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Viral Transport Tube Instruction for use

CE

[Product Name]
Viral Transport Tube
[Package Specifications]
1Pcs/Set,50Pcs/Set
[Type]
HX-K59,HX-K60,HX-K61

IVD

[Test Principle]
HX-K59: On the basis of Hanks solution, Bovine Serum Albumin V and Virus-stable ingredients such as HEPES are added. The medium maintains virus activity over a wide temperature range which facilitates the extraction of nucleic acid for the subsequent sampling and viral culture. HX-K60: Guanidine salt is used as protein denaturant and nuclease inhibitor, it can inactivate viruses without affecting the integrity of viral nucleic acids. This is beneficial for nucleic acid extraction and analysis procedures, but it is not suitable for virus culture.

HX-K61: Lithium dodecyl sulfate was used as protein denaturant and nuclease inhibitor which inactivates viruses without affecting the integrity of viral nucleic acid. It is beneficial to perform the procedure of nucleic acid extraction and analysis but not suitable for viral culture.

[Intended Use]

This product is intended for the collection, transport and storage of clinical specimens containing viruses.

[Main Components]

This product consists of a sampling swab and a tube containing the viral sampling medium.
 The packaging in this product includes various components.

The specific information is as follows:

Type	components		
HX-K59	10ml+3ml medium+1 orsal swab+1 nasal swab/ 10ml+3ml medium +1 nasal swab/		
HX-K60	5ml+2ml medium+1 orsal swab+1 nasal swab/ 5ml+2ml medium+1 nasal swab/		
HX-K61	5ml+1ml medium+1 orsal swab+1 nasal swab/ 5ml+1ml medium +1 nasal swab		

[Product Performance]

This product is used to collect nasopharyngeal/ oropharyngeal body fluids by swabs and mix the preservation solution with nasopharyngeal/ oropharyngeal samples.

(Methods and Procedures) 1. Nasopharyngeal sampling

1.1.Remove the swab:

- 1.2.Insert the swab into the nostril perpendicular to the direction of the nose. It will reach the nasopharynx when it encounters resistance. The swab should be kept in the nasal cavity for 15-30 seconds;
- 1.3.Gently rotate the swab 3 times while keeping it in the nose;
- 1.4.Place specimen in the tube with medium after collection;
 1.5.Bend the swab shaft and break it off at the breaking point;
- 1.6.Replace cap on tube and close tightly, send to the laboratory for immediate analysis.

2.Oropharyngeal sampling

- 2.1.Remove the swab;
- 2.2.Open mouth and gently press the tongue with the tongue depressor;
- 2.3. Extend the swab into the pharynx, and wipe it back and forth on both sides of the pharyngeal tonsils and posterior pharyngeal wall 3-5 times;
- 2.4.Place specimen in the tube with medium after collection;
- 2.5.Bend the swab shaft and break it off at the breaking point.
- 2.6.Replace cap on tube and close tightly, send to the laboratory for immediate analysis.

[Sample Requirement]

The nasopharyngeal/oropharyngeal samples should be clean and free of any foreign contaminants in tube

I Requirements for Transportation and Storage After Sampling I HX-K60 virus storage tube: Store for 15 days at room temperature and 60 days at 4°C.

HX-K59 virus storage tube: Freshly collected samples should be transported to the laboratory within 48 hours at 2 °C -8 °C.

HX-K61 virus storage tube: Store for 15 days at room temperature and 60 days at 4°C.

[Storage Conditions and Validity Period]

- The product must be stored in its original packaging at room temperature and it is valid for 12 months. [Precautions]
- 1. Do not pre-wet the swab with preservation solution when collect samples. Do not directly contact skin with the preservation solution:
- 2. Resampling should be done if the sample solution turns yellow or turbid after first sampling:

3. Do not eat, smoke or chew gum thirty minutes before the sample is collected.

4. Do not use for sampling if the package is not intact.

- 5. Due to individual differences, 1% of the subjects still need to be re-sampled. Operation error or contamination of the sample may result in re-collection of the sample.
- 6. The nasopharyngeal samples should be considered as infectious substances, and the operation procedure must comply with certain regulations.

7. Single-use device, do not re-use for sampling. Do not use beyond the expiry date.

[References]

- 1. MAI Qiu-Sui, HE Jun-Xian, QIN Jie-Li. Detection Rate of Central Nervous System Leukemia Can Be Improved by Cell Preservation Solution.
- 2. A clinical application study on disposable sterile cotton pledgetsetyan.1009-6493(2007)9B-2420-01. [Instruction Approval and Revision Date]

Approval Date: 20200508

Revision Date: NA

Date of Issue: 20200508

[Index of Symbols]

[]	Please read the instruction book carefully before using	LOT	Batch number
EC REP	European union authorization representative	~	Date of manufacture
<u>11</u>	Upward .	4	Manufacturer
Δ	Warning, please refer to the instruction	REF	Catalogue number
-	Temperature scope within which the product is reserved	Ω	Validity
8	Please don't reuse it	IVD	The product is used in vitro, please don't swallow it.
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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