

MedSchenker® Smart Collection System™

A FDA listed collection and transport system suitable for maintenance and long-term storage of clinical specimens containing viruses. Comes with a Nasopharyngeal CavSwab™ and a vial of Smart Transport Medium (STM™).

Product Information and How-to-Use

INTENDED USE

The MedSchenker® Smart Collection System™ is intended for the collection and transport of clinical specimens containing viruses, from the collection site to the testing laboratory. It provides a Nasopharyngeal CavSwab™ for specimen collection and a vial of STM™ for the transport of organisms in one system. The STM™ can be processed using standard clinical laboratory operating procedures for viral cultures.

SUMMARY AND EXPLANATION

One of the routine procedures in the diagnosis of infections caused by viruses, involves the collection and safe transportation of biological samples. This can be accomplished using the MedSchenker® Smart Collection System™. The MedSchenker® Smart Collection System™ includes a Nasopharyngeal CavSwab™ and STM™ which is room temperature stable and can sustain viability (and infectivity) of a plurality of organisms that include clinically important viruses during transit to the testing laboratory. The formulation of STM™ includes protein for stabilization, antibiotics to minimize bacterial and fungal contamination and a buffer to maintain a neutral pH.

The MedSchenker® Smart Collection System™ is supplied as a sample collection kit that comprises a blister pack containing one screw-cap tube of STM™ and one or two sterile specimen collection CavSwabs.

Once a sample using a Nasopharyngeal CavSwab™ is collected it should be placed immediately into the transport tube where it comes into contact with the transport medium. CavSwab™ specimens for virus, isolation should be submitted to the laboratory as quickly as possible after collection. Although the STM™ can maintain fragile 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 following collection and while in transit. If there will be a long delay before processing, specimens should be frozen at -70°C or colder and transported on dry ice. Storage at -20°C is less satisfactory than storage at 4°C or -70°C and can result in the loss of infectivity.

PRINCIPLE

The STM™ consists of liquid medium which have ingredients that inhibits growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells. The presence of sucrose acts as a cryoprotectant which aids in the preservation of viruses if specimens are frozen (-70°C) for prolonged storage.

PRECAUTIONS

- This product is For In Vitro Diagnostic Use.
- Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.
- All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Sterilize all biohazard waste including specimens, containers and media after their use.
- Directions should be read and followed carefully.

STORAGE

This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 2-25°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch and the specimen transport tube label.

PRODUCT DETERIORATION

Unless expressly approved by the manufacturer, MedSchenker® STM™ and CavSwabs should not be used if (1) there is

evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) there is evidence of breakage, tear or damage to the packaging container, (4) the color of the medium has changed from light orange-red, (5) the expiration date has passed, (6) the swab pouch is open, or (7) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION

Specimens for virus investigation should be collected and handled following published manuals and guidelines.^{2,3,4,7,9,10,11} To maintain optimum viability, transport the specimen to the laboratory as soon as possible. Best recovery is obtained when specimens are refrigerated at 2-8°C or kept on wet ice following collection and while in transit. If there will be a long delay before processing, specimens should be frozen at -70°C or colder and transported on dry ice. Specific requirements for the shipment and handling of specimens should be in full compliance with

state and federal regulations ^{8,11,12} Shipping of specimens within medical institutions should comply with internal guidelines of the institution. All Specimens should be processed as soon as they are received in the laboratory.

MATERIALS SUPPLIED

The MedSchenker® Smart Collection System™ includes a screw-cap tube containing 3ml of transport medium and a Nasopharyngeal CavSwab™

MATERIALS REQUIRED BUT NOT SUPPLIED

Appropriate materials for isolating, differentiating, and culturing viruses. These materials include tissue culture cell lines, tissue culture medium, incubation systems and reading equipment. Refer to appropriate references for recommended protocols for isolation and identification of viruses.^{2,3,4,7,10.}

DIRECTIONS FOR USE

MedSchenker Smart Collection System is available in the product configurations indicated in the table below.

SKU	Description	Sampling Sites*
STM30-A	3ml Screw cap with tube	Culture: all Viruses
AC1100	Nasopharyngeal CavSwab™	Culture: all Viruses

Specimens should be collected as soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness For STM30-A

1. Aseptically remove cap from tube
2. Aseptically place vesicle aspirates, corneal or conjunctival scrapings, small pieces of tissue or stool samples into the tube with STM medium
3. Replace cap to tube and close tightly.
4. Label with appropriate patient information
5. Send to the laboratory for immediate analysis.

QUALITY CONTROL

All lot numbers of the STM™ are tested for microbial contamination, toxicity to host cells and the ability to maintain viability of desired agents. Procedures for quality control of STM™ and virus culture media are described in several publications by the American Society for Microbiology ^{3,7,10} and by NCCLS^{5,6} If aberrant quality control results are noted, patient results should not be reported.

LIMITATIONS

1. Specimens should be handled aseptically.
2. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture

- results. Follow recommended guidelines for specimen collection.1,2,3,4,7,10.
- 3.Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
 - 4.STM™ is intended for use as a collection and transport medium for viral agents only. This medium can serve as a cryoprotectant for clinical viruses.
 - 5.Because calcium alginate swabs are toxic for many enveloped viruses and may interfere with fluorescent antibody tests, they should not be used for specimen collection. Wooden shaft swabs may contain toxins and formaldehydes and should not be used. Polyester (Dacron) tipped swabs and Flocked Swabs are suitable when specimen collection by a swab is appropriate.
 - 6.The STM™ is intended to be used with the CavSwabs provided with the System. The use of swabs from any other source could affect the performance of the product.

WARNINGS

- Do not re-sterilize unused swabs.
- Do not re-pack.
- Not suitable to collect and transport microorganisms other than viruses.
- Not suitable for any other application than intended use.
- The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
- Do not use if the swab is visibly damaged (i.e., if the swab tip is broken)
- Applicator swab is qualified as Class II a Medical Device according to European Medical Device Directive 93/42/EEC - Surgically Invasive Transient Use Class II a means swabs can be used for sampling body surfaces, body orifices (e.g., nose, throat and vagina and deep invasive surgical wounds)
- Do not ingest the medium
- To be handled by trained personnel only
- Do not use the STM™ for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling site

RESULTS

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

*Currently undergoing further testing and analysis to provide full spectrum of virus transportation data.

The MedSchenker® Smart Transport Medium (STM™) was able to maintain the viability of the following organisms for at least 48 hours at both room temperature (20-25°C) and in the refrigerator (2-8°C) under the test conditions described above.

The MedSchenker® Smart Transport Medium (STM™) is a collection and a transport medium that serves as a culture media, non-propagating transport.

*This Transport Medium has been reviewed by the FDA**

*Specimen stability for this media was not validated for recovery of viral infectious particles using a culture-based assay**