510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K242576

B Applicant

Hangzhou Alltest Biotech Co.,Ltd

C Proprietary and Established Names

AllTest Viral Transport Medium

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 the Alltest Viral Transport Medium for collection and transport of viral organisms for (1) standard laboratory culture and for (2) nucleic acid detection by a compatible molecular assay.

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:

AllTest Viral Transport Medium (VTM) is intended for collection and transport of clinical specimens containing viral agents including Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from collection site to the testing laboratory. Specimens collected in the AllTest VTM can be processed using standard clinical laboratory operating procedure for viral culture.

The AllTest Viral Transport Medium is also intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing SARS-CoV-2 nucleic acid. The AllTest VTM is suitable for use with compatible legally marketed molecular diagnostic devices.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The AllTest Viral Transport Medium (VTM) device is comprised of a screw cap polypropylene tube filled with 3 mL VTM. The VTM tube is tightly closed with a polyethylene cap. The AllTest VTM contains Hank's Balanced Buffer solution, proteins, sugar, and antimicrobials to provide stability to live viruses. The AllTest VTM also contains a pH indicator (phenol red) to provide a visual check on medium pH. The VTM appears clear and red in color. Each box of The AllTest VTM kit contains 50 vials of VTM tubes, with or without 50 sterile nylon swabs for specimen collection, and 1 package insert. The AllTest VTM is intended to be used by trained health care professionals.

B Principle of Operation:

Different components of the AllTest Viral Transport Medium contribute to different functions to support the intended use. Hank's balanced salt solution (HBBS) works as a buffer system to maintain osmolarity, and pH. Phenol red functions as a pH indicator. Fetal Bovine Serum and D-glucose contribute to specimen stabilization, along with antimicrobials, Gentamicin Sulfate and Amphotericin B to inhibit bacterial and fungal growth.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Cultura Collection and Transport System

B Predicate 510(k) Number(s):
K201674

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K242576	Predicate: K201674
Device Trade Name	Alltest Viral Transport Medium	Cultura Collection and Transport System
General Device Characteristic Similarities		
Intended Use/Indications For Use	AllTest Viral Transport Medium (VTM) is intended for collection and transport of clinical specimens containing viral agents including Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus from collection site to the testing laboratory. Specimens collected in the AllTest VTM can be processed using standard clinical laboratory operating procedure for viral culture. The AllTest Viral Transport Medium is also intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing SARS-CoV-2 nucleic acid. The AllTest VTM is suitable for use with compatible legally marketed molecular diagnostic devices.	The Merit Cultura Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.

List of Ingredients	• Hanks Balanced Salt Solution • Fetal Bovine Serum • D-Glucose • Gentamicin Sulfate • Amphotericin B	Same
Tube Material	Plastic	Same
Single Use Device	Yes	Same
Shelf Life	12 months	Same
Supported Strains (Viral recovery)	• Influenza A • Influenza B • Respiratory Syncytial Virus (RSV) • Rhinovirus	Same
Supported Strains (Nucleic acid stability)	SARS-Cov-2	Same, as noted in labeling
General Device Characteristic Differences		
Sample storage Temperature	4-25°C	2-25°C

VI Standards/Guidance Documents Referenced:

Not applicable.

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 Alltest Viral Transport Medium (VTM) was established using a real-time stability study. Stability was assessed using three lots of VTM stored at 2-8°C and 25±3°C and VTM samples were tested at regularly spaced intervals. At the end of each timepoint, 15 tubes from each of the three lots were tested for physical appearance, pH and 6 tubes were tested for microbial contamination check. All the samples passed the acceptance criteria for physical inspection (i.e., no turbidity or cloudiness or precipitation), and maintains a red color (i.e., no color change from red to yellow), pH (7.2±0.2), and no microbial growth in contamination check study. The study results support a shelf life of the Alltest VTM for up to 12 months from the date of manufacture when stored in a clean, dry, ventilated environment at 2–25°C.

6. Detection Limit:

Viral Recovery: The viral recovery performance of the AllTest VTM was evaluated for Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus in a culture-based viral infectivity studies with three lots of media (i.e., 3-month, 8-month, and 12-month-old lots). Pooled negative clinical matrix was spiked with known concentration of virus and then the contrived viral samples were spiked onto swabs, transferred with swabs into the subject VTM, and held at refrigerated temperatures (4°C) and room temperature (23-25°C) for 0 and 48 hours. At the end of respective incubation/storage in the AllTest VTM, viral recovery was assessed by inoculating the sample in a serial 10- fold to a 96-well plate seeded with a cell monolayer. Viral titer ($log_{10}TCID_{50}$) was quantified by Reed and Muench method after observation of virus induced cytopathic effect (CPE) as shown in **Table 1** below. Results were considered acceptable if the average viral recovery at 48-hour time point for each storage condition demonstrates >70% recovery compared to baseline (T=0).

Table 1: Viral Recovery Performance of AllTest VTM

Viral strains	AllTest VTM Lot Age	T=0 hour	Percent (%) Viral Recovery at T= 48 hours	
		$log_{10}(TCID_{50})$	4 °C	23-25 °C
Influenza A H1N1	New	3.337±0.037	97.7	91.4
	Mid	3.310±0.000	103.7	89.3
	Old	3.328±0.244	98.6	87.3
Influenza B IBV	New	3.265±0.156	101.9	88.7
	Mid	3.233±0.109	91.4	89.6
	Old	3.199±0.062	94.2	96.2
RSV	New	4.361±0.197	93.2	88.0
	Mid	4.341±0.482	94.5	92.8
	Old	4.591±0.129	87.8	81.9
Rhinovirus	New	3.155±0.219	95.2	89.8
	Mid	3.235±0.106	87.6	90.3
	Old	3.230±0.099	92.9	87.6

All results met the study acceptance criteria. Overall, the viral recovery results support that ability of the AllTest VTM to maintain the infectivity of Influenza A, Influenza B, RSV, and rhinovirus for up to 48 hours when the samples are stored in the Alltest VTM at refrigerated (4°C) and at room temperature (23-25°C) respectively.

Nucleic Acid Stability: The nucleic stability performance of the AllTest Viral Transport Medium was evaluated by nucleic acid amplification studies in two parts.

Part1: Determination of LoD: The limit of detection (LoD) of SARS-CoV-2 samples collected in the AllTest VTM were established through preliminary and confirmatory LoD studies using an FDA-authorized assay, ThermoFisher TaqPath COVID-19 Combo Kit (EUA200010) with the Applied Biosystems QuantStudio 5 Real-Time PCR Instrument. Preliminary LoD (the lowest concentration that gives positive results 100% of the time) was determined as 10 genome copy equivalent or GCE/reaction. The preliminary LoD was confirmed by testing additional 20 replicates at the preliminary LoD concentration. Testing at 10 GCE/reaction yielded 100% (20/20 replicates) concordant (i.e., positive) results.

Part 2: Specimen Stability Study: A specimen stability study was conducted with both clinical and contrived samples at high and challenging (2x LoD) SARS-CoV-2 concentrations using three lots of media (i.e., 3-month/new, 8-month/mid, and 12-month/old age lots). 50 µl of each sample were added to nasopharyngeal (NP) swab and transferred into the AllTest VTM. Samples were stored at 4℃ and 23-25℃ for 0 and 48 hrs. At the end of each storage timepoint, samples were tested with ThermoFisher TaqPath COVID-19 Combo Kit (EUA200010) on the Applied Biosystems QuantStudio 5 Real-Time PCR Instrument as per the assay's instructions for use (IFU). The average changes in the Ct value (Δ Ct) at 48 hrs. timepoint from the baseline (T= 0 hrs.) were calculated as shown in **Table 2** below.

Table 2: SARS-CoV-2 Nucleic Acid Stability Performance of the AllTest VTM

Target Gene	AllTest VTM Lot age	Average Change in Ct value (ΔCt) at T= 48 hours from baseline (T=0).	
		4℃	23-25 ℃
N	New	-0.10	-0.01
	Mid	0.08	-0.14
	Old	-0.12	0.11
S	New	0.06	-0.03
	Mid	0.17	0.18
	Old	0.23	0.36
ORF1	New	-0.26	-0.06
	Mid	0.11	0.20
	Old	-0.14	0.23

All results met the predefined study acceptance criteria (changes in Ct must be within +/- 1 Ct from the baseline). The data support nucleic acid stability claims for the AllTest VTM when samples are stored at 4-25℃ for up to 48 hours from the time of sample collection.

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.