**HealthLink Inc. Transport Medium (UTM®) System**

**Instructions for use**

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

**SUMMARY AND PURPOSES**
One of the routine procedures in the diagnosis of infections caused by viruses, chlamydiae, mycopla-
smas 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 Hank’s Balanced Salt Solution (HBSS) enriched with proteins and sugars with a 
neutral pH and pH indicator. The medium contains some antibodies and anticoagulants to inhibit 
overgrowth of bacteria and yeasts, maintain cellular integrity and encourage presentation of viruses 
and chlamydia if specimens are frozen at -70°C or colder until the time of processing.

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

**CATALOG NO.**

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>302HC-L</td>
<td>3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. Two regular appicator swabs polyester tipped and molded breaking point at 100 mm</td>
<td>50 kits per package 6 x 50 kits per box</td>
</tr>
<tr>
<td>30C011N-HL</td>
<td>1 ml of UTM® medium in 12x80 mm screw-cap tube with internal shaped conical bottom. One regular appicator swab with molded breaking point at 80mm</td>
<td>50 kits per package 6 x 50 kits per box</td>
</tr>
<tr>
<td>300C-L</td>
<td>3 ml of UTM® medium in 16x100 mm screw-cap tube with Internal shaped conical bottom.</td>
<td>50 tubes per package 6 x 50 tubes per box</td>
</tr>
<tr>
<td>300CN9-L</td>
<td>3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One flexible appicator swab with flokked nylon fiber and molded breaking point at 100 mm.</td>
<td>50 kits per package 6 x 50 kits per box</td>
</tr>
<tr>
<td>3030N9-L</td>
<td>3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One flexible appicator swab with flokked nylon fiber and molded breaking point at 100 mm.</td>
<td>50 kits per package 6 x 50 kits per box</td>
</tr>
<tr>
<td>30C07N-L</td>
<td>3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom.</td>
<td>50 kits per package 6 x 50 kits per box</td>
</tr>
</tbody>
</table>

**WANTINGS AND PRECAUTIONS**

2. Do not use beyond the expiry date.
3. Do not immerse the collection device in 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.
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 collected 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.

**REAGENTS**
The UTM® formulation includes proteins for virus stabilization, antibodies and anticoagulants to prevent overgrowth of bacterial and fungal flora and a buffer solution to maintain a neutral pH.

**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 and may interfere with immunofluorescence tests, they should not be used for specimen collection.
2. Wooden shaft swabs may contain toxins and formaldehydes and should not be used.
3. UTM kit is intended to be used with the medium tubes and swabs provided inside the kit.
4. The use of tubes of medium or swabs from any other source may compromise product performance.

**TABLE 1: product description**

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity (µl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugars</td>
<td>50-100</td>
</tr>
<tr>
<td>HBSS solution</td>
<td>5-20</td>
</tr>
<tr>
<td>Bovine serum albumin</td>
<td>5-20</td>
</tr>
<tr>
<td>Inferred solution</td>
<td>5-20</td>
</tr>
<tr>
<td>Lysis buffy</td>
<td>1-5</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>PH indicator</td>
<td>1-1.5</td>
</tr>
</tbody>
</table>

**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®.

**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 taken from the swabs that accompanied each transport system were directly cultured on the appropriate sensitivity panel of representative strains of the various families supported by the UTM®. The swabs that accompany each transport system were directly cultured on the appropriate sensitivity panel of representative strains of the various families supported by the UTM®.

**REFERENCES**
1. C.037N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One regular applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package 6 x 50 kits per box |
2. C.011N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One regular applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package 6 x 50 kits per box |
3. C.030N.HL | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One flexible applicator swab with flocked nylon fiber and molded breaking point at 100 mm. | 50 kits per package 6 x 50 kits per box |
4. C.030N9-L | 3 ml of UTM® medium in 16x100 mm screw-cap tube with internal shaped conical bottom. One miltip applicator swab with flokked nylon fiber and molded breaking point at 100 mm. | 50 kits per package 6 x 50 kits per box |

**HPC170A Rev.01 Date 2019.09**

**HPC170A Rev.01 Date 2019.09**
Organism                      | ATCC number          | Zero time | 48 hours time at 2-6 °C | 48 hours time at 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-877               | ++        | +                        | +                        
Mycoplasma pneumoniae         | 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 UTI 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.

BIBLIOGRAPHY