



May 3, 2024

ALB Luz
% Graziela Brum
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096-570
Brazil

Re: K232454
Trade/Device Name: Viral Transport Media (VTM)
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: April 4, 2024
Received: April 4, 2024

Dear Graziela Brum:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 866.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 866.9.

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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)
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

Indications for Use

510(k) Number (if known)

K232454

Device Name

Viral Transport Media (VTM)

Indications for Use (Describe)

The ALB Luz Viral Transport Media is intended for the collection and transport of upper respiratory clinical specimens containing Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from the collection site to the testing laboratory. The Viral Transport Media is a culture-based media that is intended to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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VIRAL TRANSPORT MEDIA**510(k) Summary: K232454****ADMINISTRATIVE INFORMATION**

Sponsor	ALB LUZ Ltda. Rua Um, 437 Valinhos, São Paulo, Brazil 13273-200 Telephone: +55 (19) 3849-7499
Contact Person and Preparer	Graziela Brum and Tatiana Jabor Botura Regulatory Affairs Specialist Passarini Regulatory Affairs e-mail: graziela@passarini.com.br Telephone: +55 (16) 3421 8488
Data Prepared	April, 02,2024

DEVICE NAME AND CLASSIFICATION

Trade Name	Viral Transport Media - VTM
Common Name	Specimen Collection and Transport System
Regulation Number	21 CFR 866.2390 – Transport Culture Medium
Regulatory Class	Class I, Reserved
Product Code	JSM
Classification Panel	MI -Microbiology

PREDICATE DEVICE INFORMATION

Predicate Device: K212856 - iClean Viral Transport System (VTM-RT kit)

Indications For Use

The ALB Luz Viral Transport Media is intended for the collection and transport of upper respiratory clinical specimens containing Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from the collection site to the testing laboratory. The Viral Transport Media is a culture-based media that is intended to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

Device Description

The Viral Transport Medium (VTM) is a non-propagating transport device composed of a culture-based media without swabs. The VTM is designed to preserve upper respiratory samples collected from a patient by placing the sample into the polymer tube containing 3 mL of media. The sample and media are then secured with a leak-proof screwcap for transportation.

The VTM maintains cellular integrity and preservation of viruses when properly stored. Prior to

use, vials should be stored at 2°C to 35°C. After specimen collection, the transport tube containing the specimen can be stored for up to 48 hours at either 2-8°C or 20-25°C, for transportation to the laboratory and storage. The medium has been evaluated for storage of the following respiratory viruses, Influenza A, Respiratory Syncytial Virus (RSV), and Rhinovirus, for viral recovery.

Technological Characteristics

The Viral Transport Media - VTM has a formulation that preserves viral viability. The VTM contains the following ingredients.

Hank's balanced salt solution (HBSS)
 Amphotericin B
 Colistin sulfate
 HEPES buffer
 Phenol red
 Bovine serum albumin fraction V (BSA)
 Dextrose
 Penicillin G potassium
 Gelatin powder

Hank's Balanced Salt Solution (HBSS) is further enriched with proteins and sugars for stabilization, and antimicrobial agents to inhibit the overgrowth of bacteria, fungi, and yeasts. A buffer system to maintain neutral pH and a pH indicator. Polymer screw-cap top tubes are filled with 3mL of VTM.

Substantial Equivalence Information

The subject and predicate devices comparison is described in the table below:

Device & Predicate Device(s):	<u>Device: K232454</u>	<u>Predicate: K212856</u>
Device Trade Name	Viral Transport Media - VTM	iClean Viral Transport System (VTM-RT kit)
Product Code and Classification	JSM, Class I	JSM, Class I
General Device Characteristic Similarities		
Intended Use/Indications For Use	The ALB Luz Viral Transport Media is intended for the collection and transport of upper respiratory clinical specimens containing Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from the collection site to the testing laboratory. The Viral Transport Media is a culture-based media	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

Device & Predicate Device(s):	Device: K232454	Predicate: K212856
	that is intended to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.	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.
Validation	Culture Media	Culture Media
Tube Material	Plastic Screw-Cap Tube	Plastic Screw-Cap Tube
Single Use Device	Yes	Yes
General Device Characteristic Differences		
Shelf Life	18 months	12 months
Storage Temperature	2 to 35°C	20 to 25°C
pH	7.4±0.2	7.4±0.4
Supported Strains	Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), Rhinovirus	Adenovirus, Cytomegalovirus, Echovirus Type 30, Herpes SimplexVirus Type 1, Herpes Simplex Virus Type 2, Influenza A, Parainfluenza 3, Respiratory Syncytial Virus, Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma hominis
List of Ingredients	Hank's balanced salt solution (HBSS) Amphotericin B Colistin sulfate HEPES buffer Phenol red Bovine serum albumin fraction V (BSA) Dextrose Penicillin G potassium Gelatin powder	Hank's balanced salt solution (HBSS) Amphotericin B Colistin HEPES buffer Phenol red Bovine Serum Albumin (BSA) Gentamicin sulfate L-Glutamic acid

Shelf life

The shelf-life for the ALB LUZ Viral Transport Media was established to be 18 months from the date of manufacture when stored in a clean, dry, ventilated environment at 2 - 35°C. The shelf-life study was conducted by using real-time aging performance test for 18 months. In this study, the shelf life was evaluated for physical stability of appearance and volume, and pH stability during the period of storage.

- 1) **Physical Stability:** To evaluate physical stability, any changes in appearance in color, turbidity and volume of the ALB LUZ Viral Transport Media were physically or visually examined at storage time points T = 0, 3, 6, 9, 12, 15, and 18 months. Three lots were tested for physical stability at storage conditions of 2°C and 35°C. At each time point, appearance of the product was inspected visually which appeared clear with slight precipitation and maintained an orange-pink color (i.e., no changes in color) and no changes in liquid media volume. All results support the claim that the ALB LUZ Viral Transport Media is physically or visually stable for 18 months.
- 2) **pH Stability:** To evaluate product stability, the pH of the ALB LUZ Viral Transport Media was tested at storage time points T = 0, 3, 6, 9, 12, 15, and 18 months. Three lots were tested for pH stability at storage condition of 2°C and 35°C. At each time point, the pH was measured by immersing the pH meter electrode into each ALB LUZ Viral Transport Media by adjusting the temperature to 25°C. For all the tubes tested, the pH measurement was within the acceptable pH range of 7.2 to 7.6. All results support the claim for pH stability of the ALB LUZ Viral Transport Media for 18 months.

The results for physical stability and pH stability collectively support the 18-month stability claim for the ALB LUZ Viral Transport Media.

- 3) **Sterilization:**

The ALB LUZ Viral Transport Media is not claimed to be sterile nor is it intended to be sterilized by the end user. To reduce the contamination, the transport media is filtered using a 0.22 µm sterile filter membrane and then 3 ml aliquot is aseptically transferred into individual sterile conical screw-capped tubes. A microbial contamination check was conducted by incubating the tubes for 48 hours at 35°C ± 2°C followed by transferring 100 µL of transport media into BHI media and incubating for 24 hours at 35°C ± 2°C. No growth was observed on any of the tested media.

Performance testing

Performance of ALB LUZ Viral Transport Media was evaluated by Culture-Based Recovery Studies for viral test strains using plaque forming assay. The viral strains and cell lines used for the plaque forming assay are shown in the Table 1.

Table 1. Viral strains and Cell Lines used for the plaque forming assay.

Virus Strains	Cell Lines
Influenza A virus H1N1 (ATCC VR-1520)	MDCK (ATCC CCL-34)
Human respiratory syncytial virus (ATCC VR-1540)	MRC-5 (Instituto Adolfo Lutz CCIAL 023)
Human rhinovirus (ATCC VR-1178)	MRC-5 (Instituto Adolfo Lutz CCIAL 023)

To perform the recovery assay, virus stock was 10-fold serially diluted into pooled negative clinical nasal matrix. Each sample dilution was transferred into ALB LUZ Viral Transport Media by using Rayon Tip Swab and stored at 2-8°C and 20-25°C for 0, 24 and 48 hours respectively. Three lots of VTM with newly manufactured, mid-range lot and close to expiry lots were used to evaluate viral recovery. For tissue culture, MDCK (ATCC CCL-34) and MRC-5 (Instituto Adolfo Lutz CCIAL 023) were seeded in 24-well plates and grown to a confluent monolayer. To perform the plaque forming assay, the viral samples from ALB LUZ Viral Transport Media were serially diluted 10-fold and added to the monolayer in triplicate and allowed for virus adsorption by incubating the plates for 1 hour at 37°C. Semisolid medium containing DMEM, 1% carboxymethyl cellulose, and 1% penicillin/streptomycin antibiotics were added to each well and incubated at 37°C for 5-7 days. For counting the plaques developed, the cell fixation was performed with 10% paraformaldehyde and the staining of cell monolayer was performed with 1% crystal violet. Plaque-forming units were counted visually. The viral titer of each sample was recorded and calculated in plaque-forming units per mL (PFU/mL) and the results from the triplicates were provided as an average PFU/mL for 0, 24 and 48 hours. Results were considered acceptable if the average viral recovery demonstrates any percent changes within $\pm 90\%$ (i.e., 1 log change).

The results are presented in the Table 2 and Table 3 below. Any reduction in the viral count in the timepoints was shown as percent changes and -ve indicates reduction.

Table 2. Viral Recovery for specimen storage at 2-8°C.

Viral Strain Tested	Lots	Average recovery in PFU/mL			Percent changes (0 to 24 hrs.) *	Percent changes (0 to 48 hrs.) *
		0 hr.	24 hrs.	48 hrs.		
Influenza A	113364	5.56E+04	5.04E+04	3.60E+04	-9%	-35%
	111777	5.76E+04	5.40E+04	3.67E+04	-6%	-36%
	111307	4.97E+04	4.97E+04	3.07E+04	0%	-38%
Respiratory Syncytial Virus	113364	2.00E+06	1.78E+06	1.11E+06	-11%	-45%
	111777	1.78E+06	1.55E+06	1.11E+06	-13%	-38%
	111307	1.56E+06	1.67E+06	7.78E+05	7%	-50%
Rhinovirus	113364	2.33E+06	2.44E+06	1.11E+06	5%	-52%
	111777	1.89E+06	1.89E+06	1.22E+06	0%	-35%
	111307	2.67E+06	2.45E+06	1.78E+06	-8%	-33%

* -ve indicates reduction

Table 3. Viral Recovery for specimen storage at 20-25°C.

Viral Strain Tested	Lots	Average recovery in PFU/mL			Percent changes (0 to 24 hrs.) *	Percent changes (0 to 48 hrs.) *
		0 hr.	24 hrs.	48 hrs.		
Influenza A	113364	5.08E+04	4.70E+04	3.39E+04	-7%	-33%
	111777	4.87E+04	4.04E+04	2.98E+04	-17%	-39%
	111307	4.73E+04	3.81E+04	2.97E+04	-20%	-37%
Respiratory Syncytial Virus	113364	2.22E+06	2.11E+06	1.33E+06	-5%	-40%
	111777	1.56E+06	1.33E+06	8.89E+05	-15%	-43%
	111307	1.55E+06	1.56E+06	9.89E+05	0%	-36%
Rhinovirus	113364	1.89E+06	1.55E+06	1.33E+06	-18%	-29%

	111777	2.67E+06	2.11E+06	1.44E+06	-21%	-46%
	111307	2.11E+06	2.11E+06	1.22E+06	0%	-42%

* -ve indicates reduction

The ALB LUZ Viral Transport Media demonstrated the recovery of tested viruses (Influenza A, RSV and RV), in all replicates at tested incubation times and storage conditions.

Conclusion:

The documentation submitted in this premarket notification demonstrates that the subject device K232454 has comparable features and performance and is substantially equivalent to the predicate device.