

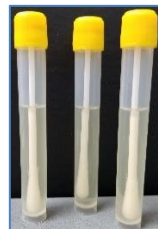
Product PN 10498315

Mod. 984

Description Swabkit Total Count 30/pk

Rev. 02

Swabkit m-TGE Total Count Swabs



PRODUCT DESCRIPTION	<p>SWABKIT TOTAL COUNT 30/pk Total Count Swab includes the swabs and culture medium, packaged with a membrane device, providing a quantitative result.</p>
MANUFACTURER NAME	<p>GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSLs@gvs.com - Website: www.gvs.com</p>
INTENDED USE / APPLICATION	<p>Total Count Swab Kit is used for the non-selective development and enumeration of all aerobic bacteria on surfaces in accordance with Hazard Analysis and Critical Control Points (HACCP). The kit includes the swabs and culture medium, packaged with a membrane device, providing a quantitative result. All bacteria develop on TGE media and produce a range of different colored and sized colonies. It is not possible using TGE to presumptively identify any bacteria. Identification can only be undertaken using traditional microbiology techniques following initial colony development.</p>
MATERIALS	<p>Liquid Media: membrane Tryptone Glucose Extract (m-TGE) Liquid Media Color: Yellow liquid</p> <p>Swab Tube: clear polypropylene Screw Cap: Yellow polyethylene with silicone washer Swab: white cotton</p> <p>Microbiological Monitor contains 56mm nitrocellulose membrane, 0.45 µm white/black grid.</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input type="checkbox"/> BSE/TSE, directive 2003/32/ <input type="checkbox"/> DEHP plasticizer Free and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> REACH 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals

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<p>PRODUCT CHARACTERISTIC</p>	<p>Yellow colored media dispensed in self standing, round bottomed capped plastic vials. The cotton swab is secured inside the screw cap. Kit includes nitrocellulose membrane device.</p> <p>Physical: Vial: 12 x 84 mm Cap: 14 x 13.25 mm polyethylene with silicone washer Swab: 78mm long Microbiological Monitor (100 ml) contains 56mm nitrocellulose membrane, 0.45 µm white/black grid.</p> <p>Volume/tube: 2.6 – 3.0 ml Incubation Temperature Range: 35°C ±2°C Storage temperature Range: From 2°C to 8°C</p> <p>Biological: Product is sold sterilized. Toxicity: See SDS for further information.</p>
<p>INSTRUCTIONS WARNINGS</p>	<p>Liquid media is temperature sensitive. Store at recommended temperature.</p> <p>Nitrocellulose membrane is flammable. Keep away from heat and open flame.</p>
<p>PRODUCT SHELF LIFE</p>	<p>12 months when stored properly</p>
<p>STERILIZATION</p>	<p>Product is sold sterilized. Microbiological monitors are sterilized by gamma irradiation at 25- 40 kgy.</p>
<p>PACKAGING AND LABELLING</p>	<p>Shrink-wrapped box contains: product insert, box of 30 swab vials and box of 30 microbiological monitors.</p> <p>LABEL:</p> <div data-bbox="422 1478 1273 2049">  <p>The label features the GVS logo and 'FILTER TECHNOLOGY' text. It includes contact information for GVS North America: Sanford, ME 04073 - USA, www.gvs.com, and +1 866-736-1250. The 'swabcheckK' logo is also present. A blue-bordered box highlights 'Total Count Swab Kit'. Below this, there are fields for REF (10498315), LOT (SAMPLE), and QTY. A 'STERILE' icon with a crossed-out '2' is shown. A temperature range of 2°C to 8°C is indicated with a thermometer icon. A barcode is present with the number 1 8339 02189 0. The text 'MADE IN USA' and 'Rev. 0' are at the bottom right. A 'Label ID: s9999999' is printed at the top right of the label area.</p> </div>

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CERTIFICATE OF COMPLIANCE	With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.																																													
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions: Magnification: none Light type: normal room lighting</p> <table><tr><th colspan="3">Liquid MediaAcceptance Requirement</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Color – yellow liquid</td><td>all</td><td rowspan="2">100%</td></tr><tr><td>2</td><td>Vial appearance – no misshapen or leaking vials. Each vial contains a swab</td><td>none</td></tr></table> <table><tr><th colspan="2">Microbiological Monitor Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Scratches or abrasion that may affect function</td><td>None</td><td rowspan="7">100%</td></tr><tr><td>2</td><td>Scratches that interfere with a clear view through the lid or graduation areas of the funnel</td><td>None</td></tr><tr><td>3</td><td>Debris or contaminants</td><td>None</td></tr><tr><td>4</td><td>Excess flash or flash that may affect function, such as at the base vacuum port</td><td>None</td></tr><tr><td>5</td><td>Proper placement of media</td><td>All</td></tr><tr><td>6</td><td>No torn or miss cut media</td><td>All</td></tr><tr><td>7</td><td>Grid lines: alignment, visible</td><td>All</td></tr></table>				Liquid MediaAcceptance Requirement			Sampling Plan	1	Color – yellow liquid	all	100%	2	Vial appearance – no misshapen or leaking vials. Each vial contains a swab	none	Microbiological Monitor Acceptance Requirement		AQL	Sampling Plan	1	Scratches or abrasion that may affect function	None	100%	2	Scratches that interfere with a clear view through the lid or graduation areas of the funnel	None	3	Debris or contaminants	None	4	Excess flash or flash that may affect function, such as at the base vacuum port	None	5	Proper placement of media	All	6	No torn or miss cut media	All	7	Grid lines: alignment, visible	All					
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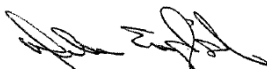
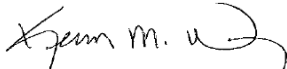
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This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____
(Name, Function) (Signature)

Date _____
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.