MedSchenker Smart Transport Medium (STM)

A combined viral transport medium and transport for viruses, chlamydia, mycoplasma and ureaplasma

Product Information and How-to-Use

INTENDED USE

MedSchenker Smart Transport Medium (STM) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. It provides a viral transport medium and a transport for the aforementioned organisms in one system. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture

SUMMARY AND EXPLANATION

One of the routine procedures in the diagnosis of infections caused by viruses, chlamydiae, mycoplasma or ureaplasma involves the collection and safe transportation of biological samples. This can be accomplished using the MedSchenker Smart Transport Medium (STM) System. Whereas in the past there had been transport systems that were dedicated for viral transport or chlamydia or mycoplasma/ureaplasma transport, MedSchenker STM provides a universal transport medium for the four organisms groups. MedSchenker STM System includes a universal transporting medium that is room temperature stable, hence the designation RT, which can sustain viability (and infectivity) of a plurality of organisms that include clinically important viruses, chlamydiae, mycoplasma and ureaplasma during transit to the testing laboratory. The formulation of UTM-RT medium includes protein for stabilization, antibiotics to minimize bacterial and fungal contamination, and a buffer to maintain a neutral pH

MedSchenker STM System medium is provided in labeled screw-cap tubes designed for transport of the clinical sample. MedSchenker STM System is also supplied as a sample collection kit that comprises a package which contains one screw-cap tube of UTM-RT medium and a peel pouch incorporating one or two sterile specimen collection swabs. A range of UTM-RT sample collection kits are available which incorporate different types of shaft swabs which facilitate the collection of specimens from different sites of the patient as described below in the Directions for Use section.

Once a swab sample is collected it should be placed immediately into the transport tube where it comes into contact with the transport medium. Swab specimens for virus, chlamydia, mycoplasma and ureaplasma isolation should be submitted to the laboratory as quickly as possible after collection. Although MedSchenker STM medium 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.

Organisms evaluated were: *Adenovirus, Cytomegalovirus, Echovirus Type 30, Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Influenza A, Parainfluenza 3, Respiratory Syncytial Virus, Varicella Zoster Virus, Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma hominis, Mycoplasma pneumoniae and Ureaplasma urealyticum.*

The results for the strains tested using MedSchenker STM System are shown in the table below

MedSchenker STM System was able to maintain the viability of the following organisms for at least 48 hours at both room temperature (20-25ºC) and in the refrigerator (2-8ºC) under the test conditions described above: *Adenovirus, Cytomegalovirus, Echovirus Type 30, Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Influenza A, Parainfluenza 3, Respiratory Syncytial Virus, Varicella Zoster Virus, Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma hominis, Mycoplasma pneumoniae and Ureaplasma urealyticum.*

Manufacturer:
Korea Standard
Jeollanamdo, South Korea

PRINCIPLE

MedSchenker STM medium consists of modified Hank's balanced salt solution supplemented with bovine serum albumin, cysteine, gelatin, sucrose, and glutamic acid. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Vancomycin, amphotericin B, and colistin are incorporated in the medium to inhibit 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 and chlamydiae if specimens are frozen (-70ºC) for prolonged storage

UTM-RT MEDIUM FORMULATION

Water (reverse osmosis)
Sucrose
L-glutamic
L-cystein
Phenol Red
Vancomycin
Amphotericin B

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 unit and the specimen transport tube labe

PRODUCT DETERIORATION

MedSchenker STM should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the color of the medium has changed from light orange-red, (4) the expiration date has passed, (5) the swab pouch is open, or (6) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION

Specimens for virus, chlamydia, mycoplasma or ureaplasma 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

MedSchenker STM System includes a screw-cap tube containing 1.5ml of transport medium

MATERIALS REQUIRED BUT NOT SUPPLIED

Appropriate materials for isolating, differentiating and culturing viruses, chlamydiae, mycoplasma and ureaplasma. 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, chlamydiae, mycoplasma and ureaplasma agents.[2,3,4,7,10]

DIRECTIONS FOR USE

MedSchenker STM System is available in the product configurations indicated in the table below

SKU	STM Tube Description	Pack Size	Sampling Sites*
STM	1.5 mL Screw cap with tube	50 qty	Culture : all Viruses, Chlamydia, Mycoplasma and Ureaplasma

*Performance testing with MedSchenker STM System was conducted using laboratory strains spiked onto a swab and not using human specimens.

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

For UTM-RT Medium Tubes
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
UTM-RT 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 UTM-RT medium are tested for microbial contamination, toxicity to host cells and the ability to maintain viability of desired agents. Procedures for quality control of UTM-RT transport medium and virus culture media are described in a number of 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. UTM-RT is intended for use as a collection and transport medium for viral, chlamydial, mycoplasma and ureaplasma agents
only. This medium can serve as a cryoprotectant for clinical viruses, including Cytomegalovirus and Varicella Zoster Virus.
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. UTM-RT kits are intended to be used with the medium tubes and swabs provided in the kit. The use of tubes of medium or 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, chlamydiae, mycoplasma and ureaplasma
• 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 IIa Medical Device according to European Medical Device Directive 93/42/EEC -
Surgically Invasive Transient Use
Class IIa 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 UTM-RT medium for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing
or irrigating the sampling sites

RESULTS

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

PERFORMANCE CHARACTERISTICS
Viability studies were performed using MedSchenker STM with a variety of viruses, chlamydiae, mycoplasma and ureaplasma. Swabs accompanying each transport system were directly inoculated in triplicate with 100µl of organisms suspension. Swabs were then placed in their respective transport medium tubes and were held for 0, 24 and 48 hours at both 4°C and room temperature (20-25°C). At the appropriate time interval, each swab was vortexed, removed from its transport medium tube and then an aliquot of this suspension was inoculated into shell vials or into appropriate culture media. All cultures were processed by standard laboratory culture technique and examined after a specified incubation time. Organism viability was determined by fluorescing foci counts for viruses and chlamydia strains and by CFU counts for mycoplasma and ureaplasma strains.