# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY ONLY

## I Background Information:

### A 510(k) Number

K232454

### B Applicant

ALB Luz

### C Proprietary and Established Names

Viral Transport Media (VTM)

### 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 ALB LUZ Viral Transport Media – VTM for the collection and transport of viral specimens for standard diagnostic/identification technique.

### 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 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.

**C Special Conditions for Use Statement(s):**

Rx - For Prescription Use Only

The Viral Transport Media is intended to be used with Rayon Tip Swab listed on FDA by the manufacturer HENSO MEDICAL (HANGZHOU) CO., LTD. The use of medium, tubes, or swabs from any other source may compromise performance.
Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results.
The Viral Transport Medium is not intended for freezing and thawing.
The medium has been evaluated for its ability to transport various respiratory viruses, which include, Influenza A, Respiratory Syncytial Virus (RSV), and Rhinovirus, for viral recovery. Results obtained largely depend on proper and adequate specimen collection as well as the promptness with which the specimens are transported to the laboratory and analyzed.

**D Special Instrument Requirements:**

## IV Device/System Characteristics:

**A 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 preserves 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.

**B Principle of Operation:**

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.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
iClean Viral Tranport System

### B Predicate 510(k) Number(s):
K212856

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | Device: K232454 | Predicate: K212856 |
|---|---|---|
| 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 that is intended to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles. | 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. |
| 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,<br>Influenza B,<br>Respiratory<br>Syncytial Virus (RSV),<br>Rhinovirus | Adenovirus,<br>Cytomegalovirus,<br>Echovirus Type 30,<br>Herpes SimplexVirus Type 1,<br>Herpes Simplex Virus Type 2,<br>Influenza A, Parainfluenza 3,<br>Respiratory Syncytial Virus,<br>*Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma hominis* |
| List of Ingredients | Hank's balanced salt solution (HBSS)<br>Amphotericin B<br>Colistin sulfate<br>HEPES buffer<br>Phenol red<br>Bovine serum albumin fraction V (BSA)<br>Dextrose<br>Penicillin G potassium<br>Gelatin powder | Hank's balanced salt solution (HBSS)<br>Amphotericin B<br>Colistin<br>HEPES buffer<br>Phenol red<br>Bovine Serum Albumin (BSA)<br>Gentamicin sulfate<br>L-Glutamic acid |

## VI Standards/Guidance Documents Referenced:

## 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):

A. 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.

i. 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 were acceptable and support the claim that the ALB LUZ Viral Transport Media is physically or visually stable for 18 months.

ii. 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 were acceptable and 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.

B. 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.

6. Detection Limit:

**Performance Testing – Viral Recovery Studies:**

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 2-8ºC and 20-25ºC 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 ±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 | 113364 | 2.00E+06 | 1.78E+06 | 1.11E+06 | -11% | -45% |

| | | | | | | |
|---|---|---|---|---|---|---|
| Syncytial Virus | 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

Conclusion: The ALB LUZ Viral Transport Media demonstrated the recovery of tested viruses (Influenza A, Respiratory Syncytial Virus, and Rhinovirus), in all replicates at tested incubation times and storage conditions. All the results appear acceptable and support specimen transport for up to 48 hours at 2-8°C or 20-25°C.

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.