

CITOSWAB® Collection and Transport Kit

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-N medium 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 Bovine Serum Albumin Gelatin, Glucose HEPES Buffer Penicillin-streptomycin Amphotericin B, Phenol Red	Tris-HCl Buffer EDTA NaCl Guanidine salt

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.

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.

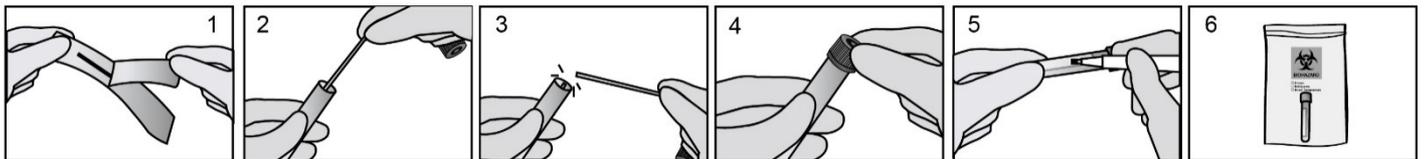
Material Provided

CITOSWAB® Collection and Transport System contains a plastic transport tube with 1 ml or 3 ml 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. 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.

Meridian Healthcare srl

Via Caronda, 446 SC/A - 95129 Catania - Italy
Tel. +39 095 725 68 69 - Fax: +39 095 725 44 54
info@meridianhealthcare.it
www.meridianhealthcare.it



CE 0197 MEDICAL DEVICE

CE IVD MEDICAL DIAGNOSTIC IN-VITRO DEVICE



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