IVD Rx Only

Dec. 2023, Ver. 02

KaiBiLi™ Extended ViralTrans

INTENDED 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.

SUMMARY

Appropriate specimen collection and transport is important to accurate laboratory diagnosis of infectious disease. Not only personnel operating skills, but also a proper specimen collection and transport system are essential attributes for reliable diagnosis result.
The KaiBiLi™ Extended ViralTrans system consists of a plastic, stand up tube with screw cap filled with universal transport medium, beads and provided with/without swabs.
The KaiBiLi™ Extended ViralTrans is room temperature stable and can sustain the viability of virus, chlamydia, mycoplasma and ureaplasma in clinical specimens when transported at 2-8℃ or 20-25℃ for up to 48 hours. The product can maintain proper pH environment and inhibit the growth of indigenous microbiota. 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.

PRINCIPLE

The 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.

MATERIALS SUPPLIED

KaiBiLi™ Extended ViralTrans is supplied as one plastic flat-bottom vial along with a screw cap for safely transporting biological specimens, and filled with 1 mL or 3 mL of transport medium and glass beads.
The KaiBiLi™ Extended ViralTrans system is offered as one of the following configurations：

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
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

REAGENTS

Hank's Balanced Salts	Sucrose
HEPES Buffer	Vancomycin
BSA	Econazole Nitrate
L-Cysteine	Polymyxin B
L-Glutamic Acid	Phenol Red
pH 7.3 ± 0.2	

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use.
2. The KaiBiLi™ Extended ViralTrans serves as a non-propagating transport culture media.
3. To be used by trained and qualified professionals.
4. Observe approved biohazard precautions and aseptic techniques.
5. It is a disposable product; please use it in accordance with relevant regulations for waste disposal after use.
6. Do not sample patients after wetting swabs with transport medium.
7. After sampling, the tube cap should be tightened to prevent liquid leakage.
8. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Special precautions should be taken when handling specimens that may have come in contact with blood and other bodily fluids.
9. Do not use if the package is damaged or passed the expiration date.
10. Do not use if the medium is contaminated. (medium change color from pink to yellow or turn turbid)
11. Single-use device, only for collection, transportation, and preservation of clinical specimen collection, and not suitable for any other application than intended use.

STORAGE CONDITIONS

The optimum storage temperature is 2-8°C or 20-25°C for up to 12 months. Do not use after expiration date, which is clearly printed on the outer box as well as the specimen transport tube label.

SAMPLE COLLECTION AND PREPARATION

Specimens should be collected and handled following laboratory guidelines.[3,4] Once the specimen is collected, the specimen should be refrigerated at 2-8°C and transport to the laboratory as soon as possible to sustain the optimal recovery rate. For the best viability, specimens should be refrigerated at 2-8°C or kept on wet ice following collection and while in transit. Specimens should be processed as soon as possible after being sent to the laboratory.

PROCEDURE

KaiBiLi™ Extended ViralTrans, 3 mL or 1mL

1. Label relevant sample information on the transport vial before sampling.
2. Aseptically remove the swab from pouch and collect the specimen from the patient.
3. Aseptically remove cap from vial and insert the swab into the tube with Transport Medium.
4. Snap off the swab shaft at the break point by bending against the tube wall.
5. Replace the cap onto the vial and close tightly.
6. Transfer the specimen to the laboratory for immediate analysis.

QUALITY CONTROL

Each lot of KaiBiLi™ Extended ViralTrans is tested for bacterial and fungal contamination. Each lot of product should be red, transparent, free of precipitation, packaging should be undamaged, media volume should not be less than the labeled amount, and pH value should be 7.3±0.2. Collection tubes should also not be used if there is sign of contamination, evidence of leakage, any turbidity, passed the expiration date, swab pouch is open, or if there are other signs of deterioration. Procedures for quality control of KaiBiLi™ Extended ViralTrans are referring to publications of American Society of Microbiology, JCM, and CLSI.[1,2]

LIMITATIONS

1. Specimens need to be handled aseptically.
2. Accurate culture results depend on proper specimen collection skills and timing, transportation temperature and time, as well as specimen handling in the laboratory.
3. KaiBiLi™ Extended ViralTrans is only recommended for collection and transport for viral, chlamydial, mycoplasma, and ureaplasma agents.
4. Freezing and thawing of specimens has not been validated.
5. Calcium alginate fiber and wooden shaft swabs are not recommended for use with KaiBiLi™ Extended ViralTrans as they may affect organism viability.
6. Any usage of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.

PERFORMANCE CHARACTERISTICS

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	Herpes Simplex Virus Type 2
Nasopharynx	Respiratory Syncytial Virus
Nasopharynx	Adenovirus
Nasopharynx	Parainfluenza3
Nasopharynx	Influenza A
Throat	*Chlamydophila pneumoniae*
Throat	*Mycoplasma pneumoniae*
Blood	Cytomegalovirus
Urine	Cytomegalovirus
Urine	*Ureaplasma urealyticum*

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 2-8℃ and 20-25℃ 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 log10 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 4ºC 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 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 4-8℃ and 20-25℃ up to 48 hours.

REFERENCES

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Index of Symbols

	Attention, see instructions for use		Manufacturer/ Manufactured by		Keep away from sunlight
CE	CE Marking	Σ	Tests per kit	EC REP	Authorized Representative
Rx Only	Prescription use only		Use by	2	Do not reuse
	Store between 2~25℃	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged	UDI	Unique device identifier		Upward

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