

Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System

Liquid Amies transport medium plus flocced swab

Product Information & How to Use Guide

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 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 of inorganic phosphate buffer, calcium and magnesium salts, and sodium chloride with a reduced environment due to the presence of sodium thioglycollate (1).

Copan ESwab is supplied in a collection kit format. Each collection kit 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 has a tip flocced with soft nylon fiber (flocced swab). Three collection kit configurations are available: one containing a regular size flocced swab applicator intended for the collection of samples from the nose, throat, vagina or wounds, one containing a minitip size flocced swab applicator intended for the collection of samples from small or less accessible areas such as the eye, ear, nasal passages, nasopharynx, throat, urogenital tract for pediatric sample collection and a third containing a flexible minitip size flocced swab applicator intended for the collection of nasopharynx samples and pediatric samples.

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 – 8°C 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 certain bacterial 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.

PRECAUTIONS

- This product is For In Vitro Diagnostic Use.
- Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.
- All specimens and materials used to process ESwab 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).
- 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 kit and the specimen transport tube label.

PRODUCT DETERIORATION

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

SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION

Specimens collected for bacteriological investigations which comprise of 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 – 8°C 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

Copan ESwab is supplied in a collection kit format. Fifty (50) collection kits are contained in a shelf pack and 10 x 50 kits are contained in a box. Each collection kit consists of 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 has a tip flocced with soft nylon fiber (see Figs 1 and 2). Three types of collection kit configurations are available; all include a tube of medium however each having a different type of swab applicator. One kit type contains a regular size flocced swab applicator intended for the collection of samples from the nose, throat, vagina or wounds, the second kit type contains a minitip size flocced swab applicator intended for the collection of samples from small or less accessible areas such as the eye, ear, nasal passages, nasopharynx, throat, urogenital tract and for pediatric sample collection and the third kit type contains a flexible minitip size flocced swab applicator intended for the collection of nasopharyngeal and pediatric samples. These different types of swab applicators facilitate the collection of specimens from different sites on a patient. Refer to the individual product descriptions for specific information about materials supplied.

Fig 1. ESwab Collection Kit



Specimen transport tube with medium

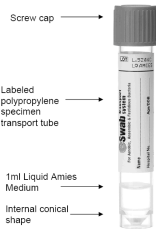
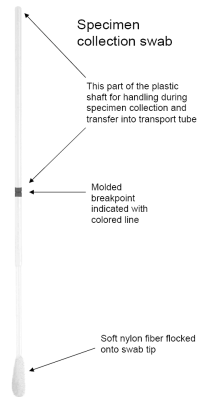


Fig 2. ESwab Collection Kit Components (Tube of Liquid Amies transport medium plus one flocked swab)



All collection swab applicators 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. ESwab tube caps have an internal molded design that is able to capture the swab shaft when it is broken off into the tube and the cap is closed. The action of screwing the cap onto the tube moves the end of the broken swab shaft into a funnel shaped molded docking receptacle in the cap. This molded funnel shape effectively captures the end of the broken applicator shaft and secures it firmly in the dock by friction grip. In the testing laboratory when the swab cap is unscrewed and removed, the swab applicator is attached to the cap. This feature allows the operator to conveniently remove the swab from the transport tube and perform various microbiology analyses using the tube cap as a handle to hold the swab applicator.

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.

Catalog No.	Copan ESwab Collection Kit - Product Descriptions	Pack Size	Sampling Sites [‡]
480C	Sterile single use sample collection pack containing: - Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one regular size flocked swab applicator The polypropylene screw-cap has a molded docking receptacle to capture the swab shaft	50 kits per shelf pack 10 x 50 kits per box	Nose, throat, vagina and wounds
481C	Sterile single use sample collection pack containing: - Polypropylene screw-cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one minitip flocked swab The polypropylene screw cap has a molded docking receptacle to capture the swab shaft	50 kits per shelf pack 10 x 50 kits per box	Eye, ear, nasal passages, nasopharynx, throat, urogenital tract and for pediatric sample collection
482C	Sterile single use sample collection pack containing: - Polypropylene screw cap tube with internal conical shape filled with 1ml of Liquid Amies Medium and one flexible minitip flocked swab The polypropylene screw cap has a molded docking receptacle to capture the swab shaft	50 kits per shelf pack 10 X 50 kits per box	Nasopharynx and pediatric sample collection

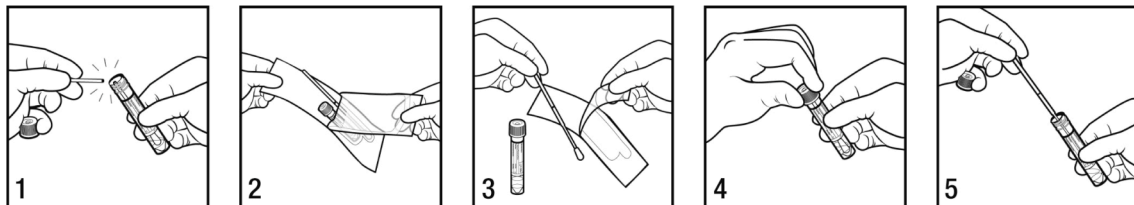
[‡] Performance testing with Copan ESwab was conducted using laboratory strains spiked onto a swab following the test protocols described in Clinical Laboratory Standards Institute M40-A Approved Standard (4). Performance testing was not conducted using human specimens.

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).

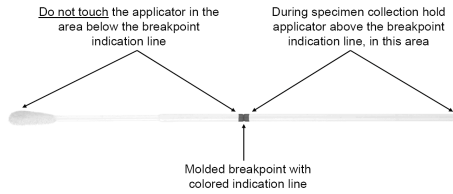
1. Open the ESwab sample collection kit and remove the tube.
2. Remove the swab applicator and collect the sample from the patient.
3. Aseptically unscrew and remove the cap from the tube.
4. Insert the swab into the tube and break the swab shaft at the breakpoint indicated by the colored line marked on 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.

Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens and care should be taken to avoid splashes and aerosols when breaking the swab stick into the tube of medium.



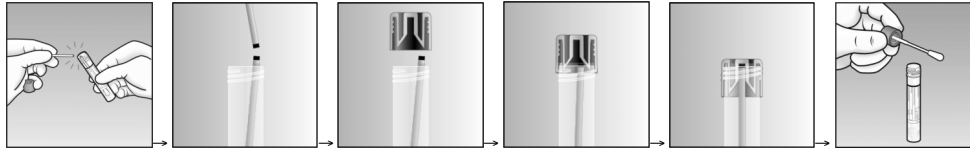
During sample collection when handling the swab applicator, the operator must not touch the area below the marked breakpoint indication line; that is the area from the line to the tip of the nylon flocked swab (see Fig 3), as this will lead to contamination of the applicator shaft and the culture thus invalidating the test results.

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



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. The action of screwing the cap onto the tube moves the end of the broken swab shaft into a funnel shaped molded docking receptacle in the cap (see Fig 4). This molded funnel shape captures the end of the broken applicator shaft and secures it firmly in the dock by friction grip.

Fig 4. Capture of broken swab applicator stick by ESwab tube cap



In the testing laboratory when the ESwab cap is unscrewed and removed, the swab applicator stick is securely attached to the cap. This feature allows the operator to conveniently remove the swab and perform various microbiology analyses using the tube cap as a handle to hold and manipulate the swab.

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).

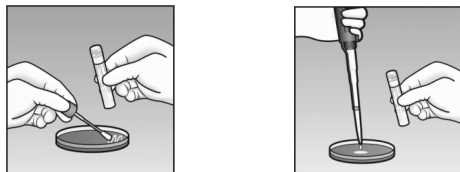
Culture investigations of swab specimens for the presence of aerobic bacteria, anaerobic bacteria and fastidious bacteria such as *Neisseria gonorrhoeae* routinely involve the use of solid agar culture medium in Petri dish plates. The procedure for inoculation of ESwab samples onto solid agar in Petri 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 applicator.
3. Roll the tip of the ESwab applicator onto the surface of one quadrant of the culture media plate to provide the primary inoculum.
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.
5. If it is necessary to inoculate additional culture media plates, return the ESwab applicator to the transport medium tube and recharge the swab applicator tip with the transport medium/patient sample suspension before inoculating each additional plate. Repeat Step No. 3.

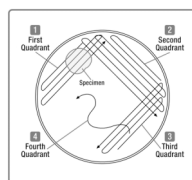
The procedure described above utilizes the ESwab applicator like an inoculation wand to transfer the suspension of patient sample in transport medium onto the surface of a culture plate creating the primary inoculum (see Fig 5). Alternatively, the operator can vortex mix the ESwab tube with the swab inside for 5 seconds and then transfer 100µl volumes of the suspension onto each culture plate using a volumetric pipetor and sterile pipet tips. Standard laboratory techniques should then be used to streak the primary inoculum of patient sample across the surface of the culture plate (see Fig 6).

Fig 5. Procedures for inoculation of ESwab specimens onto solid agar in Petri dishes



1. Using swab to inoculate specimen
2. Using pipetor and sterile pipet tips to inoculate 100µl of specimen

Fig 6. 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 describe below, by sampling an aliquot of vortexed suspension of the swab (21, 32).

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.
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 medium to the inscribed area on the glass slide.
4. Allow the specimen on the slide to air dry or place the slide in a 60°C electric slide warmer.
5. Smears may be fixed with heat or methanol. Methanol fixation may be preferable 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

All lot numbers of the ESwab are tested for sterility and all lot numbers of swab applicators are tested to ensure they are non-toxic to bacteria. ESwab Liquid Amies transport medium is tested for pH stability and bio-burden using Gram stain microscopic examination to ensure acceptable levels as defined in Clinical Laboratory Standards Institute M40-A (4). Each production lot of ESwab is quality control tested before release for ability to maintain viable bacteria at both refrigerated temperatures (4 – 8°C) and room temperature (20 – 25°C) for specified time points with a panel of aerobes, anaerobes and fastidious bacteria using both Roll-Plate and Swab Elution Methods (4). Viability performance studies also include an assessment of bacterial overgrowth at refrigerated temperatures (4 – 8°C) which should correspond to ≤ 1 log increase in growth at a specified time point. Procedures for quality control of bacteriology transport devices using a quantitative Swab Elution Method and qualitative Roll-Plate Method are described in Clinical Laboratory Standards Institute M40-A and other publications (4, 10, 12, 14, 15, 40, 41). If aberrant quality control results are noted, patient results should not be reported.

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 kit. 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

- Do not re-sterilize unused swabs.
- Do not re-pack.
- Not suitable to collect and transport microorganisms other than aerobes, anaerobes and fastidious bacteria.
- Not suitable for any other application than intended use.
- The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
- Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is broken).
- Do not use excessive force or pressure when collecting swab samples from patients as this may result in breakage of the swab shaft.
- 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., nose, throat and vagina and deep invasive surgical wounds).
- Do not ingest the medium.
- Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
- To be handled by trained personnel only.
- 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).
- 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 semiquantitative 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-A (4, 10, 12, 14, 15, 40, 41). The test organisms utilized in this study were those specifically prescribed in M40-A 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-A 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-A (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
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	diluted 10 ^{1.5}	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
<i>Streptococcus pyogenes</i> ATCC 19615	diluted 10 ²	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
<i>Streptococcus pneumoniae</i> 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
<i>Haemophilus influenzae</i> 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
<i>Bacteroides fragilis</i> ATCC 25285	diluted 10 ²	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
<i>Peptostreptococcus anaerobius</i> 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
<i>Fusobacterium nucleatum</i> 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
<i>Propionibacterium acnes</i> ATCC 6919	diluted 10 ²	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
<i>Prevotella melaninogenica</i> 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
<i>Neisseria gonorrhoeae</i> ATCC 43069	diluted 10 ²	5051	234.7	19.7		Acceptable Recovery
		5052	244.7	24.3		Acceptable Recovery
		5055	246.3	23.7		Acceptable Recovery
<i>Enterococcus faecalis</i> (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
<i>Staphylococcus aureus</i> (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
<i>Streptococcus agalactiae</i> (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
<i>Clostridium perfringens</i> 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
<i>Clostridium sporogenes</i> 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
<i>Fusobacterium necrophorum</i> 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
<i>Peptococcus magnus</i> ATCC 29328	diluted 10 ^{3.5}	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
<i>Pseudomonas aeruginosa</i>	diluted	5051	261.7	190.0	51.7	Acceptable Recovery
		5052	258.3	178.0	44.7	Acceptable Recovery

ATCC BAA-427	10 ^{3.5}	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 ^{-2.5}	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 ^{-2.5}	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 ^{-2.5}	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 ^{-1.5}	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 x 10 ⁸	1.1 x 10 ⁸	2.7 x 10 ⁵	-0.71	Acceptable Recovery
		5052	1.4 x 10 ⁸	1.0 x 10 ⁸	2.6 x 10 ⁵	-0.73	Acceptable Recovery
		5055	1.5 x 10 ⁸	9.7 x 10 ⁷	2.6 x 10 ⁵	-0.76	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 1:10	5051	6.0 x 10 ⁵	2.9 x 10 ⁵	6.0 x 10 ⁴	-1.00	Acceptable Recovery
		5052	6.0 x 10 ⁵	2.9 x 10 ⁵	6.5 x 10 ⁴	-0.97	Acceptable Recovery
		5055	6.1 x 10 ⁵	3.0 x 10 ⁵	6.8 x 10 ⁴	-0.95	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	5051	1.8 x 10 ⁶	6.0 x 10 ⁵	2.0 x 10 ⁵	-0.95	Acceptable Recovery
		5052	1.8 x 10 ⁶	6.9 x 10 ⁵	2.0 x 10 ⁵	-0.95	Acceptable Recovery
		5055	1.8 x 10 ⁶	6.4 x 10 ⁵	1.9 x 10 ⁵	-0.98	Acceptable Recovery
Haemophilus influenzae ATCC 10211	diluted 1:10	5051	3.9 x 10 ⁶	9.6 x 10 ⁵	3.9 x 10 ⁵	-1.00	Acceptable Recovery
		5052	3.8 x 10 ⁶	9.9 x 10 ⁵	3.6 x 10 ⁵	-1.02	Acceptable Recovery
		5055	3.7 x 10 ⁶	8.9 x 10 ⁵	2.8 x 10 ⁵	-1.12	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 1:10	5051	8.6 x 10 ⁷	3.7 x 10 ⁷	1.5 x 10 ⁵	-0.76	Acceptable Recovery
		5052	8.4 x 10 ⁷	3.5 x 10 ⁷	1.4 x 10 ⁵	-0.78	Acceptable Recovery
		5055	8.2 x 10 ⁷	3.3 x 10 ⁷	1.3 x 10 ⁵	-0.80	Acceptable Recovery
Peptostreptococcus anaerobius ATCC 27337	diluted 1:10	5051	1.6 x 10 ⁶	9.7 x 10 ⁵	1.2 x 10 ⁵	-1.12	Acceptable Recovery
		5052	1.7x 10 ⁶	9.6 x 10 ⁵	1.1 x 10 ⁵	-1.16	Acceptable Recovery
		5055	1.7 x 10 ⁶	9.5 x 10 ⁵	1.1 x 10 ⁵	-1.19	Acceptable Recovery
Fusobacterium nucleatum ATCC 25586	diluted 1:10	5051	2.4 x 10 ⁶	7.0 x 10 ⁵	1.8 x 10 ⁵	-1.12	Acceptable Recovery
		5052	2.4 x 10 ⁶	6.9 x 10 ⁵	1.8 x 10 ⁵	-1.12	Acceptable Recovery
		5055	2.4 x 10 ⁶	6.8 x 10 ⁵	1.9 x 10 ⁵	-1.10	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 1:10	5051	3.8 x 10 ⁶	1.9 x 10 ⁶	6.9 x 10 ⁵	-0.74	Acceptable Recovery
		5052	3.7 x 10 ⁶	1.8 x 10 ⁶	6.0 x 10 ⁵	-0.79	Acceptable Recovery
		5055	3.7 x 10 ⁶	1.8 x 10 ⁶	5.9 x 10 ⁵	-0.80	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted 1:10	5051	3.1 x 10 ⁶	9.3 x 10 ⁵	2.7 x 10 ⁵	-1.06	Acceptable Recovery
		5052	3.0 x 10 ⁶	9.3 x 10 ⁵	2.7 x 10 ⁵	-1.05	Acceptable Recovery
		5055	3.2 x 10 ⁶	9.3 x 10 ⁵	2.6 x 10 ⁵	-1.09	Acceptable Recovery
Neisseria gonorrhoeae ATCC 43069	diluted 1:10	5051	3.6 x 10 ⁶	2.8 x 10 ⁶		-1.11	Acceptable Recovery
		5052	3.5 x 10 ⁶	2.7 x 10 ⁶		-1.11	Acceptable Recovery
		5055	3.4 x 10 ⁶	2.5 x 10 ⁶		-1.13	Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted 1:10	5051	1.4 x 10 ⁸	8.4 x 10 ⁷	2.5 x 10 ⁵	-0.75	Acceptable Recovery
		5052	1.4 x 10 ⁸	8.2 x 10 ⁷	2.5 x 10 ⁵	-0.75	Acceptable Recovery
		5055	1.4 x 10 ⁸	8.5 x 10 ⁷	2.6 x 10 ⁵	-0.73	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	5051	9.9 x 10 ⁷	7.7 x 10 ⁷	1.9 x 10 ⁵	-0.72	Acceptable Recovery
		5052	9.8 x 10 ⁷	7.6 x 10 ⁷	1.8 x 10 ⁵	-0.73	Acceptable Recovery
		5055	1.0 x 10 ⁸	7.6 x 10 ⁷	2.0 x 10 ⁵	-0.70	Acceptable Recovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted 1:10	5051	5.5 x 10 ⁶	3.4 x 10 ⁶	8.1 x 10 ⁵	-0.83	Acceptable Recovery
		5052	5.6 X 10 ⁶	3.6 x 10 ⁶	8.0 x 10 ⁵	-0.85	Acceptable Recovery
		5055	5.4 X 10 ⁶	3.4 x 10 ⁶	7.8 x 10 ⁵	-0.84	Acceptable Recovery

Clostridium perfringens ATCC 13124	diluted 1:10	5051	2.3 x 10 ⁶	1.3 x 10 ⁶	3.9 x 10 ⁵	-0.77	Acceptable Recovery
		5052	2.3 x 10 ⁶	1.2 x 10 ⁶	3.6 x 10 ⁵	-0.81	Acceptable Recovery
		5055	2.2 x 10 ⁶	1.2 x 10 ⁶	3.2 x 10 ⁵	-0.84	Acceptable Recovery
Clostridium sporogenes ATCC 3584	diluted 1:10	5051	6.5 x 10 ⁵	3.0 x 10 ⁵	1.2 x 10 ⁵	-0.73	Acceptable Recovery
		5052	6.4 x 10 ⁵	4.0 x 10 ⁵	1.2 x 10 ⁵	-0.73	Acceptable Recovery
		5055	6.4 x 10 ⁵	2.9 x 10 ⁵	1.1 x 10 ⁵	-0.76	Acceptable Recovery
Fusobacterium necrophorum ATCC 25286	diluted 1:10	5051	9.6 x 10 ⁵	4.2 x 10 ⁵	1.7 x 10 ⁵	-0.75	Acceptable Recovery
		5052	9.7 x 10 ⁵	4.3 x 10 ⁵	1.8 x 10 ⁵	-0.73	Acceptable Recovery
		5055	9.4 x 10 ⁵	4.1 x 10 ⁵	1.6 x 10 ⁵	-0.77	Acceptable Recovery
Peptococcus magnus ATCC 29328	diluted 1:10	5051	4.9 x 10 ⁵	2.9 x 10 ⁵	8.6 x 10 ⁴	-0.76	Acceptable Recovery
		5052	4.9 x 10 ⁵	2.8 x 10 ⁵	8.7 x 10 ⁴	-0.75	Acceptable Recovery
		5055	4.8 x 10 ⁵	2.8 x 10 ⁵	7.9 x 10 ⁴	-0.78	Acceptable Recovery

**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 x 10 ⁶	9.8 x 10 ⁵	2.7 x 10 ⁵	-0.71	Acceptable Recovery
		5052	1.4 x 10 ⁶	9.6 x 10 ⁵	2.5 x 10 ⁵	-0.75	Acceptable Recovery
		5055	1.5 x 10 ⁶	9.8 x 10 ⁵	2.3 x 10 ⁵	-0.81	Acceptable Recovery
Streptococcus pyogenes ATCC 19615	diluted 1:10	5051	6.0 x 10 ⁵	2.6 x 10 ⁵	4.5 x 10 ⁴	-1.12	Acceptable Recovery
		5052	6.0 x 10 ⁵	2.5 x 10 ⁵	4.1 x 10 ⁴	-1.17	Acceptable Recovery
		5055	6.1 x 10 ⁵	2.5 x 10 ⁵	4.2 x 10 ⁴	-1.16	Acceptable Recovery
Streptococcus pneumoniae ATCC 6305	diluted 1:10	5051	1.8 x 10 ⁶	4.4 x 10 ⁵	1.6 x 10 ⁵	-1.05	Acceptable Recovery
		5052	1.8 x 10 ⁶	4.7 x 10 ⁵	1.5 x 10 ⁵	-1.08	Acceptable Recovery
		5055	1.8 x 10 ⁶	4.7 x 10 ⁵	1.5 x 10 ⁵	-1.08	Acceptable Recovery
Haemophilus influenzae ATCC 10211	diluted 1:10	5051	3.9 x 10 ⁵	8.2 x 10 ⁴	3.2 x 10 ⁴	-1.09	Acceptable Recovery
		5052	3.8 x 10 ⁵	8.2 x 10 ⁴	2.9 x 10 ⁴	-1.12	Acceptable Recovery
		5055	3.7 x 10 ⁵	7.2 x 10 ⁴	2.2 x 10 ⁴	-1.23	Acceptable Recovery
Bacteroides fragilis ATCC 25285	diluted 1:10	5051	8.6 x 10 ⁵	3.8 x 10 ⁵	1.2 x 10 ⁵	-0.86	Acceptable Recovery
		5052	8.4 x 10 ⁵	3.7 x 10 ⁵	1.2 x 10 ⁵	-0.85	Acceptable Recovery
		5055	8.2 x 10 ⁵	3.5 x 10 ⁵	1.0 x 10 ⁵	-0.91	Acceptable Recovery
Peptostreptococcus anaerobius ATCC 27337	diluted 1:10	5051	1.6 x 10 ⁶	8.5 x 10 ⁵	1.1 x 10 ⁵	-1.16	Acceptable Recovery
		5052	1.7 x 10 ⁶	8.5 x 10 ⁵	9.9 x 10 ⁴	-1.23	Acceptable Recovery
		5055	1.7 x 10 ⁶	8.3 x 10 ⁵	9.8 x 10 ⁴	-1.24	Acceptable Recovery
Fusobacterium nucleatum ATCC 25586	diluted 1:10	5051	2.4 x 10 ⁶	6.6 x 10 ⁵	1.6 x 10 ⁵	-1.18	Acceptable Recovery
		5052	2.4 x 10 ⁶	6.4 x 10 ⁵	1.6 x 10 ⁵	-1.18	Acceptable Recovery
		5055	2.4 x 10 ⁶	6.5 x 10 ⁵	1.7 x 10 ⁵	-1.15	Acceptable Recovery
Propionibacterium acnes ATCC 6919	diluted 1:10	5051	3.8 x 10 ⁵	1.3 x 10 ⁵	4.3 x 10 ⁴	-0.95	Acceptable Recovery
		5052	3.7 x 10 ⁵	1.2 x 10 ⁵	3.3 x 10 ⁴	-1.05	Acceptable Recovery
		5055	3.7 x 10 ⁵	1.2 x 10 ⁵	3.4 x 10 ⁴	-1.04	Acceptable Recovery
Prevotella melaninogenica ATCC 25845	diluted 1:10	5051	3.1 x 10 ⁶	5.9 x 10 ⁵	2.1 x 10 ⁵	-1.17	Acceptable Recovery
		5052	3.0 x 10 ⁶	5.9 x 10 ⁵	2.1 x 10 ⁵	-1.15	Acceptable Recovery
		5055	3.2 x 10 ⁶	6.0 x 10 ⁵	2.1 x 10 ⁵	-1.18	Acceptable Recovery
Neisseria gonorrhoeae ATCC 43069	diluted 1:10	5051	3.6 x 10 ⁶	2.2 x 10 ⁶		-1.21	Acceptable Recovery
		5052	3.5 x 10 ⁶	2.1 x 10 ⁶		-1.22	Acceptable Recovery
		5055	3.4 x 10 ⁶	1.9 x 10 ⁶		-1.25	Acceptable Recovery
Enterococcus faecalis (VRE) ATCC 51299	diluted 1:10	5051	1.4 x 10 ⁶	7.6 x 10 ⁵	2.1 x 10 ⁵	-0.82	Acceptable Recovery
		5052	1.4 x 10 ⁶	7.5 x 10 ⁵	2.0 x 10 ⁵	-0.85	Acceptable Recovery
		5055	1.4 x 10 ⁶	7.5 x 10 ⁵	1.9 x 10 ⁵	-0.87	Acceptable Recovery
Staphylococcus aureus (MRSA) ATCC 43300	diluted 1:10	5051	9.9 x 10 ⁵	6.9 x 10 ⁵	1.1 x 10 ⁵	-0.95	Acceptable Recovery
		5052	9.8 x 10 ⁵	6.5 x 10 ⁵	1.2 x 10 ⁵	-0.91	Acceptable Recovery
		5055	1.0 x 10 ⁶	6.6 x 10 ⁵	1.2 x 10 ⁵	-0.92	Acceptable Recovery
Streptococcus agalactiae (Group B Strep) ATCC 13813	diluted 1:10	5051	5.5 x 10 ⁵	3.4 x 10 ⁵	5.4 x 10 ⁴	-1.01	Acceptable Recovery
		5052	5.6 x 10 ⁵	3.3 x 10 ⁵	5.4 x 10 ⁴	-1.02	Acceptable Recovery
		5055	5.4 x 10 ⁵	3.6 x 10 ⁵	5.5 x 10 ⁴	-0.99	Acceptable Recovery
Clostridium perfringens ATCC 13124	diluted 1:10	5051	2.3 x 10 ⁶	1.0 x 10 ⁶	3.3 x 10 ⁵	-0.84	Acceptable Recovery
		5052	2.3 x 10 ⁶	9.3 x 10 ⁵	2.9 x 10 ⁵	-0.90	Acceptable Recovery
		5055	2.2 x 10 ⁶	9.3 x 10 ⁵	2.5 x 10 ⁵	-0.94	Acceptable Recovery
Clostridium sporogenes ATCC 3584	diluted 1:10	5051	6.5 x 10 ⁵	2.7 x 10 ⁵	1.1 x 10 ⁵	-0.77	Acceptable Recovery
		5052	6.4 x 10 ⁵	2.6 x 10 ⁵	9.9 x 10 ⁴	-0.81	Acceptable Recovery
		5055	6.4 x 10 ⁵	2.6 x 10 ⁵	1.0 x 10 ⁵	-0.81	Acceptable Recovery
Fusobacterium necrophorum ATCC 25286	diluted 1:10	5051	9.6 x 10 ⁵	2.7 x 10 ⁵	1.3 x 10 ⁵	-0.87	Acceptable Recovery
		5052	9.7 x 10 ⁵	2.6 x 10 ⁵	1.2 x 10 ⁵	-0.91	Acceptable Recovery
		5055	9.4 x 10 ⁵	2.6 x 10 ⁵	1.4 x 10 ⁵	-0.83	Acceptable Recovery
Peptococcus magnus ATCC 29328	diluted 1:10	5051	4.9 x 10 ⁵	2.8 x 10 ⁵	6.9 x 10 ⁴	-0.85	Acceptable Recovery
		5052	4.9 x 10 ⁵	2.7 x 10 ⁵	5.3 x 10 ⁴	-0.97	Acceptable Recovery
		5055	4.8 x 10 ⁵	2.6 x 10 ⁵	5.7 x 10 ⁴	-0.93	Acceptable Recovery

In accordance with Clinical Laboratory Standards Institute M40-A, 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 – 8°C) and room temperature (20 – 25°C). Acceptable recovery for the Roll-Plate Method is defined as >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 log₁₀ (1 x 10³ +/- 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 – 8°C). 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 log₁₀ 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 10² CFU of *Pseudomonas aeruginosa* culture. Overgrowth under these conditions is defined as greater than 1 log₁₀ 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-A.

BIBLIOGRAPHY

1. Amies CR. A modified formula for the preparation of Stuart's medium. *Canadian Journal of Public Health*, July 1967. Vol. 58, 296 – 300.
2. Miller JM. A Guide to Specimen Management in Clinical Microbiology. Second Edition. American Society for Microbiology. Washington, DC. 1999.
3. Miller JM, Holmes HT. Specimen collection, transport, and storage. In: *Manual of Clinical Microbiology*. 6th ed. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Tenover FC, eds. Washington, DC: ASM; 1995:19-20.
4. Clinical Laboratory Standards Institute CLSI (formerly National Committee for Clinical Laboratory Standards NCCLS). 2003. *Quality Control of Microbiological Transport Systems*; Approved Standard. M40-A Vol. 23 No. 34.
5. Sng E-H, Rajan VS, Teo K-L, Goh A-J. The recovery of *Neisseria gonorrhoeae* from clinical specimens: effects of different temperatures, transport times, and media. *Sex Trans Dis*. 1982; 9:74-78.
6. Sun Y, Taylor T, Williams L, Sautter RL. Comparison of bacterial viability using both the EZ brand collection and transport system with the Difco swab transport pack. Presented at: 96th ASM General Meeting. 1996; Washington DC. Abstract C35.
7. Arbique JC, Forward KR, LeBlanc J. Evaluation of four commercial transport media for the survival of *Neisseria gonorrhoeae*. *Diagnostic Microbiology and Infectious Disease*. 2000; 36:163-168.
8. Perry JL. Effects of temperature on fastidious organism viability during swab transport. 101st General Meeting of the American Society for Microbiology. 2001; Orlando, FL. Abstract C-55.
9. Wilson DA, Tuohy MS, Procop GW, Hall GS. Effects of storage on the recovery of bacteria from three swab transport systems: BD CultureSwab, BD Culturette and Starplex StarSwab II. 101st General Meeting of the American Society for Microbiology. 2001; Orlando, FL. Abstract C-61.
10. Arbique J, Campbell S, MacFarlane M, Davidson RJ. Comparison of methodologies described in NCCLS document M40-P *Quality Control of Microbiology Transport Devices*. 103rd General Meeting of the American Society for Microbiology. 2003; Washington, DC. Abstract C-40.
11. Mitchell E, Berman M, Ginocchio CC. Evaluation of two new Liquid Stuart transport systems: Platinum StarSwab II (Starplex Scientific) and BBL CultureSwab (Becton Dickinson). 102nd General Meeting of the American Society for Microbiology. 2002; Salt Lake City, UT. Abstract C-74.
12. Perry JL, Matthews JS. Compliance of two popular swab transport systems with performance standards detailed by the new NCCLS Proposed Standard, M40-P. 103rd General Meeting of the American Society for Microbiology. 2003; Washington, DC. Abstract C-42.
13. Robinson A, Gruver ML. Comparison of bacterial survival in two transport systems stored at room temperature and refrigerator temperatures. 102nd General Meeting of the American Society for Microbiology. 2002; Salt Lake City, UT. Abstract C-69.
14. Human RP, Jones GA. Evaluation of 4 transport systems against a published standard. 104th General Meeting of the American Society for Microbiology. 2004; New Orleans, LA. Abstract C-161.
15. Human RP, Jones GA. Evaluation of swab transport systems against a published standard. *J Clin Pathol* 2004; 57:762-763.
16. Arbique J, Campbell S, MacFarlane M, Davidson RJ. Comparison of methodologies for anaerobic organisms described in NCCLS document M40-P. *Quality Control of Microbiology Transport Devices*. 13th European Congress of Clinical Microbiology and Infectious Disease (ECCMID). 2003; Glasgow, UK. Abstract P-652.
17. Isenberg HD, Schoenkench FD, Von Graevenitz A, Cumitech 9, Collection and processing of bacteriological specimens. Coordinating editor, S.J. Rubin. American Society for Microbiology, Washington, DC, 1979.
18. Koneman EW, Allen SD, Janda WM, Schreckenberger PC and Winn, Jr. WC. 1992. *Color Atlas and Textbook of Diagnostic Microbiology*. 4th ed. J.B. Lippincott Co. Philadelphia, PA.
19. 42CFR72. Code of Federal Regulations, Title 42, Volume 1, Part 72. Interstate Shipment of Etiologic Agents.
20. Forbes BA, Sahm DF, Weissfeld AS. 1998. *Bailey and Scott's Diagnostic Microbiology*. 10th ed. Mosby, St. Louis, MO.
21. Isenberg HD. 2004. *Clinical Microbiology Procedures Handbook*, 2nd ed. ASM, Washington, DC.
22. Isenberg HD. 1998. *Essential Procedures for Clinical Microbiology*. Chapter 14, 12, Page 787. *Packaging and Shipping Infectious Substances*. ASM, Washington, DC.
23. Clinical Laboratory Standards Institute CLSI (formerly National Committee for Clinical Laboratory Standards NCCLS). 1994. *Procedures for Handling and Transport of Diagnostic Specimens and Etiologic Agents*; Approved Standard. H5-A3.
24. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Tenover FC, eds. *Manual of Clinical Microbiology*, 7th edition. Washington, DC: ASM; 1999.
25. Summanen P, Baron EJ, Citron D, Strong C, Wexler HM, Finegold SM. (1993). *Wadsworth Anaerobic Bacteriology Manual*, 5th ed. Star Publishing Company, Belmont, CA.
26. Marler LM, Siders JA, Allen SD. *Direct Smear Atlas, A Monograph of Gram-Stained Preparations of Clinical Specimens*. Lippincott Williams and Wilkins, 2001.
27. Rotimi VO, Yakubu Z, Abudu OO, Banjo TO. Direct Gram's stain of vaginal discharge as a means of diagnosing bacterial vaginosis. *Journal of Medical Microbiology*, 1991 Vol 35, Issue 2 103-106.
28. Spiegel CA, Amsel R, Holmes KK. Diagnosis of bacterial vaginosis by direct gram stain of vaginal fluid. *J. Clin Microbiol*. 1983 Jul; 18 (1):170-177.
29. Benavides MI, Moncada X, Rodriguez B, Castillo C. Gonococcal urethritis in men: clinical experience in 1978-1988. *Rev Med Chil*. 1992 Oct; 120(10):1140-3.
30. Mayaud P, Msuya W, Todd J, Kaatano G, West B, Begkoyian G, Grosskurth H, Mabey D. Rapid assessment in Rwandan refugee camps in Tanzania. *Genitourin Med*, 1997 Feb; 73 (1):33-8.
31. Deceuninck G, Asamoah-Adu C, Khonde N, Pepin J, Frost EH, Deslandes S, Asamoah-Abu A, Bekoe V, Alary M. Improvement of clinical algorithms for the diagnosis of *Neisseria gonorrhoeae* and Chlamydia trachomatis by the use of Gram-stained smears among female sex workers in Accra, Ghana. *Sex Transm Dis*. 2000 Aug; 27 (7):401-10.
32. Isenberg HD. 1998. *Essential Procedures for Clinical Microbiology*. Chapter 2.1, Page 41. *Gram Stain*. ASM, Washington, DC.
33. Isenberg HD. 1998. *Essential Procedures for Clinical Microbiology*. Chapter 1.1, Page 27. *Collection, Transport and Manipulation of Clinical Specimens*. Procedure for streaking plates for primary isolation. ASM, Washington, DC.
34. Fleming D. *Biological Safety: Principles and Practices*. January 2000. ASM, Washington DC.
35. Richard J. The 1, 2, 3's of Biosafety Levels. Centers for Disease Control and Prevention, Atlanta, GA. <http://www.cdc.gov/od/ohs/symp5/jyrtxt.htm>.
36. Richardson JH. *Biosafety in Microbiological and Biomedical Laboratories*. December 1994. Diane Publishing Company.
37. Hansen DJ. *Healthcare, Laboratories and Biosafety*. Vol 2., 1992. CRC Press.
38. Greenberg AE, Clerici LS, and Eaton AD. 9215 heterotrophic plate count. In: *Standard Methods for the Examination of Water and Waste Water*. 18th ed. Washington, DC APHA; 1992: 9-33-9-34.
39. Washington JA. 1986. Rapid diagnosis by microscopy. *Clin. Microbiol. Newsl*. 8:135-137.
40. Van Horn KG, Rankin I. Evaluation and comparison of two Stuart's Liquid Swab transport systems tested by the NCCLS M40 method. 105th General Meeting of the American Society for Microbiology. 2005; Atlanta, Georgia. Abstract C-292.
41. Bourbeau PP, Heiter BJ. Validation of QC standard for bacteriological transport devices as specified in the NCCLS Proposed Standard M40: *Quality Control of Microbiological Transport Systems*. 103rd General Meeting of the American Society for Microbiology. 2003; Washington, DC. Abstract C-46.



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