510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K250205

B Applicant

Jinan Babio Biotechnology Co., Ltd.

C Proprietary and Established Names

Babio Virus Transport Kit (Non-inactivating)

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 Jinan Babio Biotechnologies Co Ltd.' Babio Viral Transport kit (Non-inactivating) for collection and transport of viral organisms in clinical samples for standard laboratory culture and examinations.

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 Babio Virus Transport Kit (Non-inactivating) is intended for the collection and transportation of clinical specimens for preservation of viral agents including Influenza A, Herpes Simplex Virus-1, and Adenovirus from the collection site to the testing laboratory. The Babio Virus Transport Kit contains a culture-based medium that is intended to be used for standard laboratory procedures of virus culture and diagnostic assays which utilize stable recoverable infectious viral particles.

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 Babio Virus Transport Kit (Non-inactivating) comprised of a non-propagating media supplied in screw cap plastic tubes filled with either 2 or 3 or 3.5 mL of transport medium alone or with a combination of different type swabs in kit configuration. The Babio VTM contains Hank's Balanced Salts, Bovine Serum Albumin, HEPES, L-Cysteine, L-Glutamic Acid, Sucrose, Vancomycin, Gentamicin, Nystatin, Colistin and phenol red.

Babio Virus Transport Medium/kit will be available in the following configurations.

- **VTM only:** Contains only viral transport medium but no swab
- **Nasopharyngeal Swab Kit**: Designed for nasopharyngeal sample collection.
- **Anterior Nasal Swab Kit**: Designed for anterior nasal swab collection.
- **Throat Swab Kit**: Suitable for throat, skin lesion, or saliva sample collection.
- **Dual swab kit**; contain 2 different swabs (Anterior nasal/Nasopharyngeal + Throat)

A detailed list of kit configurations has been provided in the package insert.

B Principle of Operation:

The Babio Virus Transport Kit (non-activated) is intended for collection, transport, and preservation of clinical specimens suspected of containing viruses for viral culture and molecular detection.

The healthcare provider uses a nylon-flocked swab to collect a sample from the patient's anterior nasal or nasopharyngeal or oral cavity following site-specific standard operating procedures. The swab is then inserted into the transport tube containing the viral transport medium. The swab is swirled in the medium to release the collected specimen, following which the swab handle is broken off by bending the shaft at the scored breakpoint against the rim of the tube. Then the tube is tightly capped and stored at recommended temperatures until further processing of samples within the validated time window.

The Babio viral transport medium components such as Hank's Balanced Salts, a HEPES maintains osmotic balance, and pH. Bovine Serum Albumin, L-Cysteine, L-Glutamic Acid, and Sucrose preserve the viability of the virus by providing required nutrients. Antimicrobials such as Vancomycin, Gentamicin, Nystatin, and Colistin to inhibit the growth of contaminating bacteria and fungi, preventing specimen contamination. Phenol red functions as a pH indicator.

V Substantial Equivalence Information:

A Predicate Device Name(s):
BioSci Disposable Virus Sampling Tubes

B Predicate 510(k) Number(s):
K230035

C Comparison with Predicate(s): As provided by the sponsor

Device & Predicate Device(s):	Device: K250205	Predicate: K230035
Device Trade Name	Babio Virus Transport Kit (Non-inactivating)	BioSci Disposable Virus Sampling Tube
Product code	JSM, Class I	JSM, Class I
Intended Use/Indications For Use	The Babio Virus Transport Kit (Non-inactivating) is intended for the collection and transportation of clinical specimens for preservation of viral agents including Influenza A, Herpes Simplex Virus-1, and Adenovirus from the collection site to the testing laboratory. The Babio Virus Transport Kit contains a culture-based medium that is	BioSci Disposable Virus Sampling Tube is intended for the collection and transport of clinical specimens containing viruses or chlamydiae from the collection site to the testing laboratory. The system can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.

	intended to be used for standard laboratory procedures of virus culture and diagnostic assays which utilize stable recoverable infectious viral particles.	
General Device Characteristic Similarities		
Single Use Device	Yes	Same
Product Configuration	Medium Tubes (Plastic screw cap tube); Kit with Medium Tubes and Swab Options	Same
pH	7.3 ± 0.2	Same
Shelf-life Storage Temperature	2-25°C	Same
Shelf-life	18 months	Same
General Device Characteristic Differences		
Media Formulation	Hanks' Balances Salt, Bovine Serum Albumin L-Cystein, L-Glutamine Acid Sucrose HEPES Vancomycin Gentamicin Nystatin Colistin Phenol Red.	Hank's Balanced Salt Solution Bovine Serum Albumin Glucose HEPES buffer Amphotericin B Gentamicin Phenol red
Medium Volume	2 mL; 3 mL; 3.5 mL	1 mL; 1.5 mL; 2 mL; or 3 mL
Supported Strains	• Adenovirus • Herpes Simplex Virus Type 1 • Influenza A	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A

		• Parainfluenza 3 • Respiratory Syncytial Virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis*

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 Babio Virus Transport kit was established by conducting a real-time Shelf-life stability study with Babio VTM lots at 2-8°C and 20-25°C. Three 3-ml VTM tube lots were evaluated for appearance (e.g., visual inspection for turbidity/ precipitation/ color of VTM, package integrity, leakage of liquid from the VTM tube, etc.), pH (acceptable range: 7.3 ± 0.3), net fill volume (acceptable range: above 95% of the claimed volume), antibiotic stability, and contamination. VTM tube lots were stored at recommended shelf-storage conditions, tested at regularly spaced intervals. The study results support a shelf-life stability of Babio VTM for up to 18 months from the date of manufacture when stored in a clean, dry, ventilated environment at 2-25℃.

6. Detection Limit:

Viral Recovery: The viral recovery performance of the Babio Virus transport kit was evaluated for Influenza A, Herpes Simplex Virus Type-1, and Adenovirus in a culture-based viral viability studies with four media lots which included a new lot within two months of manufacture, a middle-age lot representing fifteen months old, and an old-age lot representing lots that were 22 months old. Pooled negative intended use clinical matrices were spiked with known concentration of virus and then the contrived viral samples were transferred into the VTM using the intended use swabs and then held at refrigerated temperatures (2-8°C) and room temperature (20-25°C) for up to 48 hours. At the end of the incubation, samples were diluted and inoculated in triplicate into cell monolayer seeded in 12-well plate to achieve 40-50% infection of the cells. After inoculations, the plates were incubated and monitored for virus-induced cytopathic effect (CPE). When the CPE was observed, the cells were washed, virus specific Immunofluorescence antibody staining was performed for detection. Infectious particles were counted as fluorescent foci, and the average recovery was calculated as the mean foci count per inoculum volume for each storage temperature and timepoint. Changes in the recovery between 0 and 48 hours were expressed as percentage (negative for decrease, positive for increase). A change <50% was considered acceptable.

Table 1: Viral Recovery Performance of Babio Virus Transport Kit

Viral strains	Babio VTM Lot Age	T=0 hour	Percent changes in Viral Recovery at T= 48 hours (-ve indicates reduction)	
		Fluorescent Foci count (x 10^4 Foci counts/mL)	2-8°C	20-25°C
Influenza A H1N1	New	1.25	-11.43%	-14.43%
	Mid	1.23	-8.28%	-12.19%
	Old	128	-13.43%	-14.64%
Herpes Simplex virus Type-1	New	1.33	-11.48%	-21.13%
	Mid	1.39	-16.36%	-41.17%
	Old	1.40	-16.05%	-41.47%
Adenovirus	New	1.20	-11.72%	-15.42%
	Mid	1.17	-10.33%	-14.53%
	Old	1.12	-5.13%	-9.3%

All results met the study acceptance criteria (**Table 1**). Overall, the viral recovery results support that ability of the Babio Virus Transport Kit to maintain the infectivity of Influenza A, Herpes Simplex Virus Type-1, and Adenovirus for up to 48 hours when the samples are stored in the Babio Virus Transport Kit at refrigerated (2-8°C) and at room temperature (20-25°C) respectively.

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.