**HealthLink Inc. Transport Medium (UTM®) System**
**Instructions for use**

HealthLink®
A Family of Medical Products

## INTENDED USE
HealthLink Inc.Transport Medium (UTM®) System is intended for collection and transport to the analysis laboratory of clinical specimens with suspected presence of viruses, chlamydiae, mycoplasmas or ureaplasmas for subsequent culture techniques.

## 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® System, the collected specimen can be stored for up to 48 hours at 2-25°C.
The UTM® 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 if specimens are frozen at -70°C or colder until the time of processing[2,3,6,13].

## PRODUCT DESCRIPTION
UTM® 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®. The packaging in kits also includes a sterile collection device.

| Catalog No. | Description | Pack Size |
|---|---|---|
| 302C.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom<br>Two regular size applicator swabs polyester tipped and molded breaking point at 100 mm | 50 kits per package<br>6 x 50 kits per box |
| 3C011N.HL | 1 ml of UTM® medium in 12x80 mm screw-cap tube with internal shaped conical bottom.<br>One regular size applicator swab with molded breaking point at 80mm | 50 kits per package<br>6 x 50 kits per box |
| 330C.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. | 50 tubes per package<br>6 x 50 tubes per box |
| 3C030N.HL | 1 ml of UTM® medium in 12x80 mm screw-cap tube with internal shaped conical bottom. | 50 kits per package<br>6 x 50 kits per box |
| 3C036N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.<br>One flexible applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package<br>6 x 50 kits per box |
| 3C037N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.<br>One minitip applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package<br>6 x 50 kits per box |



| | | |
|---|---|---|
| 3C038N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.<br>One regular applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package<br>6 x 50 kits per box |
| 3C039N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.<br>One flexible applicator swab with flocked nylon fiber and molded breaking point at 100 mm.<br>One regular applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package<br>6 x 50 kits per box |
| 3C040N.HL | 1 ml of UTM® medium in 12x80 mm screw-cap tube with internal shaped conical bottom.<br>One flexible applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package<br>6 x 50 kits per box |

Table 1: product description

## REAGENTS
The UTM® formulation includes proteins for virus stabilization[17], antibiotics and antimycotics to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH.

| Components | Quantity g/liter |
|---|---|
| Sugars | 50-100 g/l |
| HBSS solution | 5-20 g/l |
| Bovine serum albumin | 5-20 g/l |
| Buffered solution | 5-20 g/l |
| Jelly | 1-5 g/l |
| Amino acids | < 1 g/l |
| Antibiotics | < 1 g/l |
| PH indicator | < 1 g/l |

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. The collection device is not provided in packaging in bulk.

## 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 viruses[5] and may interfere with immunofluorescence tests[2], 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. UTM kit is intended to be used with the medium tubes and swabs provided inside the kit. The use of tubes of medium or swabs from any other source may compromise product performance.



## WARNINGS AND PRECAUTIONS
1. Single-use device for professional in vitro diagnostic use.
2. Do not use beyond the expiry date.
3. Do not immerse the collection device in the UTM® before sampling.
4. 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].
5. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
6. Identify the test tube containing the specimen.
7. Do not use if the device shows visible signs of damage or contamination, if you observe medium leaking from the test tube or if the medium appears murky yellow.
8. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.

## INSTRUCTIONS FOR USE
Proper collection of the specimen from the patient (e.g. aspirates, small tissue or faecal specimens, urine) is a crucial aspect for successful isolation and identification of infectious organisms.
In order to maintain optimal microorganism viability, transport the specimens to the laboratory as soon as possible considering that the viral concentrations reach the maximum values during the acute phase of the disease.

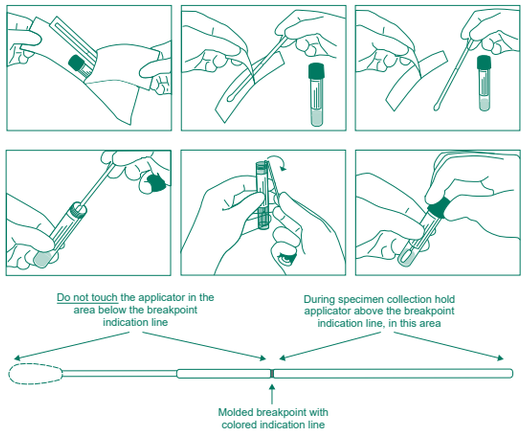
**UTM® in KIT**
1. Open the UTM® kit package and remove the medium test tube and the internal bag containing the sterile swab.
2. Take the sterile swab out of its bag and collect the clinical specimen; to prevent the risk of contamination, make sure that the swab tip comes into contact with the collection site only.
3. After collecting the specimen, unscrew and remove the cap from the test tube taking care not to spill the medium.
4. Insert the swab into the test tube until the breakpoint is level with the test tube opening.
5. Bend and break the swab at the breakpoint holding the test tube away from your face and discard the excess part.
6. Screw the cap back onto the test tube and hermetically seal it.
7. Process the specimen contained in the UTM® within 48 hours from collection storing the test tube at 2-25°C.
8. Before processing, vortex for 20 seconds in order to encourage specimen release from the swab and homogenize the medium.

**UTM® in bulk**
1. After collecting the specimen, unscrew and remove the cap from the UTM® test tube taking care not to spill the medium.
2. Insert the previously validated swab into the test tube until the breakpoint (if present) is level with the test tube opening.
3. Bend and break the swab at the breakpoint holding the test tube away from your face; should the swab used not have a breakpoint, cut the excess part of the shaft and discard it.
4. Screw the cap back onto the test tube and hermetically seal it.
5. Process the specimen contained in the UTM® within 48 hours from collection storing the test tube at 2-25°C.
6. Before processing, vortex for 20 seconds in order to encourage specimen release from the swab and homogenize the medium.

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® System is tested to guarantee the absence of 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 2-25°C in accordance with the methods described in CLSI M40-A2[5].

## 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 UTM® with a panel of representative strains of the various families supported by the UTM®. 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. At this point, 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 strains. The acceptability limits for time zero and for 48 hours were defined in accordance with the regulations M40-A2[5].
UTM® 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 | Zero time | 48 hours time 2-6 °C | 48 hours time 20-24 °C |
|---|---|---|---|---|
| Herpes Simplex Virus Type 1 | ATCC VR-539 | ++ | + | + |
| Herpes Simplex Virus Type 2 | ATCC VR-734 | ++ | + | + |
| Respiratory Syncytial Virus | ATCC VR-1580 | ++ | + | + |
| Coxsackie B1 Virus | ATCC VR-28 | ++ | + | + |
| Chlamydia trachomatis | ATCC VR-880 | ++ | + | + |
| Influenza A | ATCC-VR-1679 | ++ | + | + |
| Cytomegalovirus | VR-977 | ++ | + | + |
| Mycoplasma pneumonaie | ATCC 15331 | ++ | + | + |
| Varicella-zoster virus | ATCC VR-1367 | ++ | + | + |
| Chlamydia pneumoniae | ATCC VR-1360 | ++ | + | + |

++++=100% infected cells +++=75% infected cells ++= 50% infected cells +=25% infected cells
NOTE: The HealthLink UTM® performance tests were conducted using laboratory strains and not human samples.

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



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| Symbol | Meaning |
|---|---|
|  | Manufacturer |
| IVD | In vitro diagnostic device |
| CE 0123 | Identification number of notified body |
| STERILE EO | Sterilized using ethylene oxide |
| STERILE R | Sterilized using irradiation |
|  | Do not reuse |
| REF | Catalogue number |
|  | Temperature limitation |
|  | Use by de |
|  | Consult Instructions for Use |
|  | Peel |
| LOT | Batch code (Lot) |
|  | Contains sufficient for <n> tests |
|  | Do not use if package is damaged |
| Rx Only | Prescription Device Labeling Statement |
|  | Country of manufacture |


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