BioSci™ Disposable Virus Sampling Tube Instructions for Use

Intended Use

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.

Summary

BioSci™ Disposable Virus Sampling Tube is divided into two different types – with or without swab(s). Type with swab(s) is supplied in several customer convenient pre-packaged collection sets for routine procedures in the diagnosis of infections caused by viruses or chlamydiae. Each set comprises of a package containing one labeled screw-cap tube of Transport Medium and a peel pouch incorporating one or two specimen collection swabs for the collection and safe transportation of biological specimen. And type without swab (Model VM) contains labeled screw-cap tube with transport medium only. For details, please see **Model & Specification**.

Model & Specification

REF	Model	Description	
		Tube	Swab
6991111	VN	1 mL of Transport Medium in screw-cap tube	One minitip flocking swab with 8cm breaking point
6991311		3 mL of Transport Medium in screw-cap tube	
6991121	VO	1 mL of Transport Medium in screw-cap tube	One regular flocking swab with 3cm breaking point
6991321		3 mL of Transport Medium in screw-cap tube	
6991191	VNO	1 mL of Transport Medium in screw-cap tube	One minitip flocking swab with 8cm breaking point and one regular flocking swab with 3cm breaking point
6991391		3 mL of Transport Medium in screw-cap tube	
6991014	VM	3 mL of Transport Medium in screw-cap tube	Swab not included
6991024		2 mL of Transport Medium in screw-cap tube	
6991034		1 mL of Transport Medium in screw-cap tube	
6991074		1.5 mL of Transport Medium in screw-cap tube	

Reagents

Hank's Balanced Salt Solution
Bovine Serum Albumin
Glucose
Antibiotics
HEPES Buffer
Phenol Red
pH 7.3±0.2 @ 25℃

Principle of Procedure

Swabs are comprised of a solid molded plastic applicator shaft and the tip of the applicator is flocked and either a regular tip or a mini tip. After collecting specimens using the swab, the swab is then put into the preservation tube for storage and transportation, and subsequent detection [1].

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

Materials Provided

Transport Medium
One screw-cap tube containing specified volume of Transport Medium, for non-propagating transportation.

Swabs
1. One minitip flocking swab with 8 cm breaking point
2. One regular flocking swab with 3 cm breaking point
3. One minitip flocking swab with 8 cm breaking point and one regular flocking swab with 3 cm breaking point

NOTE: Model VM only provide Transport Medium (without swab).

Materials Required but Not Provided

Appropriate materials for isolating, differentiating and culturing the pathogens in specimens. These materials include culture cell lines, 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℃ to 25 ℃ before use, and the shelf life is 18 months. See table below for component storage conditions:

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

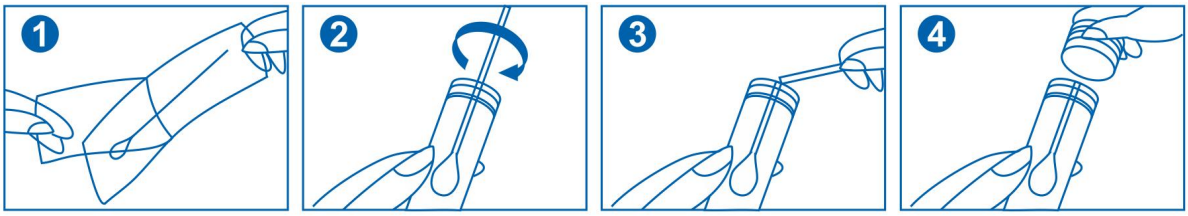
Specimens for investigation should be collected and handled following published manuals and guidelines [4, 5]. To maintain optimum viability or the most accurate test results, transport the specimen to the laboratory as soon as possible.

Better recovery of viruses and chlamydiae are achieved when specimens are processed shortly after the time of collection and within 48 hours of collection when transported at 4°C compared to 25°C.

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 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:



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

Limitations

- This product is only used for transport and storage of clinical specimens.
- Specimens should be handled aseptically.
- Condition, timing, and volume of clinical specimen collected for culture are significant variables in obtaining reliable culture results. To obtain better results, it is necessary to follow the recommended guidelines to collect specimens.
- The sets are intended to be used with the medium tubes and swabs provided in the kit. The use of swabs from any other source could affect the performance of the product.
  Because calcium alginate swabs are toxic for many enveloped viruses and may interfere with fluorescent antibody tests, they should not be used for specimen collection. Wooden shaft swabs may contain toxins and formaldehydes and should not be used.
- Freeze/thaw of the specimens has not been validated.

- **Quality Control**

The product has been tested. Transport Medium is non-toxic to host cells, and the infectivity of the pathogens in specimens remains after 48 hours of storage.

For each batch of products, the following requirements should be met:
1. Appearance: the liquid of 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 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. For transport of specimens only.
3. Observe approved biohazard precautions and aseptic techniques. For professional use only.
4. Avoid direct contact of the Transport Medium with personnel.
5. Do not immerse the swab in the Transport Medium before sampling.
6. Not to be taken internally.
7. Not for use on animals.
8. Single-use device, only for collection, transportation, and preservation of clinical specimen collection, and not suitable for any other application than intended use.
9. Sterilize all biohazard waste including specimens, containers, and media after their use.
10. Do not use if you observe the transport medium out of expiry date or leaking from the test tube.
11. Strictly follow the sampling procedures when using this product to collect specimens, operate in a laboratory that fits the security level when testing specimens.
12. Dispose all containers in accordance with national regulations, including unused items and used items.

Performance Characteristics

Performance of the BioSci Disposable Virus Sampling Tube was evaluated by Culture-Based Recovery Studies for viruses and chlamydiae. For Viral Recovery Studies, Fluorescent Foci Count method was utilized to evaluate the recovery of Adenovirus (ATCC VR-1), Cytomegalovirus (ATCC VR-977), Herpes Simplex Virus Type 1 (ATCC VR-260) and Influenza A (ATCC VR-1736). This method was also utilized to evaluate the recovery of *Chlamydia pneumoniae* (ATCC VR-1360). Performance evaluation was carried out in four lots of media that represent newly manufactured media and older

media (about to expire or recently expired).

Virus stocks were diluted into two different dilutions in pooled negative clinical matrix and each dilution was inoculated into swab in triplicate and placed into BioSci Disposable Virus Sampling Tube to store at 2 - 8ºC and 20 - 25ºC for 0 and 48 hours respectively. At each time point following inoculation, each sample was vortexed, and an aliquot was taken for recovery study using suitable tissue culture medium and host cells. For tissue culture, host cells were seeded in a 96-well plate and allowed to adhere for 24 – 48 hours. MRC-5 cells (SCSP-5040) were used for Adenovirus and Cytomegalovirus, Vero cells (GNO10) for Herpes Simplex Virus Type 1, and MDCK cells (GNO23) for Influenza A. Aliquot of 100 microliter (µL) virus suspensions prepared in gradient dilutions in triplicate were added on the monolayer plate. After incubation, specific immunofluorescent antibody staining was used for detection. For Chlamydia recovery, McCoy cells (ATCC CRL-1696) were used.

The number of infectious particles were counted as Fluorescent Foci and average recovery was calculated as mean of foci count per inoculum volume into 96-well plate (0.05 mL) for each storage temperature and time points. The changes (any increase or decrease) in the recovery between timepoints (0 to 48 hr) were presented in percent values (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 the following tables:

Recovery of viruses and Chlamydiae at 4ºC storage.

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)		Changes in 0 - 48 hrs. (-ve indicates reduction)
	0 hr.	48 hrs.	
Adenovirus	1.75	2.39	36%
Cytomegalovirus	1.65	1.46	-12%
Herpes Simplex Virus Type 1	1.33	1.56	17%
Influenza A	14.87	4.13	-72%
Chlamydia pneumoniae	15.94	14.75	-7%

Recovery of viruses and Chlamydiae at 25ºC storage.

Test Strain	Average Recovery in Foci count/mL ($\times 10^4$ Foci Counts/mL)		Changes in 0 - 48 hrs. (-ve indicates reduction)
	0 hr.	48 hrs.	
Adenovirus	1.75	2.58	47%
Cytomegalovirus	1.65	0.70	-57%
Herpes Simplex Virus Type 1	1.33	1.59	20%
Influenza A	14.87	1.44	-90%
Chlamydia pneumoniae	15.94	13.08	-18%

Supported Strains
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

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 and Transport of Diagnostic Specimens and Etiologic Agents. Approved Standard H5-A3. p. 0021-0045.

Basic Information

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Instruction Approval and Revision Date

2022.12.16

Product Label Symbol Description

Symbol	Description	Symbol	Description
REF	Cat. number	LOT	Batch code
	Date of manufacture		Manufacturer
	Expiration date	2℃ 25℃	Storage Conditions 2℃-25℃
	Do not use if package is damaged		Do not reuse
IVD	In Vitro Diagnostic		Consult instructions for use
Σ	Contains sufficient for <n> tests	**Rx Only**	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
BioSci	Product trademarks	DAKEWE	Company logo of manufacturer