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 of bacteria and yeasts. Using the UTM-RT® System, collected specimens can be stored for up to 72h at 2-8°C (according to CDC recommendations https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).

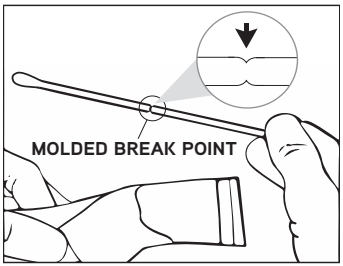
PRODUCT DESCRIPTION
UTM-RT® System is ready for use and requires no further preparation. It is available in the configurations listed in **Table 1** and supplied in a labelled screw-cap test tube.

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
3C049N	3 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom (REF. 3C047N)	One regular size applicator swab polyester tipped with breaking point (REF. 1U054S01.US)	50 tubes per package 6 x 50 tubes per box 100 pouches per package 3 x 100 pouches per box
3C057N	3 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One flexible minitip applicator swab with flocked nylon fiber tip with breaking point detectable as a narrowing of the stick	50 kits per package 6 x 50 kits per box
3C058N	3 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One minitip applicator swab with foam tip with breaking point	50 kits per package 6 x 50 kits per box
3C059N	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
3C060N	6 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	NA	50 kits per package 6 x 50 kits per box
3C061N	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 One flexible minitip applicator swab with flocked nylon fiber tip with breaking point detectable as a narrowing of the stick	50 kits per package 6 x 50 kits per box
3C062N	6 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	Five regular size applicator swabs with flocked nylon fiber tip with breaking point	10 kits per package 6x10 kits per box
3C064N	3 mL of UTM-RT® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.	One regular size applicator swab flocked 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

TECHNICAL NOTES:
a) The swab(s) included in the kits listed in the Table 1 may have molded breaking point or a red marked breaking point onto the stick.



The molded breaking point is present and detectable as a **narrowing** of the stick.
The absence of red marking does not impact molded breaking point functionality.
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: to the type of raw material, to the product sterilization treatment, to the product natural aging. Therefore product yellowing is not necessarily indicative of product deterioration.

REAGENTS
The UTM-RT® formulation includes proteins for virus stabilization[6], antibiotics to prevent overgrowth of 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 laboratory processing[2] and should not be used for specimen collection (according to CDC recommendations https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
2. Wooden shaft swabs may contain toxins and formaldehydes[2] and should not be used (according to CDC recommendations https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
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.
4. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
5. For codes 3C060N and 3C062N the number of swab sample being pooled from 2 to 5 swabs for each tube.

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. The product is ready for use, do not sterilize before use.
5. Product can not be reused or re-sterilized.
6. Specimens must be collected and handled using personal protective equipment against biological risk according to published manuals and guidelines[1,3,5,6]

7. 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 colour of the medium has changed from light orange-red, (4) the swab pouch is open or (5) there are other signs of deterioration.
8. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.
9. Do not use for processing of specimens for culture. The transport system does not include glass beads needed to enhance vertexing for disruption of cellular material to improve virus infectivity when using tissue culture diagnostic methods.
10. Do not pre-bend or shape the swab before the collection of the specimen.
11. 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.
12. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
13. It must be assumed that all specimens contain infectious micro-organisms; therefore all specimens must be handled and disposed with appropriate precautions.
14. The code 1U054S01.US included in 3C049N and 3C058N is not intended to be used for nasopharyngeal specimen collection.
15. For the codes 3C060N and 3C062N do not remove the swab tips from the tube before sampling processing.

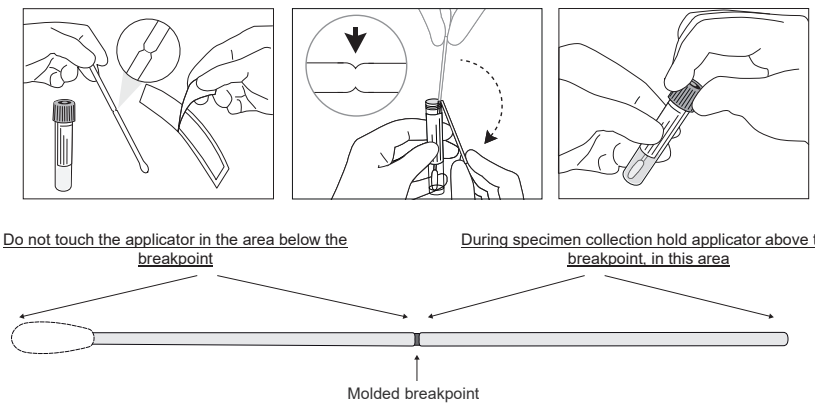
INSTRUCTIONS FOR USE

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. For code 3C049N, open the carton and take one tube and one swab in pouch.
2. Open the swab 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 pre-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 breakage of the swab shaft.
3. After collecting the specimen, insert the swab into the test tube until the breakpoint is level with the test tube opening.
4. Gently bend the swab shaft to break it off at the breaking point. Gently rotate the swab shaft to complete the breakage and take away the upper part of the swab shaft. If needed cut the swab shaft with scissors.
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



UTM-RT® in bulk

1. Open and remove cap from tube taking care not to spill the medium.
2. Place the samples 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

If processing is delayed (over 72 hours), the specimens must be frozen at -70°C or colder.
Consult molecular assay platforms manufacturers instructions for use for specific processing directions.

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 medium sterility by membrane filtration method according USP 36 Chapter 71, pH and visual appearance.

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

BIBLIOGRAPHY
1. Gary W. Procop and Elmer W. Koneman, 2016. Color Atlas and Textbook of Diagnostic Microbiology, Seventh edition. Wolters Kluwer Health.
2. 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.
3. Patricia Tille. 2014. Bailey & Scott's Diagnostic Microbiology, 13th Edition. Laboratory Medicine.
4. Clinical and Laboratory Standards Institute (CLSI), 2014. M40-A2 Quality Control of Microbiological Transport Systems; Approved Standard-Second Edition.
5. J. Michael Miller, Shelley A. Miller, 2017. A Guide to Specimen Management in Clinical Microbiology, Third Edition. ASM, Washington DC.
6. S. Specter, R. L. Hodinka, S. A. Young. Clinical Virology Manual, fifth edition, 2016.

INDEX OF SYMBOLS

Symbol	Meaning
	Manufacturer
	Sterilized using ethylene oxide
	In vitro diagnostic device
	Do not reuse
	Catalogue number
	Temperature limitation
	Use by
	Consult Instructions for Use
	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.”
	Country of Manufacture

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