DRKEWE®

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BioSci® Disposable Virus Sampling Tube

[Product Name]

Chinese name：一次性使用病毒采样管
English name：Disposable virus sampling tube

[Intended Use]

BioSci® Disposable Virus Sampling Tubes are intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. Each tube provides a viral collection device and transport medium vial for transport of organisms.

BioSci® Conventional Viral Transport Medium can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.

[Summary]

BioSci® Disposable Virus Sampling Tubes are supplied in several customer convenient pre-packaged collection sets for routine procedures in the diagnosis of infections caused by viruses. Each sampling tube comprises of a package containing one labeled screw-cap tube of Viral Transport Medium designed for transport of the clinical specimens and a peel pouch incorporating one or two specimen collection swabs for the collection and safe transportation of biological specimen. For details, please see **Model & Specification**.

[Model & Specification]

Cat. No.	Model	Description	Pack Size
3980111	FB	3 ml of Conventional Viral Transport Medium in screw-cap tube, with nasopharyngeal swabs.	50 tests per package
3980112			20 tests per package
3980121	FY	3 ml of Conventional Viral Transport Medium in screw-cap tube, with oropharyngeal swabs.	50 tests per package
3980122			20 tests per package
3980132	FBY	3 ml of Conventional Viral Transport Medium in screw-cap tube, with nasopharyngeal swabs and oropharyngeal swabs.	20 tests per package

[Principle of Procedure]

BioSci® Swabs comprise of a solid molded plastic applicator shaft and the tip of the applicator which is coated with short Nylon® fibers that are arranged in a perpendicular fashion. The swabs have no internal absorbent core to disperse and entrap the specimen– the entire specimen stays close to the surface for fast and complete elution. After collecting specimens using the swab, the swab is then put into the preservation tube for storage and transportation, and subsequent detection[1].

BioSci® Conventional Viral Transport Medium is mainly composed of modified Hank's balanced salt solution, bovine serum albumin, amino acids and glucose and the pH is buffered with HEPES buffer. Phenol red is used indicates pH. Gentamicin and amphotericin B are incorporated into the medium to inhibit competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells[2,3].

[Materials Provided]

Viral Transport Medium

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One screw-cap tube containing 3mL of Conventional Viral Transport Medium;

Swab

Nasopharyngeal swab/Oropharyngeal swab/Nasopharyngeal swab & Oropharyngeal swab

[Materials Required But Not Provided]

Appropriate materials for isolating, differentiating and culturing the pathogens in specimens. These materials include tissue culture cell lines, tissue culture medium, incubation systems and reading equipment.

[Storage Conditions and Expiry Date]

The product must be stored in the original packaging at a temperature of 2°C to 25 °C before use, and the shelf life is one year. See table below for component storage conditions:

Viral Transport Medium	Store at 2°C to 25°C
Swab	Store at 2°C to 30°C

NOTE: Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label.

[Specimen Storage]

Specimens for investigation should be collected and handled following published manuals and guidelines[4,5]. To maintain optimum viability or the most accurate test results, transport the specimen to the laboratory as soon as possible.

For BioSci® Conventional Viral Transport Medium, best recovery is obtained when specimens are refrigerated at 2°C to 8°C or kept on wet ice following collection and while in transit. If there will be a delay of more than 72 hours before processing, specimens should be frozen at –70°C or colder and transported on dry ice. Repeated freezing and thawing of specimens should be avoided.

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals[6].

[Procedures]

1. Collect specimens with the swab at corresponding parts.
2. Insert the swab into the tube with Viral Transport Medium.
3. Snap off the swab shaft at the pre-scored line by bending it against the tube wall.
4. Replace cap to tube and close tightly.
5. Label with appropriate information as required.
6. Transport the samples to the laboratory as soon as possible.
7. Specimens collected using BioSci® Disposable Virus Sampling Tubes require nucleic acid extraction before nucleic acid detection.
8. The product usage diagram is as follow:

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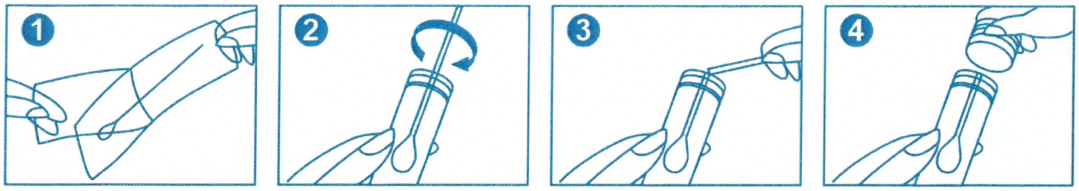

1.Take out the swab. 2.Insert the swab into sampling tube after 3.Snap off the swab. 4.Tighten the tube cap and label it.

[Disposal]

Waste must be disposed of in compliance with local legislation. Take the appropriate precautions for infected material if necessary.

[Limitations]

This product is only used for transport and storage of clinical specimens.

- Condition, timing, and volume of clinical specimen collected for culture are significant variables in obtaining reliable culture results. In order to obtain better results, it is necessary to follow the recommended guidelines to collect specimens.
- Repeated freezing and thawing of specimens may reduce the recovery.
- The sets are intended to be used with the medium tubes and swabs provided in the kit. The use of medium tubes or swabs from any other source could affect the performance of the product.

[Quality Control]

The product has been tested. BioSci® Conventional Viral Transport Medium is non-toxic to host cells, and the infectivity of the pathogens in specimens remains unchanged after 72 hours of storage.

For each batch of products, the following requirements should be met:

1. Appearance: the liquid of BioSci® Conventional Viral Transport Medium should be red, transparent and free of precipitation, and the package should be complete;
2. Net content: the net content of constituents should not be less than the labeled amount;
3. pH value: the Conventional Viral Transport Medium's pH value is 7.1-7.5;
4. Microbial detection limitation: should be sterile;
5. Stability: the product shall maintain the stability of various properties within one month after expiration date.

Collection tubes should not be used if:

- there is evidence of damage or contamination to the product;
- there is evidence of leakage;
- there is any turbidity or precipitation;
- expiration date has passed;
- swab pouch is open;
- there are other signs of deterioration.

[Precautions]

1. For in vitro diagnostic use only.
2. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trainedand qualified personnel.
3. Avoid direct contact of the Viral Transport Medium with personnel.
4. Do not immerse the swab in the Viral Transport Medium before sampling;
5. Single-use device, only for collection, transportation and preservation of clinical specimens collection, and not suitable for any other application than intended use.
6. Sterilize all biohazard waste including specimens, containers and media after their use.

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7. Do not use if you observe the transport medium out of expiry date, or leaking from the test tube .
8. Strictly follow the sampling procedures when using this product to collect specimens, operate in a laboratory that fits the security level when testing specimens.
9. Dispose of all containers in accordance with national regulations, including unused items and used items.

[References]

[1]Sarmirova, Sona, Bopegamage, Shubhada,Vari, Sandor G., et al.Assessment of a swab collection method without Viral Transport Medium for PCR diagnosis of coxsackievirus infections[J]. Journal of Virological Methods, 2018, 254:18-20.
[2]Starick, Elke, Fereidouni, Sasan R., Globig, Anja, et al. Effect of Swab Matrix, Storage Time, and Temperature on Detection of Avian Influenza Virus RNA in Swab Samples[J]. Avian Diseases, 2012, 56(Suppl.1):955-958.
[3]Esposito S, Daleno, Molteni CG. Comparison of nasopharyngeal nylon flocked swabs with universal transport medium and rayon-bud swabs with a sponge reservoir of viral transport medium in the diagnosis of paediatric influenza[J]. Journal of Medical Microbiology: An Official Journal of the Pathological Society of Great Britain and Ireland, 2010, 59(1):96-99.
[4]Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391 /EEC). Official Journal L262, 17/10/2000.
[5]Isenberg, H. D., 2004. Clinical Microbiology Procedures Handbook, 2nd ed. ASM, Washington, DC.
[6]National Committee for Clinical Laboratory Standards (NCCLS). 1994. Procedures for Handling andTransport of Diagnostic Specimens and Etiologic Agents. Approved Standard H5-A3.p. 0021-0045.

[Basic Information]

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[Voucher Number for Medical Device Production Record]

NMPA Reg. No.: YSXB20200293

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[Instruction Approval and Revision Date]

2020.06.01

[Product Label Symbol Description]

Symbol	Description	Symbol	Description
REF	Cat. number	LOT	Batch code
	Date of manufacture	2℃ 25℃	Storage Conditions 2℃-25℃
	Expiration date		Do not reuse
	Do not use if package is damaged		Consult instructions for use
BioSci®	Product trademarks	DAKEWE®	Company logo
CE	CE Certification	IVD	In Vitro Diagnostic

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