Collection Sets

FLOQSwabs™ Flocked Swabs
UTM (Universal Transport Medium)


For in vitro Diagnostic Use

Please contact Diagnostic Hybrids Technical Services for technical assistance regarding this procedure.

Symbols Lexicon/Glossary

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Device</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code/lot number</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>CE</td>
<td>Authorized representative in the European Community</td>
</tr>
</tbody>
</table>

I. INTENDED USE

Diagnostic Hybrids’ Collection Sets [FLOQSwab(s)] and Universal Transport Medium (UTM) are intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. Each Collection Set provides a viral collection device and transport medium vial for transport organisms. Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. UTM can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.

II. SUMMARY

The Diagnostic Hybrids Collection Sets are supplied in several customer convenient pre-packaged Collection Sets for routine procedures in the diagnosis of infections caused by viruses, chlamydiae, mycoplasma or ureaplasma. Each Collection Set comprises a package containing one labeled screw-cap tube of UTM medium designed for transport of the clinical sample and/or a peel pouch incorporating one or two sterile specimen collection swabs for the collection and safe transportation of biological samples. A range of Collection Set configurations are available which incorporate different types of shaft swabs which facilitate the collection of specimens from different sites of the patient as described below in the Directions for Use section.

Once 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 virus, chlamydia, mycoplasma and ureaplasma isolation should be submitted to the laboratory as quickly as possible after collection. The UTM medium formulation includes protein for stabilization, antibiotics to minimize bacterial and fungal contamination, and a buffer to maintain a neutral pH. UTM is room temperature stable, which can sustain viability (and infectivity) of a plurality of organisms that include clinically important viruses, chlamydiae, mycoplasma and ureaplasma during transit to the testing laboratory. Although UTM medium can maintain even fragile organisms for long periods of time at room temperature, it is recommended that specimens be refrigerated at 2°C to 8°C or kept on wet ice following collection and while in transit. If a long delay before processing, specimens should be frozen at -70°C or colder and transported on dry ice. Storage at -20°C is less satisfactory than storage at 4°C or -70°C. UTM medium can inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells. The presence of sucrose acts as a cryoprotectant which aids in the preservation of viruses and chlamydiae if specimens are frozen (-70°C) for prolonged storage.

III. PRINCIPLE OF THE PROCEDURE

The FLOQSwabs™ collection device comprise of a solid molded plastic applicator shaft with a tip that can vary in size and shape. The tip of the applicator is coated with short Nylon® fibers that are arranged in a perpendicular fashion. This perpendicular arrangement results from a process called flocking, where the fibers are sprayed onto the tip of the swab, while it is held in an electrostatic field. This process creates a highly absorbent thin layer with an open structure. Unlike traditional fiber wound swabs, which resemble a mattress or cushion, FLOQSwabs™ have no internal absorbent core to disperse and entrap the specimen—the entire sample stays close to the surface for fast and complete elution. The perpendicular fiber wound swabs act like a soft brush which facilitates improved collection of cellular material. Capillary action between the fiber strands facilitates strong hydraulic uptake of liquid sample, and the sample stays close to the surface allowing easy elution.

UTM medium consists of modified Hank’s balanced salt solution supplemented with bovine serum albumin, cysteine, gelatin, sucrose, and glutamic acid. The pH is buffered with HEPES buffer. Phenol red is used to indicate pH. Vancomycin, amphotericin B, and colistin are incorporated in the medium to inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells. The presence of sucrose acts as a cryoprotectant which aids in the preservation of viruses and chlamydiae if specimens are frozen (-70°C) for prolonged storage.

IV. REAGENTS

A. Collection Set Components

Collection Sets are available in the product configurations indicated in the table on the next page.

B. Warnings and Precautions

For in vitro diagnostic use only.

1. Consider all human specimens, blood derivatives, reagents and materials used for processing as capable of transmitting infectious diseases and handle them in a manner which prevents infection of laboratory personnel. No known test method can offer complete assurance that infectious agents are absent.

- Conduct all procedures in accordance with the OSHA Standard on Blood-borne Pathogens.3 The manual “Biosafety in Microbiological and Biomedical Laboratories”, CDC, 5th edition, 20072, and, the standard, CLSI/NCCLS Approved Guideline, M29-A3, “Protection of Laboratory Workers from Occupational Aquired Infections”2.
- Follow Biosafety Level 2 or other appropriate biosafety practices.
- Decontaminate specimens using a 1:10 dilution of household bleach.

2. Applicator swab is qualified as Class IIa Medical Device according to European Medical Device Directive 93/42/EEC - Surgically Invasive Transient Use; Class IIa means swabs can be used for sampling body surfaces, body orifices (e.g., nose, throat and vagina and deep invasive surgical wounds).

3. Directions should be read and followed carefully.

4. Do not re-sterilize unused swabs.

5. Do not re-pack.

6. Not suitable to collect and transport microorganisms other than viruses, chlamydiae, mycoplasma and ureaplasma.

7. Not suitable for any other application than intended use.

8. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.

9. Do not use if the swab is visibly damaged (i.e., if the swab tip is broken).

10. Do not ingest the medium --

- Amphotericin B may cause severe allergic reaction with potentially lethal side effects
- Colistin may cause an allergic reaction. Irritating to eyes, respiratory system, and skin
- L-Glutamic Acid may cause allergic skin and/or respiratory reaction. Irritating to eyes, respiratory system, and skin
- Vancomycin may cause allergic skin reaction. Irritating to eyes and respiratory system

11. Do not use the UTM medium for pre-moistening or pre-wetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites

C. Reagent Storage Instructions

<table>
<thead>
<tr>
<th>TABLE 1: Component Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Swab</td>
</tr>
<tr>
<td>2. UTM</td>
</tr>
</tbody>
</table>

1 FLOQSwab™ by Copan is the trademark of Copan Flock Technologies “flocked” collection devices (formerly known as Microheologiecs, Copan Italia S.p.A., Brescia, Italy).

2 A Material Safety Data Sheet for Diagnostic Hybrids, Inc (DHI) reagents is available by contacting DHI Technical Services.
TABLE 2: Collection Set Descriptions (FLOQSwab™ + UTM specimen collection sets)

<table>
<thead>
<tr>
<th>REF No.</th>
<th>Name of Collection Set</th>
<th>FLOQSwab™ Description</th>
<th>UTM Tube</th>
<th>Recommended Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>401C</td>
<td>UTM with Minitip FLOQSwab Set</td>
<td>Minitip (501CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Eye/conjunctival, nasopharyngeal, urethral</td>
</tr>
<tr>
<td>402C</td>
<td>UTM with Regular FLOQSwab Set</td>
<td>Standard (502CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
<tr>
<td>403C</td>
<td>UTM with Nasopharyngeal FLOQSwab Set</td>
<td>Flexible NP Minitip (503CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Eye/conjunctival, nasopharyngeal</td>
</tr>
<tr>
<td>404C</td>
<td>UTM with Minitip FLOQSwab Set</td>
<td>Minitip (501CS01)</td>
<td>1-mL UTM (350C)</td>
<td>Eye/conjunctival, nasopharyngeal</td>
</tr>
<tr>
<td>405C</td>
<td>UTM with Regular FLOQSwab Set</td>
<td>Standard (502CS01)</td>
<td>1-mL UTM (350C)</td>
<td>Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
<tr>
<td>406C</td>
<td>UTM with Flexible Minitip FLOQSwab Set</td>
<td>Flexible NP Minitip (503CS01)</td>
<td>1-mL UTM (350C)</td>
<td>Eye/conjunctival, nasopharyngeal</td>
</tr>
<tr>
<td>407C</td>
<td>UTM with Adult Contoured FLOQSwab Set</td>
<td>Adult Contoured (56380CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Nasal</td>
</tr>
<tr>
<td>408C</td>
<td>UTM with Pediatric Contoured FLOQSwab Set</td>
<td>Pediatric Contoured (56780CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Nasal</td>
</tr>
<tr>
<td>409C</td>
<td>UTM with Pediatric Contoured FLOQSwab Set</td>
<td>Pediatric Contoured (56750CS01)</td>
<td>1-mL UTM (350C)</td>
<td>Nasal</td>
</tr>
<tr>
<td>410C</td>
<td>UTM with Ultra Minitip FLOQSwab Set</td>
<td>Ultra Minitip (516CS01)</td>
<td>1-mL UTM (350C)</td>
<td>Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
<tr>
<td>411C</td>
<td>UTM with Ultra Minitip FLOQSwab Set</td>
<td>Ultra Minitip (516CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
<tr>
<td>99-08020</td>
<td>UTM with 2X Flexible Minitip FLOQSwab Set</td>
<td>Two (2) Flexible NP Minitip (503CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Eye/conjunctival, nasopharyngeal</td>
</tr>
<tr>
<td>99-08021</td>
<td>UTM with FLOQSwabs (1X Flexible Minitip/Regular) Set</td>
<td>Standard (502CS01) and Flexible NP Minitip (503CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Throat, nasal, nasopharyngeal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
<tr>
<td>99-08024</td>
<td>UTM with FLOQSwabs (2 Regular) Set</td>
<td>Two (2 Standard) (502CS01)</td>
<td>3-mL UTM (330C)</td>
<td>Throat, nasal, nasopharyngeal, cervical, vulvar, rectal, dermal, mucosal, and genitai lesions</td>
</tr>
</tbody>
</table>

V. SPECIMEN COLLECTION, TRANSPORT, AND STORAGE

Specimens for virus, chlamydia, mycoplasma or ureaplasma investigation should be collected and handled following published manuals and guidelines.1 3.5.7.9.12.14 To maintain optimum viability, transport the specimen to the laboratory as soon as possible. Best recovery is obtained when specimens are refrigerated at 2° to 8°C or kept on wet ice following collection and while in transit. If there will be a delay of more than 72-hours before processing, specimens should be frozen at -70°C or colder and transported on dry ice. 71 Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations.13,10,13 Shipping of specimens within medical institutions should comply with internal guidelines of the institution. All specimens should be processed as soon as they are received in the laboratory.

VI. PROCEDURE

A. Materials Provided

1. UTM includes a screw-cap tube containing 1-mL or 3-mL of transport medium plus three 3mm size glass beads.
2. Swab, refer to the individual product descriptions for specific information about materials supplied.

B. Materials Required But Not Provided

1. Appropriate materials for isolating, differentiating and culturing viruses, chlamydiae, mycoplasma and ureaplasma.
2. Swabs individually wrapped in peel pouch.
3. The ‘grayed’ UTM suffix (HL or SH) is the Health Canada licenced product.
5. Sterile conical bottom. Each tube contains three 3mm glass beads. Sterile.
6. Sterile
7. The ‘grayed’ UTM suffix (HL or DHI) is the internal DHI product code.
8. Swab clinical specimen for Bordetella pertussis testing.

The REF No. in TABLE 2 are “made-to-order” and will require a lead time.

V. SPECIMEN COLLECTION, TRANSPORT, AND STORAGE

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UTM tubes should not be used if:
1. there is evidence of damage or contamination to the product;
2. there is evidence of leakage;
3. color of the medium has changed from light orange-red;
4. expiration date has passed;
5. swab pouch is open;
6. there are other signs of deterioration.

XI. PERFORMANCE CHARACTERISTICS

VII. QUALITY CONTROL

All lot numbers of the UTM medium are tested for microbial contamination, toxicity to host cells and the ability to maintain viability of desired agents. Procedures for quality control of UTM transport medium and virus culture media are described in a number of publications by the American Society for Microbiology1-4 and by NCCLS.5-10 If aberrant quality control results are noted, patient results should not be reported.

XI. EXPECTED VALUES

Comparison of Liquid Volume Uptake by a Regular Sized Foam Swab versus a Flocked Swab. [http://www.copanflocktech.com/index.php/prod/flockedswabs/]

XI. BIBLIOGRAPHY


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