

Product PN 10498316

Mod. 984

Description Swabkit Yeast and Mold 30/pk

Rev. 02

Swabkit Yeast and Mold



PRODUCT DESCRIPTION	<p>SWABKIT Yeast and Mold 30/pk</p> <p>Yeast and Mold Swab Kit is used for the enumeration of yeast and molds on surfaces in accordance with HACCP. The kit 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>Yeast and Mold Swab Kit is used for the enumeration of yeast and molds on surfaces in accordance with HACCP. The kit includes the swabs and culture medium, packaged with a membrane device, providing a quantitative result. M-Green yeast and mold is an improved modification of the liquid medium, and was developed to improve efficiency of detection and enumeration of fungi in sugar based drinks using the membrane filtration method.</p>
MATERIALS	<p>Liquid Media: m-green yeast and mold Liquid Media Color: Green liquid</p> <p>Swab Tube: clear polypropylene Screw Cap: Green polyethylene with silicone washer Swab: white cotton</p> <p>Microbiological Monitor contains 56mm nitrocellulose membrane, 0.45 µm black/white 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>Green 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 black/white grid.</p> <p>Volume/tube: 2.6 – 3.0 ml Incubation Temperature Range: 25°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>  <p>The label features the GVS logo and 'FILTER TECHNOLOGY' text. It includes contact details for GVS North America: Sanford, ME 04073 - USA, www.gvs.com, and +1 866-736-1250. The 'swabcheckK' logo is also present. The product name 'Yeast and Mold Swab Kit' is highlighted in a blue oval. Below this, there is a table with fields: REF (10498316), LOT (SAMPLE), QTY, and a barcode. To the right of the barcode is the Label ID: s9999999. At the bottom, it says 'MADE IN USA' and 'Rev. 0'. There are also icons for 'STERILE', a temperature range of 2°C to 8°C, and a biohazard symbol.</p>

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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><thead><tr><th colspan="3">Liquid Media Swab Acceptance Requirement</th><th>Sampling Plan</th></tr></thead><tbody><tr><td>1</td><td>Color – green 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></tbody></table> <table><thead><tr><th colspan="2">Microbiological Monitor Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr></thead><tbody><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></tbody></table>				Liquid Media Swab Acceptance Requirement			Sampling Plan	1	Color – green 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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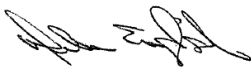
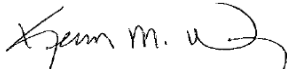
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This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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.