1. Information on the Substance/Preparation and Company

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

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

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

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Product name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99-08011.v2</td>
<td>Female Collection with UTM Kit</td>
<td>(one (1) regular collection (340-012) swab and one (1) cleaning swab with 3-mL UTM (330CHL))</td>
</tr>
<tr>
<td>99-08012.v2</td>
<td>Male Collection with UTM Kit</td>
<td>(wire tip urethral swab (340-013) with 3-mL UTM (330CHL))</td>
</tr>
<tr>
<td>99-08013.v2</td>
<td>Unisex Configuration Kit</td>
<td>(two (2) regular mattress swabs (340-014) with 3-mL UTM (330CHL))</td>
</tr>
<tr>
<td>303CHL</td>
<td>Combination Swab Set: Male/Female</td>
<td>(one (1) regular collection swab (340-012) and one (1) wire tip urethral (340-013) with 3-mL UTM (330CHL))</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Product name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99-08011-VCM</td>
<td>VCM with Cervical Swab (Quest)</td>
<td>(Cervical Swabs (cleaning swab + collection swab) (DHI 99-07011.v2) with 3-mL VCM (455-050))</td>
</tr>
<tr>
<td>99-08013-VCM</td>
<td>VCM with Lesion Swab (Quest)</td>
<td>(Package with two (2) Lesion Swabs (DHI 99-07013.v2) with 3-mL VCM (455-050))</td>
</tr>
<tr>
<td>99-08014-VCF</td>
<td>VCM with Urethral FLOQSwab™ (Quest)</td>
<td>(Urethral FLOQSwab™ (DHI 99-07012.v3) with 3-mL VCM (455-050))</td>
</tr>
<tr>
<td>99-08015-VCF</td>
<td>VCM with Nasopharyngeal FLOQSwab™ (Quest)</td>
<td>(Nasopharyngeal FLOQSwab™ (DHI 99-07011.v2) with 3-mL VCM (455-050))</td>
</tr>
</tbody>
</table>

* FLOQSwab™ by Copan is the trademark of Copan Flock Technologies “flocked” collection devices (formerly known as Microrheologics, Copan Italia S.p.A., Brescia, Italy).
1.4 Product name: **UTM** (Universal Transport Medium)  
Catalog # UTM product name:  
330C 330CHL 3-mL UTM-RT medium in 10-mL size screw cap with conical bottom; each tube contains three 3-mm glass beads  
350C 350CHL 1-mL UTM-RT medium in 5-mL size screw cap with conical bottom; each 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 contain 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]
MATERIAL SAFETY DATA SHEET

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

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°C 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

<table>
<thead>
<tr>
<th>Chemical/Component</th>
<th>TLV/NIOSH REL</th>
<th>OSHA PEL</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>10 mg/m³ TWA</td>
<td>15 mg/m³ TWA</td>
<td>57-50-1</td>
</tr>
</tbody>
</table>

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
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:

<table>
<thead>
<tr>
<th></th>
<th>Swabs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UTM / VCM:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bovine Serum</td>
<td>None identified</td>
<td>None identified</td>
</tr>
<tr>
<td>Amphoterin B</td>
<td>LD₅₀ oral, rat</td>
<td>&gt;5000 mg/kg</td>
</tr>
<tr>
<td>Colistin</td>
<td>LD₅₀ oral, rat</td>
<td>121 mg/kg</td>
</tr>
<tr>
<td>L-Cysteine</td>
<td>LD₅₀ oral, rat</td>
<td>1890 mg/kg</td>
</tr>
<tr>
<td>Gelatin</td>
<td>None identified</td>
<td>None identified</td>
</tr>
<tr>
<td>L-Glutamic Acid</td>
<td>LD₅₀ oral, rat</td>
<td>30000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ oral, mouse</td>
<td>21700 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ oral, rabbit</td>
<td>&gt;2300 mg/kg</td>
</tr>
<tr>
<td>Phenol Red</td>
<td>None identified</td>
<td>None identified</td>
</tr>
<tr>
<td>Sucrose</td>
<td>LD₅₀ oral, rat</td>
<td>29700 mg/kg</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>LD₅₀ oral, rat</td>
<td>10000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ IV, rat</td>
<td>319 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ oral, mouse</td>
<td>&gt;5000 mg/kg</td>
</tr>
</tbody>
</table>

Chronic toxicity:

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

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

- **Amphoterin 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.
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
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 succrose 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.

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

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.

[End of Document]