INTENDED USE
Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydia, 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, mycoplasmal and ureaplasma cultures.

SUMMARY AND EXPLANATION
One of the major procedures in the diagnosis of infections caused by viruses, chlamydia, mycoplasma or ureaplasma involves the collection and safe transportation of biological samples. This can be accomplished by using the Copan Universal Transport Medium (UTM-RT) System. Copan UTM-RT System includes a universal transport medium that is room temperature stable, hence the designation RT, which can assure viability (and infectivity) of a plurality of organisms. These include clinically important viruses, chlamydia, mycoplasma and ureaplasma during transit to the testing laboratory. The formulation of UTM-RT medium includes protein for stabilization, antibiotics to minimize hematical and bacterial contamination, andbuffer to ensure neutral pH.

Copan UTM-RT System medium is provided in labeled screw-cap tubes designed for transport of the clinical sample. Copan UTM-RT System is also supplied as a sample collection kit that comprises a package which contains one screw-cap type of UTM-RT medium and a peel pouch incorporating one or two sterile specimen collection swabs. A range of UTM-RT sample collection kits are available which incorporate different types of swab shafts which facilitate the collection of specimens from different sites and patient types as described in the Directions for Use section.

When a swab sample is collected it should be placed immediately into the transport tube where it comes into contact with transport medium. Swab specimens for viruses, chlamydia, mycoplasma and ureaplasma isolations should be submitted to the laboratory as quickly as possible after collection. Although Copan UTM-RT medium can maintain even fragile organisms for long periods of time at room temperature, it is recommended that specimens be refrigerated at 24°C or kept on wet ice for following collection and while in transit. If there will be a long delay before processing specimens should be frozen at -70°C or cooled and transported on dry ice. Storage at -20°C is less satisfactory than storage at 4°C or -70°C and can result in the loss of infectivity.

PRINCIPLE
Copan UTM RT medium consists of modified Hank’s balanced salt solution supplemented with bovine serum albumin, cysteine, glutamine, sodium bicarbonate and glucose. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Vancomycin, ampicillin B, and colistin are incorporated in the medium to inhibit growth of competing bacteria and yeast. The medium is autolytic and non-toxic to mammalian host cells. The presence of succinic acid as a cytoprotector which aids in the preservation of viruses and chlamydia if specimens are frozen (-70°C) for prolonged storage.

UTM-RT MEDIUM FORMULATION
Hank's Balanced Salts
Bovine Serum Albumin
L-Cysteine
Glutamine
Sodium HCO3
Ampicillin B
Colistin
Phenol Red
pH (1.3-1.5) ± 0.2 at 25°C

CATALOG No.
UTM-RT Medium Tube Descriptions
Pack Size
Sampling Sites
330C
30 of UTM RT medium in 16x50mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
8 x 30 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs
331C
50 of UTM RT medium in 30 x 100mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
5 x 50 tubes
Virological, arterial, cervical or conjunctival swabs, small pieces of tissue or material swabs
333C
200 of UTM RT medium in 125mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
8 x 25 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs
335C
200 of UTM RT medium in 125mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
8 x 25 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs

CATALOG No.
UTM-RT Collection Kit Description
Pack Size
Sampling Sites
350C
10 of UTM RT medium in 16x50mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
2 x 10 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs
351C
100 of UTM RT medium in 16x50mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
10 x 10 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs
352C
100 of UTM RT medium in 16x50mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
10 x 10 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs
353C
100 of UTM RT medium in 16x50mm screw-cap tube with internal shaped collection buffer. Each tube contains three 5mm glass beads.
10 x 10 tubes
Virological, arterial, cervical, oral or conjunctival swabs, small pieces of tissue or material swabs

For UTM-RT Medium
1. Anatomically remove cap from tube
2. Anatomically remove swab from swab or large outer cap, inner cap, and swab shaft
3. Replace cap to tube and close tightly
4. Label with appropriate patient information
5. Send to the laboratory for immediate analysis

For UTM-RT Collection Kit
1. Collect specimen with swab
2. Anatomically remove cap from tube
3. Insert swab into the tube with UTM-RT medium
4. Break swab by handing it against the tube wall
5. Place swab, break shaft at the pre-scored line
6. Label with appropriate patient information
7. Send to the laboratory for immediate analysis

QUALITY CONTROL
All kits of the UTM-RT medium are tested for microbial contamination, toxicity to host cells and the ability to maintain viability of diverse organisms. Procedures for quality control of UTM-RT transport medium and clinical media are described in a number of publications by the American Society for Microbiology5 and by NCCLS.5 All relevant quality control results are noted; patient results should not be reported.

LIMITATIONS
1. Specimens should be handled aseptically.
2. Conditions, timing, and volume of specimens collected for culture are significant variables in obtaining reliable culture results. Follow institutional guidelines when collecting specimens for culture.
3. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
4. UTM-RT is intended for use with viruses, chlamydia, mycoplasma and ureaplasma organisms.
5. Before culturing, aliquots swabs are tanned for any contaminated swabs and then processed for fluorescent antibody tests. They should not be used for specimen collection. Wooden swab shafts may contain traces of formaldehyde and should not be used. Polyvinyl (PVC) swabs are suitable when specimens collected by a swab is a swab.
6. 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 test.

WARNINGS
1. Do not reprocess or recondition swabs.
2. Do not store.
3. Not suitable to collect and transport microorganisms other than viruses, chlamydia, mycoplasma and ureaplasma organisms.
4. Not suitable for any other application than intended use.
5. The product of this investigation with a rapid diagnostic test kit or diagnostic investigation should be performed by a properly trained individual.
6. Do not use the swab as diagnostic tool.
7. To be handled by trained personnel only.
8. Do not use for the UTM-RT medium for disinfecting or preventing the applicator swab prior to collecting the sample or fermenting or triaging the sampling site.

RESULTS
Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.
### PERFORMANCE CHARACTERISTICS

Viable strains were performed using Copan UTM-RT with a variety of viruses, chlamydia, mycoplasma and ureaplasma. Swabs accompanying each transport system were directly inoculated in triplicate with 100µl of organism suspensions. Swabs were then placed in their respective transport media tubes and held for 0, 24 and 48 hours at both 4°C and room temperature (20-25°C). At the appropriate time interval, each swab was mixed with transport media and then all of the suspensions were inoculated into shell vials or two appropriate culture media. All cultures were processed by standard laboratory culture technique and examined for a specific inoculation time. Organization viability was determined by fluorescent test results for viruses and chlamydia strains and by CFU counts for mycoplasma and ureaplasma strains.

The results for the strains tested using Copan UTM-RT System are shown in the table below.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Holding Time (hours)</th>
<th>Incubation Time Before Reading (days)</th>
<th>Viable Challenge at 4°C and 25°C (Foot of infected cells/200 mL)</th>
<th>Viable Challenge at RT (Fluorescent inclusion/200 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adenovirus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 70% of cells)</td>
<td>0 24</td>
<td>123 119</td>
<td>35 30</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 42% of cells)</td>
<td>24 24</td>
<td>82 67</td>
<td>5 3</td>
<td></td>
</tr>
<tr>
<td><strong>Cytomegalovirus</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 2% of cells)</td>
<td>0 24</td>
<td>17 13</td>
<td>5 3</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 3% of cells)</td>
<td>24 24</td>
<td>14 10</td>
<td>5 3</td>
<td></td>
</tr>
<tr>
<td><strong>Extravirina Type 30</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 33% of cells)</td>
<td>0 24</td>
<td>5 3</td>
<td>5 3</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Virus Stock Suspension* (dilution produces infectivity of 44% of cells)</td>
<td>24 24</td>
<td>7 5</td>
<td>5 3</td>
<td></td>
</tr>
<tr>
<td><strong>Chlamydia pneumoniae</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Chlamydia pneumoniae Suspension* (neat produces TNC/TC inclusions over entire HeLa cell/Dish shell vials)</td>
<td>0 3</td>
<td>256 257</td>
<td>30 30</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Chlamydia pneumoniae Suspension* (TC/TC inclusions over entire HeLa cell/Dish shell vials)</td>
<td>24 24</td>
<td>173 170</td>
<td>30 30</td>
<td></td>
</tr>
<tr>
<td><strong>Chlamydia trachomatis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Chlamydia trachomatis Suspension* (neat produces TNC/TC inclusions over entire GCME/Dish shell vials)</td>
<td>0 3</td>
<td>216 217</td>
<td>171 171</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Chlamydia trachomatis Suspension* (TC/TC inclusions over entire GCME/Dish shell vials)</td>
<td>24 24</td>
<td>164 164</td>
<td>48 48</td>
<td></td>
</tr>
<tr>
<td><strong>Mycoplasma hominis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Mycoplasma hominis Suspension* (neat produces fluorescents)</td>
<td>0 3</td>
<td>7 16</td>
<td>10 10</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Mycoplasma hominis Suspension*</td>
<td>0 3</td>
<td>11 12</td>
<td>10 10</td>
<td></td>
</tr>
<tr>
<td><strong>Mycoplasma pneumoniae</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Mycoplasma pneumoniae Suspension* (neat produces fluorescents)</td>
<td>0 3</td>
<td>7 16</td>
<td>10 10</td>
<td></td>
</tr>
<tr>
<td>10(^{3}) Mycoplasma pneumoniae Suspension*</td>
<td>0 3</td>
<td>17 17</td>
<td>10 10</td>
<td></td>
</tr>
</tbody>
</table>

*B 100 µl of suspensions were inoculated into the shell vials without platelet transport media and held at 25°C. TNC/TC: Too numerous to count.

### BIBLIOGRAPHY