Puritan®
Quality since 1919

Puritan® Opti-Swab® Liquid Amies Collection & Transport System

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Puritan® Opti-Swab® Liquid Amies Collection & Transport System

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INTENDED USE

The Puritan Opti-Swab Liquid Amies Collection & Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

SUMMARY AND EXPLANATION

Specialized systems for collecting and transporting bacteriological specimens are commonly used in laboratories to aid in the diagnosis of bacterial infections, especially when there is a delay between specimen collection and processing.

The Puritan Opti-Swab Liquid Amies Collection and Transport System consists of a sterile peel-open pouch containing a pre-scored HydraFlock® flocked swab and a polypropylene screw-cap vial containing 1 ml of modified liquid Amies medium. HydraFlock multiple split polyester fibers facilitate quick absorption and release of clinical specimens.[1,2] HydraFlock flocked swabs are available in various score points and configurations to facilitate specimen collection from various sites on patients' bodies.[3,4,5] Modified liquid Amies transport medium is a nonnutritive phosphate-buffered medium capable of maintaining the viability of aerobic, anaerobic, and fastidious bacteria such as *Neisseria gonorrhoeae* during transport to the laboratory. It also contains thioglycolate salt to provide a reduced environment and chloride salts to help maintain osmotic balance and control permeability of bacterial cells.[6,7]

PRINCIPLES OF THE PROCEDURE

Once a specimen is collected with a swab, it should be placed into the vial containing the transport medium immediately and processed as soon as possible to achieve optimum recovery. In cases where immediate processing (i.e., within 2 hours) is not possible, specimens can be stored at 2-25 °C and processed within 48 hours (except for *Neisseria gonorrhoeae*, which should be processed within 24 hours). Recent independent studies suggest that the viability of certain bacteria in swab transport systems will improve when transported or stored at refrigerated temperature.[8,9,10,11]

REAGENTS

Approximate modified liquid Amies medium formulation per liter

Sodium chloride 3.0g	Monopotassium phosphate 0.2g	Calcium chloride 0.1g
Disodium phosphate 1.2g	Potassium chloride 0.2g	Magnesium chloride 0.1g
Sodium thioglycolate 1.0g		

TECHNICAL NOTES

Puritan modified liquid Amies medium may look cloudy. This is a physical characteristic caused by its chemical composition and is normal.

PRECAUTIONS

- All clinical specimens should be considered biohazards and handled with care. Wear appropriate personal protective equipment and follow laboratory and biosafety guidelines when handling clinical specimens.
- The Puritan Opti-Swab Liquid Amies Collection and Transport System is for use by trained and qualified personnel. Please read and follow the instructions in this package insert carefully and use aseptic techniques.
- Refer to the recommendations of the Centers for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories* for *in vitro* diagnostic use.[12,13,14,15]
- Do not use the device beyond the expiration date printed on the label.
- Do not use the device if the sterile peel pouch seal is damaged.
- The HydraFlock flocked swab provided in the pouch is scored at a specific point to allow for easy breakage after transferring the swab tip to the vial containing the transport medium. While collecting specimens from patients, care should be taken not to use excessive force or pressure that might lead to breakage of the swab shaft.
- Flexible HydraFlock nasopharyngeal swab shafts have a 100mm breakpoint, which may cause coil within vial. These may not be held within grip feature of cap. Use caution when removing swab from vial. Sterile forceps may be necessary.
- Sterilize the unit after use, and dispose of it according to biohazard waste disposal regulations.
- Do not ingest modified liquid Amies medium.

STORAGE

For optimum performance, store at 2-25 °C. Avoid freezing and excessive heat.[5,16,17]

MATERIALS PROVIDED

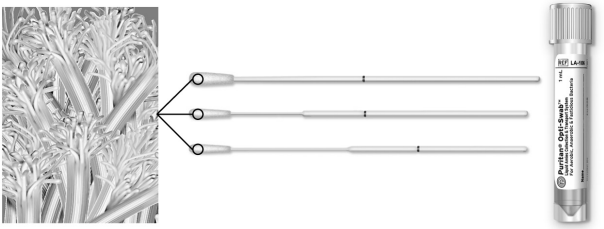
Each Puritan Opti-Swab Liquid Amies Collection & Transport System pouch is provided with the following materials:

- One sterile pre-labeled screw-cap polypropylene vial containing 1 ml of modified liquid Amies medium
- One of three configurations of scored sterile HydraFlock flocked swabs:
  [1] Standard HydraFlock elongated flocked swab
  [2] HydraFlock mini-tip flocked swab
  [3] HydraFlock ultrafine flocked swab

All HydraFlock swabs in Puritan Opti-Swab Liquid Amies Collection and Transport Systems are scored and color printed for ease of use. This allows the swab to break at the scored point and remain inside the vial containing transport medium. Self-centering screw cap is designed to guide and capture the swab handle and the cap is screwed tightly onto the vial.

Note: The swab capture feature does not apply to the item number LA-117 due to the flexibility of the swab handle. Sterile forceps should be used to remove the swab from the vial or from the cap in case the swab is attached loosely to the screw cap.

Figure 1: Opti-Swab Collection and Transport System Kit Components



MATERIALS NOT PROVIDED

Materials for the microscopic examination, cultivation, differentiation, and isolation of bacteria from clinical specimens are not provided. Please refer to standard laboratory procedures or referenced standards for the cultivation, isolation, and identification of bacteria from clinical specimens.[4,5,16]

DIRECTIONS FOR USE

Puritan Opti-Swab Liquid Amies Collection and Transport System is available in product configurations indicated in the table below.

Item Number	Puritan Opti-Swab Product Descriptions	Sample Sites	Pack Size
LA-106 LA-106 US (US only)	• White polypropylene screw-cap tube with 1 ml of liquid Amies medium • One standard HydraFlock elongated flocked swab	Nose, throat, vagina, rectum, and wounds	50 / Box 6x50 / Case
LA-116	• Green polypropylene screw-cap tube with 1 ml of liquid Amies medium • One HydraFlock mini-tip flocked swab	Eye, ear, urogenital, and pediatric	50 / Box 6x50 / Case
LA-117	• Blue polypropylene screw-cap tube with 1 ml of liquid Amies medium • One HydraFlock ultrafine flocked swab	Nasopharyngeal	50 / Box 6x50 / Case

INSTRUCTIONS FOR USE: SPECIMEN COLLECTION

[1] Peel open the pouch from the side marked with the arrow. Remove the swab and the vial from the pouch.

[2] Collect the specimen from the patient.

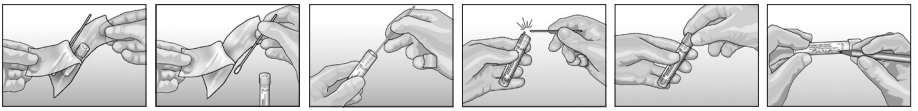
[3] Using appropriate aseptic technique, remove the vial cap and insert the swab into the vial.

[4] Carefully bend and break the swab at the printed breakpoint line. Properly discard the broken handle part of the swab.

[5] Replace the vial cap, securing tightly.

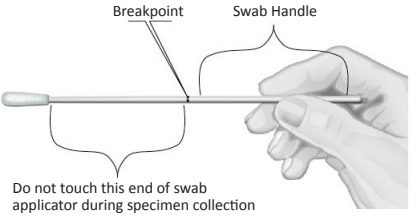
[6] Record patient information in the space provided on the vial label. Transport the specimen to the laboratory for testing.

Figure 2: Specimen Collection Instructions for Use



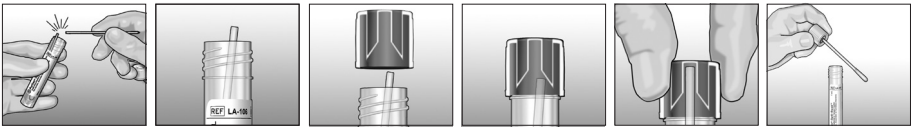
Clinical specimens are considered biohazardous and appropriate protective clothing should be worn when collecting and handling potential infectious specimens. Care should be taken to avoid splashes and aerosols when breaking the swab handle into the vial containing medium. When collecting specimen with swab applicator, the area below the color printed breakpoint must not be touched (area from the breakpoint to the tip of the HydraFlock flocked swab).

Figure 3: Collection swab showing breakpoint indication line and proper hand placement



Puritan Opti-Swab Liquid Amies Collection and Transport Systems with regular and flexible handles (LA-106 and LA-116) are offered with swab capture feature. After collecting specimen place the swab inside the vial and break the handle at the breakpoint. The broken off handle is discarded; the cap is replaced and tightly secured.

Figure 4: Capture of broken swab applicator stick by vial cap



Specimen collection, storage and transport

Proper specimen collection from the patient is critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals. [3,4,5,18,23] To maintain optimum organism viability, transport the specimens collected using Puritan Opti-Swab Liquid Amies Collection and Transport System to the laboratory within 2 h of collection. If immediate delivery or processing is delayed, then specimens should be refrigerated at 2-8 °C or stored at room temperature (20-25 °C) and processed within 48 h except for *Neisseria gonorrhoeae* cultures which should be processed within 24 h. Specimens should be processed as soon as they are received in the laboratory.

Specimen cultures in the laboratory

Manual Processing

[1] Vortex or mix well by shaking the Opti-Swab vial with the swab inside to release cells and create even suspension in the liquid medium.

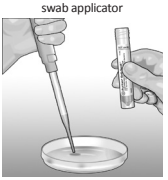
[2] Remove the cap with swab applicator.

[3] Using the swab applicator, streak the first quadrant of the agar plate while rolling the swab tip to create a primary inoculum. If additional plates are required replace swab back into the vial for a few seconds to recharge the swab and repeat section 3. NOTE: When using LA-117, it is recommended to remove the swab applicator from the vial with sterile forceps. Using a pipette with a sterile pipet tip, transfer 100µl of the suspension onto an agar plate.

[4] Use standard laboratory practices to streak or spread the primary inoculum of the specimen onto the rest of the agar culture plate.

Manual processing *with* swab applicator

Manual processing *without* swab applicator



Streak plating example

Automated Processing

Puritan Opti-Swab Liquid Amies Collection and Transport Systems are compatible and validated for use with most automated microbiology platforms. Consult with microbiology automated platform manufacturer instructions for specific information.

Puritan Opti-Swab Liquid Amies Collection & Transport System specimens 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.[3,4,16,18,21,23]

Direct microscopic examination

The Gram stain procedure is commonly used in laboratories for direct microscopic examination of patient clinical samples. The procedure is a useful tool that allows laboratory personnel to assess the quality of the specimen and provide additional information to the physician managing the patient. It can also be used by laboratory clinicians to make a presumptive diagnosis of an infectious disease.[18,19,20] Microscope slides of specimens transported in Puritan Opti-Swab Liquid Amies Collection and Transport System can be prepared for Gram stain by removing aliquots of vortexed suspension of the liquid medium.

Preparation of Gram Stain Smears:

[1] Retrieve a clean glass microscope slide.

[2] Vortex or mix well by shaking the Opti-Swab vial with the swab inside to release cells and create even suspension in the liquid medium.

[3] Remove the cap and using a sterile pipette, transfer a drop or 30 µl of the suspension onto the glass slide. Spread thin and evenly over a circle of 1.5-2 cm in diameter.

[4] Allow the specimen to air dry on the slide at room temperature on a flat surface.

[5] Fix the smear onto the slide by placing a few drops of methanol on the slide for 1 minute, drain off remaining methanol without rinsing, and allow slide to air dry. Methanol fixation prevents lysis of red blood cells, avoids damage to all host cells, and results in a cleaner background.[24]

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.[3,4,5,16,18,23]

Processing Specimens for Molecular Testing

Any use of the Puritan Opti-Swab Liquid Amies Collection and Transport System in conjunction with molecular assays should be validated before use.

QUALITY CONTROL

All raw materials used in the manufacture of Puritan Opti-Swab Liquid Amies Collection & Transport System are tested and qualified before use. Every batch of Puritan Opti-Swab Liquid Amies Collection and Transport System is tested prior to release for sterility, pH, and background count using microscopic examination. Representative samples of each batch are further evaluated for their ability to maintain the viability of selected bacterial agents over predefined time periods.

All bacterial test isolates and testing procedures were established using the criteria outlined in the Clinical and Laboratory Standards Institute's M40-A2 document.[21,22]

LIMITATIONS

1. Reliable specimen collection and transport depends on many factors, including collection and handling techniques, specimen condition and volume, and timing. Best results are achieved when specimens are processed shortly after the time of collection. Refer to the corresponding reference standard and procedures for optimum collection techniques.[16,18,22,23]
2. The Puritan Opti-Swab Liquid Amies Collection & Transport System is recommended for aerobic, anaerobic, and fastidious organisms. Viruses, Chlamydiae, mycoplasmas, and ureaplasmas require a transport medium formulated specifically for use with these organisms. [8,11,22]
3. Viability of microorganisms in the Puritan Opti-Swab Liquid Amies Collection & Transport System other than the ones shown in the Performance Characteristics section is not established.
4. The performance of the Puritan Opti-Swab Liqiud Amies Collection & Transport System for storage time over 48 h has not been evaluated.
5. Extreme temperatures should be avoided during transportation of the collection system.
6. Use of the Puritan Opti-Swab Liquid Amies Collection & Transport System in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Puritan Opti-Swab Liquid Amies Collection & Transport System were determined using the procedures outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document.[21] A variety of aerobic, anaerobic, and fastidious organisms were included in this study. The test organisms were comprised of the ten ATCC strains that are recommended in the CLSI M40-A2 document for determining performance characteristics of swab transport systems.[21] To determine the performance characteristics of the Puritan Opti-Swab Liquid Amies Collection & Transport System, bacterial viability studies were performed. These studies were conducted at two different temperatures to reflect refrigerated (2-8 °C) and room temperature (20-25 °C) conditions. The swabs from each transport system were inoculated in duplicate with a specified volume of select bacterial concentrations. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hours; at the designated time intervals the swabs were removed and processed. These studies were conducted using both the Roll-Plate and Swab Elution Methods.

Organisms evaluated:

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

Additional organisms evaluated:
Bordetella bronchiseptica ATCC 10580, *Bordetella parapertussis* ATCC 15311, *Bordetella pertussis* ATCC 8467, S*taphylococcus aureus* (MRSA) ATCC 43300, *Enterococcus faecalis* (VRE) ATCC 51299, *Streptococcus agalactiae* (Group B Strep) ATCC 13813, *Clostridium perfringens* ATCC 13124, *Clostridium sporogenes* ATCC 3584, *Finegoldia magna* ATCC 29328.

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A2 was followed. For Roll-Plate Method, the viability to be considered acceptable, there shall be ≥5 CFU following the specified holding time from the specific dilution that yielded zero-time plate counts closest to 300 CFU. For viability in the Swab Elution Method to be considered acceptable there shall be no more than a 3 $\log_{10}$ (1×10^3 +/- 10%) decline in CFU between the zero-time CFU count and the CFU of the swabs that were stored.

The results of the study by Roll-Plate Method and the Swab Elution Method are presented in Tables 1-4. The results demonstrate the ability of Puritan Opti-Swab Liquid Amies Collection and Transport System to sustain the viability and recovery of test bacteria within acceptance criteria for at least 48 h at refrigerated (2-8 °C) and room (20-25 °C) temperatures. *Neisseria gonorrhoeae* results support acceptable recoveries up to 24 h as recommended in the CLSI guidance M40-A2.[21]

Viability performance studies also included an assessment of bacterial overgrowth at the refrigerated temperature. Overgrowth assessment as defined in CLSI M40-A2 guideline is greater than 1 $\log_{10}$ increase in CFU between zero-time and the holding time point. There was no increase in bacterial count when the samples were stored at 2-8 °C for 48 h and analyzed by the Roll-Plate Method (Table 2) and the Swab Elution Method (Table 4).

Table 1. Bacterial recovery results for the Roll-Plate Method at room temperature (20-25°C) conditions.

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-4}	Puritan - 111101	308	310	81
		Puritan - 110907	241	251	111
		Puritan - 111209	267	260	106
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 111101	250	204	77
		Puritan - 110907	194	210	131
		Puritan - 111209	245	191	77
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 111101	134	101	34
		Puritan - 110907	200	88	65
		Puritan - 111209	171	164	74
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 111101	264	254	82
		Puritan - 110907	236	136	48
		Puritan - 111209	250	198	61
Bacteroides fragilis ATCC 25285	Diluted 10^{-3}	Puritan - 111101	320	265	109
		Puritan - 110907	200	117	64
		Puritan - 111209	270	285	105
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-3}	Puritan - 111101	265	118	41
		Puritan - 110907	260	130	85
		Puritan - 111209	225	150	18
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-3}	Puritan - 111101	199	105	26
		Puritan - 110907	265	109	40
		Puritan - 111209	213	281	33
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 111101	280	161	57
		Puritan - 110907	279	96	29
		Puritan - 111209	202	196	65
Prevotella melaninogenica ATCC 25845	Diluted 10^{-3}	Puritan - 111101	271	121	29
		Puritan - 110907	264	96	21
		Puritan - 111209	289	165	16
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-4}	Puritan - 111101	264	150	
		Puritan - 110907	226	131	
		Puritan - 111209	258	158	
Bordetella bronchiseptica ATCC 10580	Diluted 10^{-4}	Puritan - 121010	250	168	94
		Puritan - 121011	222	126	83
		Puritan - 130930	239	110	80
Bordetella parapertussis ATCC 15311	Diluted 10^{-4}	Puritan - 121010	260	152	78
		Puritan - 121011	235	130	95
		Puritan - 130930	229	154	106
Bordetella pertussis ATCC 8467	Diluted 10^{-4}	Puritan - 121010	227	168	112
		Puritan - 121011	248	145	106
		Puritan - 130930	226	136	89
Staphylococcus aureus (MRSA) ATCC 43300	Diluted 10^{-4}	Puritan - 121010	300	210	116
		Puritan - 121011	250	164	86
		Puritan - 130930	286	179	112
Enterococcus faecalis (VRE) ATCC 51299	Diluted 10^{-4}	Puritan - 121010	290	202	95
		Puritan - 121011	258	150	74
		Puritan - 130930	231	117	52
Streptococcus agalactiae (Group B Strep) ATCC 13813	Diluted 10^{-4}	Puritan - 121010	196	91	33
		Puritan - 121011	133	74	28
		Puritan - 130930	187	113	59
Clostridium perfringens ATCC 13124	Diluted 10^{-4}	Puritan - 121010	238	159	46
		Puritan - 121011	260	170	61
		Puritan - 130930	200	93	38
Clostridium sporogenes ATCC 3584	Diluted 10^{-4}	Puritan - 121010	270	173	83
		Puritan - 121011	297	180	87
		Puritan - 130930	245	176	74
Finegoldia magna ATCC 29328	Diluted 10^{-4}	Puritan - 121010	152	68	36
		Puritan - 121011	131	63	30
		Puritan - 130930	125	47	23

Table 2. Bacterial recovery results for the Roll-Plate Method at refrigerated (2-8°C) conditions.

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-4}	Puritan - 111101	308	240	46
		Puritan - 110907	241	113	54
		Puritan - 111209	267	281	128
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 111101	250	200	41
		Puritan - 110907	194	111	78
		Puritan - 111209	245	102	81
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 111101	134	61	16
		Puritan - 110907	200	35	35
		Puritan - 111209	171	122	59
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 111101	264	134	45
		Puritan - 110907	236	83	38
		Puritan - 111209	250	136	47
Bacteroides fragilis ATCC 25285	Diluted 10^{-3}	Puritan - 111101	320	220	52
		Puritan - 110907	200	103	33
		Puritan - 111209	270	230	96
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-3}	Puritan - 111101	265	101	49
		Puritan - 110907	260	96	39
		Puritan - 111209	225	158	10
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-3}	Puritan - 111101	199	85	14
		Puritan - 110907	265	67	21
		Puritan - 111209	213	181	41
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 111101	280	186	23
		Puritan - 110907	279	77	25
		Puritan - 111209	202	164	108
Prevotella melaninogenica ATCC 25845	Diluted 10^{-3}	Puritan - 111101	271	114	19
		Puritan - 110907	264	121	16
		Puritan - 111209	289	77	46
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-4}	Puritan - 111101	264	119	
		Puritan - 110907	226	90	
		Puritan - 111209	258	160	
Bordetella bronchiseptica ATCC 10580	Diluted 10^{-4}	Puritan - 121010	250	178	113
		Puritan - 121011	222	160	120
		Puritan - 130930	239	183	117
Bordetella parapertussis ATCC 15311	Diluted 10^{-4}	Puritan - 121010	260	234	151
		Puritan - 121011	235	190	126
		Puritan - 130930	229	182	121
Bordetella pertussis ATCC 8467	Diluted 10^{-4}	Puritan - 121010	227	179	135
		Puritan - 121011	248	202	144
		Puritan - 130930	226	193	121
Staphylococcus aureus (MRSA) ATCC 43300	Diluted 10^{-4}	Puritan - 121010	300	204	129
		Puritan - 121011	250	181	98
		Puritan - 130930	286	210	134
Enterococcus faecalis (VRE) ATCC 51299	Diluted 10^{-4}	Puritan - 121010	290	164	116
		Puritan - 121011	258	129	88
		Puritan - 130930	231	134	79
Streptococcus agalactiae (Group B Strep) ATCC 13813	Diluted 10^{-4}	Puritan - 121010	196	114	74
		Puritan - 121011	133	69	51
		Puritan - 130930	187	98	66
Clostridium perfringens ATCC 13124	Diluted 10^{-4}	Puritan - 121010	238	143	89
		Puritan - 121011	260	136	71
		Puritan - 130930	200	110	52
Clostridium sporogenes ATCC 3584	Diluted 10^{-4}	Puritan - 121010	270	212	93
		Puritan - 121011	297	217	92
		Puritan - 130930	245	176	81
Finegoldia magna ATCC 29328	Diluted 10^{-4}	Puritan - 121010	152	116	66
		Puritan - 121011	131	104	45
		Puritan - 130930	125	99	56

Table 3. Bacterial recovery results for the Swab Elution Method at room temperature (20-25°C) conditions.

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Log_{10} Decline
Pseudomonas aeruginosa ATCC BAA-427	Diluted 1:10	Puritan - 111101	$1.0x10^6$	$1.2x10^6$	$2.1x10^5$	-0.68
		Puritan - 110907	$1.2x10^6$	$1.3x10^6$	$6.1x10^5$	-0.29
		Puritan - 111209	$2.7x10^6$	$1.9x10^6$	$1.8x10^6$	-0.18
Streptococcus pyogenes ATCC 19615	Diluted 1:10	Puritan - 111101	$2.1x10^6$	$2.7x10^6$	$7.4x10^5$	-0.45
		Puritan - 110907	$2.6x10^6$	$9.1x10^5$	$3.5x10^5$	-0.87
		Puritan - 111209	$7.6x10^5$	$1.0x10^6$	$2.5x10^5$	-0.48
Streptococcus pneumoniae ATCC 6305	Diluted 1:10	Puritan - 111101	$2.2x10^6$	$1.8x10^6$	$5.5x10^5$	-0.60
		Puritan - 110907	$1.4x10^6$	$8.8x10^5$	$3.1x10^5$	-0.65
		Puritan - 111209	$2.1x10^6$	$1.1x10^6$	$9.1x10^5$	-0.36
Haemophilus influenzae ATCC 10211	Diluted 1:10	Puritan - 111101	$2.6x10^6$	$7.8x10^5$	$7.1x10^5$	-0.56
		Puritan - 110907	$2.1x10^6$	$1.4x10^6$	$5.1x10^5$	-0.61
		Puritan - 111209	$3.1x10^6$	$2.0x10^6$	$1.5x10^6$	-0.32
Bacteroides fragilis ATCC 25285	Diluted 1:10	Puritan - 111101	$1.7x10^6$	$1.2x10^6$	$2.1x10^5$	-0.91
		Puritan - 110907	$9.9x10^5$	$5.4x10^5$	$2.8x10^5$	-0.55
		Puritan - 111209	$2.9x10^6$	$2.1x10^6$	$1.3x10^6$	-0.35
Peptostreptococcus anaerobius ATCC 27337	Diluted 1:10	Puritan - 111101	$3.1x10^6$	$1.5x10^6$	$4.1x10^5$	-0.88
		Puritan - 110907	$2.0x10^6$	$1.3x10^6$	$4.2x10^5$	-0.68
		Puritan - 111209	$1.9x10^6$	$7.0x10^5$	$3.9x10^5$	-0.69
Fusobacterium nucleatum ATCC 25586	Diluted 1:10	Puritan - 111101	$2.0x10^6$	$8.6x10^5$	$2.5x10^5$	-0.90
		Puritan - 110907	$1.9x10^6$	$7.8x10^5$	$2.1x10^5$	-0.96
		Puritan - 111209	$2.6x10^6$	$6.1x10^5$	$3.0x10^5$	-0.94
Propionibacterium acnes ATCC 6919	Diluted 1:10	Puritan - 111101	$2.3x10^6$	$1.2x10^6$	$7.7x10^5$	-0.48
		Puritan - 110907	$2.0x10^6$	$9.9x10^5$	$6.2x10^5$	-0.51
		Puritan - 111209	$1.0x10^6$	$6.2x10^5$	$2.1x10^5$	-0.68
Prevotella melaninogenica ATCC 25845	Diluted 1:10	Puritan - 111101	$1.8x10^6$	$8.9x10^5$	$5.6x10^5$	-0.51
		Puritan - 110907	$1.5x10^6$	$5.3x10^5$	$3.5x10^5$	-0.63
		Puritan - 111209	$1.9x10^6$	$4.2x10^5$	$1.7x10^5$	-1.05
Neisseria gonorrhoeae ATCC 43069	Diluted 1:10	Puritan - 111101	$1.1x10^6$	$1.0x10^5$		-1.04
		Puritan - 110907	$9.9x10^5$	$4.6x10^5$		-0.33
		Puritan - 111209	$1.3x10^6$	$1.3x10^5$		-1.00
Bordetella bronchiseptica ATCC 10580	Diluted 1:10	Puritan - 121010	$2.5x10^6$	$1.1x10^6$	$4.5x10^5$	-0.74
		Puritan - 121011	$1.3x10^6$	$9.1x10^5$	$5.1x10^5$	-0.41
		Puritan - 130930	$2.2x10^6$	$1.5x10^6$	$8.4x10^5$	-0.42
Bordetella parapertussis ATCC 15311	Diluted 1:10	Puritan - 121010	$2.6x10^6$	$2.1x10^6$	$5.9x10^5$	-0.64
		Puritan - 121011	$3.1x10^6$	$1.9x10^6$	$1.0x10^6$	-0.49
		Puritan - 130930	$2.3x10^6$	$1.7x10^6$	$9.1x10^5$	-0.40
Bordetella pertussis ATCC 8467	Diluted 1:10	Puritan - 121010	$2.3x10^6$	$2.2x10^6$	$2.9x10^5$	-0.90
		Puritan - 121011	$1.6x10^6$	$1.2x10^6$	$3.7x10^5$	-0.64
		Puritan - 130930	$1.8x10^6$	$1.7x10^6$	$3.3x10^5$	-0.74
Staphylococcus aureus (MRSA) ATCC 43300	Diluted 1:10	Puritan - 121010	$2.2x10^6$	$2.0x10^5$	$1.3x10^5$	-1.23
		Puritan - 121011	$2.1x10^6$	$1.6x10^5$	$1.7x10^5$	-1.09
		Puritan - 130930	$2.5x10^6$	$2.2x10^5$	$1.1x10^5$	-1.35
Enterococcus faecalis (VRE) ATCC 51299	Diluted 1:10	Puritan - 121010	$2.0x10^6$	$1.1x10^6$	$2.4x10^5$	-0.92
		Puritan - 121011	$9.4x10^5$	$9.1x10^5$	$2.9x10^5$	-0.51
		Puritan - 130930	$1.7x10^6$	$1.2x10^6$	$3.1x10^5$	-0.74
Streptococcus agalactiae (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 121010	$1.5x10^6$	$8.0x10^5$	$4.6x10^5$	-0.51
		Puritan - 121011	$1.0x10^6$	$7.2x10^5$	$5.8x10^5$	-0.24
		Puritan - 130930	$8.9x10^5$	$5.9x10^5$	$1.8x10^5$	-0.69
Clostridium perfringens ATCC 13124	Diluted 1:10	Puritan - 121010	$3.9x10^5$	$7.0x10^4$	$4.7x10^4$	-0.92
		Puritan - 121011	$5.1x10^5$	$6.2x10^4$	$4.8x10^4$	-1.03
		Puritan - 130930	$3.3x10^5$	$1.7x10^5$	$2.5x10^4$	-1.12
Clostridium sporogenes ATCC 3584	Diluted 1:10	Puritan - 121010	$9.5x10^5$	$1.8x10^5$	$9.8x10^4$	-0.99
		Puritan - 121011	$9.2x10^5$	$1.2x10^5$	$9.0x10^4$	-1.01
		Puritan - 130930	$7.4x10^5$	$1.0x10^5$	$9.6x10^4$	-0.89
Finegoldia magna ATCC 29328	Diluted 1:10	Puritan - 121010	$1.9x10^6$	$8.3x10^5$	$3.1x10^5$	-0.79
		Puritan - 121011	$2.3x10^6$	$6.6x10^5$	$1.6x10^5$	-1.15
		Puritan - 130930	$1.4x10^6$	$7.1x10^5$	$2.7x10^5$	-0.71

Table 4. Bacterial recovery results for the Swab Elution Method at refrigerated (2-8°C) conditions.

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Log_{10} Decline
Pseudomonas aeruginosa ATCC BAA-427	Diluted 1:10	Puritan - 111101	$1.0x10^6$	$9.5x10^5$	$5.0x10^5$	-0.30
		Puritan - 110907	$1.2x10^6$	$9.5x10^5$	$3.0x10^5$	-0.6
		Puritan - 111209	$2.7x10^6$	$4.3x10^5$	$8.8x10^5$	-0.49
Streptococcus pyogenes ATCC 19615	Diluted 1:10	Puritan - 111101	$2.1x10^6$	$7.7x10^5$	$2.5x10^5$	-0.92
		Puritan - 110907	$2.6x10^6$	$5.0x10^5$	$2.3x10^5$	-1.05
		Puritan - 111209	$7.6x10^5$	$1.0x10^6$	$6.1x10^5$	-0.1
Streptococcus pneumoniae ATCC 6305	Diluted 1:10	Puritan - 111101	$2.2x10^6$	$1.1x10^6$	$1.3x10^5$	-1.23
		Puritan - 110907	$1.4x10^6$	$6.8x10^5$	$1.3x10^5$	-1.03
		Puritan - 111209	$2.1x10^6$	$1.1x10^6$	$1.6x10^6$	-0.12
Haemophilus influenzae ATCC 10211	Diluted 1:10	Puritan - 111101	$2.6x10^6$	$4.1x10^5$	$3.4x10^5$	-0.88
		Puritan - 110907	$2.1x10^6$	$1.0x10^6$	$2.0x10^5$	-1.02
		Puritan - 111209	$3.1x10^6$	$3.8x10^5$	$4.2x10^5$	-0.87
Bacteroides fragilis ATCC 25285	Diluted 1:10	Puritan - 111101	$1.7x10^6$	$8.1x10^5$	$7.8x10^5$	-0.34
		Puritan - 110907	$9.9x10^5$	$6.1x10^5$	$2.0x10^5$	-0.69
		Puritan - 111209	$2.9x10^6$	$7.9x10^5$	$9.9x10^5$	-0.47
Peptostreptococcus anaerobius ATCC 27337	Diluted 1:10	Puritan - 111101	$3.1x10^6$	$5.5x10^5$	$1.3x10^5$	-1.38
		Puritan - 110907	$2.0x10^6$	$7.7x10^5$	$1.5x10^5$	-1.12
		Puritan - 111209	$1.9x10^6$	$6.1x10^5$	$9.7x10^5$	-0.29
Fusobacterium nucleatum ATCC 25586	Diluted 1:10	Puritan - 111101	$2.0x10^6$	$2.4x10^5$	$1.4x10^5$	-1.15
		Puritan - 110907	$1.9x10^6$	$3.0x10^5$	$1.8x10^5$	-1.02
		Puritan - 111209	$2.6x10^6$	$5.0x10^5$	$5.8x10^5$	-0.65
Propionibacterium acnes ATCC 6919	Diluted 1:10	Puritan - 111101	$2.3x10^6$	$7.5x10^5$	$4.4x10^5$	-0.72
		Puritan - 110907	$2.0x10^6$	$4.6x10^5$	$4.9x10^5$	-0.61
		Puritan - 111209	$1.0x10^6$	$9.6x10^5$	$4.5x10^5$	-0.35
Prevotella melaninogenica ATCC 25845	Diluted 1:10	Puritan - 111101	$1.8x10^6$	$3.0x10^5$	$3.2x10^5$	-0.75
		Puritan - 110907	$1.5x10^6$	$3.5x10^5$	$1.7x10^5$	-0.95
		Puritan - 111209	$1.9x10^6$	$3.0x10^5$	$1.2x10^5$	-1.2
Neisseria gonorrhoeae ATCC 43069	Diluted 1:10	Puritan - 111101	$1.1x10^6$	$2.3x10^5$		-0.68
		Puritan - 110907	$9.9x10^5$	$6.7x10^5$		-0.17
		Puritan - 111209	$1.3x10^6$	$1.6x10^6$		-0.09
Bordetella bronchiseptica ATCC 10580	Diluted 1:10	Puritan - 121010	$2.5x10^6$	$2.4x10^6$	$1.5x10^6$	-0.22
		Puritan - 121011	$1.3x10^6$	$1.1x10^6$	$9.2x10^5$	-0.15
		Puritan - 130930	$2.2x10^6$	$2.1x10^6$	$1.3x10^6$	-0.23
Bordetella parapertussis ATCC 15311	Diluted 1:10	Puritan - 121010	$2.6x10^6$	$2.3x10^6$	$1.3x10^6$	-0.30
		Puritan - 121011	$3.1x10^6$	$2.2x10^6$	$1.4x10^6$	-0.35
		Puritan - 130930	$2.3x10^6$	$2.1x10^6$	$1.1x10^6$	-0.32
Bordetella pertussis ATCC 8467	Diluted 1:10	Puritan - 121010	$2.3x10^6$	$2.3x10^6$	$1.7x10^6$	-0.13
		Puritan - 121011	$1.6x10^6$	$1.2x10^6$	$8.8x10^5$	-0.26
		Puritan - 130930	$1.8x10^6$	$1.6x10^6$	$1.1x10^6$	-0.21
Staphylococcus aureus (MRSA) ATCC 43300	Diluted 1:10	Puritan - 121010	$2.2x10^6$	$2.2x10^6$	$8.2x10^5$	-0.43
		Puritan - 121011	$2.1x10^6$	$2.0x10^6$	$4.7x10^5$	-0.65
		Puritan - 130930	$2.5x10^6$	$2.2x10^6$	$7.0x10^5$	-0.55
Enterococcus faecalis (VRE) ATCC 51299	Diluted 1:10	Puritan - 121010	$2.0x10^6$	$2.2x10^5$	$9.9x10^5$	-0.31
		Puritan - 121011	$9.4x10^5$	$2.3x10^5$	$5.6x10^5$	-0.22
		Puritan - 130930	$1.7x10^6$	$1.9x10^5$	$7.3x10^5$	-0.37
Streptococcus agalactiae (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 121010	$1.5x10^6$	$1.3x10^6$	$9.7x10^5$	-0.19
		Puritan - 121011	$1.0x10^6$	$9.1x10^5$	$8.2x10^5$	-0.09
		Puritan - 130930	$8.9x10^5$	$6.8x10^5$	$5.2x10^5$	-0.23
Clostridium perfringens ATCC 13124	Diluted 1:10	Puritan - 121010	$3.9x10^5$	$1.9x10^5$	$1.8x10^5$	-0.34
		Puritan - 121011	$5.1x10^5$	$1.7x10^5$	$1.6x10^5$	-0.50
		Puritan - 130930	$3.3x10^5$	$1.6x10^5$	$5.3x10^4$	-0.79
Clostridium sporogenes ATCC 3584	Diluted 1:10	Puritan - 121010	$9.5x10^5$	$6.3x10^5$	$3.0x10^5$	-0.50
		Puritan - 121011	$9.2x10^5$	$7.1x10^5$	$2.0x10^5$	-0.66
		Puritan - 130930	$7.4x10^5$	$5.5x10^5$	$1.5x10^5$	-0.69
Finegoldia magna ATCC 29328	Diluted 1:10	Puritan - 121010	$1.9x10^6$	$4.2x10^3$	$6.8x10^5$	-0.45
		Puritan - 121011	$2.3x10^6$	$2.8x10^4$	$5.6x10^5$	-0.61
		Puritan - 130930	$1.4x10^6$	$1.2x10^5$	$8.5x10^5$	-0.22

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