April 4, 2025

Hangzhou Alltest Biotech Co.,Ltd
C/O Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K242576
Trade/Device Name: AllTest Viral Transport Medium
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: March 2, 2025
Received: March 3, 2025

Dear Jenny Xia:

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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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., D(ABMM)
Branch 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242576

Device Name
AllTest Viral Transport Medium

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K242576

1. Date: April 4, 2025

2. Submitter: Hangzhou Alltest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou, zhejiang, China 310018

3. Contact person: Jenny Xia
LSI International Inc.
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

4. Device Names: AllTest Viral Transport Medium

Product Code	Classification	Regulation Section	Panel
JSM	I	21 CFR § 868.2390 Transport Culture Medium	Microbiology

5. Predicate Devices:

Merit Cultura™ Collection and Transport System (K201674)

6. 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.

7. 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 (HBBS), 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.

Table 1 shows the list of ingredients in purified water. The packaging also includes a biohazard specimen bag.

Table 1. Reagent Concentrations

Component	**Concentration (g/L)**
Hank's Balanced Salt Solution (HBSS)	10
Fetal Bovine Serum (FBS)	20
D-glucose	1
Phenol Red	< 1

Gentamicin sulfate	< 1
Amphotericin B	< 1

The AllTest VTM maintains infectivity of viruses when properly stored. Prior to use, vials should be stored at either 2-8°C or 23-25°C. After specimen collection, the transport tube containing the specimen can be stored for up to 48 hours at either 4°C or at 23-25°C, which provides convenience for transportation to the laboratory and storage. Each box of the AllTest VTM kit will contain 50 vails 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.

8. 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 Gentamicin Sulfate and Amphotericin B inhibit bacterial and fungal growth.

9. Substantial Equivalence

Alltest VTM was compared with the predicate device, Merit Cultura Collection and Transport System (K201674) for the intended use, medium ingredients, shelf-life, and culture recovery and nucleic acid stability performance, etc. The safety and effectiveness of the AllTest VTM is adequately supported by the substantial equivalence information and testing results provided. The Table (**Table 2**) below is a summary of a substantial equivalence comparison table between the Alltest VTM and the predicate device K201849:

Table 2: Comparison with Predicate Device:

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	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

	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.	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 the labeling
General Device Characteristic Differences		
Sample storage Temperature	4-25°C	2-25°C

10. Performance Characteristics

a. 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 test 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.

b. 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/new, 8-month/mid, and 12-

month/old age 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 3** 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 3: 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 ℃	23-25 ℃
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.

c. 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°C and 23-25°C 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 4** below.

Table 4: 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°C	23-25 °C
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°C for up to 48 hours from the time of sample collection.

11. Conclusion

Based on the indications for use, technological characteristics, safety, and performance testing, the subject device the AllTest Viral Transport Medium meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Cultura™ Collection and Transport System (K201674).