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

INTENDED USE
Copan Universal Transport Medium (UTM-RT®) System, **with no beads**, is intended for the collection, transport and preservation of clinical specimens for viral molecular diagnostic testing.

SUMMARY AND PRINCIPLES
UTM-RT® consists of an enriched Hanks' Balanced Salt Solution (HBSS) that supports virus preservation. Antibiotics are added to inhibit overgrowth by bacteria and yeasts. Using the UTM-RT® System, collected specimens can be stored for up to 48 hours at 2-25 °C.

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. The packaging in kits also includes a sterile collection device.

REF	PRODUCT DESCRIPTION		PACKAGING
	TUBE	SWAB	
3C047N	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
3C048N	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

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

Table 1: product description

REAGENTS
The UTM-RT® formulation includes proteins for virus stabilization[6], antibiotics to prevent overgrowth by bacteria and yeasts 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
Test systems/kits and reagents for molecular testing of viruses.

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. Calcium alginate swabs are toxic for many enveloped viruses[4], may interfere with immunofluorescence tests[2] and should not be used for specimen collection.
2. Wooden shaft swabs may contain toxins and formaldehydes[2] and should not be used.
3. 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. Do not re-sterilize.
5. Specimens for the search of viruses must be collected and handled using personal protective equipment against biological risk according to published manuals and guidelines[1,3,5,6]
6. 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.
7. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.
8. Do not use for processing of specimens for culture. The transport system does not include glass beads needed to enhance vortexing for disruption of cellular material to improve virus infectivity when using tissue culture diagnostic methods.
9. 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

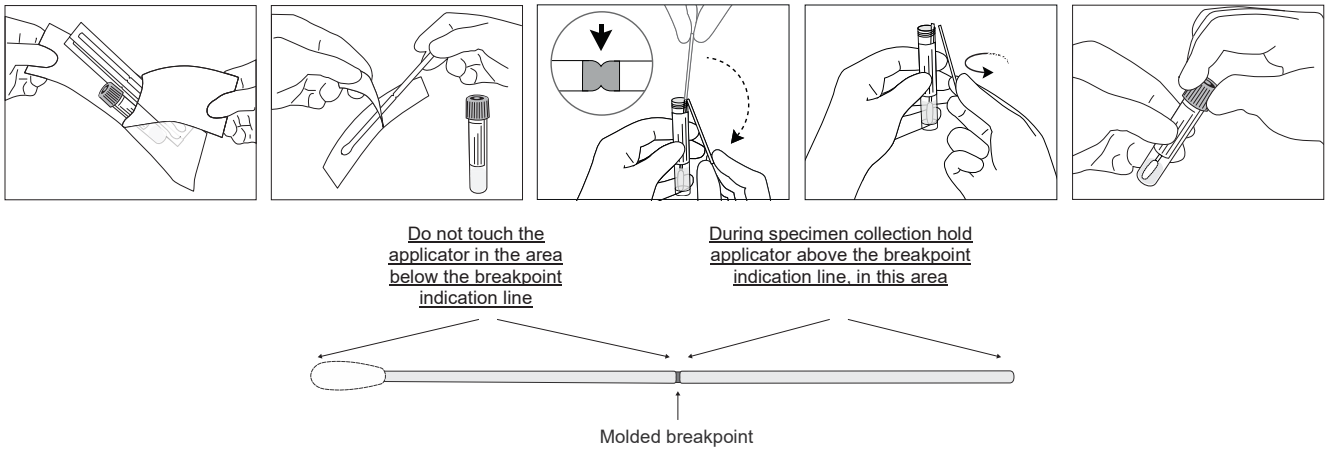
INSTRUCTIONS FOR USE
Proper collection of the specimen from the patient is a crucial aspect for successful isolation and identification of infectious organisms. Specimens should be collected as soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness.

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.
7. Identify the tube containing the specimen.
8. Send he laboratory for immediate analysis

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

Consult molecular assay manufacturers instructions for use for specific processing directions.

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 biohazard precautions for infected material if necessary.

QUALITY CONTROL
The UTM-RT® lots are tested for microbial contamination.

TABLE OF SYMBOLS
See the table of symbols at the end of the instructions for use.

INDEX OF SYMBOLS

Symbol	Meaning
	Manufacturer
IVD	In vitro diagnostic device
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
	Do not reuse
REF	Catalogue number
	Temperature limitation
	Use by
	Consult Instructions for Use
	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.”

BIBLIOGRAPHY

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4. Clinical and Laboratory Standards Institute (CLSI), 2014. M40-A2 Quality Control of Microbiological Transport Systems; Approved Standard- Second Edition.
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