

STANDARD

Transport Medium

STANDARD™ Transport Medium

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST



INTENDED USE

STANDARD Transport Medium (STM) is intended for the collection and transport of clinical specimens containing viruses, Chlamydiae, Mycoplasma or Ureaplasma from the collection site to the testing laboratory. This transport medium can be processed using standard clinical laboratory operating procedures for virus, Chlamydia, Mycoplasma and Ureaplasma culture.

SUMMARY AND EXPLANATION

One of the routine procedures in the diagnosis of infections caused by viruses, Chlamydia, Mycoplasma or Ureaplasma involves the collection and safe transportation of biological samples. This can be accomplished using STANDARD Transport Medium. STM is room temperature stable, hence the designation RT, which can sustain viability (and infectivity) of a plurality of organisms that include clinically important viruses, Chlamydia, Mycoplasmas and Ureaplasma during transit to the testing laboratory. The formulation of STANDARD Transport Medium includes antibiotics to minimize bacterial and fungal contamination, and inorganic phosphate buffer and sodium chloride with a reduced environment. STM is provided with labeled screw-cap tubes designed for transport of the clinical sample. A range of STM specimen 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 specimen is collected it should be placed immediately into the transport tube where it comes into contact with transport medium. Swab specimens for virus, Chlamydia, Mycoplasma and Ureaplasma isolation should be submitted to the laboratory as quickly as possible after collection. After collection, the specimen should be stored at 2-30°C (36-86°F) and processed within 48 hours. If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at -70°C (-94°F) or colder.

PRODUCT DESCRIPTION

STANDARD Transport Medium (STM) is ready for use and requires no further preparation.

Product Description	Packaging
2.5 ml of STM medium in 16 x 100 mm screw-cap tube with internal shaped conical bottom.	25 ea per package

STANDARD TRANSPORT MEDIUM CONDITION

pH 7.4 ±0.2 / 25°C

CONTENTS

1. STANDARD Transport Medium 2. Instructions for Use

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, container and media after use.
- Directions should be read and followed carefully.
- To be handled by trained personnel only.
- Do not freeze or heat before use.
- Please don't use after expiry date.
- Do not use if it is damaged, broken, contaminated or leaking.
- Please do not contact the reagent in tube.
- This is single-use a medical device.
- Do not reuse opened and used products.
- Record information on the label to deliver and analysis.
- Do not use if the package is damaged or opened.

WARNINGS

- Do not re-pack.
- 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 ingest the medium.
- Do not use the STM for premoistening or prewetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.
- Do not use for more than one patient.
- The STM is for single use only; reuse may cause a risk of infection and/or inaccurate results.
- Avoid skin contact with medium.
- After use, dispose it as infected waste according to local regulations.

STORAGE & EXPIRY DATE

This product is ready for use and no further preparation is necessary. The product should be transported and stored in its original container at 2-30°C (36-86°F) 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 (18 months after production), which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label.

PRODUCT DETERIORATION

STM should not be used in the following cases:

- There is evidence of damage or contamination to the product.
- There is evidence of leakage.
- The color of the medium has changed from light orange-red.
- The expiration date has passed.
- There are other signs of deterioration.

DIRECTIONS FOR USE

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. Specimens should be collected as soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness.

- Aseptically remove cap from vial.
- Aseptically place sample into the vial with medium.
- Replace cap on vial and close tightly.
- Label with appropriate patient information.
- Send to the laboratory for immediate analysis.



NOTE

If processing is delayed (over 48 hours), the specimens must be frozen at -70°C (-94°F) or colder.



NOTE

STANDARD Transport Medium contains antimicrobial substances intended to inhibit commensal bacteria and fungi. When collecting specimens from sites of the body known to contain high levels of commensal organisms it is good practice to refrigerate specimens and process as soon as possible in order to minimize breakthrough growth of bacteria or fungi. It is also common practice to add an antibiotic mixture to cell culture re-feed medium when the specimen is inoculated. This procedure helps avoid bacterial and fungal contamination of the cell culture. For specific information about process and cultivation techniques for specimens, consult laboratory reference manuals and standards.

QUALITY CONTROL

All lot numbers of the STM are tested for microbial contamination, toxicity to host cells and the ability to maintain viability of viral, Chlamydia and Mycoplasma strains for up to 48 hours at 2-30°C (36-86°F) in accordance with the methods described in CLSI standard M40-A2.

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 STM with a variety of viruses, Chlamydial, Mycoplasma and Ureaplasma. The swabs accompanying each transport was directly inoculated in triplicate with 100ul of organism suspension. Swabs were then placed in their respective transport medium tubes and were held for 0, 12, 24 and 48 hours at both 2-6°C (36-42°F) and room temperature (20-30°C/68-86°F). 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 (volume). All cultures were processed by standard laboratory culture technique and examined after a specified incubation time. Organism viability was determined by CFU counting for gram-positive/negative bacterium and Mycoplasma strains and fluorescent cell counting for viral and Chlamydia strains. The acceptability limits for time zero and for 48 hours were defined in accordance with the 5 regulations M40-A2. STANDARD Transport Medium preserved the viability of all the organisms tested for 48 hours at both controlled room temperature and in the refrigerator in the above described test conditions. The organisms evaluated and the results obtained are given in the table below.

Organism	ATCC number	% of reduction of CFUs after 48 hours at 2-6°C	% of reduction of CFUs after 48 hours at 20-30°C
<i>Pseudomonas Aeruginosa</i>	ATCC 9027	≈ 45%	≈ 30%
<i>Staphylococcus Aureus</i>	ATCC 6538	≈ 40%	≈ 30%
<i>Bacillus Subtilis</i>	ATCC 6633	≈ 35%	≈ 25%
<i>Salmonella Abony</i>	ATCC 14028	≈ 40%	≈ 35%
<i>Mycoplasma Pneumoniae</i>	ATCC VR-880	≈ 45%	≈ 45%

Organism	ATCC number	% of reduction of fluorescing infected cells after 48 hours at 2-6 °C	% of reduction of fluorescing infected cells after 48 hours at 20-30 °C
<i>Chlamydia Trachomatis</i>	ATCC VR-880	≤ 50%	≤ 50%
<i>Influenza A</i>	ATCC VR-1679	≤ 50%	≤ 50%

LIMITATIONS

- Specimens should be handled aseptically.
- Conditions, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results.
- Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
- STM is intended for use as a collection and transport medium for viral, Chlamydial, Mycoplasma and Ureaplasma agents only.
- 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 tipped swabs are suitable when specimen collection by a swab is appropriate.

BIBLIOGRAPHY

- Gary W. Procop and Elmer W. Koneman, 2016. Color Atlas and Textbook of Diagnostic Microbiology, Seventh edition. Wolters Kluwer Health.
- James H. Jorgensen, Michael A. Pfaller, Karen C. Carroll, Guido Funke, Marie Louise Landry, Sandra S. Richter, David W. Warnock, 2015. Manual of Clinical Microbiology, 11th Edition. ASM, Washington, DC.
- Patricia Tille. 2014. Bailey & Scott's Diagnostic Microbiology, 13th Edition. Laboratory Medicine.
- Clinical and Laboratory Standards Institute (CLSI), 2014. M40-A2 Quality Control of Microbiological Transport Systems; Approved Standard Second Edition.
- Clinical and Laboratory Standards Institute (CLSI), 2006. M41-A Viral Culture; Approved guidelines.
- Wardford, A., M. Chernesky, and E. M. Peterson, 1999. Cumitech 19A, Laboratory Diagnosis of Chlamydia trachomatis Infections. ASM, Washington DC.

SYMBOL

	Reference number		Consult Instructions for use
	Batch code		<i>In vitro</i> diagnostic medical device
	Manufacturer		Date of manufacture
	Contains Sufficient for <n> Tests		Do not re-use
	Use-by date		Temperature limit
	Caution		Note
	Keep dry		Keep away from sunlight
	Do not use if package is damaged		Fulfill the requirements of Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices
	Authorized representative in the European Community		

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