August 18, 2022

Huachenyang (Shenzhen) Technology Co. Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212856
Trade/Device Name: iClean Viral Transport System (VTM-RT kit)
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: September 7, 2021
Received: September 8, 2021

Dear Prithul Bom:

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 (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 located 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Uwe Scherf, M.Sc., Ph.D.
Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212856

Device Name
iClean Viral Transport System (VTM-RT kit)

Indications for Use *(Describe)*
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.

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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510(k) Summary – K212856

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the iClean Viral Transport System (VTM- RT).

Submitted by	Huachenyang (Shenzen) Technology Co., Ltd.
Contact Person	Gong Zanbin, Production & Regulation Manager
	Huachenyang (Shenzen) Technology Co., Ltd. F8/Bldg. 4, Hengchangrong High Industrial Park, No.128 East Road, Shangnan, Shajing Street, Baoan, Shenzhen, China Email: info@chenyanglobal.com; c06@chenyanglobal.com Telephone Number: + 86-755-27393226 Fax Number: + 86-755-27381080
Proprietary Name	iClean Viral Transport System (VTM-RT)
Common Name	Transport culture medium
Review Panel	Microbiology
Classification Name and Reference	21 CFR 886.2390, Culture Media, Non-Propagating Transport
Device Product Code and Panel Code	JSM; Transport culture medium
Predicate Device	Copan Universal Transport Medium (UTM-RT) System (K042970)

1. Intended Use and 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, culture or with other assays that utilize stable recoverable infectious viral particles or bacteria.

2. Device Description

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. iClean Viral Transport System (VTM-RT) includes a plastic screw-cap tube with conical bottom containing 3mL transport medium. iClean Viral Transport System (VTM-RT) tubes 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).

iClean Viral Transport System (VTM-RT) medium is stable at room temperature and consists of: Hanks balanced salt solution (HBSS), Bovine Serum Albumin (BSA), Gentamicin sulfate, Amphotericin B, Colistin, L-glutamic acid, HEPES buffer and Phenol red. The neutral environment constructed by Hank's buffer helps to increase the stability of the virus. 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. As this medium does not contain cysteine, gelatin, or sucrose, it cannot be used to freeze virus samples for long-term preservation. The medium is isotonic and non-toxic to mammalian host cells.

3. Device Specification

iClean transport medium tubes can be supplied alone including a screw-cap tube containing 3mL of transport medium or in a kit format with one of the following collection swab configurations in a sterile peel pouch (or 100 kits packed together in a color box):

Catalog No.	Description	Pack
CY-B-F005-20	3mL transport medium vial with iClean® nasopharyngeal flocked Swab	Single pack or 10*10 kits
CY-B-F005-20	3mL transport medium vial with iClean® buccal flocked Swab	Single pack or 10*10 kits
CY-B-F005-20	3mL transport medium vial with iClean® oropharyngeal flocked Swab	Single pack or 10*10 kits
CY-B-F005-20	3mL transport medium vial with iClean® nasopharyngeal flocked Swab and oropharyngeal flocked Swab	Single pack or 10*10 kits

The swabs in this kit are listed according to 21CFR Part 807 under the proprietary name of "Antiseptic Swab Applicator, Specimen Collection Flocked / Polyester / Foam / Cotton / Rayon Swab, Nasal / Oral / Throat / Cervical", registered under Huachenyang (Shenzhen) Technology Company Ltd (Registered establishment number: 3011649813). These swabs are not purchased in bulk, but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their device listing criteria and status. Also, there were no recorded adverse events and/or quality problems of the swabs so far.

Media Formulation:

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

iClean Viral Transport System (VTM-RT) should be stored in a clean, dry, ventilated environment at 2 - 25°C. The shelf-life of iClean Viral Transport System (VTM-RT) is 12 months after the manufacture date.

4. Principle of Operation

The iClean VTM-RT 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 (HCPs), 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.

Proper specimen collection plays a critical role for successful isolation and identification of infectious organisms. Once the sample is collected it should be placed immediately into the media inside the tube and transported to the laboratory. Although the media can maintain even fragile organisms for long periods of time at room temperature, it is recommended that specimens be refrigerated at 2 - 8°C while in transit.

5. Substantial Equivalence

The iClean Viral Transport System (VTM-RT) is compared with the predicate device, Copan Universal Transport Medium (UTM-RT) System, in intended use, medium formulation, container, product configuration, shelf life, packaging and volume. The safety and effectiveness of the iClean Viral Transport System (VTM-RT) with the expanded claims is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification. Below is a summary of comparison between iClean VTM-RT and predicate Copan Universal Transport Medium (UTM-RT) System:

	Subject Device (K212856)	**Predicate Device (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, culture 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	$20^{o} – 25^{o}C$	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 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3 • Respiratory Syncytial Virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma hominis*	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • 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*

As seen with the comparison above, the differences between iClean Viral Transport System (VTM-RT) and the predicate's specification, safety and performance are comparable.

6. Shelf Life

The shelf life for the iClean VTM-RT 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 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 3.0mL. All results were acceptable and support the claim that the VTM-RT 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 and each of the three lots, the pH was within the targeted 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 $5.0 \times 10^5 – 4.5 \times 10^6$ 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 9.0×10^4 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.

7. 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 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 in the timepoints (0 to 48 hr.) was shown in percent decline.

Table 1. Recovery of viruses and Chlamydiae 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 Chlamydiae 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	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		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

(ATCC VR-14027)	2021060201	Mid	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

8. Conclusion of the Culture-based Recovery Studies

The iClean VTM demonstrated the recovery of tested viruses, *Chlamydia pneumoniae, C. trachomatis* and *Mycoplasma hominis* in all replicates at tested incubation times and storage conditions.