

KaiBiLi™ Extended ViralTrans

INTENDED USE

The KaiBiLi™ Extended ViralTrans is designed for specimen collection and transport for clinical samples suspect containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing site.

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 is suitable for collection, transport, maintenance and long-term freezer storage of clinical specimens containing viruses, chlamydia, and mycoplasma or ureaplasma. The system is consists of a plastic, stand up tube with screw cap filled with universal transport medium, and with/without flocced swabs.

The KaiBiLi™ Extended ViralTrans is room temperature stable and can sustain the viability of virus, chlamydiae, mycoplasma, and ureaplasma with flexibility in transport temperature ranges. The product can maintain proper pH environment; inhibit the growth of indigenous microbiota, and preserves the infectious organisms for long-term frozen storage.

Specimens need to be placed in to 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. For long term storage, specimens need to be frozen at -70°C or colder.

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 pathogens that are sensitive to pH changes. Phenol red is used to indicate pH. Sucrose aids in the preservation of viruses and chlamydiae when specimens are frozen for long term storage. To

minimize the contamination of commensal bacteria and fungi, Vancomycin, Econazole Nitrate, and Polymyxin B are incorporated into the medium formula.

MATERIALS SUPPLIED

KaiBiLi™ Extended ViralTrans is supplied as one plastic flat-bottomed vial along with a screw up cap for safely contain and transport biological specimens, and filled with 1 or 3ml of transport medium and glass beads. The KaiBiLi™ Extended ViralTrans system is offered with 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 flocced swab 3 mL viral transport medium/vial, with a minitip flocced swab
M221007	KaiBiLi™ Extended ViralTrans 3 mL with regular flocced swab 3 mL viral transport medium/vial, with a regular flocced swab
M221008	KaiBiLi™ Extended ViralTrans 3 mL with regular floccedswab and minitip flocced swab 3 mL viral transport medium/vial, with a regular flocced swab and a minitip flocced swab
M221009	KaiBiLi™ Extended ViralTrans 1 mL 1 mL viral transport medium/vial
M221010	KaiBiLi™ Extended ViralTrans 1 mL with minitip flocced swab 1 mL viral transport medium/vial, with a minitip flocced swab
M221011	KaiBiLi™ Extended ViralTrans 1 mL with regular flocced swab 1 mL viral transport medium/vial, with a regular flocced swab
M221012	KaiBiLi™ Extended ViralTrans 1 mL with regular flocced swab and minitip flocced swab 1 mL viral transport medium/vial, with a regular flocced swab and a minitip flocced swab

REAGENTS

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

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use
2. To be used by trained and qualified professionals.
3. Observe approved biohazard precautions and aseptic techniques.
4. It is a disposable product; please use it in accordance with relevant regulations for waste disposal after use.
5. Do not sample patients after wetting swabs with transport medium.
6. After sampling, the tube cap should be tightened to prevent liquid leakage.
7. 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.
8. Do not use if the package is damaged.
9. Do not use if the medium is contaminated. (medium change color from pink to yellow or turn turbid)

STORAGE CONDITIONS

The optimum storage temperature is 2~25°C until used.

SAMPLE COLLECTION AND PREPARATION

Specimens should be collected and handled following laboratory guidelines. 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. If long term storage is needed, they should be stored at -70°C or below. Specimens should be processed as soon as possible after being sent to the laboratory.

PROCEDURE

KaiBiLi™ Extended ViralTrans, 3 mL or 1mL

1. Mark relevant sample information on the transport vial before sampling,

2. Aseptically remove cap from vial.
3. Aseptically place aspirates, conjunctival scrapings, small pieces tissue or stool samples into the vial containing medium.
4. Replace cap to vial and close tightly.
5. Transfer the specimen to the laboratory for immediate analysis.

KaiBiLi™ Extended ViralTrans ---Collection Kit

1. Before sampling, mark relevant sample information on the transport vial.
2. Collect specimen with swab.
3. Aseptically remove cap from vial.
4. Insert the swab into the transport medium tube.
5. Break swab shaft by bending it against the vial wall.
6. Replace cap to vial and close tightly.
7. Transfer the specimen to the laboratory for immediate analysis.

QUALITY CONTROL

Each lot of KaiBiLi™ Extended ViralTrans is tested for bacterial and fungal contamination and medium pH. Procedures for quality control of KaiBiLi™ Extended ViralTrans are referring to publications of American Society of Microbiology, JCM, and CLSI.

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. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
5. Calcium alginate fiber and wooden shaft swabs are not recommended for use with KaiBiLi™ Extended ViralTrans as they may affect organism viability.
6. KaiBiLi™ Extended ViralTrans is validated with the use of polyester tipped swabs and Flocked Swabs along with the kit. Swabs and transport medium from other resources have not been validated.
7. Any usage of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.

PERFORMANCE CHARACTERISTICS













The performance characteristics of KaiBiLi™ Extended ViralTrans was evaluated for the viability and recovery rate of viruses, chlamydiae, mycoplasmas and ureaplasmas. Two different dilutions of the stock organism suspensions were prepared, and directly inoculated 100µL onto swabs in triplicate. Swabs were then placed into extended viral transport medium and stored at both 4°C and room temperature (20~25°C) for 0, 24, and 48 hours. At the appropriate time interval, each swab was vortexed and removed from its transport medium vial. Suspension was then inoculated into appropriate culture media. All cultures were processed by standard laboratory culture technique and examined after a specified incubation time. Organism viability was determined by fluorescing foci counts for viruses and chlamydia strains and by CFU counts for mycoplasma and ureaplasma strains. Test organisms used for evaluation of KaiBiLi™ Extended ViralTrans Medium were : 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* and *Ureaplasma urealyticum*. KaiBiLi™ Extended ViralTrans Medium was able to maintain the viability of the following organisms for at least 48 hours at both room temperature (20~25°C) and in the refrigerator (2~8°C) under the test conditions described above.

REFERENCES

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Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2~25°C		Lot number		Catalog#
	Keep away from sunlight		Manufacturer/Manufactured by		CE Marking

Manufactured for CLIAwaived, Inc
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