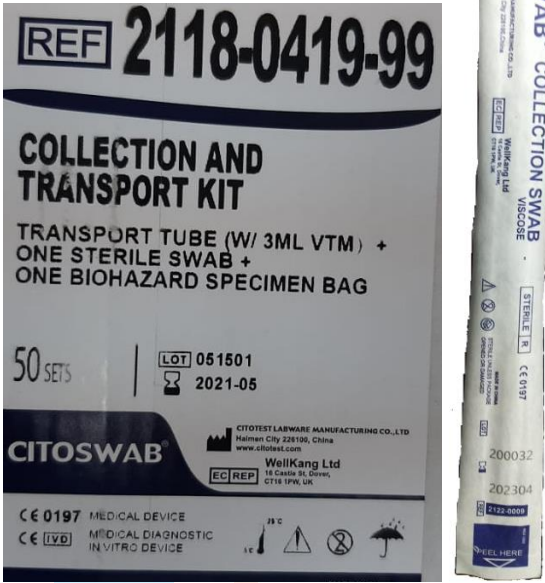


Safety Communication

رسالة سلامة

Missing information in the labelling and Instructions for Use

Device/ Product Description:	Collection and transport kit for Covid-19	
Affected product:	Reference Number:	2118-0419-99 (for Throat)
		2118-1504-99 (for Nasopharynx)
Manufacturer:	CITOTEST LABWARE MANUFACTURING CO,LTD	
Problem:	The supplied Instruction for Use is only basic general document, it does not include the Swab's way of use, and it is not obvious which swab for nasal or throat. This may cause Problems/issues with the correct use of the swab during sample collection.	
Recommendation /Actions:	<ol style="list-style-type: none"> 1. Review this notice and ensure that all affected personnel within your organization are aware of the contents. 2. Inspect the inventory to identify the affected products and consider the supplied instructions for use (check the attachments below) 3. Contact the Authorized Representative for required assistance. <p>For more information, please check the “FSCA”</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>	

<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>AL OSOOL MEDICAL TRADING COMPANY</p>
	<p>Assigned Contact Person:</p>	<p>AbdulKader Al Husainan</p>
	<p>Mobile/Phone:</p>	<p>0554743900</p>
	<p>Email:</p>	<p>info@alosoolumedical.com</p>

CITOTEST®

CITOSWAB® Collection and Transport Kit

REF.2118-0419-99

Intended Use

CITOSWAB® Collection and Transport kit is a ready-to-use system used for the collection and transport of viruses obtained from clinical specimens.

Summary and Explanation

CITOSWAB® Collection and Transport Kit provides a safe and convenient way to collection and transport clinical specimens. Each Collection and Transport Kit comprises a sterile peel pouch containing a swab used to collect the sample, a transport tube containing medium into which the swab is placed after sampling, and a biohazard bag used to place the transport tube for transportation.

Once a swab sample is collected, it should be placed immediately into the transport tube, and submitted to the laboratory as quickly as possible. Although VTM can maintain organisms for long periods of time at room temperature, it is recommended that specimens should be refrigerated at 2-8 °C or kept on wet ice while in transit. If there will be a long delay before processing, specimens should be frozen at -70 °C.

Principle

The kit is available with VTM and VTM-N media. VTM medium consists of modified Hank's-HEPES buffer solution supplemented with bovine serum albumin, gelatin, glucose, antibiotic and etc. It is osmotically balanced and buffered to maintain the viability of virus specimens during transportation to laboratory. VTM-Nmedium consists of Tris-HCl buffers, EDTA and guanidine salt. The presence of guanidine salts acts as the protein deformers and nuclease inhibitors which makes the virus inactive, but does not affect the integrity of the viral nucleic acid.

The nominal formula for each medium is as follows:

VTM Medium	VTM-N Medium
Hank's Balanced Salts	Tris-HCl Buffer
Bovine Serum Albumin	EDTA
Gelatin, Glucose	NaCl
HEPES Buffer	Guanidine salt
Penicillin-streptomycin	
Amphotericin B	
Phenol Red	

Precautions

1. For in-vitro diagnostic use only.
2. To be used only by adequately trained and qualified personnel.
3. Use aseptic technique and biohazard precautions when collecting and handling specimen.
4. Sterilize all biohazard waste including specimens, containers and media after their use.
5. Delays in transportation and lack of refrigeration may reduce recovery of the organisms.
6. Don't use after expiry date, and don't use if there is evidence of leakage, the color of the medium has changed color or appears turbid.
7. Directions should be read and followed carefully.

CITOTEST®

Storage

Room temperature, optimum storage temperature is 5°C to 25°C. Do not overheat, incubate, or freeze prior to use. Improper storage will result in a loss of efficacy. Don't 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.

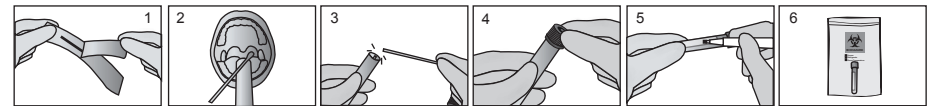
Material Provided

CITOSWAB® Collection and Transport System contains a plastic transport tube with 1ml or 3ml medium which is supplied alone or in a kit with one or more sterile swabs with snappable plastic shaft and synthetic fiber tip, and one Biohazard bag optional.

Material Not Provided

Other materials required for culturing, identification and extracting purposes.

Directions for Use



1. Peel off the pouch and collection;
2. Insert the swab into the back of the throat near the tonsils, and then put the swab into the medium;
3. Snap the stick of swab;
4. Screw the tube cap tightly;
5. Label the specimen information;
6. Put into the Biohazard bag.

Quality Control

All batches of swab are subjected to rigorous quality control, including sterility and toxicity to host cells. And representative samples of each lot of transport tube are tested for microbial contamination.

Results

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

Limitations

This product is not intended to be used for the collection and transportation of bacterial cultures. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.



CITOTEST LABWARE MANUFACTURING CO.,LTD

Address: No.48, Xinxu Road, Haimen, Jiangsu Province

Contact: TEL 0513-82259348; FAX 0513-82110195

Web: www.citotest.com

CE 0197 MEDICAL DEVICE

CE [IVD] MEDICAL DIAGNOSTIC IN VITRO DEVICE



WellKang Ltd
16 Castle St, Dover,
CT16 1PW, UK

物料号

402000815

尺寸

140*200mm

颜色

 Pantone187CVC

CITOTEST®

CITOSWAB® Collection and Transport Kit

REF.2118-1504-99

Intended Use

CITOSWAB® Collection and Transport kit is a ready-to-use system used for the collection and transport of viruses obtained from clinical specimens.

Summary and Explanation

CITOSWAB® Collection and Transport Kit provides a safe and convenient way to collection and transport clinical specimens. Each Collection and Transport Kit comprises a sterile peel pouch containing a swab used to collect the sample, a transport tube containing medium into which the swab is placed after sampling, and a biohazard bag used to place the transport tube for transportation.

Once a swab sample is collected, it should be placed immediately into the transport tube, and submitted to the laboratory as quickly as possible. Although VTM can maintain organisms for long periods of time at room temperature, it is recommended that specimens should be refrigerated at 2-8 °C or kept on wet ice while in transit. If there will be a long delay before processing, specimens should be frozen at -70 °C.

Principle

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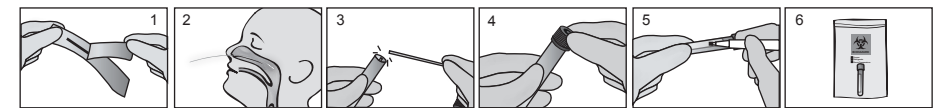
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Material Not Provided

Other materials required for culturing, identification and extracting purposes.

Directions for Use



1. Peel off the pouch and collection; 2. Insert the swab into nostril and back to nasopharynx, and then put the swab into the medium; 3. Snap the stick of swab; 4. Screw the tube cap tightly; 5. Label the specimen information; 6. Put into the Biohazard bag.

Quality Control

All batches of swab are subjected to rigorous quality control, including sterility and toxicity to host cells. And representative samples of each lot of transport tube are tested for microbial contamination.

Results

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