Copan

EIFU058R01 Date 2025.03

UTM®

Instructions for Use

IVD

English

Copan Universal Transport Medium (UTM-RT®) System
Instructions for use

INTENDED USE
UTM-RT® is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT® is intended for use with compatible molecular assays.

SUMMARY AND PRINCIPLES
One of the routine procedures in the diagnosis of infections caused by upper respiratory viruses involves collection and transport of biological specimens[1].

The UTM-RT® consists of a Hanks' Balanced Salt Solution (HBSS) enriched with proteins and sugars with a neutral pH and pH indicator. The medium contains some antibiotics and antimycotics to inhibit overgrowth of bacteria and yeasts.

Copan UTM-RT® System medium is provided in labeled screw-cap tubes designed for transport of the clinical sample. Copan UTM-RT® 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 sterile specimen collection swabs. A range of UTM-RT® sample collection kits are available which incorporate different types of shaft swabs and facilitate the collection of specimens from different sites of the patient as described below in the Product Description section. Once a swab sample is collected, it should be placed immediately into the transport tube where it comes into contact with transport medium. Transport the specimens to the laboratory as soon as possible.

Specimens transported in UTM for respiratory viral nucleic acids investigations should be processed within 96 hours when stored at 2–25°C.

For use of the Copan UTM-RT® System medium with a molecular assay, consult the manufacturer's instructions for use for compatibility and specific target analyte processing directions.

REAGENTS
The UTM-RT® formulation includes proteins for virus stabilization, antibiotics and antimycotics to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH along with a pH indicator.

Components
Sucrose
HBSS solution
Bovine serum albumin
Buffered solution
Gelatin
Amino acids
Antibiotics
Phenol Red

pH 7.3 ± 0.2 at 20–25°C

PRODUCT DESCRIPTION
UTM-RT® System is ready for use and requires no further preparation. Copan UTM-RT® System includes a screw-cap tube with conical or round bottom containing 3mL of light orange-red transport medium.

UTM-RT® System tubes of transport medium are supplied alone (in bulk) or in a kit format. Each kit unit consists of a package containing: a pre-labeled screw cap tube and a peel pouch incorporating sterile specimen collection swabs. For more details on available configurations please refer to Table 1. The collection swab applicators FLOQSwabs® provided with UTM-RT® have a molded breakpoint in the shaft of the applicator.

Table 1: product description

REF	PRODUCT DESCRIPTION		PACK SIZE	PRODUCT DESIGNED FOR HAVING CAPTURE CAP FEATURE
	TUBE	SWAB		
3C098N	3 mL of UTM-RT® medium in 15,5 x100 mm screw-cap tube with round bottom.	N/A	50 tubes per package 6 x 50 tubes per box	NO
3C099N01	3 mL of UTM-RT® medium in 15,5 x 100 mm screw-cap tube with round bottom.	One regular size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	NO
3C100N01	3 mL of UTM-RT® medium in 15,5 x 100 mm screw-cap tube with round bottom.	One minitip size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	NO
3C047N	3 mL of UTM-RT® medium in 16 x 100 mm screw-cap tube with conical bottom.	N/A	50 tubes per package 6 x 50 tubes per box	NO

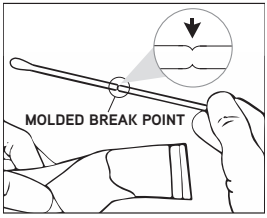
3C057N	3 mL of UTM-RT® medium in 16 x 100 mm screw-cap tube with conical bottom.	One flexible minitip size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	NO
3C064N	3 mL of UTM-RT® medium in 16 x 100 mm screw-cap tube with conical bottom.	One regular size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	NO
3C071N	3 mL of UTM-RT® medium in 12 x 100 mm screw-cap tube with round bottom.	One mini-tip applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	YES
3C075N	3 mL of UTM-RT® medium in 12 x 100 mm screw-cap tube with round bottom.	N/A	50 tubes per package 6 x 50 tubes per box	N/A Capture cap feature depends on the type of swab. For information regarding the correct combined, please contact customer service
3C085N01	3 mL of UTM-RT® medium in 16 x 100 mm screw-cap tube with conical bottom.	One mini-tip applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	NO
3C088N01	3 mL of UTM-RT® medium in 12 x 100 mm screw-cap tube with round bottom.	One regular size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box	YES

Not all the product codes (REF) are available for sale in all Countries. Please contact Copan Customer care service for product codes availability for a specific Country.

Performance testing with Copan UTM-RT® System *was conducted using laboratory strains. Performance testing was not conducted using human clinical specimens. Please refer to your internal procedures to choose the most appropriate device for the specific sampling site.*

TECHNICAL NOTES:

a) Each of the swab(s) included in the kits listed in the Table 1 has a molded breaking point.



The molded breaking point is present and detectable as a **narrowing** of the stick.

Take time to visually locate the position of breaking point onto the stick when using the swab for collecting samples and for subsequent transfer in the transport tube as applicable.

b) A slight yellowing of the tip is a well-known phenomenon. This could be due to many factors: the type of raw material, the product sterilization treatment, and/or the product natural aging. Therefore, product yellowing is not necessarily indicative of product deterioration.

PRODUCT STORAGE

The product must be stored in its original packaging at a temperature between 2 and 25°C until the time of use prior to the indicated date of expiry (not to exceed 18 months from the date of manufacturing). Do not overheat or freeze prior to use.

REQUIRED MATERIALS BUT NOT PROVIDED

Test systems/kits and reagents for molecular testing of viruses.

SPECIMEN COLLECTION, TRASNPORT AND PRESERVATION

Transport the specimen to the laboratory as soon as possible.
Specimens transported in UTM for respiratory viral nucleic acids investigations should be processed within 96 hours when stored at 2–25°C.
Consult the manufacturer's instructions for use of the molecular assay platforms for specific processing directions.
Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. 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.

LIMITATIONS

1. Because calcium alginate swabs are toxic for many enveloped viruses, they should not be used for specimen collection.
2. Wooden shaft swabs may contain toxins and formaldehydes and should not be used.
3. The product codes without beads are not suitable for use with mucous or particularly viscous specimens when homogenization of the specimen by vortexing in presence of the beads is required.
4. 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.
5. Do not freeze specimens intended to be processed for nucleic acids investigations. Stability of nucleic acids when frozen in UTM-RT® has not been evaluated and validated.
6. UTM-RT® must be used by healthcare professional only.

WARNINGS AND PRECAUTIONS

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. For in vitro diagnostic use only.
3. UTM-RT® System is ready for use and requires no further preparation.
4. Do not use beyond the expiry date.
5. 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.
6. Condition, timing, and volume of specimen collected are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
7. Do not re-sterilize unused swabs.
8. Do not re-pack.
9. Not suitable to collect and transport microorganisms other than respiratory viruses.
10. Do not ingest the medium.
11. Specimens for the search of viruses must be collected and handled using personal protective equipment against biological risk according to published manuals and guidelines.
12. Do not use UTM-RT® 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 swab pouch is open, or (5) there are other signs of deterioration.
13. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.
14. Do not bend or shape the swab before the collection of the specimen. Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft.
15. Due to the design of the flexible minitip, the swab will coil when placed in the tube. Therefore, if necessary, remove the swab from the tube, use caution and observe adequate biohazard precaution to protect the operator and the environment in case of splash.
16. Check the version of the operating instructions. The correct version is the one supplied with the device or available in electronic format and can be identified by the e-IFU indicator on the packaging label.

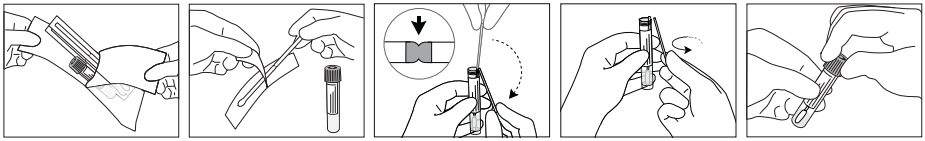
INSTRUCTIONS FOR USE

Proper collection of the specimen from the patient is a crucial aspect for successful detection 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.

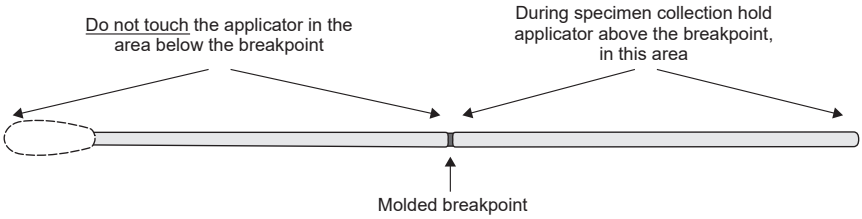
UTM-RT® in kit

1. Open the UTM-RT® kit package and remove the medium tube and the sterile swab in peel pouch.
2. Take the sterile swab out of its peel pouch and collect the clinical specimen; to prevent the risk of contamination, make sure that the swab tip comes into contact with the collection site only. **NOTE:** Do not bend the swab before the collection of the specimen. Do not use excessive force, pressure or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft.
3. After collecting the specimen, insert the swab into the medium tube until the breakpoint is at the same level as the medium tube opening.
4. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. If needed, gently rotate the swab shaft to complete the breakage and take away the upper part of the swab shaft.
5. Discard the broken handle part of the swab shaft into an approved medical waste disposal container.
6. Screw the cap back onto the test tube and hermetically seal it.
7. Identify the tube containing the specimen.
8. Send to the laboratory for immediate analysis.

Fig 1. Collection swab showing breakpoint and area for holding the applicator



Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens and care should be taken to avoid splashes and aerosols when breaking the swab stick into the tube of medium. During sample collection when handling the swab applicator, the operator must not touch the area below the breakpoint; that is the area from the breakpoint to the tip of the nylon flocked swab, as this will lead to contamination of the applicator shaft thus invalidating the test results.



UTM-RT® in bulk

1. Remove cap from tube, taking care not to spill or to contaminate the medium.
2. Place sample into the tube with UTM-RT® medium. If the sample is taken with a swab, insert and snap/cut off the swab(s) into the tube, pay attention to not splash the medium.
3. Screw the cap back onto the test tube and hermetically seal it.
4. Identify the tube containing the specimen.
5. Send to the laboratory for immediate analysis.

LABORATORY

Specimens transported in UTM for respiratory viral nucleic acids investigations should be processed within 96 hours when stored at 2–25°C. Consult the manufacturer's instructions for use of the molecular assay platforms for specific processing directions.

DISPOSAL

Waste must be disposed of in compliance with local legislation.

QUALITY CONTROL

The UTM-RT® medium is verified by USP membrane filtration test; optimal pH range at 20–25°C between 7.10 and 7.50; the absence of amplifiable respiratory viruses' nucleic acids.

PERFORMANCE CHARACTERISTICS

The results obtained largely depend on proper and adequate specimen collection as well as the promptness with which the specimens are transported to the laboratory and analyzed.

Copan UTM RT was tested to verify the stabilization and transportation of respiratory viruses' nucleic acids using compatible molecular assay. One representative molecular assay was selected for testing: Cepheid Xpert® Xpress CoV-2/Flu/RSV plus assay, run on GeneXpert® Dx.

For each virus tested, a single viral strain stock form ATCC was diluted into a synthetic nasopharyngeal matrix and 100 µL of viral suspension were added to 3 mL UTM RT.

The cycle threshold (Ct) values obtained from the molecular assay were used to assess performance and calculate the difference in Ct values (ΔCt) at tested time points relative to baseline (Time 0). Results were considered acceptable if the ΔCt of < 3 was observed. RSV, Flu A and Flu B target nucleic acids were amplified acceptably with stable ΔCt values relative to baseline after storage in UTM-RT® for up to 96 hours at both room temperature (22–28°C) and refrigerated temperature (2–8°C), demonstrating medium stability during the product shelf life of 18 months, as summarized in the table below.

Virus	Beads	Lot age of UTM-RT at testing*	ΔCt at 96 hrs. ($T_{96} - T_0$) PASS criterion: ΔCt <3			
			2–8°C	Result	22–28°C	Result
Flu A1	UTM-RT® tube With beads or without beads	Freshly produced (new), Middle-Aged, or Old/Expired	0–0.9	PASS	0.3–1.4	PASS
Flu A2			0–0.8	PASS	0.3–1.1	PASS
Flu B			-1–0.4	PASS	-0.8–1	PASS
RSV			-0.4–1	PASS	-0.1–1.1	PASS

*Lot age (in months from production) at testing was in the following range: New (0.8–4.2), Middle-aged (11.1–13.5) and Old/Expired (18.7–22.7).

BIBLIOGRAPHY

1. Charlton CL et al (2018) Practical Guidance for Clinical Microbiology Laboratories: Viruses Causing Acute Respiratory Tract Infections. Clin Microbiol Rev 32:1

TABLE OF SYMBOLS

Symbol	Meaning
	Manufacturer
IVD	In vitro diagnostic device
MD	Medical Device
UDI	Unique Device Identifier
STERILE EO	Sterilized using ethylene oxide
	Do not reuse
	Single sterile barrier system
	Do not resterilize
REF	Catalogue number
	Temperature limitation
	Use by
	Peel
LOT	Batch code (Lot)
	Contains sufficient for <n> tests
	Do not use if package is damaged
Rx Only	This only applies to US: “Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.”
	Date of Manufacture
 eIFU Indicator	Consult the operating instructions supplied with the device or available in electronic format, and which can be identified by the e-IFU indicator on the packaging label
	Caution

Copan

Copan Italia S.p.A.
Via F. Perotti, 10
25125 Brescia, Italy
Tel +39 030 2687211
Fax +39 030 2687250

Email: info@copangroup.com
Website: www.copangroup.com

North American Distributor:
Copan Diagnostics Inc.
26055 Jefferson Avenue
Murrieta, CA 92562, USA
Tel: 951-696-6957
Fax: 951-600-1832

E-mail: customerservice@copanusa.net
Website: www.copanusa.com