



Disposable Virus Sampling Kit

Instructions for Use

【PRODUCT NAME】

Disposable Virus Sampling Kit

【PACKING】

1. Product model: disposable virus sampling kit A1; disposable virus sampling kit A2; disposable virus sampling kit B1; disposable virus sampling kit B2.
2. Packing specification: 25 tests / box; 50 tests / box; 100 tests / box.

【INTENDED USE】

Used for collection, transportation and storage of the specimens (virus).

【TEST PRINCIPLE】

This product mixes the collected specimen with Virus Transport Media A / Virus Transport Media B. Virus Transport Media A keeps the morphological structure of virus; Virus Transport Media B inactivates the virus while effectively ensure the stability of the viral nucleic acid during in-vitro storage and transportation.

【MAIN COMPOSITION】

It consists of a sampling swab and / or cell preservation solution (non-inactivated / inactivated type).

Model	Composition	Specification		
		25 tests/box	50 tests/box	100 tests/box
A1	Sampling tube (including tube lid)	25 bottles	50 bottles	100 bottles
	Cell preservation solution A	2ml or 3ml/bottle*25 bottles	2ml or 3ml/bottle*50 bottles	2ml or 3ml/bottle*100 bottles
	Instruction for Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy
A2	Sampling swab	25 pieces	50 pieces	100 pieces
	Sampling tube (including tube lid)	25 bottles	50 bottles	100 bottles
	Cell preservation solution A	2ml or 3ml/bottle*25 bottles	2ml or 3ml/bottle*50 bottles	2ml or 3ml/bottle*100 bottles
	Instructions or Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy
A3	Sampling swab	25 pieces *2	50 pieces *2	100 pieces *2
	Sampling tube (including	25 bottles	50 bottles	100 bottles



	tube lid)			
	Cell preservation solution A	2ml or 3ml/bottle*25 bottles	2ml or 3ml/bottle*50 bottles	2ml or 3ml/bottle*100 bottles
	Instructions or Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy
B1	Storing tube (including tube lid)	25 bottles	50 bottles	100 bottles
	Cell preservation solution B	2ml or 3ml/bottle*25 bottles	2ml or 3ml/bottle*50 bottles	2ml or 3ml/bottle*100 bottles
	Instructions for Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy
B2	Sampling swab	25 pieces	50 pieces	100 pieces
	Storing tube (including tube lid)	25 bottles	50 bottles	100 bottles
	Cell preservation solution B	2ml/bottle*25 bottles	2ml/bottle*50 bottles	2ml/bottle*100 bottles
	Instructions for Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy
B3	Sampling swab	25 pieces *2	50 pieces * 2	100 pieces * 2
	Storing tube (including tube lid)	25 bottles	50 bottles	100 bottles
	Cell preservation solution B	2ml or 3ml/bottle*25 bottles	2ml or 3ml/bottle*50 bottles	2ml or 3ml/bottle*100 bottles
	Instructions for Use	1 Copy	1 Copy	1 Copy
	Inspection Certificate	1 Copy	1 Copy	1 Copy

Note:

1. Virus transport media A (non-inactivation type) and virus transport media B (inactivation type) are stored in sampling tube.
2. The product is provided non-sterile.
3. The main components of virus transport media A are Eagle culture solution, bacteriostatic agent, etc; the main components of cell preservation solution B are guanidine isothiocyanate, sodium dodecyl sarcosinate, Tris-HCl, phenol red solution, etc.

【STORAGE CONDITION & SHELF LIFE】



1. Storage condition: 4 °C ~ 30 °C
2. Shelf life: 12 months.

【APPLICABLE INSTRUMENT】

Not applicable

【SAMPLE REQUIREMENT】

Freshly collected specimens can be delivered to the laboratory at room temperature (5-25 °C). Using ice packs are better for transportation. Specimens used for nucleic acid testing should be tested as soon as possible.

Specimens tested within 48 hours should be stored at 2-8 °C; specimens that cannot be tested within 48 hours should be stored at or below -70 °C, and guaranteed to be shipped to the corresponding laboratory for testing within one week. The specimen should avoid repeated freezing and thawing.

【TEST METHOD】

1. Place the sampling swab with collected specimen in the sampling tube of virus transport media.
2. Break the swab at the break point of the sampling swab rod and discard the tail;
3. Tighten the lid of virus transport media;
4. Mark the information on the label of tube as required.
5. The specific sampling and preservation methods can refer to the following:

1) Pharyngeal swab specimens:

Use a dedicated sampling swab to wipe the back wall of the pharynx and the tonsils on both sides with moderate force, avoid touching the tongue. Quickly immerse the swab head in the virus transport media, and break the swab at the breaking point of the sampling swab rod, discard the tail.

2) Nasopharyngeal swab specimen: gently insert the nasal swab into the nasal palate of the nasal canal, stay for a while, then slowly rotate to exit; quickly immerse the swab head in the virus transport media and break the swab at the breaking point of the sampling swab rod, and discard the tail.

【POSITIVE VALUE OR REFERENCE RANGE】

Not applicable

【INTERPRETATION OF TEST RESULT】

Not applicable

【LIMITATION OF TEST METHOD】

Not applicable

【PRODUCT PERFORMANCE INDEX】

1. Appearance: the liquid inside tube is red, transparent, and there is no visible suspended matter.
2. pH requirement: 7.5 ± 0.2;
3. Loading capacity: not less than the marked quantity.

【NOTES】

1. Confirm that the outer packaging of the product is intact, check the transport media tube and confirm that there is no leakage.



2. This product is for one-time use. It is forbidden to use it twice, and it is forbidden for different patients to use the same transport media tube.
3. The specimen collection process should be considered as a potential infected risk, the operation and dispose must comply with the relevant regulations.
4. Do not eat, smoke, chew gum, or drink water within 30 minutes before sampling.
5. Only professional or qualified personnel can operate.
6. This product should be used within the shelf life, and cannot be used after its expiration date.
7. This product is for single use.
8. After using this product, the waste should be disposed according to the regulations of the hospital or environmental protection department to avoid any potential danger.
9. This product should be used as soon as possible after opening, and the lid should be tightened after storing the specimen in the preservation solution.

【ILLUSTRATION OF MARK】



Warning



Never re-use



Only for in-vitro diagnosis



Temperature Limit

【REFERENCES】

1. National Influenza Surveillance Plan (2017 version)
2. WHO Global Influenza Network Surveillance Program
3. Technical solutions for the collection and detection of HFMD specimens

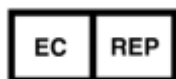


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