



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K222613

B Applicant

ARX Sciences, Inc.

C Proprietary and Established Names

ARX Liquid Amies Collection & Transport System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LIO, JTW, JTX	Class I, reserved	21 CFR 866.2900 - Microbiological Specimen Collection And Transport Device	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Not Applicable

C Type of Test:

Specimen Collection and Transport System for Clinical Specimens from a patient to the laboratory for bacteriological testing.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The ARX Liquid Amies Collection & Transport System (ARX) is intended for use in the collection of clinical specimens (i.e., nasal secretion/wash; lachrymal secretion/tears; auricular secretion/cerumen; urethral, rectal, or vaginal swab; wound/abscess material) potentially containing aerobic, anaerobic, and fastidious bacteria and their transport at 2–8°C or 25–30°C from the patient to the laboratory for bacteriological examination and culture. In the laboratory, the collected and transported clinical specimens of nasal, lachrymal, ceruminous, vaginal, urethral, rectal, and wound/abscess origin are processed using standard clinical laboratory operating procedures for bacterial culture.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

D Special Instrument Requirements:

Not Applicable

IV Device/System Characteristics:**A Device Description:**

The ARX Liquid Amies Collection & Transport System consists of a polypropylene screw-cap vial containing Liquid Amies transport medium and three (3) sterile peel-open pouches containing a pre-scored Microbrush nylon flocked swab for collecting specimens. The three (3) nylon flocked swabs are provided with various score points, tip sizes, and configuration to facilitate specimen collection from various sites on patients' bodies. Nylon flocked swabs facilitate quick absorption and release of clinical specimens. Proper specimen collection from the patient is critical for successful isolation and identification of infectious organisms.

Amies liquid medium is a non-nutritive balanced salt solution containing inorganic phosphates to provide buffering capability, sodium chloride, potassium chloride, calcium chloride, and magnesium chloride to provide essential ions that help maintain osmotic balance and control permeability of bacterial cells. It also contains sodium thioglycolate to provide a reduced environment. ARX Liquid Amies transport medium is capable of maintaining the viability of aerobic, anaerobic, and fastidious bacteria (such as *Neisseria gonorrhoeae*) during specimen transport to the laboratory for bacteriological testing and culture.

All raw materials used in the manufacture of ARX Liquid Amies Collection & Transport System are qualified before use. Every batch of ARX Liquid Amies Collection & 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.

B Principle of Operation:

Once a specimen is collected with a swab and added to the ARX liquid Amies transport medium vial, it is immediately processed to achieve optimal recovery. For cases where immediate

processing (i.e., within 2 hours) is not possible, specimens are stored at 2–30°C and processed within 48 hours (except for *Neisseria gonorrhoeae*, which should be processed within 24 hours).

V Substantial Equivalence Information:

A Predicate Device Name(s):

Puritan Liquid Amies Collection and Transport System

B Predicate 510(k) Number(s):

K120846

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: <u>K222613</u>	Predicate: <u>K120846</u>
Device Trade Name	ARX Liquid Amies Collection & Transport System	Puritan Liquid Amies Collection and Transport System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The ARX Liquid Amies Collection & Transport System (ARX) is intended for use in the collection of clinical specimens (i.e., nasal secretion/wash; lachrymal secretion/tears; auricular secretion/cerumen; urethral, rectal, or vaginal swab; wound/abscess material) potentially containing aerobic, anaerobic, and fastidious bacteria and their transport at 2–8°C or 25–30°C from the patient to the laboratory for bacteriological examination and culture. In the laboratory, the collected and transported clinical specimens of nasal, lachrymal, ceruminous, vaginal, urethral, rectal, and wound/abscess origin are processed using standard clinical laboratory operating procedures for bacterial culture.	Puritan Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.
Product Code	LIO, JTW, JTX	SAME
Use/Reuse information	Single Use Device (SUD)	SAME

Device & Predicate Device(s):	Device: <u>K222613</u>	Predicate: <u>K120846</u>
Product Configuration	Base Transport Medium in a screw-capped, conical-bottom tube; specimen collection swabs individually in sterile peel pouches	SAME
Base Transport Medium	Modified Liquid Amies	SAME
Transport Medium tube / volume	Plastic (polypropylene) / 1 mL	SAME
Swab shaft	Plastic, pre-scored	SAME
Amies Formulation	Sodium chloride Disodium phosphate Sodium thioglycolate Monopotassium phosphate Potassium chloride Calcium chloride Magnesium chloride	SAME
pH	7.3 ± 0.2 (range 7.1–7.5)	SAME
Product Storage temperature (refrigerated and room)	2–8°C, 20–25°C	SAME
Shelf life	18 months	SAME
General Device Characteristic Differences		
Kit configuration	Medium tubes (50 count) in a kit box with blister peel pouches (50 count) with swabs inside	Single peel pouch containing sterile swab and Medium tube
Swab tip	Microbrush Nylon Flocked Swab	HydraFlock Swab (Polyester)

VI Standards/Guidance Documents Referenced:

Declaration of Conformity was provided by the sponsor via a signed, dated statement for the following standards. All requirements were met, no deviations from each applicable standard were applied and there were no differences between the tested device and the device to be marketed.

Document	FR Recognition Number	Title / Content
CLSI M40-A2 (R2019)	7-250	Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition (reaffirmed September 2019)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Precision/Reproducibility, Linearity, Analytical Specificity/Interference, Assay Reportable Range, Detection Limit, Assay Cut-Off; Traceability, Expected Values (Controls, Calibrators, or Methods):

Not Applicable

Shelf-life Stability:

Shelf-life stability of four (4) manufactured lots of ARX Liquid Amies Collection & Transport System was evaluated at room temperature (20–25°C) in real time in support of claims of media stability prior to sample collection. Shelf-life stability tests included: (a) pH monitoring, (b) visual estimation of turbidity, and (c) viscosity measurement. Based on available data, the sponsor's claim of shelf-life stability of 18 months for the ARX Liquid Amies Collection & Transport System is acceptable.

The pH of the ARX Liquid Amies Media was measured in real-time at monthly intervals from the date of manufacture (**Table 1**). Random tubes from independent lots stored at room temperature (20–25°C) were tested and found to maintain their pH within the specified range (7.30 ± 0.2).

Table 1: Real-time Stability (20–25°C Storage) — pH Readings

Time (months)	Lot A030921 Manufactured 03/09/21	Lot AR1001 Manufactured 01/07/22	Lot AR1002 Manufactured 01/24/22	Lot AR1003 Manufactured 02/04/22
0	7.30	7.20	7.20	7.20
1	7.30	7.20	7.20	7.20
2	7.30	7.20	7.20	7.20
3	7.30	7.20	7.20	7.20
4	7.30	7.20	7.20	7.20
5	7.30	7.20	7.20	7.20
6	7.30	7.20	7.20	7.20
7	7.30	7.20	7.20	7.20
8	7.30	7.20	7.20	7.20
9	7.30	7.20	7.20	7.20
10	7.25	7.20	7.20	7.20
11	7.25	7.15	7.15	7.15
12	7.25	7.15	7.15	7.15
13	7.25	7.15	7.15	7.15
14	7.25	7.15	7.15	7.20
15	7.20	7.10	7.15	7.15
16	7.20	7.10	7.15	7.15
17	7.20	7.10	7.10	7.15
18	7.20	7.10	7.10	7.15

Visual estimation of Turbidity of the ARX Liquid Amies Media was conducted in real-time at monthly intervals from the date of manufacture using random tubes from independent media lots

stored at room temperature (20–25°C). All lots passed visual inspection with testing time ranging from time zero through 18 months for all 4 lots.

The Viscosity of the ARX Liquid Amies Media was measured at a liquid temperature of approximately 20°C in 4-month intervals from the date of manufacture. Random tubes from independent lots stored at room temperature (20–25°C) were tested and found to maintain viscosity within a range of 1.075 ± 0.015 milliPascal.Second (**Table 2**).

Table 2: Real-time Stability (20–25°C Storage) — Viscosity Readings in mPa.S at 20°C

Time (months)	Lot A030921 Manufactured 03/09/21	Lot AR1001 Manufactured 01/07/22	Lot AR1002 Manufactured 01/24/22	Lot AR1003 Manufactured 02/04/22
0	1.08	1.09	1.08	1.08
4	1.09	1.09	1.07	1.08
8	1.06	1.07	1.06	1.07
12	1.07	1.07	1.06	1.07
16	1.05	1.07	1.07	1.08
20	1.05	1.07	1.06	1.06

Specimen Stability:

Bacterial Recovery Studies:

Performance of ARX Liquid Amies Collection & Transport System for bacterial recovery was determined using roll plate and swab elution methods, following the FDA-recognized sections of Clinical Laboratory Standards Institute (CLSI) M40-A2:2014 *Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition*. As shown in **Table 3**, a total of three (3) aerobic, six (6) facultative anaerobic (including one (1) fastidious organism), and eight (8) obligate anaerobic bacteria was included in the bacterial recovery studies. Additionally, **Table 3** also lists the appropriate Negative Clinical Matrix (NCM) that was used in all these studies. For dilution of the inoculum, a subset of these organisms was tested in the presence of NCM or sterile saline (in a separate set where negative clinical matrix was omitted), whereas another subset of the organisms used saline only. The data indicated no impact on performance for the most challenging organisms when diluted in either matrix or saline. Additionally, justification was provided to support the claim that the subset of organisms tested in saline is expected to have equivalent performance in the presence of matrix.

Performance was assessed using the Roll-Plate and Swab Elution methods. Manual colony counts were conducted for both at all time intervals for each swab-organism combination, and the mean count was recorded per anatomical site. Three (3) dilutions were analyzed for each test organism and the dilution yielding colony counts nearest 300 CFU at time zero was reported and/or used for mean CFU/mL estimations, following the recommendations of CLSI M40-A2 (sections 8.12.1, 8.12.3, and 8.12.4 for Roll-Plate studies; sections 8.11.1, 8.11.2, 8.11.4 for Swab Elution studies). Acceptance criteria for bacterial recovery (minimum acceptable viability of at least 2% CFU relative to time 0 for Roll-plate studies; maximum 3 log₁₀ decline in CFU acceptable relative to time 0 for Swab Elution studies) were followed as recommended in CLSI M40-A2. As discussed in the respective sections below and shown in Tables 4–11 below, the performance of all bacterial recovery, when used with or without NCM, was found to be acceptable.

Table 3: Bacterial strains used for Roll-Plate and Swab Elution studies in Negative Clinical Matrix (NCM) or Saline

Bacteria (ATCC Part #)	Characteristic	0.5 McFarland suspension diluted with		Matrix (Swab Types: NPS, nasopharyngeal, including tapered tip type; OPS, oropharyngeal)	
		NCM	Saline	NCM	Saline
<i>Haemophilus influenzae</i> (ATCC 10211)	Facultative anaerobe	10 ⁻⁴	10 ⁻⁴	Nasal Irrigation/Wash (NPS & OPS)	(NPS)
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Facultative anaerobe	10 ⁻⁴	10 ⁻⁴	Nasal Irrigation/Wash (NPS & OPS)	(NPS)
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Aerobe	10 ⁻⁴	10 ⁻⁴	Tears, Pooled Human Donors (NPS)	(NPS)
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Aerobe	10 ⁻⁴	10 ⁻⁴	Auricular material/cerumen (NPS)	(NPS)
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Aerobe	10 ⁻⁴	10 ⁻⁴	Vaginal & Rectal Swab (NPS & OPS)	(NPS)
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Fastidious, facultative Anaerobe	10 ⁻⁴	10 ⁻⁴	Vaginal Swab (NPS & OPS); Urethral Swab (NPS)	(NPS)
<i>Bacteroides fragilis</i> (ATCC 25285)	Anaerobe	10 ⁻³	10 ⁻³	Wound/Abscess (NPS & OPS)	(NPS)
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Anaerobe	10 ⁻³	10 ⁻³	Wound/Abscess (NPS & OPS)	(NPS)
<i>Streptococcus pyogenes</i> (ATCC 19615)	Facultative anaerobe		10 ⁻⁴		(NPS)
<i>Propionibacterium acnes</i> (ATCC 6919)	Facultative anaerobe		10 ⁻⁵		(NPS)
<i>Enterococcus faecalis</i> (ATCC 51299)	Facultative anaerobe		10 ⁻⁴		(NPS)
<i>Peptostreptococcus anaerobius</i> (ATCC 27337)	Anaerobe		10 ⁻³		(NPS)
<i>Prevotella melaninogenica</i> (ATCC 25845)	Anaerobe		10 ⁻⁵		(NPS)

Bacteria (ATCC Part #)	Characteristic	0.5 McFarland suspension diluted with		Matrix (Swab Types: NPS, nasopharyngeal, including tapered tip type; OPS, oropharyngeal)	
		NCM	Saline	NCM	Saline
<i>Clostridium perfringens</i> (Strain S 107) (ATCC 13124)	Anaerobe		10 ⁻⁴		(NPS)
<i>Clostridium sporogenes</i> (ATCC 3584)	Anaerobe		10 ⁻⁴		(NPS)
<i>Fingoldia magna</i> (Strain WAL2508) (ATCC 29328)	Anaerobe		10 ⁻⁴		(NPS)
<i>Fusobacterium necrophorum</i> (ATCC 25286)	Anaerobe		10 ⁻⁴		(NPS)

Roll-Plate Method:

For the roll-plate method, bacterial suspensions were prepared to approximately 0.5 McFarland standard in NCM (as indicated in **Table 3**) followed by 10-fold serial dilutions in pooled NCM. The performance characteristics of ARX Liquid Amies Collection & Transport System were determined using procedures outlined in CLSI M40-A2 using three sterile flocked swab types (i.e., NPS, nasopharyngeal swab, with or without tapered tip design; OPS, oropharyngeal swab) designed for throat, urogenital and nasal specimen collection. This study was conducted at two different temperatures to reflect refrigerated (2–8°C) and room temperature (25–30°C) conditions in NCM and used three (3) independent lots of ARX Liquid Amies representing old (Lot #A030921, post-production age at study: 23–24 months), middle-aged (Lot #AR1002, age: 6–7 months), and newly manufactured (Lot #A1229222, age: 1–2 months) lots. The swabs from each transport system were inoculated in triplicate with a specified volume of select bacterial suspensions prepared in NCM and saline or in saline only. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hrs. (except *Neisseria gonorrhoeae* held only for 24 hrs.); at the designated time intervals the swabs were removed and processed for recovery of bacterial CFU counts (refer to **Table 4** and **Table 5**).

Additional set of roll-plate testing was performed using 0.5 McFarland suspensions prepared and serially diluted in sterile saline to the desired concentration. The performance characteristics of ARX Liquid Amies Collection & Transport System in saline were determined as above using the two NPS types. This study was conducted at two different temperatures to reflect refrigerated (2–8°C) and ambient temperature (20–25°C) conditions in saline, along with the addition of additional bacterial strains (as indicated in **Table 3**), and used three (3) independent lots of ARX Liquid Amies representing old (Lot #A030921; post-production age at study: 17 months), middle-aged (Lot #AR1001/2/3, age: 6–7 months), and newly manufactured (Lot #A061422, age: 2 months) lots. The swabs from each transport system were inoculated in triplicate with a specified volume of select bacterial suspensions prepared in sterile saline, placed in their respective transport vials, and held for 0, 24, and 48 hrs. (except *Neisseria gonorrhoeae* held only for 24 hrs.); at the designated time intervals the swabs were removed and processed for recovery of bacterial CFU counts (refer to **Table 6** and **Table 7**).

Table 4: Roll-Plate Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions using NCM.

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	219	186	87
	Middle	226	191	93
	New	223	191	91
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	259	226	110
	Middle	254	223	109
	New	261	228	113
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	228	140	77
	Middle	242	135	72
	New	247	145	79
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	268	256	119
	Middle	276	258	128
	New	290	269	124
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	267	136	
	Middle	269	138	
	New	281	146	
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	275	134	53
	Middle	276	132	56
	New	281	136	55
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	258	181	73
	Middle	258	183	79
	New	261	185	81
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	223	156	32
	Middle	228	165	37
	New	233	166	40

* *Neisseria gonorrhoeae* recovery tested only at 24 hrs.

Table 5: Roll-Plate Method of Bacterial Recovery following Storage at Room Temperature (25–30°C) Conditions using NCM.

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	216	170	64
	Middle	218	163	63
	New	225	176	72
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	218	144	63
	Middle	229	149	62
	New	233	148	63
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	243	135	59
	Middle	239	143	67
	New	249	145	69

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	286	234	106
	Middle	287	236	105
	New	293	246	106
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	251	137	
	Middle	266	142	
	New	262	142	
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	285	118	52
	Middle	290	123	52
	New	287	117	52
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	281	177	92
	Middle	276	175	89
	New	278	181	97
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	204	150	40
	Middle	214	153	37
	New	222	151	43

* *Neisseria gonorrhoeae* recovery tested only at 24 hrs.

Table 6: Roll-Plate Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions using Saline.

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Streptococcus pyogenes</i> (ATCC 19615)	Old	249	247	135
	Middle	239	177	105
	New	195	199	94
<i>Peptostreptococcus anaerobius</i> (ATCC 27337)	Old	215	163	38
	Middle	261	180	32
	New	214	144	37
<i>Propionibacterium acnes</i> (ATCC 6919)	Old	257	163	42
	Middle	275	159	37
	New	230	137	34
<i>Prevotella melaninogenica</i> (ATCC 25845)	Old	259	121	27
	Middle	247	126	34
	New	260	119	33
<i>Enterococcus faecalis</i> (ATCC 51299)	Old	236	114	38
	Middle	252	108	35
	New	237	113	43
<i>Clostridium perfringens</i> (Strain S-107) (ATCC 13124)	Old	280	146	44
	Middle	288	161	51
	New	289	158	42
<i>Clostridium sporogenes</i> (ATCC 3584)	Old	245	97	39
	Middle	251	93	38
	New	238	97	34

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Finegoldia magna</i> (Strain WAL2508) (ATCC 29328)	Old	273	150	48
	Middle	280	142	44
	New	274	143	52
<i>Fusobacterium necrophorum</i> (ATCC 25286)	Old	283	144	56
	Middle	288	146	51
	New	275	150	53
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	305	270	95
	Middle	284	241	92
	New	299	274	86
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	253	230	110
	Middle	246	216	85
	New	214	171	68
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	210	184	88
	Middle	229	195	74
	New	223	189	73
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	302	215	107
	Middle	247	181	82
	New	273	192	99
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	232	160	32
	Middle	237	156	31
	New	212	136	26
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	273	120	
	Middle	267	133	
	New	268	130	
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	255	145	76
	Middle	249	131	61
	New	254	126	63
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	299	128	50
	Middle	292	122	47
	New	307	128	53

* *Neisseria gonorrhoeae* recovery tested only at 24 hrs.

Table 7: Roll-Plate Method of Bacterial Recovery following Storage at Room Temperature (20–25°C) Conditions using Saline.

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Streptococcus pyogenes</i> (ATCC 19615)	Old	254	227	120
	Middle	230	177	98
	New	199	193	84
<i>Peptostreptococcus anaerobius</i> (ATCC 27337)	Old	223	150	32
	Middle	248	176	40
	New	220	140	29

Organism (ATCC Part #)	Lot Age	Average CFUs Recovered: Time 0 hr.	Average CFUs Recovered: Time 24 hrs.	Average CFUs Recovered: Time 48 hrs.
<i>Propionibacterium acnes</i> (ATCC 6919)	Old	253	163	44
	Middle	258	157	38
	New	225	128	31
<i>Prevotella melaninogenica</i> (ATCC 25845)	Old	261	122	31
	Middle	252	119	39
	New	268	127	44
<i>Enterococcus faecalis</i> (ATCC 51299)	Old	238	119	39
	Middle	259	107	43
	New	241	112	37
<i>Clostridium perfringens</i> (Strain S- 107) (ATCC 13124)	Old	276	152	48
	Middle	283	164	53
	New	280	159	56
<i>Clostridium sporogenes</i> (ATCC 3584)	Old	253	106	45
	Middle	244	97	42
	New	236	92	37
<i>Fingoldia magna</i> (Strain WAL2508) (ATCC 29328)	Old	183	124	67
	Middle	173	122	64
	New	187	127	62
<i>Fusobacterium necrophorum</i> (ATCC 25286)	Old	273	136	39
	Middle	281	142	32
	New	279	140	42
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	299	298	99
	Middle	292	288	102
	New	300	298	103
<i>Streptococcus pneumoniae</i> (ATCC 6305) [10 ⁻⁴]	Old	234	137	59
	Middle	227	147	67
	New	209	148	53
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	224	170	64
	Middle	216	172	71
	New	215	157	51
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	298	209	95
	Middle	240	179	73
	New	270	188	83
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	230	152	31
	Middle	222	145	35
	New	202	116	22
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	250	131	
	Middle	270	138	
	New	268	135	
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	252	141	70
	Middle	246	134	58
	New	247	121	56
	Old	284	115	53
	Middle	289	122	54

<i>Organism (ATCC Part #)</i>	<i>Lot Age</i>	<i>Average CFUs Recovered: Time 0 hr.</i>	<i>Average CFUs Recovered: Time 24 hrs.</i>	<i>Average CFUs Recovered: Time 48 hrs.</i>
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	New	290	117	47

* *Neisseria gonorrhoeae* recovery tested only at 24 hrs.

Swab Elution Method:

For the Swab-Elution method, bacterial suspensions were prepared in NCM similar to the roll-plate method (as indicated in **Table 3**). The performance characteristics of ARX Liquid Amies Collection & Transport System were determined using the procedures outlined in CLSI M40-A2 using three sterile flocked swab types (i.e., NPS, nasopharyngeal swab, with or without tapered tip design; OPS, oropharyngeal swab) designed for throat, urogenital and nasal specimen collection. This study was conducted at two different temperatures to reflect refrigerated (2–8°C) and room temperature (25–30°C) conditions in NCM and used three (3) independent lots of ARX Liquid Amies representing old (Lot #A030921, post-production age at study: 23–24 months), middle-aged (Lot #AR1002, age: 6–7 months), and newly manufactured (Lot #A1229222, age: 1–2 months) lots. The swabs from each transport system were inoculated in triplicate with a specified volume of select bacterial suspensions prepared either in NCM or in saline or in saline only. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hrs. (except *Neisseria gonorrhoeae* held only for 24 hrs.); at the designated time intervals the swabs were removed and processed for recovery of bacterial CFU/mL counts (refer to **Table 8** and **Table 9**).

Additional swab elution testing was performed using bacterial suspensions prepared and serially diluted in sterile saline to the desired concentration. The performance characteristics of ARX Liquid Amies Collection & Transport System in saline were determined as above using the two NPS types. This study was conducted at two different temperatures to reflect refrigerated (2–8°C) and room temperature (20–25°C) conditions in saline, along with the addition of additional bacterial strains (as indicated in **Table 3**), and used three (3) independent lots of ARX Liquid Amies representing old (Lot #A030921; post-production age at study: 17 months), middle-aged (Lot #AR1001/2/3, age: 6–7 months), and newly manufactured (Lot #A061422, age: 2 months) lots. The swabs from each transport system were inoculated in triplicate with a specified volume of select bacterial suspensions prepared in sterile saline, placed in their respective transport vials, and held for 0, 24, and 48 hrs. (except *Neisseria gonorrhoeae* held only for 24 hrs.); at the designated time intervals the swabs were removed and processed for recovery of bacterial CFU counts (refer to **Table 10** and **Table 11**).

Table 8: Swab Elution Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions using NCM.

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	2.84E+07	1.03E+07	3.58E+06	-0.90
	Middle	3.00E+07	1.08E+07	4.05E+06	-0.87
	New	3.05E+07	1.12E+07	4.08E+06	-0.87
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	1.62E+07	5.43E+06	2.18E+06	-0.87
	Middle	1.85E+07	5.58E+06	2.23E+06	-0.92
	New	1.94E+07	5.72E+06	2.20E+06	-0.94
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	2.40E+07	5.40E+06	3.03E+06	-0.90
	Middle	2.59E+07	6.30E+06	3.60E+06	-0.86
	New	2.65E+07	7.23E+06	3.23E+06	-0.91
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	1.10E+07	8.80E+06	4.00E+06	-0.44
	Middle	1.21E+07	9.90E+06	4.00E+06	-0.48
	New	1.29E+07	1.02E+07	4.67E+06	-0.44
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	2.97E+07	2.06E+07		-0.85
	Middle	3.12E+07	2.19E+07		-0.77
	New	3.21E+07	2.22E+07		-0.74
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	1.56E+07	8.29E+06	4.48E+06	-0.54
	Middle	1.63E+07	9.24E+06	5.19E+06	-0.50
	New	1.66E+07	9.73E+06	5.30E+06	-0.49
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	2.40E+06	1.89E+06	8.00E+05	-0.48
	Middle	2.49E+06	1.88E+06	8.03E+05	-0.49
	New	2.47E+06	1.88E+06	8.18E+05	-0.48
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	2.26E+06	1.37E+06	3.37E+05	-0.83
	Middle	2.32E+06	1.40E+06	3.38E+05	-0.84
	New	2.28E+06	1.40E+06	3.42E+05	-0.82

* *Neisseria gonorrhoeae* Change in Log₁₀ is (0–24 hrs.)

Table 9: Swab Elution Method of Bacterial Recovery following Storage at Room Temperature (25–30°C) Conditions using NCM.

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	2.22E+07	1.67E+07	6.32E+06	-0.54
	Middle	2.22E+07	1.62E+07	5.98E+06	-0.57
	New	2.42E+07	1.66E+07	5.82E+06	-0.62
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	2.25E+07	1.35E+07	5.37E+06	-0.62
	Middle	2.33E+07	1.43E+07	6.48E+06	-0.55
	New	2.37E+07	1.41E+07	6.08E+06	-0.59

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	2.11E+07	1.86E+07	8.03E+06	-0.42
	Middle	2.18E+07	1.91E+07	7.53E+06	-0.46
	New	2.10E+07	1.85E+07	8.07E+06	-0.42
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	1.52E+07	8.40E+06	4.20E+06	-0.56
	Middle	1.64E+07	9.33E+06	5.20E+06	-0.50
	New	1.66E+07	9.70E+06	5.37E+06	-0.49
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	2.67E+07	1.91E+07		-0.99
	Middle	2.73E+07	1.04E+07		-0.42
	New	2.78E+07	1.01E+07		-0.44
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	1.60E+07	6.90E+06	4.03E+06	-0.60
	Middle	1.67E+07	7.45E+06	4.23E+06	-0.60
	New	1.71E+07	8.44E+06	4.40E+06	-0.59
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	2.83E+06	1.87E+06	7.58E+05	-0.57
	Middle	2.86E+06	1.91E+06	8.18E+05	-0.54
	New	2.93E+06	1.94E+06	8.25E+05	-0.55
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	2.11E+06	1.54E+06	3.50E+05	-0.78
	Middle	2.16E+06	1.54E+06	3.45E+05	-0.80
	New	2.21E+06	1.54E+06	3.60E+05	-0.79

* *Neisseria gonorrhoeae* Change in Log₁₀ is (0–24 hrs.)

Table 10: Swab Elution Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions in Saline.

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Streptococcus pyogenes</i> (ATCC 19615)	Old	5.90E+06	2.77E+06	6.33E+05	-0.97
	Middle	6.30E+06	2.97E+06	8.00E+05	-0.90
	New	6.13E+06	2.93E+06	7.33E+05	-0.92
<i>Peptostreptococcus anaerobius</i> (ATCC 27337)	Old	1.63E+06	8.73E+05	1.53E+05	-1.03
	Middle	1.62E+06	8.20E+05	1.47E+05	-1.04
	New	1.57E+06	7.07E+05	1.33E+05	-1.07
<i>Propionibacterium acnes</i> (ATCC 6919)	Old	3.27E+08	1.27E+08	4.37E+07	-0.87
	Middle	3.18E+08	1.17E+08	3.80E+07	-0.92
	New	3.25E+08	1.28E+08	3.07E+07	-1.02
<i>Prevotella melaninogenica</i> (ATCC 25845)	Old	2.95E+08	7.57E+07	2.40E+07	-1.09
	Middle	2.89E+08	7.53E+07	3.17E+07	-0.96
	New	2.92E+08	9.03E+07	3.57E+07	-0.91
<i>Enterococcus faecalis</i> (ATCC 51299)	Old	1.42E+07	8.00E+06	2.60E+06	-0.74
	Middle	1.45E+07	7.47E+06	2.83E+06	-0.71
	New	1.48E+07	7.43E+06	2.73E+06	-0.73

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Clostridium perfringens</i> (Strain S-107) (ATCC 13124)	Old	2.98E+07	1.19E+07	3.30E+06	-0.96
	Middle	2.91E+06	1.24E+07	4.20E+06	-0.84
	New	3.00E+07	1.29E+07	4.13E+06	-0.86
<i>Clostridium sporogenes</i> (ATCC 3584)	Old	2.83E+07	1.75E+07	8.43E+06	-0.53
	Middle	2.74E+07	1.74E+07	9.07E+06	-0.48
	New	2.89E+07	1.80E+07	6.20E+06	-0.67
<i>Fingoldia magna</i> (Strain WAL2508) (ATCC 29328)	Old	2.02E+07	8.53E+06	3.13E+06	-0.81
	Middle	2.10E+07	6.90E+06	3.03E+06	-0.84
	New	2.19E+07	7.57E+06	2.60E+06	-0.93
<i>Fusobacterium necrophorum</i> (ATCC 25286)	Old	2.92E+07	1.51E+07	5.83E+06	-0.70
	Middle	3.02E+07	1.52E+07	5.57E+06	-0.73
	New	2.98E+07	1.56E+07	3.40E+06	-0.94
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	1.02E+06	9.43E+05	2.70E+05	-0.58
	Middle	1.01E+06	9.43E+05	2.87E+05	-0.55
	New	1.03E+06	9.47E+05	2.93E+05	-0.55
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	1.83E+06	4.70E+05	1.60E+05	-1.06
	Middle	1.75E+06	4.83E+05	1.40E+05	-1.10
	New	1.86E+06	4.83E+05	1.63E+05	-1.06
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	3.07E+06	8.17E+05	3.37E+05	-0.96
	Middle	3.13E+06	9.40E+05	3.03E+05	-1.01
	New	3.11E+06	9.53E+05	3.13E+05	-1.00
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	9.50E+04	3.60E+04	1.50E+04	-0.80
	Middle	8.70E+04	3.27E+04	1.63E+04	-0.73
	New	8.63E+04	4.10E+04	1.57E+04	-0.74
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	2.33E+05	6.43E+04	1.70E+04	-1.14
	Middle	2.25E+05	6.03E+04	1.70E+04	-1.12
	New	2.22E+05	6.67E+04	1.97E+04	-1.05
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	3.23E+06	2.13E+06		-0.18
	Middle	3.21E+06	2.05E+06		-0.19
	New	3.24E+06	1.99E+06		-0.21
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	8.00E+05	2.60E+05	1.00E+05	-1.19
	Middle	7.47E+05	2.83E+05	1.03E+05	-1.08
	New	7.43E+05	2.73E+05	9.00E+04	-1.09
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	1.64E+06	8.37E+05	4.77E+05	-0.54
	Middle	1.56E+06	8.37E+05	4.20E+05	-0.57
	New	1.65E+06	8.17E+05	5.13E+05	-0.51

* *Neisseria gonorrhoeae* Change in Log₁₀ is (0–24 hrs.)

Table 11: Swab Elution Method of Bacterial Recovery following Storage at Room Temperature (20–25°C) Conditions using Saline.

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log₁₀ (0–48 hrs.)*
<i>Streptococcus pyogenes</i> (ATCC 19615)	Old	2.54E+07	2.27E+07	1.20E+07	-0.32
	Middle	2.30E+07	1.93E+07	9.70E+06	-0.38
	New	1.99E+07	1.77E+07	7.73E+06	-0.41
<i>Peptostreptococcus anaerobius</i> (ATCC 27337)	Old	2.23E+06	1.50E+06	3.20E+05	-0.84
	Middle	2.48E+06	1.76E+06	4.03E+05	-0.79
	New	2.20E+06	1.40E+06	2.93E+05	-0.88
<i>Propionibacterium acnes</i> (ATCC 6919)	Old	2.53E+08	1.63E+08	4.37E+07	-0.76
	Middle	2.58E+08	1.57E+08	3.80E+07	-0.83
	New	2.25E+08	1.28E+08	3.07E+07	-0.86
<i>Prevotella melaninogenica</i> (ATCC 25845)	Old	2.61E+08	1.22E+08	3.07E+07	-0.93
	Middle	2.52E+08	1.19E+08	3.90E+07	-0.81
	New	2.68E+08	1.27E+08	4.40E+07	-0.79
<i>Enterococcus faecalis</i> (ATCC 51299)	Old	1.71E+07	5.63E+06	3.30E+06	-0.71
	Middle	1.58E+07	5.97E+06	3.67E+06	-0.64
	New	1.68E+07	5.47E+06	3.00E+06	-0.75
<i>Clostridium perfringens</i> (Strain S-107) (ATCC 13124)	Old	2.75E+06	1.43E+07	4.83E+06	-0.76
	Middle	2.69E+07	1.43E+07	4.50E+06	-0.78
	New	2.78E+07	1.46E+07	4.20E+06	-0.82
<i>Clostridium sporogenes</i> (ATCC 3584)	Old	2.62E+07	1.42E+07	5.87E+06	-0.65
	Middle	2.50E+07	1.34E+07	5.07E+06	-0.69
	New	2.58E+07	1.51E+07	5.17E+06	-0.70
<i>Finegoldia magna</i> (Strain WAL2508) (ATCC 29328)	Old	1.94E+07	7.17E+06	6.37E+06	-0.48
	Middle	1.88E+07	6.93E+06	6.53E+06	-0.46
	New	1.97E+07	6.33E+06	6.07E+06	-0.51
<i>Fusobacterium necrophorum</i> (ATCC 25286)	Old	2.92E+07	1.48E+07	5.57E+06	-0.72
	Middle	2.78E+07	1.44E+07	5.23E+06	-0.72
	New	2.72E+07	1.59E+07	4.60E+06	-0.77
<i>Pseudomonas aeruginosa</i> (ATCC BAA-427)	Old	1.26E+06	1.68E+06	1.22E+06	-0.53
	Middle	1.35E+06	1.68E+06	1.19E+06	-0.51
	New	1.16E+06	1.55E+06	1.10E+06	-0.53
<i>Streptococcus pneumoniae</i> (ATCC 6305)	Old	2.34E+06	1.37E+06	5.60E+05	-0.62
	Middle	2.27E+06	1.47E+06	6.67E+05	-0.53
	New	2.09E+06	1.47E+06	5.27E+05	-0.60
<i>Haemophilus influenzae</i> (ATCC 10211)	Old	2.24E+06	1.70E+06	6.43E+05	-0.54
	Middle	2.16E+06	1.72E+06	7.10E+05	-0.48
	New	2.15E+06	1.57E+06	5.13E+05	-0.62
<i>Bacteroides fragilis</i> (ATCC 25285)	Old	2.98E+05	2.09E+05	7.50E+04	-0.60
	Middle	2.40E+05	1.79E+05	7.30E+04	-0.52
	New	2.70E+05	1.88E+05	8.27E+04	-0.51

Organism (ATCC Part #)	Lot Age	Average CFU/mL Recovery: Time 0 hr.	Average CFU/mL Recovery: Time 24 hrs.	Average CFU/mL Recovery: Time 48 hrs.	Change in Log ₁₀ (0–48 hrs.)*
<i>Fusobacterium nucleatum</i> (ATCC 25586)	Old	2.30E+05	1.52E+05	3.13E+04	-0.87
	Middle	2.22E+05	1.45E+05	3.47E+04	-0.81
	New	2.02E+05	1.16E+05	2.40E+04	-0.93
<i>Neisseria gonorrhoeae</i> (ATCC 43069)	Old	2.60E+06	9.40E+05		-0.44
	Middle	2.80E+06	9.43E+05		-0.47
	New	2.92E+06	9.67E+05		-0.48
<i>Staphylococcus aureus</i> (MRSA) (ATCC 43300)	Old	2.05E+06	1.92E+06	8.43E+05	-0.39
	Middle	2.20E+06	1.99E+06	7.63E+05	-0.46
	New	2.20E+06	1.95E+06	7.83E+05	-0.45
<i>Streptococcus agalactiae</i> (Group B Strep) (ATCC 13813)	Old	1.72E+06	7.80E+05	4.47E+05	-0.58
	Middle	1.37E+06	5.10E+05	3.77E+05	-0.56
	New	1.74E+06	7.90E+05	4.43E+05	-0.59

* *Neisseria gonorrhoeae* Change in Log₁₀ is (0–24 hrs.)

Conclusions from Bacterial Recovery Studies:

Using both the Roll-Plate and Swab Elution Methods, the ARX Liquid Amies Collection & Transport System showed recovery of bacteria within the acceptance criteria comparable to the predicate device for all holding temperatures tested. This demonstrates the acceptability of a stability claim of up to 48 hours for all organisms (except 24 hours for *Neisseria gonorrhoeae*) in clinical samples during storage and/or transport in this transport system.

B Comparison Studies:

Method Comparison with Predicate Device, Matrix Comparison:

Not Applicable

C Clinical Studies:

Clinical Sensitivity, Clinical Specificity, Other Clinical Supportive Data, Clinical Cut-Off, Expected Values/Reference Ranges:

Not Applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.