CE

QUIDEL

Collection Sets
FLOQSwab™ Flocked Swabs
UTM (Universal Transport Medium)

For collection and transport of clinical specimens.

FOR *IN VITRO* DIAGNOSTIC USE

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.

SUMMARY

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 Collection Set Components 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 there will be 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 and can result in the loss of infectivity.

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 Nylon fibers 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.

MATERIALS PROVIDED

UTM (Universal Transport Medium) **1 or 3 mL**

Includes a screw-cap tube containing 1 mL or 3 mL of transport medium plus three 3mm size glass beads

FLOQSwab *

Refer to the individual product descriptions for specific information about materials supplied.

* FLOQSwab by Copan is the trademark of Copan Flock Technologies "flocked" collection devices (formerly known as Microrheologics, Copan Italia S.p.A., Brescia, Italy).

Collection Set Components

Collection Sets are available in the product configurations indicated in Table 1.

Table 1. Collection Set Descriptions
(FLOQSwab + UTM specimen collection sets)

REF No.	Name of Collection Set	FLOQSwab§	UTM Tube‡	Recommended Usage
401C	UTM with Minitip FLOQSwab Set	Minitip (501CS01)	3 mL UTM (330C)	Eye/conjunctival, nasopharyngeal, urethral
402C	UTM with Regular FLOQSwab Set	Standard (502CS01)	3 mL UTM (330C)	Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions
403C	UTM with Nasopharyngeal FLOQSwab Set	Flexible NP Minitip (503CS01)	3 mL UTM (330C)	Eye/conjunctival, nasopharyngeal
404C	UTM with Minitip FLOQSwab Set	Minitip (501CS01)	1 mL UTM (350C)	Eye/conjunctival, nasopharyngeal, urethral
405C	UTM with Regular FLOQSwab Set	Standard (502CS01)	1 mL UTM (350C)	Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions
406C	UTM with Flexible Minitip FLOQSwab Set	Flexible NP Minitip (503CS01)	1 mL UTM (350C)	Eye/conjunctival, nasopharyngeal
407C	UTM with Adult Contoured FLOQSwab Set	Adult Contoured (56380CS01)	3 mL UTM (330C)	Nasal
408C	UTM with Pediatric Contoured FLOQSwab Set	Pediatric Contoured (56780CS01)	3 mL UTM (330C)	Nasal
409C	UTM with Pediatric Contoured FLOQSwab Set	Pediatric Contoured (56750CS01)	1 mL UTM (350C)	Nasal

REF No.	Name of Collection Set	FLOQSwab§	UTM Tube‡	Recommended Usage
410C	UTM with Ultra Minitip FLOQSwab Set	Ultra Minitip (516CS01)	1 mL UTM (350C)	Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions
411C	UTM with Ultra Minitip FLOQSwab Set	Ultra Minitip (516CS01)	3 mL UTM (330C)	Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions
99-08020	UTM with 2X Flexible Minitip FLOQSwab Set	Two (2) Flexible NP Minitip (503CS01)	3 mL UTM (330C)	Eye/conjunctival, nasopharyngeal
99-08021	UTM with FLOQSwab (1X Flexible Minitip/Regular) Set	Standard (502CS01) and Flexible NP Minitip (503CS01)	3 mL UTM (330C)	Throat, nasal, nasopharyngeal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions
99-08024	UTM with FLOQSwabs (2 Regular) Set	Two (2) Standard (502CS01)	3 mL UTM (330C)	Throat, nasal, cervical, vulvar, rectal, dermal, mucosal, and genital lesions

REF No.	§ Components: FLOQSwab Description (NOTE: All FLOQSwab listed below are packaged as a sterile swab individually wrapped in peel pouch)
501CS01	Minitip FLOQSwab with 80 mm breakpoint
502CS01	Standard FLOQSwab with 80 mm breakpoint
503CS01	Flexible NP Minitip FLOQSwab with 100 mm breakpoint
516CS01	Ultra Minitip FLOQSwab with 100 mm breakpoint
56380CS01	Adult Contoured FLOQSwab with 80 mm breakpoint
56750CS01	Pediatric Contoured FLOQSwab with 50 mm breakpoint
56780CS01	Pediatric Contoured FLOQSwab with 80 mm breakpoint
REF No.	**‡ Components: UTM Medium Tubes Description**
330CHL*	3 mL of UTM medium in 16x100 mm size screw-cap tube with internal shaped conical bottom. Each tube contains three 3mm glass beads. Sterile.
350CHL*	1 mL of UTM medium in 12x80 mm size screw-cap tube with internal shaped conical bottom. Each tube contains three 3mm glass beads. Sterile.

*The REF 'HL' suffix on UTM boxes is an internal reference to HealthLink® branded products.

NOTES: Product availability, product REF numbers, and Quidel internal code designations:

- The 'grayed' shaded rows are "made-to-order" and will require a lead time.
- The 'grayed' FLOQSwab prefix (56xxxCS01) is the Health Canada licenced product.
- The 'grayed' UTM suffix (HL) is the internal Quidel product code.

MATERIALS REQUIRED BUT NOT PROVIDED

- Appropriate materials for isolating, differentiating and culturing viruses, *chlamydiae*, mycoplasma and ureaplasma. These materials include tissue culture cell lines, tissue culture medium, incubation systems and reading equipment. Refer to appropriate references for recommended protocols for isolation and identification of viruses, *chlamydiae*, mycoplasma and ureaplasma agents.[4,5,6,7,9]

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- 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.
- Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.

- Pathogenic microorganisms, including hepatitis viruses (e.g., HBV, HCV), human immunodeficiency virus (e.g., HIV-1 and HIV-2), Human T-cell lymphotropic virus (HTLV, types I and II), STS, etc. may be present in clinical specimens. "Standard Precautions"[1-5] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.
- Sterilize all biohazard waste including specimens, containers and media after their use.
- 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).
- Directions should be read and followed carefully.
- Do not re-sterilize unused swabs.
- Do not re-pack.
- Not suitable to collect and transport microorganisms other than viruses, *chlamydiae*, mycoplasma and ureaplasma.
- Not suitable for any other application than intended use.
- The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
- Do not use if the swab is visibly damaged (i.e., if the swab tip is broken).
- Do not ingest the medium.
- Avoid skin contact with medium. Contains small quantities of Amphotericin B, Colistin, L-Glutamic Acid, Vancomycin and Phenol Red
- 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.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

Storage

Table 2. Component Storage Conditions

Swab	Store at 2°C to 30°C
UTM	Store at 2°C to 25°C

Universal Transport Medium – UTM

This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 2°C to 25°C until used. Do not overheat. Do not incubate, or freeze prior to use. Improper storage will result in a loss of efficacy.

Swab

This product is ready for use; packaged as a sterile swab individually wrapped in peel pouch. The product should be stored at 2°C to 30°C until used. Swabs sterilized by ethylene oxide (EO).

NOTE: Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label.

SPECIMEN COLLECTION, TRANSPORT, AND STORAGE

Specimens for virus, *chlamydia*, mycoplasma or ureaplasma investigation should be collected and handled following published manuals and guidelines.[4,5,6,7,8,9,10] To maintain optimum viability, transport the specimen to the laboratory as soon as possible. Best recovery is obtained when specimens are refrigerated at 2°C 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.[11]

Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations.[12,10,13] 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.

Proper specimen collection from the patient is **extremely critical** for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals.[4,5,6,7,8,9,10,14] Specimens should be collected as soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness.

PROCEDURE

For UTM Medium Tubes

1. Aseptically remove cap from tube.
2. Aseptically place vesicle aspirates, corneal or conjunctival scrapings, small pieces of tissue or stool samples into the tube with UTM medium.
3. Replace cap to tube and close tightly.
4. Label with appropriate patient information.
5. Send to the laboratory for immediate analysis.

For Collection Sets (UTM + swab)

1. Collect specimen with swab.
2. Aseptically remove cap from tube.
3. Insert swab into the tube with UTM medium.
4. Break swab shaft by bending it against the tube wall. For Minitip swabs, break shaft evenly at the pre-scored line.
5. Replace cap to tube and close tightly.
6. Label with appropriate patient information.
7. Send to the laboratory for immediate analysis.

Additional educational and training videos are available at
http://www.copanusa.com/index.php/education/videos/

- *Nasopharyngeal Sample Collection using Copan UTM and Flocked Swabs* [One of the most widely used methods for detection of influenza viruses is to collect a nasopharyngeal swab sample. A patient collection pack comprising of a UTM and Flocked Swabs is ideal to collect and transport such samples. http://www.copanusa.com/index.php/products/utm/]
- *Nasopharyngeal Sample Collection: Part 1 – Introduction* [Dr. Aleta Bonner of Dell Children's Hospital in Austin, TX introduces and demonstrates nasopharyngeal specimen collection using Copan's flocked swabs.]
- *Nasopharyngeal Sample Collection: Part 2 - Patient Sampling* [Dr. Aleta Bonner demonstrates nasopharyngeal specimen collection with 5 different patients of various ages.]
- *SWAB: Collecting a Nasopharyngeal Swab Clinical Specimen* [A video by the U.S. Department of Health and Human Services and the Center for Disease Control demonstrates the proper collection of a nasopharyngeal swab clinical specimen for *Bordetella pertussis* testing.]

- *Collection of Nasopharyngeal Specimens with the Swab Technique* [Courtesy of Francisco M. Marty, M.D., Brigham and Women's Hospital.]
- *Nasopharyngeal Sample Collection in Infants, Adults and Seniors* [Dr. Kevin Fonseca, Clinical Virologist at the Provincial Laboratory for Public Health in Calgary, Alberta, Canada presents an overview of the appropriate swabs and transport medium, as well as patient information to be collected when taking a nasopharyngeal sample. Also illustrated is the collection of a nasopharyngeal sample in a child, an adult, and a senior citizen.]
- *Comparison of Liquid Volume Uptake by a Regular Sized Foam Swab versus a Flocked Swab*. [http://www.copanflocktech.com/index.php/prod/flockedswabs/]

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 Microbiology[5,7,9] and by NCCLS.[15,16] If aberrant quality control results are noted, patient results should not be reported.

UTM tubes **should not be used** if:

- there is evidence of damage or contamination to the product;
- there is evidence of leakage;
- color of the medium has changed from light orange-red;
- expiration date has passed;
- swab pouch is open; or
- there are other signs of deterioration.

LIMITATIONS OF PROCEDURE

- Specimens should be handled aseptically.
- Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection.[4,5,6,7,8,9,14]
- Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.
- UTM is intended for use as a collection and transport medium for viral, chlamydial, mycoplasma and ureaplasma agents only. This medium can serve as a cryoprotectant for clinical viruses, including cytomegalovirus and Varicella zoster virus.
- Because calcium alginate swabs are toxic for many enveloped viruses and may interfere with fluorescent antibody tests, they should not be used for specimen collection. Wooden shaft swabs may contain toxins and formaldehydes and should not be used. Polyester (Dacron) tipped swabs and Flocked Swabs are suitable when specimen collection by a swab is appropriate.
- UTM products 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.

EXPECTED VALUES

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

PERFORMANCE CHARACTERISTICS

Viability studies have been performed by Copan using UTM with a variety of viruses, *chlamydiae*, mycoplasma and ureaplasma are summarized below.[17] Swabs accompanying each transport system were directly inoculated in triplicate with 100 µL of organism suspension. Swabs were then placed in their respective transport medium tubes and were held for 0, 24 and 48 hours at both 4°C and room temperature (20°C to 25°C). At the

appropriate time interval, each swab was vortexed, removed from its transport medium tube and then an aliquot of this suspension was inoculated into shell vials or into appropriate culture media. All cultures were processed by standard laboratory culture technique and examined after a specified incubation time. Organism viability was determined by fluorescing foci counts for viruses and chlamydia strains and by CFU counts for mycoplasma and ureaplasma strains. UTM medium was able to maintain the viability of the following organisms for at least 48 hours at both room temperature (20°C to 25°C) and in the refrigerator (2°C to 8°C) under the test conditions described above: a*denovirus, cytomegalovirus*, e*chovirus type 30, Herpes simplex virus types 1 and 2, influenza A virus, parainfluenza type 3, respiratory syncytial virus, Varicella zoster virus, Chlamydia pneumoniae, Chlamydia trachomatis*, *Mycoplasma hominis, Mycoplasma pneumoniae and Ureaplasma urealyticum*. Details available from Copan Diagnostics Inc. (26055 Jefferson Avenue, Murrieta, CA 92562 USA).

Additional scientific studies[18,19,20,21,22,23,24,25,26,27,28,29,30,31] show that that FLOQSwabs significantly improve the quantity of samples collected and samples released into various culture and assay systems, improving the sensitivity of various diagnostic tests and the quality of diagnostics.
http://products.copangroup.com/index.php/educational-center/scientific-studies

ASSISTANCE

To place an order or for technical support, please contact a Quidel Representative at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 8:00 a.m. to 5:00 p.m., Eastern Time. Orders may also be placed by fax at 740.592.9820. For e-mail support contact customerservice@quidel.com or technicalsupport@quidel.com.

For services outside the U.S.A., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com.

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REF 401C, 402C, 403C, 404C, 405C, 406C, 407C, 408C, 409C, 410C, 411C, 99-08020, 99-08021, 09-08024 Collection Sets FLOQSwab Flocked Swabs/UTM (Universal Transport Medium)

IVD

Diagnostic Hybrids, Inc. – a subsidiary of Quidel Corporation
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PI9070000EN00 (09/18)

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
 Consult e-labeling instructions for use	 Do not reuse
IVD For *In Vitro* diagnostic use	CONT Contents/Contains