

Product Code: [various]

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Product Name: Swab, UTM (Universal Transport Medium), and VCM (Viruses-Chlamydiae-Mycoplasmas Medium) Sets

1. Information on the Substance/Preparation and Company

1.1 Product name: **UTM + FLOQSwab™** (nylon®) “Sets”

Catalog #	UTM / FLOQSwab™ Set product name:
401C	UTM with Minitip FLOQSwab™ Set [Urethral Minitip FLOQSwab™ (501CS01) with 3-mL UTM (330CHL)]
402C	UTM with Regular FLOQSwab™ Set [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
403C	UTM with Nasopharyngeal FLOQSwab™ Set [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
404C	UTM with Minitip FLOQSwab™ Set [Urethral Minitip FLOQSwab™ (501CS01) with 1-mL UTM (350CHL)]
405C	UTM with Regular FLOQSwab™ Set [Standard FLOQSwab™ (502CS01) with 1-mL UTM (350CHL)]
406C	UTM with Flexible Minitip FLOQSwab™ Set [Flexible NP Minitip FLOQSwab™ (503CS01) with 1-mL UTM (350CHL)]
407C	UTM with Adult Contoured FLOQSwab™ Set [Adult Midturbinate FLOQSwab™ (380CS01) with 3-mL UTM (330CHL)]
408C	UTM with Pediatric Contoured FLOQSwab™ Set [Pediatric Midturbinate FLOQSwab™ w/ 80mm breakpoint (780CS01) with 3-mL UTM (330CHL)]
409C	UTM with Pediatric Contoured FLOQSwab™ Set [Pediatric Midturbinate FLOQSwab™ w/ 50mm breakpoint (750CS01) with 1-mL UTM (350CHL)]
410C	UTM with Ultra Minitip FLOQSwab™ Set [Ultra minitip FLOQSwab™ (516CS01) with 1-mL UTM (350CHL)]
411C	UTM with Ultra Minitip FLOQSwab™ Set [Ultra minitip FLOQSwab™ (516CS01) with 3-mL UTM (330CHL)]
99-08020	UTM with 2 Flexible Minitip FLOQSwab™s Set [Two (2) Flexible NP Minitip FLOQSwab™s (503CS01) with 3-mL UTM (330CHL)]
99-08021	UTM with FLOQSwab™s (1 Flexible Minitip, 1 Regular) Set [Standard FLOQSwab™ (502CS01) and Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
99-08024	UTM with FLOQSwab™s (2 Regular) Set [Two (2) Standard FLOQSwab™s (502CS01) with 3-mL UTM (330CHL)]

1.2 Product name: **UTM + Mattress Swab** (polyester fibers) “Sets”

Catalog #	UTM / Swab Set product name:
99-08011.v2	Female Collection with UTM Kit [one (1) regular collection (340-012) swab and one (1) cleaning swab with 3-mL UTM (330CHL)]
99-08012.v2	Male Collection with UTM Kit [wire tip urethral swab (340-013) with 3-mL UTM (330CHL)]
99-08013.v2	Unisex Configuration Kit [two (2) regular mattress swabs (340-014) with 3-mL UTM (330CHL)]
303CHL	Combination Swab Set: Male/Female [one (1) regular collection swab (340-012) and one (1) wire tip urethral (340-013) with 3-mL UTM (330CHL)]

1.3 Product name: **Custom Collection “Sets”**

Catalog #	VCM / Swab Set product name:
99-08011-VCM	VCM with Cervical Swab (Quest) [Cervical Swabs (cleaning swab + collection swab) (DHI 99-07011.v2) with 3-mL VCM (455-050)]
99-08013-VCM	VCM with Lesion Swab (Quest) [Package with two (2) Lesion Swabs (DHI 99-07013.v2) with 3-mL VCM (455-050)]
99-08014-VCF	VCM with Urethral FLOQSwab™ (Quest) [Urethral FLOQSwab™ (DHI 99-07012.v3) with 3-mL VCM (455-050)]
99-08015-VCF	VCM with Nasopharyngeal FLOQSwab™ (Quest) [Nasopharyngeal FLOQSwab™ (DHI 99-07011.v2) with 3-mL VCM (455-050)]

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

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99-08018A	UTM with Regular FLOQSwab™ (Sonora) [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
99-08019A	UTM with Flexible Minitip FLOQSwab™ (Sonora) [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
99-08019E	UTM with Flexible Minitip FLOQSwab™ (Erie) [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
401C-A	UTM with Minitip FLOQSwab™ ARUP [Urethral Minitip FLOQSwab™ (501CS01) with 3-mL UTM (330CHL)]
402C-A	UTM with Regular FLOQSwab™ ARUP [Standard FLOQSwab™ (502CS01) with 3-mL UTM (330CHL)]
403C-A	UTM with Nasopharyngeal FLOQSwab™ ARUP [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]
403C-B	UTM with Flexible Minitip FLOQSwab™, For Respiratory Virus Testing from NP site only [Flexible NP Minitip FLOQSwab™ (503CS01) with 3-mL UTM (330CHL)]

1.4 Product name: **UTM** (Universal Transport Medium)

Catalog #	UTM product name:
330C	3-mL UTM-RT medium in 10-mL size screw cap with conical bottom; each
330CHL	tube contains three 3-mm glass beads
350C	1-mL UTM-RT medium in 5-mL size screw cap with conical bottom; each
350CHL	tube contains three 3-mm glass beads

1.6 Company Diagnostic HYBRIDS, Inc.
1055 East State Street, Suite 100
Athens, OH 45701, USA
(740) 589-3300 or (866) 344-3477

1.7 In emergencies Call your local emergency center

2. Components and Hazardous Ingredients

Note: These products contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200(i)(1), the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.

3. Hazards Identification

Note: The concentration of all chemical constituents are below the regulatory threshold limits, but there may be a potential for accumulative hazards from various active ingredients identified below and in the following Sections: 11. Toxicological Information and 15. Regulatory Information.

Swabs: No hazards to skin or eye contact.

UTM / VCM: Irritating to eyes, respiratory system and skin.

- Bovine Serum may cause eye and skin irritation. May be harmful if inhaled and may be irritating to mucous membranes and upper respiratory tract. May be harmful if swallowed.
- 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.
- Gelatin may cause allergic skin and/or respiratory 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.

4. First Aid Measures

Swabs:

Eye contact: [Not applicable]

Skin contact: [Not applicable]

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After inhalation: [Not applicable]
After ingestion: Immediately call doctor/medical service

UTM / VCM:

- Eye contact:*
- Flush eyes immediately with water for 15 minutes, occasionally lifting the upper and lower eyelids
 - Consult a doctor/medical service
- Skin contact:*
- Wash with soap
 - Rinse with plenty of water
- After inhalation:*
- Remove the victim into fresh air
 - Consult a doctor/medical service
- After ingestion:*
- Consult a doctor/medical service

5. Fire Fighting Measures

- Suitable extinguishing media:* ▪ All non combustible extinguishing media allowed
- Unsuitable extinguishing media:* ▪ No data available
- Special exposure hazards:* ▪ No data available
- Instructions:* ▪ No data available
- Special protective equipment for firefighters:* ▪ No protective equipment required

6. Accidental Release Measures

- Personal protection:* ▪ See 8, below
- Environmental precautions:*
- Prevent soil and water pollution
 - Discharge according to local regulations
- Clean-up:* ▪ Ensure adequate ventilation

7. Handling and Storage

- Handling:* ▪ No special measures required
- Storage:*
- 2° to 25°C
 - Store away from oxidizing agents
 - Store in cool, dry conditions in well sealed receptacles

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Chemical/Component	TLV/NIOSH REL	OSHA PEL	CAS No.
Sucrose	10 mg/m ³ TWA	15 mg/m ³ TWA	57-50-1

Note: Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2005.

* 4-(2-Hydroxyethyl)piperazine-1-ethanesulfonic acid, N-(2-Hydroxyethyl)piperazine-N'-(2-ethanesulfonic acid)

8.2 Control of Exposure

- Eye protection:* ▪ Safety glasses or Face shield
- Hand protection:*
- Gloves
 - Suitable materials: Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene, PVC
 - Hands should be washed after working with this product.
- Skin protection:* ▪ Protective clothing
- Respiratory protection:* ▪ Area ventilation is generally adequate; avoid generation mists or other airborne forms when working with the product

9. Physical and Chemical Properties

Swabs: solid molded plastic applicator shaft with a tip that can vary in size and shape; odorless

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UTM / VCM: reddish-orange, clear aqueous solution; odorless; three glass beads in each tube facilitate the release and dispersion of patient sample material and virus particles from the swab during vortexing
Note: Boiling and Freezing Points for all aqueous components are near those of pure water.

10. Stability and Reactivity

- *Stability:* Stable if stored in specified conditions (see labeling)
- *Reactivity/Hazardous decomposition products:* No decomposition if used according to specifications
- *Conditions/Materials to avoid:* Oxidizing agents

11. Toxicological Information

Acute toxicity:

Swabs	No irritant	
<i>UTM / VCM:</i>		
<i>Bovine Serum</i>	None identified	None identified
<i>Amphotericin B</i>	LD ₅₀ oral, rat	>5000 mg/kg
<i>Colistin</i>	LD ₅₀ oral, rat	121 mg/kg
<i>L-Cysteine</i>	LD ₅₀ oral, rat	1890 mg/kg
<i>Gelatin</i>	None identified	None identified
<i>L-Glutamic Acid</i>	LD ₅₀ oral, rat LD ₅₀ oral, mouse LD ₅₀ oral, rabbit	30000 mg/kg 21700 mg/kg >2300 mg/kg
<i>Phenol Red</i>	None identified	None identified
<i>Sucrose</i>	LD ₅₀ oral, rat	29700 mg/kg
<i>Vancomycin</i>	LD ₅₀ oral, rat LD ₅₀ IV, rat LD ₅₀ oral, mouse	10000 mg/kg 319 mg/kg >5000 mg/kg

Chronic toxicity:

<i>Bovine Serum</i>	Target Organ(s): None identified
<i>Amphotericin B</i>	Target Organ(s): kidneys
<i>Colistin</i>	Target Organ(s): lungs, thorax, or respiratory sensitivity, kidney
<i>L-Cysteine</i>	Target Organ(s): lungs, respiratory sensitizer, kidney
<i>Gelatin</i>	Target Organ(s): None identified
<i>L-Glutamic Acid</i>	Target Organ(s): lungs
<i>Phenol Red</i>	Target Organ(s): eyes, skin, respiratory system
<i>Sucrose</i>	Target Organ(s): lungs
<i>Vancomycin</i>	Target Organ(s): kidneys, ears, skin, cardiovascular system

Note: Toxicity levels listed in the table above are for the ingredients when in their pure state.

Routes of exposure

- Ingestion, inhalation, eyes and skin
- Caution! Most components contain (a) substance(s) that are absorbed through the skin.

Acute effects/symptoms

Amphotericin B: Known to have severe and potentially lethal side effects consisting of high fever, shaking chills, hypotension, anorexia, nausea, vomiting, headache, dyspnea, and tachypnea.

Colistin: Prolonged or repeated exposure can cause: neurotoxic effects; liver injury may occur; anorexia, headache, vomiting, diarrhea, nausea, ataxia.

L-Glutamic Acid: Irritation, itching, gastrointestinal upset, nausea, vomiting, headache, possible mutagenic effects, breathing difficulties, blood pressure changes.

Vancomycin: Irritation, itching, gastrointestinal upset, headache, nausea, vomiting, possible reproductive effects, kidney impairment, ear damage, cardiac abnormalities, blood pressure lowering, dermatitis, allergic reaction, blood effects.

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Chronic effects

Amphotericin B: Multiple organ damage associated with therapeutic doses with significant nephrotoxicity (damage to the kidneys) and/or hepatotoxicity (damage to liver). Several forms of anemia and other blood dyscrasias have been reported.

Colistin: Multiple organ damage associated with therapeutic doses with nephrotoxicity and neurotoxicity (damage to the nerves).

Vancomycin: Multiple organ damage associated with therapeutic doses with significant nephrotoxicity and/or ototoxicity (damage to hearing).

12. Ecological Information

Aquatic toxicity: No known to be hazardous to water.

Other Information:

- *Effect on the ozone layer:* Not dangerous for the ozone layer (1999/45/EC)
- *Greenhouse effect:* No data available
- *Effect on waste water purification:* No data available

13. Waste Disposal Considerations

Disposal methods: Dispose of material according to local regulations.

14. Transport Information

USA: No restrictions.

Canada: No restrictions.

EU: No restrictions.

DOT regulations:

Hazard class: *none*

Land transport ADR/RID (cross-border)

ADR/RID class: *none*

Maritime transport IMDG:

IMDG Class: *none*

Marine pollutant: *No*

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: *none*

15. Regulatory Information

- SARA Section 355 (extremely hazardous substances)
None of the ingredients is listed.
- SARA Section 313 (specific toxic chemical listings)
None of the ingredients is listed.
- TSCA (Toxic Substances Control Act)
 - 7732-18-5 water
 - 7647-14-5 sodium chloride
 - 10043-52-4 calcium chloride
 - 7487-88-9 magnesium sulfate
 - 7447-40-7 potassium chloride
 - 57-50-1 sucrose
 - 52-90-4 L-cysteine
 - 143-74-8 phenol red
 - 6893-26-1 D-glutamic acid
 - 7558-79-4 sodium phosphate, dibasic
 - 7758-11-4 potassium phosphate, dibasic

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- California Proposition 65 - Chemicals known to cause cancer
None of the ingredients is listed.
- California Proposition 65 - Chemicals known to cause reproductive toxicity for females:
None of the ingredients is listed.
- California Proposition 65 - Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.
- California Proposition 65 - Chemicals known to cause developmental toxicity:
None of the ingredients is listed.

Carcinogenic categories



- NTP (National Toxicology Program)
None of the ingredients is listed.
- TLV (Threshold Limit Value established by ACGIH)
57-50-1 sucrose A4

Product related hazard information:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations pertaining to regulations on hazardous materials.

Classification according to directives 67/548/EEC and 1999/45/EC.

Symbol	Risk and Safety Precaution
	R20: Harmful by inhalation R22: Harmful if swallowed R25: Toxic if swallowed R36/37/38: Irritating to eyes, respiratory system and skin R42/43: May cause sensitization by inhalation and skin contact
	R48: Danger of serious damage to health by prolonged exposure R68: Possible risks of irreversible effects
Xn – harmful Xi – irritant	S22/23: Do not breathe dust/aerosols S24/25: Avoid contact with skin and eyes S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S36/37/39: Wear suitable protective clothing, gloves and eye/face protection S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

16. Other Information

- Based on: US 29 CFR 1910:1200(g); Canadian Hazardous Product Act, Part II; Directive 911155/EEC et seq.
- This product is designed for use by professionals.
- The above information is believed to be accurate and represents the information available to date, but Diagnostic Hybrids does not purport it to be all-inclusive; this should be used only as a guide.
- Refer to the Product Insert for this Product for additional details on the proper storage, handling, use, and disposal of the reagents included in this Product.
- Contact Diagnostic Hybrids, Inc. if additional information is required.

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