March 27, 2024

ARX Sciences, Inc.
Chad Werts
President
160 Lawrence Bell Drive
Suite 120
Amherst, New York 14221

Re: K222613
Trade/Device Name: ARX Liquid Amies Collection & Transport System
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological Specimen Collection And Transport Device
Regulatory Class: Class I, reserved
Product Code: LIO, JTW, JTX
Dated: March 31, 2023
Received: March 31, 2023

Dear Chad Werts:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K222613

Device Name
ARX Liquid Amies Collection and Transport System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221

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510(k) Summary

March 12th, 2024

Sponsored by:

ARX Sciences, Inc.
160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221
Contact: Chad Werts
Telephone Number: (914) 821-1775

Device Name

Classification Name:	Microbiology Devices
Common Name:	Microbiological Specimen Collection and Transport Device
Proprietary Name:	*ARX Liquid Amies Collection & Transport System*
Regulation Section:	21 CFR 866.2900 Microbiological specimen collection and transport device
Classification:	Class I
Product Codes:	LIO: Device, Specimen Collection JTW: System, Transport, Aerobic JTX: Transport Systems, Anaerobic
Predicate Device:	K120846 *Transport Culture Medium Device* Puritan Medical Products LLC.

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 configurations 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.

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160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221

Once a specimen is collected with a swab and added to the 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).

Intended Use / Indications of 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. **Special Conditions for Use:** ARX Liquid Amies Collection & Transport System is intended For Prescription Use (Rx) Only.

Comparison to Predicate Device Technological Characteristics (Table 1):

Device & Predicate Device(s):	Device: K222613	Predicate: K120846
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
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

Device & Predicate Device(s):	Device: K222613	Predicate: K120846
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)

Performance Characteristics

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 2**, 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 2** 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 $\log_{10}$ 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 3–10

below, the performance of all bacterial recovery, when used with or without NCM, was found to be acceptable.

Table 2: 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
Haemophilus influenzae (ATCC 10211)	Facultative anaerobe	10^{-4}	10^{-4}	Nasal Irrigation/Wash (NPS & OPS)	(NPS)
Streptococcus pneumoniae (ATCC 6305)	Facultative anaerobe	10^{-4}	10^{-4}	Nasal Irrigation/Wash (NPS & OPS)	(NPS)
Staphylococcus aureus (MRSA) (ATCC 43300)	Aerobe	10^{-4}	10^{-4}	Tears, Pooled Human Donors (NPS)	(NPS)
Pseudomonas aeruginosa (ATCC BAA-427)	Aerobe	10^{-4}	10^{-4}	Auricular material/cerumen (NPS)	(NPS)
Streptococcus agalactiae (Group B Strep) (ATCC 13813)	Aerobe	10^{-4}	10^{-4}	Vaginal & Rectal Swab (NPS & OPS)	(NPS)
Neisseria gonorrhoeae (ATCC 43069)	Fastidious, facultative Anaerobe	10^{-4}	10^{-4}	Vaginal Swab (NPS & OPS); Urethral Swab (NPS)	(NPS)
Bacteroides fragilis (ATCC 25285)	Anaerobe	10^{-3}	10^{-3}	Wound/Abscess (NPS & OPS)	(NPS)
Fusobacterium nucleatum (ATCC 25586)	Anaerobe	10^{-3}	10^{-3}	Wound/Abscess (NPS & OPS)	(NPS)
Streptococcus pyogenes (ATCC 19615)	Facultative anaerobe	[redacted]	10^{-4}	[redacted]	(NPS)
Propionibacterium acnes (ATCC 6919)	Facultative anaerobe		10^{-5}		(NPS)
Enterococcus faecalis (ATCC 51299)	Facultative anaerobe		10^{-4}		(NPS)
Peptostreptococcus anaerobius (ATCC 27337)	Anaerobe		10^{-3}		(NPS)
Prevotella melaninogenica (ATCC 25845)	Anaerobe		10^{-5}		(NPS)

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160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221

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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
Clostridium perfringens (Strain S 107) (ATCC 13124)	Anaerobe	[redacted]	10^{-4}	[redacted]	(NPS)
Clostridium sporogenes (ATCC 3584)	Anaerobe		10^{-4}		(NPS)
Finegoldia magna (Strain WAL2508) (ATCC 29328)	Anaerobe		10^{-4}		(NPS)
Fusobacterium necrophorum (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 2**) 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. 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 3** and **Table 4**).

Additional set of roll-plate testing was performed using 0.5 McFarland suspensions prepared and serially diluted in sterile saline to the desired concentration (as shown in **Table 2**). 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 2**), 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 5** and **Table 6**).

Table 3: Roll-Plate Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions using NCM.

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

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

Table 4: 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.**
Haemophilus influenzae (ATCC 10211)	Old	216	170	64
	Middle	218	163	63
	New	225	176	72
Streptococcus pneumoniae (ATCC 6305)	Old	218	144	63
	Middle	229	149	62
	New	233	148	63
Staphylococcus aureus (MRSA) (ATCC 43300)	Old	243	135	59
	Middle	239	143	67
	New	249	145	69
Pseudomonas aeruginosa (ATCC BAA-427)	Old	286	234	106
	Middle	287	236	105
	New	293	246	106
	Old	251	137	

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160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221

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Organism (ATCC Part #)	**Lot Age**	**Average CFUs Recovered: Time 0 hr.**	**Average CFUs Recovered: Time 24 hrs.**	**Average CFUs Recovered: Time 48 hrs.**
Neisseria gonorrhoeae (ATCC 43069)	Middle	266	142	[redacted]
	New	262	142	
Streptococcus agalactiae (Group B Strep) (ATCC 13813)	Old	285	118	52
	Middle	290	123	52
	New	287	117	52
Bacteroides fragilis (ATCC 25285)	Old	281	177	92
	Middle	276	175	89
	New	278	181	97
Fusobacterium nucleatum (ATCC 25586)	Old	204	150	40
	Middle	214	153	37
	New	222	151	43

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

Table 5: 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.**
Streptococcus pyogenes (ATCC 19615)	Old	249	247	135
	Middle	239	177	105
	New	195	199	94
Peptostreptococcus anaerobius (ATCC 27337)	Old	215	163	38
	Middle	261	180	32
	New	214	144	37
Propionibacterium acnes (ATCC 6919)	Old	257	163	42
	Middle	275	159	37
	New	230	137	34
Prevotella melaninogenica (ATCC 25845)	Old	259	121	27
	Middle	247	126	34
	New	260	119	33
Enterococcus faecalis (ATCC 51299)	Old	236	114	38
	Middle	252	108	35
	New	237	113	43
Clostridium perfringens (Strain S-107) (ATCC 13124)	Old	280	146	44
	Middle	288	161	51
	New	289	158	42
Clostridium sporogenes (ATCC 3584)	Old	245	97	39
	Middle	251	93	38
	New	238	97	34
Finegoldia magna (Strain WAL2508) (ATCC 29328)	Old	273	150	48
	Middle	280	142	44
	New	274	143	52
	Old	283	144	56

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Amherst, NY 14221

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Organism (ATCC Part #)	**Lot Age**	**Average CFUs Recovered: Time 0 hr.**	**Average CFUs Recovered: Time 24 hrs.**	**Average CFUs Recovered: Time 48 hrs.**
Fusobacterium necrophorum (ATCC 25286)	Middle	288	146	51
	New	275	150	53
Pseudomonas aeruginosa (ATCC BAA-427)	Old	305	270	95
	Middle	284	241	92
	New	299	274	86
Streptococcus pneumoniae (ATCC 6305)	Old	253	230	110
	Middle	246	216	85
	New	214	171	68
Haemophilus influenzae (ATCC 10211)	Old	210	184	88
	Middle	229	195	74
	New	223	189	73
Bacteroides fragilis (ATCC 25285)	Old	302	215	107
	Middle	247	181	82
	New	273	192	99
Fusobacterium nucleatum (ATCC 25586)	Old	232	160	32
	Middle	237	156	31
	New	212	136	26
Neisseria gonorrhoeae (ATCC 43069)	Old	273	120	
	Middle	267	133	
	New	268	130	
Staphylococcus aureus (MRSA) (ATCC 43300)	Old	255	145	76
	Middle	249	131	61
	New	254	126	63
Streptococcus agalactiae (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 6: 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.**
Streptococcus pyogenes (ATCC 19615)	Old	254	227	120
	Middle	230	177	98
	New	199	193	84
Peptostreptococcus anaerobius (ATCC 27337)	Old	223	150	32
	Middle	248	176	40
	New	220	140	29
Propionibacterium acnes (ATCC 6919)	Old	253	163	44
	Middle	258	157	38
	New	225	128	31
	Old	261	122	31

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Organism (ATCC Part #)	**Lot Age**	**Average CFUs Recovered: Time 0 hr.**	**Average CFUs Recovered: Time 24 hrs.**	**Average CFUs Recovered: Time 48 hrs.**
Prevotella melaninogenica (ATCC 25845)	Middle	252	119	39
	New	268	127	44
Enterococcus faecalis (ATCC 51299)	Old	238	119	39
	Middle	259	107	43
	New	241	112	37
Clostridium perfringens (Strain S-107) (ATCC 13124)	Old	276	152	48
	Middle	283	164	53
	New	280	159	56
Clostridium sporogenes (ATCC 3584)	Old	253	106	45
	Middle	244	97	42
	New	236	92	37
Finegoldia magna (Strain WAL2508) (ATCC 29328)	Old	183	124	67
	Middle	173	122	64
	New	187	127	62
Fusobacterium necrophorum (ATCC 25286)	Old	273	136	39
	Middle	281	142	32
	New	279	140	42
Pseudomonas aeruginosa (ATCC BAA-427)	Old	299	298	99
	Middle	292	288	102
	New	300	298	103
Streptococcus pneumoniae (ATCC 6305) [10^{-4}]	Old	234	137	59
	Middle	227	147	67
	New	209	148	53
Haemophilus influenzae (ATCC 10211)	Old	224	170	64
	Middle	216	172	71
	New	215	157	51
Bacteroides fragilis (ATCC 25285)	Old	298	209	95
	Middle	240	179	73
	New	270	188	83
Fusobacterium nucleatum (ATCC 25586)	Old	230	152	31
	Middle	222	145	35
	New	202	116	22
Neisseria gonorrhoeae (ATCC 43069)	Old	250	131	
	Middle	270	138	
	New	268	135	
Staphylococcus aureus (MRSA) (ATCC 43300)	Old	252	141	70
	Middle	246	134	58
	New	247	121	56
Streptococcus agalactiae (Group B Strep) (ATCC 13813)	Old	284	115	53
	Middle	289	122	54
	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 in NCM. 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 7** and **Table 8**).

Additional swab elution testing was performed using bacterial suspensions prepared and serially diluted in sterile saline to the desired concentration (as indicated in **Table 2**). 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 2**), 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/mL counts (refer to **Table 9** and **Table 10**).

Table 7: 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.)*
Haemophilus influenzae (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
Streptococcus pneumoniae (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
Staphylococcus) aureus (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
Pseudomonas aeruginosa (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
Neisseria gonorrhoeae (ATCC 43069)	Old	2.97E+07	2.06E+07	[redacted]	-0.85
	Middle	3.12E+07	2.19E+07		-0.77
	New	3.21E+07	2.22E+07		-0.74
	Old	1.56E+07	8.29E+06	4.48E+06	-0.54

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.)*
Streptococcus agalactiae (Group B Strep) (ATCC 13813)	Middle	1.63E+07	9.24E+06	5.19E+06	-0.50
	New	1.66E+07	9.73E+06	5.30E+06	-0.49
Bacteroides fragilis (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
Fusobacterium nucleatum (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 Log_{10} is (0–24 hrs.)*

Table 8: 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.)*
Haemophilus influenzae (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
Streptococcus pneumoniae (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
Staphylococcus aureus (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
Pseudomonas aeruginosa (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
Neisseria gonorrhoeae (ATCC 43069)	Old	2.67E+07	1.91E+07	[redacted]	-0.99
	Middle	2.73E+07	1.04E+07		-0.42
	New	2.78E+07	1.01E+07		-0.44
Streptococcus agalactiae (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
Bacteroides fragilis (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
Fusobacterium nucleatum (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 Log_{10} is (0–24 hrs.)*

Table 9: Swab Elution Method of Bacterial Recovery following Storage at Refrigerated (2–8°C) Conditions in Saline.

ARX Sciences, Inc.
160 Lawrence Bell Drive, Suite 120
Amherst, NY 14221

ARX SCIENCES

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.)***
Streptococcus pyogenes (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
Peptostreptococcus anaerobius (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
Propionibacterium acnes (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
Prevotella melaninogenica (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
Enterococcus faecalis (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
Clostridium perfringens (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
Clostridium sporogenes (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
Finegoldia magna (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
Fusobacterium necrophorum (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
Pseudomonas aeruginosa (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
Streptococcus pneumoniae (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
Haemophilus influenzae (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
Bacteroides fragilis (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
Fusobacterium nucleatum (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
	Old	3.23E+06	2.13E+06	[redacted]	-0.18
	Middle	3.21E+06	2.05E+06	[redacted]	-0.19

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.)*
Neisseria gonorrhoeae (ATCC 43069)	New	3.24E+06	1.99E+06		-0.21
Staphylococcus aureus (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
Streptococcus agalactiae (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 Log_{10} is (0–24 hrs.)*

Table 10: 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 Log_{10} (0–48 hrs.)*
Streptococcus pyogenes (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
Peptostreptococcus anaerobius (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
Propionibacterium acnes (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
Prevotella melaninogenica (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
Enterococcus faecalis (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
*Clostridium perfringens (*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
Clostridium sporogenes (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
*Finegoldia magna (*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
Fusobacterium necrophorum (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
	Old	1.26E+06	1.68E+06	1.22E+06	-0.53

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.)*
Pseudomonas aeruginosa (ATCC BAA-427)	Middle	1.35E+06	1.68E+06	1.19E+06	-0.51
	New	1.16E+06	1.55E+06	1.10E+06	-0.53
Streptococcus pneumoniae (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
Haemophilus influenzae (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
Bacteroides fragilis (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
Fusobacterium nucleatum (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
Neisseria gonorrhoeae (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
Staphylococcus aureus (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
Streptococcus agalactiae (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 Log_{10} is (0–24 hrs.)*

Additional studies were conducted with four (4) manufactured lots of ARX Liquid Amies Collection & Transport System for the evaluation of shelf-life stability at room temperature (20–25°C) in real time in support of claims of media stability prior to sample collection, as shown in **Table 11**. The outcomes were acceptable and supported a stability claim of 18 months on the shelf for ARX Liquid Amies Collection & Transport System.

Table 11: Summary of Shelf-life Stability studies with ARX Liquid Amies Collection & Transport System

Shelf-life Stability tests in real time	Test Interval	Test Outcome
(a) pH monitoring	Monthly	Random tubes from independent lots stored at room temperatures (20–25ºC) maintained their pH within the specified range (7.30 ± 0.2) with testing time ranging from time zero through 18 months.
(b) Visual estimation of turbidity	Monthly	Random tubes from independent lots stored at room temperatures (20–25ºC) passed visual inspection with testing time ranging from time zero through 18 months.

(c) Viscosity measurement	4-month	Random tubes from independent lots stored at room temperatures (20–25ºC) maintained viscosity within a range of 1.075 ± 0.015 milliPascal.Second with testing time ranging from time zero through 18 months.

Conclusions from non-clinical Performance 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. Additional studies conducted with the ARX Liquid Amies Collection & Transport System support the shelf-life stability claim of 18 months.