510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231027

B Applicant

Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.

C Proprietary and Established Names

KaiBiLi Extended ViralTrans

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 make a substantial equivalence determination for the KaiBiLi Extended ViralTrans media for the collection and transport of clinical specimens, containing viruses, chlamydiae, mycoplasmas, and ureaplasmas, to the laboratory for 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 KaiBiLi Extended ViralTrans is intended for the collection and transportation of clinical specimens containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the test site. The KaiBiLi Extended ViralTrans is a culture-based medium that has been validated with multiple sample types and can be used to process clinical specimens using standard laboratory operating procedures for culture of clinical specimens or with other assays that utilize stable recoverable infectious viral particles or bacteria.

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 KaiBiLi Extended ViralTrans is room temperature stable and can sustain the viability of virus, chlamydiae, mycoplasma and ureaplasma when transported at 2-8ºC or 20-25ºC. The product can maintain proper pH environment and inhibit the growth of indigenous microbiota.

KaiBiLi Extended Viral Trans is supplied as one plastic flat-bottom vial along with a screw cap. The vial is filled with either 1 mL or 3 mL of transport medium and glass beads, or in a kit format with the collection swabs in the following configurations indicated below:

Cat. No.	Description
M221001	KaiBiLi Extended ViralTrans 3 mL- 3 mL viral transport medium/vial
M221006	KaiBiLi Extended ViralTrans 3 mL with minitip swab- 3 mL viral transport medium/vial, with a minitip swab
M221007	KaiBiLi Extended ViralTrans 3 mL with regular swab- 3 mL viral transport medium/vial, with a regular swab
M221008	KaiBiLi Extended ViralTrans 3 mL with regular swab and minitip swab- 3 mL viral transport medium/vial, with a regular swab and a minitip swab
M221009	KaiBiLi Extended ViralTrans 1 mL- 1 mL viral transport medium/vial

Cat. No.	Description
M221010	KaiBiLi Extended ViralTrans 1 mL with minitip swab- 1 mL viral transport medium/vial, with a minitip swab
M221011	KaiBiLi Extended ViralTrans 1 mL with regular swab- 1 mL viral transport medium/vial, with a regular swab
M221012	KaiBiLi Extended ViralTrans 1 mL with regular swab and minitip swab- 1 mL viral transport medium/vial, with a regular swab and a minitip swab

B Principle of Operation:

KaiBiLi Extended ViralTrans consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, cysteine, glutamic acid, sucrose and HEPES. The HEPES buffer protects against pH changes. Phenol red is used as a pH indicator. Sucrose aids in the preservation of organism viability. To minimize the contamination of commensal organisms, Vancomycin, Econazole Nitrate, and Polymyxin B are incorporated into the medium formula.

Specimens need to be placed into the tube containing transport medium immediately after sample collection and submitted to the laboratory as soon as possible. It is recommended that 2-8°C is the most appropriate temperature for specimen transportation.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Copan Universal Transport Medium (utm-rt) System

B Predicate 510(k) Number(s):

K042970

C Comparison with Predicate(s):

Device & Predicate Device(s):	**Device: K231027**	**Predicate: K042970**
Device Trade Name	KaiBiLi Extended ViralTrans	Copan Universal Transport Medium (UTM-RT) System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The KaiBiLi Extended ViralTrans is intended for the collection and transportation of clinical specimens containing viruses, chlamydiae, mycoplasmas and	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae,

Device & Predicate Device(s):	Device: K231027	Predicate: K042970
	ureaplasmas from the collection site to the test site. The KaiBiLi Extended ViralTrans is a culture-based medium that has been validated with multiple sample types and can be used to process clinical specimens using standard laboratory operating procedures for culture of clinical specimens or with other assays that utilize stable recoverable infectious viral particles or bacteria.	mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
Storage Temperature	2-8°C or 20-25°C	Same
Product configuration	Medium tubes; kit with medium tubes and swab options	Same
Single use device	Yes	Same
Container	Tube: plastic; self-standing with a screw cap; with glass beads	Same
Shelf Life	12 months	Same
pH	7.3 +/-0.2	Same
General Device Characteristic Differences		
Media Formulation	Hank's Balanced Salts HEPES Buffer BSA L-Cysteine L-Glutamic Acid Sucrose Vancomycin Econazole Nitrate Polymyxin B Phenol Red	Hank's Balanced Salts Bovine Serum Albumin L-Cysteine Gelatin Sucrose L-Glutamic Acid HEPES Buffer Vancomycin Amphotericin B Colistin Phenol Red

Device & Predicate Device(s):	Device: K231027	Predicate: K042970
Supported Strains	Adenovirus Cytomegalovirus Herpes Simplex Virus Type 1 Herpes Simplex Virus Type 2 Influenza A Parainfluenza 3 Respiratory Syncytial Virus Varicella Zoster Virus *Mycoplasma pneumoniae* *Chlamydia pneumoniae* *Ureaplasma urealyticum*	Adenovirus Cytomegalovirus Echovirus Type 30 Herpes Simplex Virus Type 1 Herpes Simplex Virus Type 2 Influenza A Parainfluenza 3 Respiratory Syncytial Virus Varicella Zoster Virus *Chlamydia pneumoniae* *Chlamydia trachomatis* *Mycoplasma hominis* *Mycoplasma pneumoniae* *Ureaplasma urealyticum*
Medium volume	1 mL or 3 mL	3 mL or 6 mL

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 Stability:
The shelf life for the KaiBiLi Extended ViralTrans media was determined to be 12 months from the date of manufacture when stored at temperature 2-8°C and 20-25°C. The shelf-life of the KaiBiLi Extended ViralTrans media was established using real-time aging performance test at time points T= 0, 6, 9, 11, and 12 months. Three lots each of the KaiBiLi Extended ViralTrans media in the 1 mL and 3 mL configurations (a total of 6 lots) were evaluated for appearance, net volume, pH value, bacteriostasis, and sterility at each time point in the real-time aging performance test.

a. Shelf-life, Appearance, Bacteriostasis, Net volume, and pH value:
The shelf-life stability was conducted by visual inspection with the following criteria: the media should be a clear transparent pink liquid; the media should have no turbidity, sediment, or color change. All lots tested at each time point passed the criteria for appearance.

The bacteriostasis ability of the transport media was evaluated by measuring for growth of microorganisms, spiked into the transport media, after 48 hours at 37°C. No microorganism growth was observed and all lots tested at each time point passed the criteria for bacteriostasis.

Net volume stability was evaluated by measuring the volume of the transport media. The net volume should not fall outside the range of 2.7-3.3 mL for the 3 mL media configuration or 0.9-1.1 mL for the 1 mL media configuration. All lots tested at each time point passed the criteria for net volume.

The pH stability of the transport media was determined by measuring the pH of the transport media. The pH value for each transport media at each time point should be within the pH range of 7.1-7.5. For all tubes at each time point, the pH value was within the predefined pH range and had an average of 7.22 ± 0.2.

b. Sterility:
The KaiBiLi Extended ViralTrans tube and media are not sold as sterile nor are they intended to be sterilized by the user. These vials are single use devices. To minimize contamination, the tubes are filled aseptically under control conditions. The swabs provided with the KaiBiLi Extended ViralTrans media are individually packaged and are sold as sterile.

The results for appearance, net volume, and pH value collectively support the claim for 12 months of storage for the KaiBiLi Extended ViralTrans media at 2-8°C and 20-25°C.

6. Detection Limit:

Performance Testing- Recovery Studies:

Performance of the KaiBiLi Extended ViralTrans media was evaluated using culture-based recovery studies for viruses and bacteria at different incubation times and temperatures.

For Recovery Studies, virus titer ($TCID_{50}$/mL) was quantified to evaluate the recovery of the following viruses in the corresponding matrices listed in Table 1 below: Herpes Simplex Virus Type 1 (ATCC VR-733; HSV-1), Herpes Simplex Virus Type 2 (ATCC VR-734; HSV-2), Respiratory Syncytial Virus (ATCC VR-26; RSV), Cytomegalovirus (ATCC VR-977), Adenovirus (ATCC VR-3), Parainfluenza 3 (ATCC VR-93), Influenza A (ATCC VR-822; Flu A), and Varicella Zoster Virus (ATCC VR-1832; VZV). Recovery of *Chlamydophila pneumoniae* (ATCC VR-2282) was evaluated using Fluorescent Foci Count method (IFU/mL). Recovery of *Mycoplasma pneumoniae* (ATCC 15531) and *Ureaplasma urealyticum* (ATCC 27618) was evaluated using the Swab Elution and Roll Plate methods (CFU/mL). Performance evaluation was carried out in three lots of media that represent newly manufactured, middle-aged, and recently expired media. Negative clinical matrix pools were contrived from a minimum of five donors. Matrix pools were determined to be negative prior to use in the specimen stability recovery studies.

Table 1: Negative clinical matrix used for organism validation.

Negative Clinical specimen Type	Microbial Testing
Skin	Herpes Simplex Virus Type 1
Skin	Varicella Zoster Virus
Genital specimens[1]	Herpes Simplex Virus Type 2
Nasopharynx	Respiratory Syncytial Virus
Nasopharynx	Adenovirus
Nasopharynx	Parainfluenza3
Nasopharynx	Influenza A
Throat	*Chlamydophila pneumoniae*
Throat	*Mycoplasma pneumoniae*
Blood[2]	Cytomegalovirus
Urine	Cytomegalovirus
Urine	*Ureaplasma urealyticum*

[1]pooled swab-collected vaginal exudates; [2]pooled venous blood.

Viral stocks were diluted into two different dilutions into the corresponding pooled negative clinical matrix and 100 µL of each dilution was transferred onto a dry sterile swab and placed into the KaiBiLi Extended ViralTrans media tubes in triplicate and stored at 2-8ºC and 20-

25ºC for 0, 24, and 48 hours. At each incubation time point, the sample was vortexed and a 200µL aliquot was removed for the recovery study. The recovery study was conducted using suitable host cells and tissue culture media. For tissue culture, host cells were plated in a microwell plate and allowed to adhere for 48-72 hours prior to recovery testing. Hep-2 cells were used for HSV-1, RSV, and *C. pneumoniae*; Vero cells were used for HSV-2; MRC-5 cells were used for Cytomegalovirus and VZV; A549 cells were used for Adenovirus; LLC-MK2 cells were used for Parainfluenza 3; MDCK cells were used for Flu A.

Bacterial stocks were diluted into four different dilutions into the corresponding pooled negative clinical matrix and 100 µL of each dilution was transferred onto a dry sterile swab and placed into the KaiBiLi Extended ViralTrans media tubes in duplicate and stored at 2-8ºC and 20-25ºC for 0, 24, and 48 hours. For the swab elution method, at each incubation time point, each sample was vortexed, serially diluted and a 100µL aliquot was removed for the recovery study. The recovery study was conducted using *Mycoplasma pneumoniae* culture medium for *M. pneumoniae* and *Ureaplasma urealyticum* culture medium for *U. urealyticum.* For the roll-plate method, a single dilution was tested in triplicate by streaking the swab from the various KaiBiLi Extended ViralTrans media tube incubation time point over the agar media specified above and incubating for CFU enumeration.

Viral titer for the viruses and foci counts for *C. pneumoniae* were evaluated, and CFU was enumerated for *M. pneumoniae* and *U. urealyticum.* The average recovery was calculated as mean viral titer ($TCID_{50}$/mL), mean foci count (IFU/mL), or mean CFU/mL, respectively, for each storage temperature and time points. The changes (any increase or decrease) in the recovery between time points (each time point compared to time point 0) were presented in percent values or $\log_{10}$ change (negative for decrease and positive for increase). Any change that was within one log difference (+/-90%) was considered acceptable. Results were combined for all the lots, irrespective of age, as all changes were acceptable. The results are presented in Tables 2 and 3 below.

Table 2: Recovery of viruses and bacteria at 2-8ºC storage

Test strain	Average recovery ($TCID_{50}$/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
HSV-1	$3.53x10^3$	$2.84x10^3$	$2.23x10^3$	-20%	-38%
HSV-2	$4.31x10^3$	$3.54x10^3$	$2.37x10^3$	-18%	-46%
RSV	$1.29x10^4$	$1.13x10^4$	$7.14x10^3$	-14%	-45%
Cytomegalovirus[1]	$5.89x10^3$	$4.75x10^3$	$3.32x10^3$	-19%	-44%
Cytomegalovirus[2]	$5.87x10^3$	$4.76x10^3$	$3.26x10^3$	-19%	-45%
Adenovirus	$1.31x10^5$	$1.06x10^5$	$8.53x10^4$	-20%	-36%
Parainfluenza 3	$2.70x10^4$	$2.19x10^4$	$1.83x10^4$	-19%	-33%
Flu A	$1.46x10^4$	$1.19x10^4$	$9.71x10^3$	-19%	-35%
VZV	$1.25x10^3$	$1.08x10^3$	$7.37x10^2$	-14%	-41%
Test strain	Average recovery (IFU/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
C. pneumoniae	$3.40x10^5$	$2.72x10^5$	$2.12x10^5$	-21%	-39%

Test strain	Average recovery using swab elution method (CFU/mL)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$6.36x10^4$	$5.89x10^4$	$2.43x10^4$	-0.03	-0.45
U. urealyticum	$6.74x10^4$	$5.81x10^4$	$2.19x10^4$	-0.08	-0.53
Test strain	Average recovery using roll plate method (CFU)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M. pneumoniae	$2.97x10^2$	$2.18x10^2$	$1.13x10^2$	-0.13	-0.42
U. urealyticum	$2.98x10^2$	$2.11x10^2$	$9.80x10^1$	-0.15	-0.48

[1]Cytomegalovirus recovery in blood; [2]Cytomegalovirus recovery in urine

Table 3: Recovery of viruses and bacteria at 20-25ºC storage

Test strain	Average recovery ($TCID_{50}$/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
HSV-1	$3.53x10^3$	$2.83x10^3$	$2.14x10^3$	-21%	-41%
HSV-2	$4.31x10^3$	$3.49x10^3$	$2.30x10^3$	-20%	-48%
RSV	$1.29x10^4$	$1.02x10^4$	$6.76x10^3$	-21%	-48%
Cytomegalovirus[1]	$5.89x10^3$	$4.71x10^3$	$3.22x10^3$	-20%	-45%
Cytomegalovirus[2]	$5.87x10^3$	$4.73x10^3$	$3.07x10^3$	-20%	-48%
Adenovirus	$1.31x10^5$	$1.05x10^5$	$7.89x10^4$	-21%	-41%
Parainfluenza 3	$2.70x10^4$	$2.15x10^4$	$1.78x10^4$	-20%	-35%
Flu A	$1.46x10^4$	$1.17x10^4$	$9.39x10^3$	-20%	-38%
VZV	$1.25x10^3$	$1.04x10^3$	$6.86x10^2$	-17%	-45%
Test strain	Average recovery (IFU/mL)			Percent observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
C.pneumoniae	$3.40x10^5$	$2.69x10^5$	$2.09x10^5$	-21%	-39%
Test strain	Average recovery using swab elution method (CFU/mL)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M.pneumoniae	$6.36x10^4$	$5.92x10^4$	$2.40x10^4$	-0.03	-0.46
U.urealyticum	$6.74x10^4$	$5.60x10^4$	$2.04x10^4$	-0.10	-0.56
Test strain	Average recovery using roll plate method (CFU)			Log_{10} observed changes (-ve indicate reduction)	
	0 hrs	24 hrs	48 hrs	0-24 hrs	0-48 hrs
M.pneumoniae	$2.47x10^2$	$2.09x10^2$	$1.03x10^2$	-0.15	-0.46
U.urealyticum	$2.98x10^2$	$1.74x10^2$	$9.40x10^1$	-0.23	-0.50

[1]Cytomegalovirus recovery in blood; [2]Cytomegalovirus recovery in urine

Conclusion: The KaiBiLi Extended ViralTrans media demonstrated the recovery of tested viruses (HSV-1, HSV-2, RSV, Cytomegalovirus, Adenovirus, Parainfluenza, Flu A, and VZV) and bacteria (*C. pneumoniae*, *M. pneumoniae*, and *U. urealyticum*) at an acceptable rate when stored at 2-8ºC and 20-25ºC up to 48 hours.

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.