

Disposable Sample Collection Kit

Intended Use

The Disposable Sample Collection Kit is a ready-to-use system used for the collection and transport of viruses obtained from clinical specimens.

Summary and Explanation

The Disposable Sample Collection Kit provides a safe and convenient way to collect and transport clinical specimens. Each sample collection kit comprises of a sterile peel pouch containing a swab, a transport tube with viral transport medium (VTM), and a biohazard bag.

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

Principle

The viral transport medium consists of modified Hank's-HEPES buffer solution supplemented with Cresol Red, etc. It is osmotically balanced and buffered to maintain the viability of virus specimens during transportation to laboratory. The nominal formula for the medium is shown on the right.

Viral transport medium
Hank's Balanced Salts
HEPES Buffer
Cresol Red, etc.

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. Delays in transportation and lack of refrigeration may reduce recovery of the organisms.
5. Do not use if the product has passed its expiry date or if there is evidence of leakage, the color of the medium has changed or appears turbid.
6. Directions should be read and followed carefully.

Storage

Room temperature, optimum storage temperature is 15°C to 30°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

Each Disposable Sample Collection Kit contains a plastic transport tube with 2ml or 3ml medium which can be supplied alone, one or more sterile swabs with breakable plastic shaft and rayon fiber tip, and one optional biohazard bag.

Material Not Provided

Other materials required for culturing, identification and extracting purposes.

Directions for Use



1. Peel off the pouch and collect the specimen.



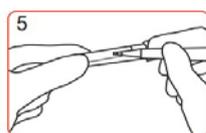
2. Place the swab into the medium.



3. Break the shaft at the breakpoint.



4. Screw the tube cap tightly.



5. Label the specimen information.



6. Put into the biohazard bag.

Quality Control

All batches of swab were subjected to rigorous quality control, including sterility and toxicity to host cells. 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.