisseria gonorrhoeae* at the 24 hrs time point. In both the Roll-Plate and Swab Elution viability performance studies, Copan ESwab® System was able to maintain acceptable recovery of all organisms evaluated at both refrigerator (4 – 8ºC) and room temperature (20 – 25ºC). Acceptable recovery for the Roll-Plate Method is defined as $\geq$5 CFU following the specified holding time from the specific dilution that yielded zero-time plate counts closest to 300 CFU. Acceptable recovery for the Swab Elution Method is defined as no more than a 3 $\log_{10}$ (1 x 10^3 +/- 10%) decline in CFU between the zero-time CFU count and the CFU of the swabs after the specified holding time.

Viability performance studies also include an assessment of bacterial overgrowth at refrigerated temperatures (4 – 8ºC). For the Swab Elution Method, an overgrowth assessment is made on all bacteria species tested at the 48 hrs holding time point except for *Neisseria gonorrhoeae* which is assessed at the 24 hrs holding time point. Overgrowth assessment using the Swab Elution Method is defined as greater than 1 $\log_{10}$ increase in CFU between the zero-time CFU count and the holding time point. For the Roll-Plate Method, an overgrowth assessment is made with a separate analysis in which swabs are dosed with 100µl containing 10^2 CFU of *Pseudomonas aeruginosa* culture. Overgrowth under these conditions is defined as greater than 1 $\log_{10}$ increase in CFU between zero-time CFU and the 48 hrs holding time point. Copan ESwab® Collection and Transport System demonstrated no overgrowth in either the Swab Elution or Roll-Plate Methods based on the acceptance criteria described in Clinical Laboratory Standards Institute M40-A2.

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Index of Symbols

Symbol	Meaning
	Manufacturer
CE 0123	Identification number of notified body
STERILE R	Sterilized using ionizing radiation
	Do not reuse
REF	Catalogue number
	Temperature limits
	Use before
	Consult the instructions for use
	Peel
LOT	Batch code (lot)
	Contents sufficient for <n> tests

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