510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233449

B Applicant

Hanchang Medic Co., Ltd. (Han Chang Medic)

C Proprietary and Established Names

Avantik 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 Han Chang Medic Avantik VTM for the collection, transport and storage 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:

The Avantik VTM is intended for the collection and transport of upper respiratory clinical specimens containing respiratory viruses, 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Avantik VTM is indicated for the collection and transport of respiratory viruses. The performance of the Avantik VTM has not been established with non-respiratory or other viruses or microorganisms.

The Avantik VTM is only intended for use with upper respiratory clinical specimens and has not been evaluated with other human specimens.

The Avantik VTM has not be validated to stabilize frozen specimens.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The Avantik VTM is a Non-Propagating Transport Medium Device for the secure collection and transportation of biological samples for diagnosing viral infections. The device includes a conical polypropylene vial filled with 3 mL of culture medium, secured with a high-density polyethylene screw-on cap. The device is provided in boxes of 50 tubes.

The device can be stored at 2 to 25°C for up to 12 months. Upon collection of a swab sample and transfer into the Avantik VTM, the specimen can be transported at 2 to 25°C and should be processed within 48 hours. It is recommended to refrigerate the samples between 2 and 8°C or store them on wet ice to maintain a temperature of 2 to 8°C during transit since performance studies indicated better virus recovery at lower temperatures. Avantik VTM is only for use by Trained Healthcare Professionals.

B Principle of Operation:

The Avantik VTM kit consists of liquid medium and a conical polypropylene vial with screw-on cap to hold the medium securely that are a standard configuration for VTM tubes. The conical shape allows for the easy recovery of the viral particles after the specimen is collected and the medium is agitated to release the viral particles. The liquid medium consists of a mixture of Hank's balanced salt solution (HBSS), Bovine Serum Albumin (BSA), L-cysteine, Gelatin, Sucrose, L-glutamic acid, HEPES, Vancomycin, Amphotericin B, Colistin, and Phenol Red. These ingredients help to maintain the integrity and recovery of infectious viral particles and inhibit growth of competing bacteria and fungi.

V Substantial Equivalence Information:

A Predicate Device Name(s):
MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System

B Predicate 510(k) Number(s):
K212743

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K233449	Predicate: K212743
Device Trade Name	Han Chang Medic Avantik VTM	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System
General Device Characteristic Similarities		
Product Code and Classification	JSM, Class I	Same
Intended Use/Indications For Use	The Avantik VTM is intended for the collection and transport of upper respiratory clinical specimens containing respiratory viruses, 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.	MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is intended for the collection and transport of upper respiratory clinical specimens, containing respiratory viruses, from the collection site to the testing laboratory. MedSchenker Smart Transport Medium (STM15-A/STM20-A/STM30-A/SCS30-A) System is a culture-based medium that can be processed using standard clinical laboratory operating procedures for the recovery of infectious viral particles.
Media Formulation	• Amphotericin B • Bovine Serum Albumin • Hank's Balanced Salt Solution • Vancomycin • Colistin • Gelatin • HEPES • L-cysteine • L-glutamic acid • Phenol Red • Sucrose	Same
Tube	Plastic, conical bottom	Same

Storage Temperature	2 - 25°C (refrigerated and room temperature)	Same
Shelf-Life	12 months	Same
pH	7.3 ± 0.5	Same
Single Use	Yes	Same
Sterile	No	Same
General Device Characteristic Differences		
Validated Viruses	Influenza A (H1N1) RSV Human Coronavirus	Influenza A (H1N1) Type 5 Adenovirus Herpes Simplex 1 Herpes Simplex 2 Varicella-Zoster Virus
Swab	None	Nylon tip with break point
Product Configuration	Medium Tubes only	Medium Tubes; Kit option with Medium Tubes and Swab
Sample Stability	48 hours	72 hours for HSV-1, HSV-2, and Adenovirus 24 hours for IFA and VZV

VI Standards/Guidance Documents Referenced:

1. ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
2. CLSI M40-A2:2014 Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition

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 Han Chang Medic Avantik VTM was established using real-time stability studies. Stability was assessed in an initial study using randomly selected samples from three consecutive lots and tested at various timepoints. Selected lots were evaluated at each timepoint as described in the table below to determine whether lots remained stable. Additional testing was conducted on three different lots stored at ambient temperature, and additional timepoints were obtained in triplicate. For these additional timepoints, contamination checks were additionally performed by plating the VTM onto solid media and incubating at 37°C for 48 hours. All samples from all lots at all timepoints gave passing results for all acceptance criteria. The data support a stability claim of 12 months when stored at 2 to 25°C.

Transport. Shipping stability of the Han Chang Medic Avantik VTM was demonstrated using a simulated transport study. Select cases from three lots were subjected to simulated distribution testing per "*ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems*" to evaluate whether the product maintains acceptable stability under known, stressed shipping conditions. Cases were shipped to the US and subjected to distribution methods before being shipped back to Korea for evaluation. Samples were evaluated according to the methods described in **Table 1**. All samples from all lots at all timepoints met all the specifications based on the predefined acceptance criteria.

Table 1. Acceptance Criteria for Stability Studies

Criterion	Description
Visual growth check	Specification: No growth/turbidity visible Method: Inspect the VTM tubes for growth. The medium should be clear, with no turbidity, and no signs of growth.
Visual color check	Specification: Medium is red-orange, transparent Method: Inspect the VTM tubes for clarity and color. The color of the VTM is a transparent red-orange. Alternatively, the technician can compare the color to a pH verified lot produced within a month from the manufacturing date.
Vial leak check	Specification: No visible signs of leakage Method: Inspect the lid area for signs of leakage. The technician can challenge the lid with the medium (e.g., by turning upside down) and inspect for leakage.
Vial/Cap integrity check	Specification: No visible abnormalities of tube and cap Method: Inspect tubes for abnormalities like cracks and deformities.
Post-incubation visual contamination check	Specification: No growth/turbidity visible, medium transparent orange-red color following incubation. Method 1: Incubate the tubes at 37°C for 24 hours. Post-incubation, the medium should be clear, with no turbidity and no signs of growth. Growth may appear as an unexpected foreign object in the medium. Method 2*: One hundred (100 µL) is transferred onto blood agar culture plates, spread across the agar surface, and transferred to a 37°C incubator for 48 hours. After incubation period, the plates were

Criterion	Description
	checked for evidence of microbial growth.
VTM tube volume check (weight)	Specification: Weight of finished product shall fall within 8.9g ± 5% (± 0.445g) Method: The finished product shall be weighed on a scale. The equipment ID/Management Code, and results shall be documented.
pH check (destructive)	Specification: pH shall fall within 7.3 ± 0.5 at 25°C Method: The finished product shall undergo verification of pH using a pH monitor. The pH monitor shall be operated according to its IFU/Instruction Manual. The equipment ID and results shall be documented.

*Method 2 was used for testing of additional lots in the real-time stability studies.

6. Detection Limit:

The performance of the Han Chang Medic Avantik VTM was evaluated in culture-based viral recovery studies to determine virus viability at different storage times and temperatures. Testing was performed in accordance with the general guidelines of "*CLSI M40-A2 Quality Control of Microbiological Transport Systems; Approved Standard - Second Edition*".

Sample Preparation. Strains of Influenza A (H3N2) virus, Respiratory syncytial virus (RSV) VR-26, and Human coronavirus (hCoV) NL63 were used for media validation. Viral stocks were prepared at 1.4 to 4.2 × 10^6 $TCID_{50}$/mL such that when virus preparations were inoculated into the VTM, they would ideally achieve ~40 to 50% infection when seeded into host cell monolayers for the viral quantification assay; the dilution strategy for each viral strain was previously determined in a pilot study. Samples were prepared in negative clinical matrix (NCM) composed of commercial nasal fluid diluted 1:1 in physiological saline.

Viral Recovery. Viability was assessed by using three non-consecutive lots selected to represent fresh, middle, and expired representative samples. Lots were stored at ambient room temperature (20 to 30°C) with the humidity ranging from 30 to 60% RH prior to use. A total of 162 samples were used with testing performed in triplicate for each lot, virus, and test condition (3 replicates × 3 lots × 3 strains × 2 temperatures × 3 timepoints). Samples were prepared in 1:1 dilutions of virus stock and NCM (1:1 dilutions of nasal fluid:saline). One hundred (100) µL of each sample was dispensed into an empty 1.5 mL tube, and a swab is used to collect the sample and transfer it into the individual VTM tubes. Samples were stored at controlled temperatures of 4 and 22°C for 0 and 48 hours. To demonstrate recovery, aliquots of each tube mixture were transferred to host cell culture plates, and a viral quantification assay was performed in which virus infectivity was measured by immunofluorescence to assess viral preservation compared to baseline. Study results are shown as normalized percentages of reduction in virus infectivity relative to Time 0 in the **Table 2** below. The Han Chang Medic Avantik VTM demonstrated acceptable recovery of influenza A, RSV, and hCoV at refrigerated or room temperature up to 48 hours.

Table 2. Percent Reduction in Virus Infectivity After 48 Hours

Samples	Temperature	Percent reduction in virus infectivity relative to 0h		
		Influenza A	RSV	hCoV
Lot 1	4°C	21.97 ± 3.64	59.26 ± 5.90	-23.55 ± 7.85
Lot 2	4°C	9.52 ± 6.79	55.24 ± 3.13	1.50 ± 5.21
Lot 3	4°C	7.06 ± 1.14	65.27 ± 4.02	-18.26 ± 3.99
Lot 1	22°C	-9.89 ± 5.86	76.18 ± 3.50	4.84 ± 3.25
Lot 2	22°C	6.13 ± 2.04	75.85 ± 2.85	21.06 ± 1.55
Lot 3	22°C	11.70 ± 3.15	70.16 ± 1.22	-1.92 ± 3.86

Cytotoxicity Assessment. The cytotoxicity profile of the Han Chang Medic Avantik VTM was also assessed to ensure that the volume of VTM added during the viral quantification assay does not demonstrate any cytopathic effects on the assay cells. Assay cell cultures were incubated with VTM, and cytotoxicity was measured using an MTT assay, which is a colorimetric assay for assessing cell metabolic activity. The results demonstrate that the medium is non-toxic to mammalian host cells.

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.