510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212856

B Applicant

Huachenyang (Shenzhen) Technology Co. Ltd.

C Proprietary and Established Names

iClean Viral Transport System (VTM-RT kit)

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 Huachenyang (Shenzhen) Technology Co. Ltd. iClean Viral Transport System (VTM-RT kit) for the collection and transport of viral specimens for laboratory culture and downstream testing.

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:

iClean Viral Transport System (VTM-RT) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

IV Device/System Characteristics:

A Device Description:

iClean Viral Transport System (VTM-RT) is a non-propagating transport device with culture medium. It includes a plastic screw-cap tube with conical bottom containing a 3mL transport medium. The tube can be supplied alone or in a kit format with a flocked swab in a sterile peel pouch (or 100 kits packed together in a color box). The different kit configurations with various swab types, nasopharyngeal (NP) and Oropharyngeal (OP) are included in the table below.

Catalog No.	Description	Pack
CY-B-F005-20	3mL transport medium vial with iClean nasopharyngeal flocked Swab	Single kit/pack or 100 kits/pack
CY-B-F005-20	3mL transport medium vial with iClean buccal flocked Swab	Single kit/pack or 100 kits/pack
CY-B-F005-20	3mL transport medium vial with iClean oropharyngeal flocked Swab	Single kit/pack or 100 kits/pack
CY-B-F005-20	3mL transport medium vial with iClean nasopharyngeal flocked Swab and oropharyngeal flocked Swab	Single kit/pack or 100 kits/pack

The iClear VTM-RT kit functions as a general transport medium kit for collecting and transporting clinical specimens. This transport medium is used to safely collect and transport viruses, Chlamydiae, or *Mycoplasma hominis* from collection sites to the testing laboratories. It is intended for use by Health Care Professionals, the transport system allows for the collection of the specimen via the sterile swab, maintenance through a buffered media, prevention of microbial growth via antimicrobial agents, as well as a pH indicator. The media has been validated with culture recovery of virus. The sterile swab provided in the kit is packaged in peeled pouch for specimen collection. The cap from the vial is intended to be removed aseptically, and the sample collection swab is inserted into the vial containing the iClean VTM-

RT Medium. After the collected sample is placed into the transport media, it is transported to the laboratory. The media can be maintained at room temperature but for optimal performance the specimen should be refrigerated at 2 - 8°C while in transit.

B Principle of Operation:

The neutral environment (7.0~7.8) provided by Hank's buffer aids in the stability of the viruses. Bovine Serum Albumin (BSA) acts as a protein stabilizer, 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. Gentamicin sulfate, amphotericin B, and colistin inhibit growth of bacteria or yeast. 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 value environment thus increases the stability of virus. Phenol red is a pH indicator which serves as a visual quality control mechanism. The medium is isotonic and non-toxic to mammalian host cells.

Formulation of iClean VTM-RT:
- Hanks balanced salt solution (HBSS)
- Bovine Serum Albumin (BSA)
- Gentamicin sulfate
- Amphotericin B
- Colistin
- L-glutamic acid
- HEPES buffer
- Phenol red

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):

The iClean and predicate devices are single-use products intended for the transport of specimens containing viruses, Chlamydiae, and *Mycoplasma hominis*. Both the iClean and predicate devices are offered as media tubes alone or in kit format, with media and specimen collection swab (NP or OP).

Device & Predicate Device(s):	**Device: K212856**	**Predicate: K042970**
Device Trade Name	iClean Viral Transport System (VTM-RT kit)	Copan Universal Transport Medium (UTM-RT) System
Device Product Code and Classification	JSM, Class I	JSM, Class I

General Device Characteristic Similarities		
Intended Use / Indications For Use	iClean Viral Transport System (VTM-RT) 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, culure or with other assays that utilize stable recoverable infectious viral particles or bacteria.	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.
Storage Temperature	20º – 25ºC	Same
Tube Material	Plastic Screw-Cap Tube	Same
Single Use Device	Yes	Same
pH	7.4 ± 0.4	Same
Shelf-life	12 months	Same
Validation	Culture	Same
General Device Characteristic Differences		
Media Formulation	• Hanks balanced salt solution (HBSS) • Bovine Serum Albumin (BSA) • Gentamicin sulfate • Amphotericin B • Colistin • L-Glutamic acid • HEPES buffer • Phenol red	• Hank's Balanced Salts solution (HBSS) • Bovine Serum Albumin (BSA) • Vancomycin • Amphotericin B • Colistin • L-Glutamic Acid • L-Cysteine • HEPES Buffer • Phenol Red • Gelatin Sucrose
Supported strains	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1	• 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*	• Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3 • Respiratory Syncytial Virus • **Varicella Zoster Virus** • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma hominis* • ***Mycoplasma pneumoniae*** • ***Ureaplasma urealyticum***

VI Standards/Guidance Documents Referenced:

CLSI M40-A2:2014 Quality Control of Microbiological Transport Systems; Approved Standard Second Edition
ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the radiation dose

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 for the iClean VTM-RT kit was determined to be 12 months from the date of manufacture when stored in a clean, dry, ventilated environment at 20 – 25ºC. The shelf life of the iClean VTM-RT kit was established using real-time aging performance test at time points T = 0, 1, 3, 6, 9 and 12 months. At each time point, appearance, volume, pH, antibiotic stability, and recovery study were assessed.

   a. Appearance Inspection:

To evaluate appearance stability, three lots of iClean VTM were physically or visually examined for real-time aging at timepoints T = 0, 1, 3, 6, 9, and 12 months. The media was stored in a clean, dry, ventilated environment at 20 – 25ºC. At each time point, appearance of the product was inspected visually to be clear (i. e. no turbidity, no cloudy nor precipitation) and maintains a pink color (i. e. no color change from pink to yellow). Media volume was assessed to ensure each tube was filled to 3.0 mL. All results were acceptable and support the claim that the VTM-RT kit is physically or visually stable for 12 months.

b. pH Stability

The pH of the media was used as one of the indicators to support product stability. The media was tested at time points T = 0, 1, 3, 6, 9 and 12 months after the manufacturing date. Three lots of VTM-RT media were stored in a clean, dry, ventilated environment under the recommended temperature conditions (20 – 25ºC) and at the specified time intervals, 15 tubes from each of the three lots were removed from storage. The media inside each of the vials was evaluated using a calibrated pH meter. For all the tubes at each time point for each of the three lots, the pH was within the predefined pH range of 7.4 ± 0.4.

c. Antibiotic Stability:

iClean VTM-RT contains gentamicin sulfate, amphotericin B, and colistin to inhibit growth of bacteria or yeast. Stability of these antibiotics was evaluated through inoculating 5.0 x 10^5 – 4.5 x 10^6 CFU/mL of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8099, and *Candida albicans* ATCC 10231 into iClean VTM media followed by appropriate storage and incubation. The inoculated media was tested immediately or stored in VTM for 24 hrs. and 48 hrs. Spiked media was transferred by pipetting 0.5 mL onto nutrient agar plates for *S. aureus* and *E. coli* and Sabouraud media for *C. albicans.* All plates evaluated at time T = 0 had 9.0 x 10^4 cfu/mL growth or greater while plates evaluated at 24 and 48 hrs. all had no growth.

d. Sterilization:

The iClean VTM kit is not claimed to be sterile nor is it intended to be sterilized by the end user. To decrease the chances of contamination the media uses specific manufacturing steps including sterilization of tubes and packaging by gamma radiation set at a dose of 5.3 Kilo Gray (KGy), in accordance with ISO 11137-2:2015. The media is filtered using a 0.22 µm sterile fiber membrane and then is aseptically filled into the pre-sterilized tubes. The aseptic status of the filtered iClean VTM-RT was then validated by a quality control process which evaluates the absence of growth of bacteria and fungi by spreading 0.1 mL of the filtered VTM-RT medium on nutrient agar and Sabouraud media plates and incubated at 35ºC ± 2ºC for 24 – 48 hours. No growth on any of the plates tested was observed.

The results collectively for appearance, volume, pH, antibiotic stability support the 12-month stability claim for the iClean VTM-RT kit.

6. Detection Limit:

Performance Testing - Recovery Studies:

Performance of the iClean VTM was evaluated by Culture-Based Recovery Studies for viral and bacterial test strains. For Viral Recovery Studies, Fluorescent Foci Count method was utilized to evaluate the recovery of Influenza A (ATCC VR-544), Parainfluenza 3 (ATCC VR-93) and Respiratory Syncytial Virus (ATCC VR-1401). This method was also utilized to evaluate the recovery of *Chlamydia pneumoniae* (ATCC VR-53592) and *C. trachomatis* (ATCC VR-880). For Bacterial Recovery Studies, Roll-Plate and Swab Elution Methods were utilized to evaluate the recovery of *Mycoplasma hominis* (ATCC VR-14027). Performance testing included nine lots of media. Each performance study summarized below used media lots that represents "New" for newly manufactured media, "Mid" for middle aged media (~5 months old) and "Old" for older media about to expire or recently expired media.

Viral and Chlamydial Recovery Studies:

Virus stocks were diluted in pooled negative clinical matrix and each chosen dilution was inoculated into swab and placed into iClean VTM to store at 4ºC and 25ºC for 0, 24 and 48 hours respectively. For tissue culture, Hep-2 cells (ATCC CCL-23) or McCoy cells (ATCC CRL-1696) were grown to 95% confluency. When tissue culture plates were ready, 200 µl of each test samples were used to infect the monolayers and incubated. For detection, specific immunofluorescent antibody staining was used. The number of infectious particles were counted as Fluorescent Foci and calculated for each storage temperature and time points. McCoy cell cultures were used for the recovery of *Chlamydia pneumoniae* (ATCC VR-53592) and *C. trachomatis* (ATCC VR-880). The results are presented in the Table 1 and Table 2 below. Any reduction in the foci count for the timepoints (0 to 48 hr.) was shown as percent decline.

Table 1. Recovery of viruses and Chlamydae at 4ºC storage.

Test Strain	Lot No.	Lot Age	Average Recovery in Foci count/mL			Decline in 0 - 48 hrs.
			0 hr.	24 hrs.	48 hrs.	
Influenza A	2021010105	Old	7.1×10^3	6×10^3	4.9×10^3	31%
	2021010108		1×10^4	6.5×10^3	5.7×10^3	43%
	2021010205		1.1×10^4	8.8×10^3	7×10^3	36%
	2021060105	Mid	1.1×10^4	9×10^3	7.6×10^3	31%
	2021060108		1.2×10^4	8.6×10^3	6.5×10^3	46%
	2021060201		8.6×10^3	7.4×10^3	4.8×10^3	44%
	2021120101	New	9.2×10^3	8.6×10^3	6.7×10^3	27%
	2021120102		1.2×10^4	6.4×10^3	8.8×10^3	27%
	2021120103		9.1×10^4	8.5×10^3	7.1×10^3	92%
Parainfluenza 3	2021010105	Old	8.2×10^3	7.9×10^3	8.6×10^3	-5%
	2021010108		7.9×10^3	7×10^3	7.1×10^3	10%
	2021010205		1.2×10^4	7×10^3	5×10^3	58%
	2021060105	Mid	1×10^4	8.4×10^3	7.7×10^3	23%
	2021060108		1.1×10^4	8.2×10^3	4.9×10^3	55%

	2021060201		1.4×10^4	7.2×10^3	6.2×10^3	56%
	2021120101	New	1×10^4	9.5×10^3	5.5×10^3	45%
	2021120102		1.1×10^4	7.2×10^3	8.4×10^3	24%
	2021120103		1.3×10^4	1×10^4	5.8×10^3	55%
Respiratory Syncytial Virus	2021010105	Old	7.3×10^3	8.5×10^3	6.3×10^3	14%
	2021010108		8.6×10^3	8.4×10^3	7.5×10^3	13%
	2021010205		1.2×10^4	9.3×10^3	7.8×10^3	35%
	2021060105	Mid	1.1×10^4	8.1×10^3	6.3×10^3	43%
	2021060108		1.1×10^4	8.3×10^3	7.4×10^3	33%
	2021060201		1.2×10^4	8.9×10^3	6.1×10^3	49%
	2021120101	New	8.6×10^3	1.1×10^4	7.8×10^3	9%
	2021120102		8.5×10^3	1×10^4	5.3×10^3	38%
	2021120103		8×10^3	7.6×10^3	6.2×10^3	23%

Chlamydia pneumoniae	2021010105	Old	1.1×10^6	3.2×10^5	2.4×10^5	78%
	2021010108		2.8×10^6	1.0×10^6	5.3×10^5	81%
	2021010205		2.6×10^6	1.5×10^6	3.1×10^5	88%
	2021060105	Mid	1.9×10^6	1.4×10^6	1.9×10^5	90%
	2021060108		2.4×10^6	1.5×10^6	5.8×10^5	76%
	2021060201		1.8×10^6	5.1×10^5	5.7×10^5	68%
	2021120101	New	1.5×10^6	8.4×10^5	3.3×10^5	78%
	2021120102		1.9×10^6	1.4×10^6	3.3×10^5	83%
	2021120103		1.2×10^6	1.0×10^6	8.1×10^5	33%
Chlamydia trachomatis	2021010105	Old	1.6×10^6	4.6×10^5	5.0×10^5	69%
	2021010108		8.0×10^5	4.0×10^5	8.5×10^5	-6%
	2021010205		1.5×10^6	6.5×10^5	2.3×10^5	85%
	2021060105	Mid	2.3×10^6	5.3×10^5	3.2×10^5	86%
	2021060108		8.3×10^5	4.3×10^5	4.9×10^5	41%
	2021060201		2.4×10^6	1.4×10^6	5.0×10^5	79%
	2021120101	New	1.2×10^6	9.2×10^5	6.6×10^5	45%
	2021120102		2.7×10^6	7.7×10^5	4.5×10^5	83%
	2021120103		1.6×10^6	1.1×10^6	7.3×10^5	54%

Table 2. Recovery of viruses and Chlamydae at 25ºC storage.

Test Strain	Lot No.	Lot Age	Average Recovery in Foci count/mL			Decline in 0 - 48 hrs.
			0 hr.	24 hrs.	48 hrs.	
Influenza A	2021010105	Old	8.1×10^3	7.3×10^3	7×10^2	91%
	2021010108		9.3×10^3	7.2×10^3	1.1×10^3	88%

	2021010205		1.1×10^4	7.2×10^3	1.7×10^3	85%
	2021060105	Mid	1.2×10^4	8.2×10^3	1.3×10^3	89%
	2021060108		1×10^4	8×10^3	2.1×10^3	79%
	2021060201		9.4×10^3	5.6×10^3	1.9×10^3	80%
	2021120101	New	9.5×10^3	6.9×10^3	1.5×10^3	84%
	2021120102		1.1×10^4	6.7×10^3	2.2×10^3	80%
	2021120103		1.2×10^4	7.7×10^3	1.4×10^3	88%
Parainfluenza 3	2021010105	Old	1.3×10^4	6.1×10^3	1×10^3	92%
	2021010108		1.3×10^4	7.9×10^3	8.8×10^2	93%
	2021010205		1.1×10^4	8.7×10^3	9.1×10^2	92%
	2021060105	Mid	9.3×10^3	5.9×10^3	1.9×10^3	80%
	2021060108		9.2×10^3	8.1×10^3	8.4×10^2	91%
	2021060201		9.5×10^3	7.4×10^3	7×10^2	93%
	2021120101	New	1×10^4	9.1×10^3	2.1×10^3	79%
	2021120102		1.2×10^4	8.6×10^3	1.7×10^3	86%
	2021120103		1.1×10^4	7.3×10^3	1.6×10^3	85%
Respiratory Syncytial Virus	2021010105	Old	9.2×10^3	7.8×10^3	1.9×10^3	79%
	2021010108		8×10^3	9.4×10^3	1.1×10^3	86%
	2021010205		1.1×10^4	5.6×10^3	9.5×10^2	91%
	2021060105	Mid	1.3×10^4	6×10^3	6.8×10^2	95%
	2021060108		8.7×10^3	6.4×10^3	5.9×10^2	93%
	2021060201		1.2×10^4	8.7×10^3	1.3×10^3	89%
	2021120101	New	8.4×10^3	5.9×10^3	6.3×10^2	93%
	2021120102		1×10^4	7.8×10^3	1.1×10^3	89%
	2021120103		9.6×10^3	6.5×10^3	1.3×10^3	86%

Chlamydia pneumoniae	2021010105	Old	1.5×10^6	6.6×10^5	1.9×10^5	87%
	2021010108		8.5×10^5	4.2×10^5	2.5×10^6	-194%
	2021010205		1.4×10^6	1.1×10^6	2.3×10^5	84%
	2021060105	Mid	1.8×10^6	8.3×10^5	1.8×10^5	90%
	2021060108		2.7×10^6	9.1×10^5	1.9×10^5	93%
	2021060201		1.4×10^6	1.0×10^6	2.2×10^5	84%
	2021120101	New	1.7×10^6	3.0×10^5	2.4×10^5	86%
	2021120102		1.3×10^6	9.1×10^5	7.9×10^4	94%
	2021120103		1.7×10^6	8.5×10^5	2.1×10^5	88%
Chlamydia trachomatis	2021010105	Old	1.2×10^6	6.7×10^5	1.7×10^5	86%
	2021010108		2.6×10^6	4.8×10^5	1.7×10^5	93%
	2021010205		2.2×10^6	4.3×10^5	9.6×10^4	96%
	2021060105	Mid	1.5×10^6	4.7×10^5	2.4×10^5	84%
	2021060108		9.2×10^5	3.4×10^5	1.5×10^5	84%

	2021060201		1.3×10^6	7.7×10^6	7.5×10^4	42%
	2021120101	New	1.1×10^6	1.0×10^6	7.2×10^4	35%
	2021120102		2.4×10^6	9.0×10^5	2.0×10^5	92%
	2021120103		1.7×10^6	1.0×10^6	1.8×10^5	89%

Bacterial Recovery Studies:

Performance of iClean VTM for bacterial recovery was determined using roll plate swab elution methods. Both the roll plate and swab elution studies follow the FDA recognized sections of CLSI M40-A2:2014 Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition.

Roll-plate method:

For the roll-plate method, *Mycoplasma hominis* suspensions were prepared to approximately 0.5 McFarland standard (1.5×10^8 CFU/mL) in 0.85% physiological saline followed by 10-fold serial dilutions in pooled negative matrix. Swabs in triplicate were spiked with 100 µL of each dilution and placed in the iClean VTM and maintained under refrigerated or at room temperature. After 0, 24 and 48 hours, the swabs were removed and rolled directly onto agar plates which were incubated to grow colonies. Average CFU/roll-plate calculated for each timepoints were presented in Table 3 and Table 4. According to CLSI M40 A2 guidelines, the inoculum dilutions yielding time-zero plates with closely approaching 300 CFU was used to complete the viability studies. The acceptance criteria were set to a recovery of ≥ 10 CFU following the specified maintenance time at the iClean VTM.

Table 3. Roll-Plate Method of recovery for storage at refrigerated conditions (2-8°C).

Test Strain	Lot No.	Lot Age	Average Recovery in CFU/roll-plate		
			0 hr.	24 hrs.	48 hrs.
Mycoplasma hominis (ATCC VR-14027)	2021010105	Old	275	233	150
	2021010108		277	252	165
	2021010205		264	220	118
	2021060105	Mid	267	248	139
	2021060108		283	240	158
	2021060201		279	250	95
	2021120101	New	252	234	100
	2021120102		292	289	181
	2021120103		248	212	111

Table 4. Roll-Plate Method of recovery for storage at room temperature (22-25°C).

Test Strain	Lot No.	Lot Age	Average Recovery in CFU/Roll-plate		
			0 hr.	24 hrs.	48 hrs.
Mycoplasma hominis (ATCC VR-14027)	2021010105	Old	267	283	107
	2021010108		323	227	94
	2021010205		310	282	112
	2021060105	Mid	261	207	92
	2021060108		276	246	130
	2021060201		276	215	108
	2021120101	New	320	251	72

	2021120102		297	278	82
	2021120103		306	247	134

Swab Elution Method:

For the swab elution method, the *Mycoplasma hominis* inocula were prepared in a manner similar to that for the roll-plate method. The initial bacterial suspensions were diluted by 10^{-4} and dispensed 100 µL onto swabs in triplicate. The swabs were then placed in the iClean VTM and maintained under refrigerated or at room temperature for the specified timepoints. After 0, 24, and 48 hours the swabs were removed, and 10-fold serial dilutions were prepared. From each of the dilution, 50 µL was dispensed onto the agar plate and incubated to allow the growth of colonies. The results calculated in average CFU/mL for the specified time points are presented in Table 5 and 6. According to CLSI document M40-A2, the acceptance criteria for viability in the swab elution method was considered to be no more than a 3 $\log_{10}$ change in CFU count between the zero-time and the 48 hours – time points.

Table 5. Swab Elution Method of recovery for storage at refrigerated conditions (2-8°C).

Test Strain	Lot No.	Lot Age	Average Recovery in CFU/mL			Change in $\log_{10}$ (0 to 48 hrs.)
			0 hr.	24 hrs.	48 hrs.	
Mycoplasma hominis (ATCC VR-14027)	2021010105	Old	2.1×10^6	5.1×10^5	2.1×10^5	-1.0
	2021010108		1.3×10^6	7.2×10^5	3.3×10^5	-0.6
	2021010205		1.4×10^6	3.4×10^5	1.4×10^5	-1.0
	2021060105	Mid	1.5×10^6	7.2×10^5	2.5×10^5	-0.8
	2021060108		2.3×10^6	4.1×10^5	2.2×10^5	-1.0
	2021060201		1.9×10^6	5.8×10^5	2.6×10^5	-0.9
	2021120101	New	8.9×10^5	4.9×10^5	1.8×10^5	-0.7
	2021120102		1.1×10^6	8.7×10^5	2.9×10^5	-0.6
	2021120103		1.9×10^6	1.0×10^6	6.4×10^5	-0.5

Table 6. Swab Elution Method of recovery for storage at room temperature (22-25°C).

Test Strain	Lot No.	Lot Age	Average Recovery in CFU/mL			Change in $\log_{10}$ (0 to 48 hrs.)
			0 hr.	24 hrs.	48 hrs.	
Mycoplasma hominis (ATCC VR-14027)	2021010105	Old	2.7×10^6	8.9×10^5	1.4×10^5	-1.3
	2021010108		2.1×10^6	1.1×10^6	2.2×10^5	-1.0
	2021010205		1.8×10^6	3.5×10^5	8.6×10^4	-1.3
	2021060105	Mid	8.4×10^5	7.0×10^5	1.8×10^5	-0.7
	2021060108		1.2×10^6	5.7×10^5	1.6×10^5	-0.9
	2021060201		2.0×10^6	8.9×10^5	1.1×10^5	-1.3
	2021120101	New	1.7×10^6	3.9×10^5	2.1×10^5	-0.9
	2021120102		2.7×10^6	8.7×10^5	1.0×10^5	-1.4
	2021120103		2.2×10^6	2.8×10^5	9.4×10^4	-1.4

Conclusion of the Culture-based Recovery Studies: The iClean VTM demonstrated the recovery of tested viruses (Influenza A, Parainfluenza 3 and RSV), *Chlamydia pneumoniae, C. trachomatis* and *Mycoplasma hominis* in all replicates at tested incubation times and storage conditions. All the results appear acceptable.

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.