



Instructions for Use



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

INTENDED USE

Copan Universal Transport Medium (UTM-RT®) 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. UTM-RT® can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections caused by viruses, chlamydiae, mycoplasmas or ureaplasmas involves collection and refrigerated transport of biological specimens. Using the UTM-RT® System, the collected specimen can be stored for up to 48 hours at 2-25 °C. 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, maintain cellular integrity and encourage preservation of viruses and chlamydiae.

After collection, the specimen should be stored at 2-25 °C 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 or colder.

PRODUCT DESCRIPTION

UTM-RT® System is ready for use and requires no further preparation. It is available in the various configurations listed in **Table 1** and supplied in a labelled screw-cap test tube filled with different volumes of UTM-RT®. The packaging in kits also includes a sterile collection device.

REF	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
302C; 302C.LC.	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	Two regular size applicator swabs polyester tipped with breaking point	50 kits per package 6 x 50 kits per box
305C; 305CMH;	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One flexible size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
328C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swabs polyester tipped with breaking point	50 kits per package 6 x 50 kits per box
306C; CA302MH; 346C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped 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
307C; CA303MH; 357C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One minitip size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
321C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One flexible size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
		One regular size applicator swab with flocked nylon fiber tip with breaking point	
323C, 3U031N	2 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped 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
338C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One minitip size applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
		One regular size applicator swab with flocked nylon fiber tip with breaking point	
340C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swab polyester tipped with breaking point	50 kits per package 6 x 50 kits per box
		One Combo wire - plastic shaft minitip size applicator swab polyester tipped pre-scored	
347C	3 ml of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One minitip applicator swab with flocked nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
355C; 355CW	3 ml of UTM-RT® medium in 12x80 mm screw-cap tube with internal shaped 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
356C	3 ml of UTM-RT® medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swab polyester tipped with breaking point	50 kits per package 6 x 50 kits per box
359C; 359CE.A	1 ml of UTM-RT® medium in 12x80 mm screw-cap tube with internal shaped 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

360C	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One flexible applicator swab with flocekd nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
361C	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One minitip size applicator swab with flocced nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
365C	2 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One flexible applicator swab with flocekd nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
366C; 3C004N	2 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swab with flocced nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
367C.TD	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One contoured size with low stopper applicator swab with flocced nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
368C	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swab with flocced nylon fiber tip with breaking point One flexible size applicator swab with flocekd nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
3U006N; 3U008N	3 ml of UTM-RT [®] medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One flexible applicator swab with flocekd nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
3E010N.A	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with round bottom.	One regular size applicator swab with flocced nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
3E012N.A	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with round bottom.	One flexible size applicator swab with flocekd nylon fiber tip with breaking point	50 kits per package 6 x 50 kits per box
330C;	3 ml of UTM-RT [®] medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box
331C; CA339MH	10 ml of UTM-RT [®] medium in 25x90 mm screw-cap tube with internal shaped conical bottom.	NA	15 tubes per package 6 x 15 tubes per box
348C	2,5 ml of UTM-RT [®] medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box
349C;	1,5 ml of UTM-RT [®] medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box
363C	1,5 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box
350C; 350CV	1 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box
353C	3 ml of UTM-RT [®] medium in 12x80 mm screw-cap tube with internal shaped conical bottom.	NA	50 tubes per package 6 x 50 tubes per box

Not all the product codes (REF) are salable in all countries. Please contact Copan Customer care service for product codes availability for a specific country.

Table 1: product description

For all the product codes, excluding 3U008N, 331C and 348C, the tube contains three glass beads that allow homogenizing the specimen by vortexing.

REAGENTS

The UTM-RT[®] formulation includes proteins for virus stabilization¹⁷, antibiotics and antimycotics to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH.

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

pH 7,3 ± 0,2 a 2+25 °C

REQUIRED MATERIALS BUT NOT PROVIDED

Materials suitable for isolation, differentiation and culture of viruses, chlamydiae, mycoplasmas and ureaplasmas.

STORAGE

The product must be stored in its original packaging at a temperature between 2 and 25 °C until the time of use. Do not overheat or freeze prior to use.

LIMITATIONS

1. Because calcium alginate swabs are toxic for many enveloped viruses⁵ and may interfere with immunofluorescence tests², they should not be used for specimen collection.
2. Wooden shaft swabs may contain toxins and formaldehydes^{2,6} and should not be used.
3. The product codes without beads (REF 3U008N, 331C and 348C) are not suitable for use with mucous or particularly viscous specimens.
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.

WARNINGS AND PRECAUTIONS

1. Single-use device for professional in vitro diagnostic use.
2. Do not use beyond the expiry date.
3. 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
4. Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.⁷
5. Do not re-sterilize unused swabs.
6. Do not re-pack
7. Not suitable to collect and transport microorganisms other than viruses, chlamydiae, mycoplasma and ureaplasma
8. Do not ingest the medium
9. Specimens for the search of viruses, chlamydiae, mycoplasmas and ureaplasmas must be collected and handled using personal protective equipment against biological risk according to published manuals and guidelines.^{1,4,6,7,9,17}
10. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
11. 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.
12. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.
13. Due to the design of the minitip flocked swab, the swab will coil when placed in the tube. Therefore, it is not recommended to remove the swab from the tube. To process the specimen, collect the liquid using a sterile pipet or loop. If the user must remove the swab, use caution and observe adequate biohazard precaution to protect the operator and the environment in case of splash.

INSTRUCTIONS FOR USE

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

UTM-RT[®] in kit

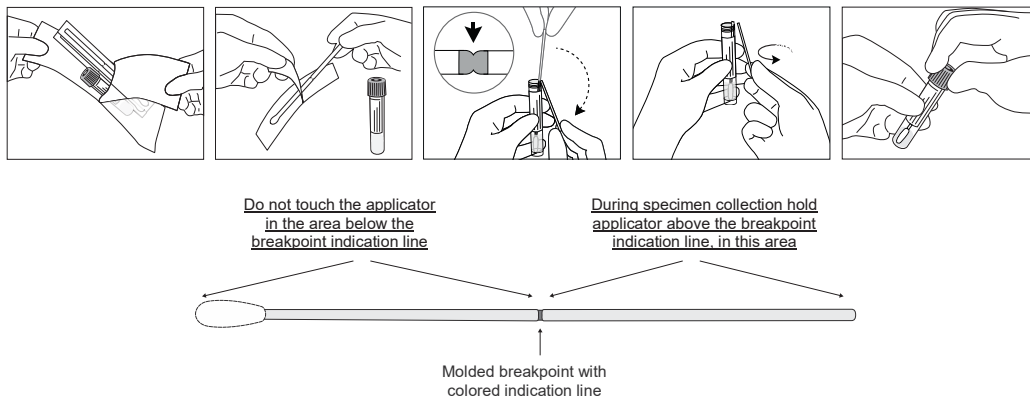
1. Open the UTM-RT[®] kit package and remove the medium test tube and the internal bag containing the sterile swab.
2. Take the sterile swab out of its bag and collect the clinical specimen; to prevent the risk of contamination, make sure that the swab tip comes into contact with the collection site only.
3. After collecting the specimen, insert the swab into the test tube until the breakpoint is level with the test 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.

UTM-RT[®] in bulk

1. Aseptically remove cap from tube taking care not to spill the medium.
2. Aseptically place vesicle aspirates²⁶, corneal or conjunctival scrapings²⁸, small pieces of tissue or stool³⁰ samples into the tube with UTM-RT[®] 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

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

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



DISPOSAL

Waste must be disposed of in compliance with local legislation. Take the appropriate precautions for infected material if necessary.

QUALITY CONTROL

The UTM-RT[®] lots are tested for microbial contamination, toxicity for the cellular lines used for the viral cultures and the ability to maintain the viability of viral, chlamydia and mycoplasma strains for up to 48 hours at 2-2.5°C in accordance with the methods described in CLSI M40-A2⁵.

RESULTS AND PERFORMANCE

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 analysed.

Viability studies were performed using Copan UTM-RT[®] with a panel of representative strains of the various families supported by the UTM-RT[®]. The swabs that accompany each transport system were directly inoculated in triplicate with 100 µl of organism suspension. Subsequently, the swabs were inserted in the respective test tubes containing the transport medium and stored for 0 and 48 hours at 2-6°C and at controlled room temperature (20-25°C). At the time of processing, each swab was vortexed for 20 seconds and removed from its transport medium test tube, then, an aliquot of the suspension was inoculated into the cellular line (200 µl) or into the appropriate culture medium^{6,15}. All the cultures were processed using the standard laboratory culture technique^{6,15}. Organism viability was determined by fluorescent cell counting for viral and chlamydia strains and CFU counting for mycoplasma and ureoplasma strains. The acceptability limits for time zero and for 48 hours were defined in accordance with the regulations M40-A2⁵.

Copan UTM-RT[®] System 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 fluorescing infected cells after 48 hours time 2-6 °C	% of reduction of fluorescing infected cells after 48 hours time 20-25 °C
Herpes Simplex Virus Type 1	ATCC VR-539	≤50%	≤50%
Herpes Simplex Virus Type 2	ATCC VR-734	≤50%	≤50%
Respiratory Syncytial Virus	ATCC VR-1580	≤50%	≤50%
Coxsackie B1 Virus	ATCC VR-28	≤50%	≤50%
Chlamydia trachomatis	ATCC VR-880	≤50%	≤50%
Influenza A	ATCC VR-1679	≤50%	≤50%
Cytomegalovirus	ATCC VR-977	≤50%	≤50%
Varicella-zoster virus	ATCC VR-1367	≤50%	≤50%
Chlamydia pneumoniae	ATCC VR-1360	≤50%	≤50%
Adenovirus	DHI 20-4740010	45%	47%
Parainfluenza virus type 3	DHI 20-4770010	0%	41%

Echovirus type 30	ATCC VR-322	13%	24%
Organism	ATCC number	% of reduction of CFUs after 48 hours time 2-6 °C	% of reduction of CFUs after 48 hours time 20-25 °C
Mycoplasma hominis	ATCC 23114	35%	25%
Ureaplasma urealyticum	ATCC 27618	0%	6%
Mycoplasma pneumoniae	ATCC 15531	50%	50%

TABLE OF SYMBOLS

See the table of symbols at the end of the instructions for use.

ITALIANO

Copan Universal Transport Medium (UTM-RT®) System

Istruzioni per l'uso

DESTINAZIONE D'USO

Copan Universal Transport Medium (UTM-RT®) System è indicato per il prelievo e il trasporto di campioni clinici contenenti virus, chlamydiae, micoplasmi o ureaplasmi dal sito di prelievo al laboratorio di analisi. UTM-RT® può essere processato usando procedure operative standard dei laboratori clinici per la coltura di virus, chlamydiae, micoplasma e ureaplasma.

SOMMARIO E PRINCIPI

Una delle procedure di routine nella diagnosi delle infezioni causate da virus, chlamydiae, micoplasmi o ureaplasmi, prevede il prelievo e il trasporto refrigerato di campioni biologici. L'utilizzo di UTM-RT® System consente invece la conservazione del campione prelevato fino a 48 ore a 2+25 °C.

Il terreno UTM-RT® consiste in una soluzione HBSS (Hanks' Balanced Salt Solution) arricchita con proteine e zuccheri, con pH neutro e indicatore di pH. Il terreno contiene alcuni antibiotici e antimicotici per inibire la sovracrescita di batteri e lieviti, mantenere l'integrità cellulare e favorire la conservazione di virus e chlamydiae. Dopo il prelievo i campioni devono essere conservati a 2-25 °C e processati entro 48 ore.

Se la consegna o il processamento superano le 48 ore, i campioni devono essere trasportati in ghiaccio secco e una volta arrivati in laboratorio, congelati a -70 °C o a temperature inferiori.

DESCRIZIONE PRODOTTO

UTM-RT® System è pronto all'uso e non necessita di ulteriori preparazioni. È disponibile nelle diverse configurazioni riportate in **Tabella 1** e viene fornito in una provetta etichettata e chiusa con tappo a vite e riempita con diversi volumi di terreno. Con il confezionamento in kit è incluso anche il dispositivo sterile di prelievo.

RIF	DESCRIZIONE DEL PRODOTTO		CONFEZIONE
	PROVETTA	TAMPONE	
302C; 302C.LC.	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Due applicatori per tampone di formato medio con punta in poliestere e punto di rottura	50 kit per confezione 6 x 50 kit per scatola
305C; 305CMH;	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Un applicatore per tampone di formato flessibile con punta in fibra di nylon floccato e punto di rottura	50 kit per confezione 6 x 50 kit per scatola
328C	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Un applicatore per tampone di formato medio con punta in poliestere e punto di rottura	50 kit per confezione 6 x 50 kit per scatola
306C; CA302MH; 346C	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Un applicatore per tampone di formato medio con punta in fibra di nylon floccato e punto di rottura	50 kit per confezione 6 x 50 kit per scatola
307C; CA303MH; 357C	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Un applicatore per tampone minitip con punta in fibra di nylon floccato e punto di rottura	50 kit per confezione 6 x 50 kit per scatola
321C	3 ml di terreno UTM-RT® in provetta con tappo a vite e fondo interno conico da 16x100 mm.	Un applicatore per tampone di formato flessibile con punta in fibra di nylon floccato e punto di rottura Un applicatore per tampone di formato medio con punta in fibra di nylon floccato e punto di rottura	50 kit per confezione 6 x 50 kit per scatola