510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K202531

B Applicant

Azer Scientific, Inc.

C Proprietary and Established Names

Azer Scientific Universal Transport Medium

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 a substantial equivalence determination for the Azer Scientific Universal Transport Medium for the collection and transport of clinical specimens containing viruses.

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:

The Azer Scientific Universal Transport Medium is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses from the collection site to the testing laboratory. The Azer Scientific Universal Transport Medium is a culture-based media that can be processed using standard clinical laboratory operating procedures for the isolation and detection of upper respiratory viruses including Influenza A, Respiratory Syncytial Virus (RSV) and Adenovirus.

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 Azer Scientific Universal Transport Medium includes a plastic screw-cap tube with conical bottom containing 3 mL of transport medium and three, 3 mm size glass beads. Azer Scientific Universal Transport Medium tubes can be supplied alone or in a kit format with one of three different collection swab options in a sterile peel pouch.

Swab Options:

- PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint) (SKU#: 25-3306-U).
- PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint) (SKU#: 25-3320-U EMB 80MM)
- Azer Scientific 3" Foam Swab, individually wrapped, sterile (ES45019S)

The Azer Scientific Universal Transport Medium is offered in the following configurations**:**

SKU	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
PFUTM-10	3 mL universal transport medium in 10mL screw cap tube with internal shaped conical bottom with 3 mm size glass beads	NA	50/Pack
PFUTM-15	3 mL universal transport medium in 15mL screw cap tube with internal shaped conical bottom with 3 mm size glass beads	NA	50/Pack

ES45019S	NA	Azer Scientific Foam Swab, individually wrapped, sterile	500/pack
NPKIT-10	PFUTM-10	PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint)	50/pack
MCKIT-10	PFUTM-10	PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint)	50/pack
FOAMKIT-10	PFUTM-10	3" Foam Specimen Collection Swab	50/pack
NPKIT-15	PFUTM-15	PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Revised Ultrafine Flock Tipped Applicator with Plastic Handle (80mm breakpoint)	50/pack
MCKIT-15	PFUTM-15	PurFlock Ultra 6" Sterile Standard Flock Swab w/Polystyrene Handle, 80mm Breakpoint. Regular Flock Tipped Specimen Collection Applicator and Plastic Handle (80mm Breakpoint)	50/pack
FOAMKIT - 15	PFUTM-15	3" Foam Specimen collection Swab	50/pack

B Principle of Operation:

The Azer Scientific Universal Transport Medium System is an isotonic and non-toxic medium. The medium consists of the following: Hank's Balanced Salt Solution. Bovine Serum Albumin,

L-cysteine, L-glutamic acid, Vancomycin, Amphotericin B, Colistin, gelatin, HEPES Buffer, sucrose and Phenol red. The Hank's buffer creates a neutral environment to help increase the stability of the virus. Bovine Serum Albumin (BSA) acts as a protein stabilizer by forming a protective film on the protein shell of the virus, making it less likely to break down and ensuring the integrity of the virus. Vancomycin, Amphotericin B, and Colistin inhibit the proliferation of competing bacteria and yeasts. L-glutamic acid serves as an auxiliary energy source to keep cell and virus stability. HEPES buffer provides additional help to maintain a stable pH. Phenol red is a pH indicator which serves as a visual quality control mechanism. The L-cysteine, gelatin, and sucrose, helps in preserving the virus.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Copan Universal Transport Medium (utm-rt) System

B Predicate 510(k) Number(s):
K042970

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K202531	Predicate: K042970
Device Trade Name	Azer Scientific Universal Transport Medium	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Azer Scientific Universal Transport Medium is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses from the collection site to the testing laboratory. The Azer Scientific Universal Transport Medium is a culture-based media that can be processed using standard clinical laboratory operating procedures for the isolation and detection of upper respiratory	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, *Chlamydiae*, *Mycoplasma* or *Ureaplasma* from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.

	viruses including Influenza A, Respiratory Syncytial Virus (RSV) and Adenovirus.	
Single-Use Device	Yes	Same
Medium Formulation	Hank's Balanced Salt Solution Bovine Serum Albumin L-cysteine Gelatin Sucrose L-glutamic acid HEPES buffer Vancomycin Amphotericin B Colistin Phenol red	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2 – 25°C	Same
Glass Beads	3 x 3 mm	Same
Container	Plastic, conical bottom	Same
Product Configuration	Media in tube with cap or Media Kit; Media in tube with cap and sterile swab options	Same
Shelf Life	12 months	Same
General Device Characteristic Differences		
Fill Volume	3 mL	1.5 mL; 3 mL; or 10 mL
Swab Tip	Flocked Nylon (Specimen Collection and NP Swabs) Reticulated Polyurethane Foam (Mid-turbinate Foam Swab)	Polyester
Swab Shaft	Polypropylene (Specimen Collection,	Plastic; Stainless Steel - Plastic

	NP, and Foam Swabs)	
Supported Strains	**Viruses:** Influenza A Adenovirus Respiratory Syncytial Virus (RSV)	**Viruses:** Adenovirus Cytomegalovirus (CMV) Echovirus Type 30 (Echo 30) Herpes Simplex Virus Type 1 (HSV1) HSV2 Influenza A Parainfluenza Type 3 Respiratory Syncytial Virus (RSV) Varicella Zoster Virus (VZV) **Chlamydiae:** *Chlamydia pneumoniae Strain CM-1* *Chlamydia trachomatis Type 1 Strain UW-12/UR* **Mycoplasma:** *Mycoplasma hominis* *Mycoplasma pneumoniae* **Ureaplasma:** *Ureaplasma urealyticum*
Sample Stability	48 hrs. at 2-8°C or 20-25°C	48 hrs. at 4°C or 20-25°C

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:
   The shelf-life of the Azer Scientific Universal Transport Medium was determined to be 12 months from the date of manufacture when stored at 2-25°C. Three lots of Azer Scientific Universal Transport Medium were assessed qualitatively at each time point for functionality and physical characteristics using real time ageing studies. In the real time study, media lots were held at 2-8°C, and 20-25°C for 12 months (T=0, 3, 6, 9, and 12 months).

   a) Appearance
   To evaluate appearance, the different lots of the Azer Scientific Universal Transport Medium were visually examined. The appearance of the product was observed to have no significant color change (pink, transparent), precipitate, particulates, or cloudy appearance. All lots tested at each time point passed the criteria for appearance when held at 2-8°C, and 20-25°C.

   b) pH Stability
   The pH of the media was used as one of the indicators to support product stability. For all the tubes at each time point and each lot, the pH was within the targeted range of 7.3±0.2 when held at 2-8°C and 20-25°C only.

   c) Microbial contamination check
   Microbial contamination was determined by incubating an appropriate number of Azer Scientific Universal Transport Medium lots overnight at 37±2°C and examined for growth contaminants. All lots tested at each time point and each temperature passed the criteria for no contamination (no growth) when held at 2-8°C, and 20-25°C.

   Sterility**:**
   The Azer Scientific Universal Transport Medium is not claimed to be sterile nor is it intended to be sterilized by the end user. To decrease the chances of contamination, components of the Azer Scientific Universal Transport Medium are either sterilized by moist heat sterilization or filter sterilization and the transport medium is filled aseptically under controlled conditions. The swabs provided with the Azer Scientific Universal Transport Medium are individually packaged and are sold as sterile.

6. Detection Limit:

Performance Testing - Viral Recovery:

Performance of the Azer Scientific Universal Transport Medium was evaluated by performing culture-based recovery studies. The viral recovery study was conducted by spiking virus stock Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1), Human Adenovirus 10 JJ (AV), and Human Respiratory Syncytial Virus, Strain A1998/3-2 (HRSV) into pooled, human nasopharyngeal swab sample matrix tested as negative using an FDA cleared RT-PCR assay.

Performance evaluation was carried out using three (3) lots of test kits each including a PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/Polystyrene Handle, 80 mm Breakpoint swab provided with Azer Scientific Universal Transport Medium with serial dilutions of each virus (10^{-1}, 10^{-2}, 10^{-3} and 10^{-4}) spiked into negative clinical matrix in triplicate. Contrived samples were held at both 2-8°C and 20-25°C for 0, 24, and 48 hours in a 96-well plate.

Samples in the 96-well plate were examined under the microscope for cytopathic effect (CPE) after the appropriate incubation period for each virus time point. Viral titers of samples collected at 0, 24, and 48 hours were calculated for recovery and determined by percent log reduction of $TCID_{50}$/mL using the Reed-Muench method. Host cell lines used for the different viruses are outlined in **Table 1**. Viral Recovery study data is outlined in **Table 2**. Any change of virus titer that was within one log (+/-90%) from the baseline (time point 0) was considered acceptable.

Table 1: Host Cells

Organism	Strain ID	Host Cell/Growth Medium
Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1)	NR-29027	MDCK cells/EMEM + 10% FBS
Human Adenovirus 10 JJ (AV)	NR-53907	A549 cells/EMEM + 10% FBS
Human Respiratory Syncytial Virus, Strain A1998/3-2 (HRSV)	NR-28529	HEP-2 cells/EMEM + 10% FBS

Table 2: Viral Recovery

Viral Strain	Duration (hrs.)	2-8°C		20-25°C	
		Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)	Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)
Influenza A/Puerto Rico-8-9VMC2/1934 (H1N1)	0	4.74×10^3	N/A	4.74×10^3	N/A
	24	11.03×10^3	133%*	8.76×10^3	85%
	48	8.38×10^3	77%	6.69×10^3	41%
Adenovirus 10 JJ (AV)	0	22.43×10^3	N/A	22.43×10^3	N/A
	24	14.30×10^3	-36%	39.47×10^3	76%
	48	9.53×10^3	-58%	13.94×10^3	-38%
Human Respiratory	0	16.48×10^3	N/A	16.48×10^3	N/A
	24	10.01×10^3	-39%	15.50×10^3	-6%

Viral Strain	Duration (hrs.)	2-8°C		20-25°C	
		Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)	Average $TCID_{50}$/mL	Average Percent Change (- is a reduction)
Syncytial Virus (HRSV)	48	16.47×10^3	-0%	12.63×10^3	-23%

*Considered acceptable because subsequent timepoint, i.e., 48 h time points showed ≤ 90% increase.

Conclusion of the culture-based viral recovery study:
The Azer Scientific Universal Transport Medium demonstrated the recovery of H1N1 Influenza BEI NR-29027, Adenovirus 10 JJ, and Human Respiratory Syncytial Virus (HRSV) in all replicates at tested incubation times and storage conditions met the acceptance criteria. This data supports the transportation of Influenza A, Adenovirus, and Respiratory Syncytial Virus (RSV) in Azer Scientific Universal Transport Medium when stored refrigerated (2-8°C) or room temperature (20-25°C) for up to 48 hours.

7. Assay Cut-Off:

   Not Applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not Applicable.

2. Matrix Comparison:

   Not Applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not Applicable.

2. Clinical Specificity:

   Not Applicable.

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

   Not Applicable.

D Clinical Cut-Off:

Not Applicable.

E 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.