510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231843

B Applicant

ARX Sciences, Inc.

C Proprietary and Established Names

ARX Viral Transport Media Collection and Transport System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM	Class I, reserved	21 CFR 866.2390 - Transport Culture Medium	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the ARX Viral Transport Media Collection & Transport System (ARX-VTM) for collection of viral organisms for laboratory culture and standard laboratory examinations.

B Measurand:

Not applicable

C Type of Test:

Non-propagating Transport Device with culture medium

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1 & 2, Echovirus, and Cytomegalovirus.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The ARX Viral Transport Media Collection and Transport System (ARX-VTM) is a non-propagating media supplied in individual polypropylene (PP) tubes filled with either 1mL or 3 mL of transport medium or as a kit. The kits contain a PP tube with 1mL or 3 mL of transport medium and a sterile peel pouch containing a nylon flocked swab applicator for collecting specimens.

ARX-VTM System is ready for use and requires no further preparation. It is available in the configurations listed in **Table 1** and supplied in a labelled screw-cap test tube.

Table 1: ARX-VTM configurations

REF	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
AR-071	1 mL of ARX-VTM medium in 13x90 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 10 x 50 tubes per box
AR-071-N	1 mL of ARX-VTM medium in 13x90 mm screw-cap tube with internal shaped conical bottom	One Nasopharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box
AR-071-O	1 mL of ARX-VTM medium in 13x90 mm	One Oropharyngeal Test Swab	50 kits per package 10 x 50 kits per box

	screw-cap tube with internal shaped conical bottom.	with breaking point	
AR-103	3 mL of ARX-VTM medium in 16x110 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 10 x 50 tubes per box
AR-103-N	3 mL of ARX-VTM medium in 16x110 mm screw-cap tube with internal shaped conical bottom.	One Nasopharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box
AR-103-O	3 mL of ARX-VTM medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One Oropharyngeal Test Swab with breaking point	50 kits per package 10 x 50 kits per box

B Principle of Operation:

ARX-VTM maintains cellular integrity and the preservation of viruses when properly stored. Prior to use, vials should be stored at either 2-8°C or 25-30°C. Once a specimen is collected with the appropriate swab, it should be placed into the vial containing the transport medium immediately and processed as soon as possible to achieve optimal recovery. In cases where immediate processing is not possible, the transport tube containing the specimen can be stored for up to 72 hours at either 2-8°C or 25-30°C.

The ARX-VTM contains the following ingredients:

- Hank's Balanced Salt Solution (HBSS)
- Fetal Bovine Serum (FBS)
- Gentamicin
- Amphotericin B
- Phenol red
- Deionized water.

HBBS and FBS provide the nutrients. Gentamicin and Amphotericin B inhibit bacterial and fungal contamination, respectively. Phenol red functions as a pH indicator.

V Substantial Equivalence Information:

A Predicate Device Name(s):

iClean Viral Transport System (VTM-RT kit)

B Predicate 510(k) Number(s):

K212856

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K231843	Predicate: K212856
Device Trade Name	ARX Viral Transport Media Collection and Transport System (ARX-VTM)	iClean Viral Transport System (VTM-RT Kit)
General Device Characteristic Similarities		
Intended Use/Indications For Use	ARX Viral Transport Media Collection & Transport System (ARX-VTM) is intended for the collection and transport of clinical specimens containing viruses from the collection site to the testing laboratory. The ARX-VTM is a culture-based media that is intended to be used in the laboratory to perform viral culture or diagnostic assays for viruses including, Influenza A, Parainfluenza type 3, Coronavirus OC43, Respiratory Syncytial Virus (RSV) A, Herpes Simplex virus 1 & 2, Echovirus, and Cytomegalovirus.	iClean Viral Transport System (VTM-RT Kit) is intended for the collection and transport of clinical specimens containing respiratory viruses, *Chlamydiae*, or *Mycoplasma hominis* from the collection site to the testing laboratory. The collection system is a culture-based media that is intended to be used with standard laboratory examination, culture or with other assays that utilize stable recoverable infectious viral particles or bacteria.
Tube Material	Plastic Screw cap tube	Same
Single Use Device	Yes	Same
pH	7.4 ± 0.4	Same
Sterility	Non-sterile	Same
General Device Characteristic Differences		
Media Formulation	• Hanks Balanced Salt Solution (HBSS)	• Hanks Balanced Salt Solution (HBSS)

	• Fetal Bovine Serum • Gentamicin Sulfate • Amphotericin B • Phenol red	• Bovine Serum Albumin (BSA) • Gentamicin Sulfate • Amphotericin B • Colistin • L-Glutamic acid • HEPES buffer • Phenol Red
Sample Storage Time	• Specimen should be processed within 72 hours from collection.	• Specimen should be processed within 48 hours
Sample storage temperature	2-30 °C	2-25 °C
Supported Strains	• Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3 • Respiratory Syncytial Virus • Coronavirus OC43	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3 • Respiratory Syncytial Virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma hominis*

VI Standards/Guidance Documents Referenced:

Not Applicable.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Not Applicable.

2. Linearity:

   Not Applicable.

3. Analytical Specificity/Interference:

   Not Applicable.

4. Assay Reportable Range:

   Not Applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Shelf Life:
   To evaluate Shelf-life, three lots of ARX-VTM samples were tested and visually examined at every month for real-time aging from 0 to 20 months. The lots of media were stored at 2-8°C or room temperature (25-30°C). Duplicate samples from each lot were visually inspected for turbidity (the appearance of the product is expected to be clear (i.e., no turbidity, not cloudy, and no precipitation)) and maintains a pink color (i.e., no color change from pink to yellow). The media lots were tested for pH (acceptable range: 7.4 ± 0.4) and osmolarity (acceptable range: 290 ± 30 mOsm/Kg). All results were acceptable. This and the performance data from recovery studies do support that ARX-VTM is stable for up to 20 months.

   Sterility:
   The ARX-VTM tube and media are not sold as sterile nor are they intended to be sterilized by the user. These vials are single use devices. To minimize contamination, the tubes are filled aseptically during manufacturing under control conditions. The swabs provided with the ARX-VTM are individually packaged and are sold as sterile.

6. Detection Limit:

   Performance Testing - Recovery Studies:
   Performance of the ARX-VTM was evaluated using a culture-based viral recovery study. Dilutions of the virus stock suspensions for Coronavirus OC43, Cytomegalovirus (CMV), Echovirus Type 30, Herpes Simplex Virus Type 1 (HSV-1), Herpes Simplex Virus Type 2 (HSV-2), Influenza A, Parainfluenza 3, and Respiratory Syncytial Virus (RSV) A were prepared in negative clinical matrix. The matrix was then transferred with the swabs into the ARX-VTM and held at both 2-8°C and room temperature (25-30°C) for 0, 24, 48, and 72 hours. The inoculum dilution for preparing the contrived virus specimen was predetermined by demonstrating ~40 to~50% infection via Fluorescent Foci Unit (FFU) after 24-48 hours in culture. Recovery study was conducted with three variously aged lots (new lot: 0-3 months old, middle-age lot: 11-12 months old, and old lot: 17 to 19 months old) of 3 ml ARX-VTM. At the end of each incubation of the swab samples in the ARX-VTM, an aliquot of the mixture was inoculated into the cell monolayer and incubated for 24-48 hours before the cells were washed, fixed and immunostained by fluorescein isothiocyanate (FITC)-labeled antibodies for each target virus. The virus titer was determined by visual enumeration of fluorescent foci units (FFU) of each target virus. **Table 2** below exhibits the viral recovery performance of the ARX-VTM at 2-8°C. **Table 3** below exhibits the viral recovery

performance of the ARX-VTM at 25-30°C. Any change of virus titer that was within one log (+/-90%) from the baseline (time point 0) was considered acceptable.

Table 2: Viral recovery performance of ARX-VTM at 2-8°C

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)	Percent Changes in viral recovery from the baseline (T= 0 hr.) at 2-8°C (-ve indicates reduction)		
	0 h	24 h	48 h	72 h
Cytomegalovirus	3.52E+04	-0.34%	-5.65%	-29.91%
Coronavirus OC43	1.93E+04	13.53%	-4.90%	-20.29%
Echovirus Type 30	4.29E+04	2.27%	-0.60%	-13.54%
Herpes Simplex Virus Type 1	3.06E+04	-1.26%	-15.39%	-29.74%
Herpes Simplex Virus Type 2	3.71E+04	-18.51%	-23.41%	-29.78%
Influenza A H3N2	3.39E+04	36.00%	61.69%	26.89%
Parainfluenza Type 3	3.61E+04	61.16%	9.21%	-36.19%
Respiratory Syncytial Type A	1.12E+04	31.29%	-24.14%	-41.66%

Table 3: Viral recovery performance of ARX-VTM at 25-30°C

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)	Percent Changes in viral recovery from the baseline (T= 0 hr.) at 25-30°C (-ve indicates reduction)		
	0 h	24 h	48 h	72 h
Cytomegalovirus	3.52E+04	4.85%	-24.86%	-34.58%
Coronavirus OC43	1.93E+04	12.82%	-6.68%	-27.68%
Echovirus Type 30	4.29E+04	10.16%	-5.16%	-19.81%
Herpes Simplex Virus Type 1	3.06E+04	-3.33%	-12.47%	-36.23%
Herpes Simplex Virus Type 2	3.71E+04	-13.19%	-23.06%	-33.85%
Influenza A H3N2	3.39E+04	32.50%	45.29%	8.63%
Parainfluenza Type 3	3.61E+04	41.75%	-16.68%	-46.93%

Respiratory Syncytial Type A	1.12E+04	98.71%*	61.86%	23.07%

* Considered acceptable because subsequent timepoints, i.e., 48 h and 72 h time points showed < 90% increase.

The viral recovery study data supports the recovery of the above indicated viruses for up to 72 hours from collection when the specimen containing viruses are stored in the ARX-VTM at 2-8°C or at room temperature (25-30°C).

Based on the overall analysis of viral recovery data, the following statements were added in the package insert:

1. ARX-VTM was also tested for viral recovery of Adenovirus. However, due to data irregularities, the data was insufficient to support use of this medium for collection and storage of specimens for Adenovirus culture or testing.
2. The recovery performance of other viruses beyond the ones tested in the recovery study are not known.

Assay Cut-Off:

Not Applicable.

Comparison Studies:

Method Comparison with Predicate Device:

Not Applicable.

Matrix Comparison:

Not Applicable.

Clinical Studies:

Clinical Sensitivity:

Not Applicable.

Clinical Specificity:

Not Applicable.

Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not Applicable.

Clinical Cut-Off:

Not Applicable.

Expected Values/Reference Range:

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.