

PRODUCT SPECIFICATION

Product PN 10498406

Mod. 984

Description Coliform SwabCheck 25/pk

Rev. 02

Coliform SwabCheck 25/pk



PRODUCT DESCRIPTION	Coliform SwabCheck 25/pk A simple test for the detection of coliforms and <i>E. coli</i> in the environment.
MANUFACTURER NAME	GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSLs@gvs.com - Website: www.gvs.com
INTENDED USE / APPLICATION	<i>Escherichia coli</i> and coliforms are traditionally used as indicator organism for fecal contamination in water and other environmental samples. Detection of these organisms usually points to poor hygiene at some stage in the production process or pollution of water at source. Based on traditional test for coliforms, the Coliform SwabCheck provides a simple method for detecting these organisms – showing a definite color change from purple to yellow when coliforms are present.
MATERIALS	Culture Media: Coliform SwabCheck media Culture Media Color: Purple Swab Tube: 15 cm Swab: Yellow-capped swab Regulatory Documentation Required: ☐ Biocompatibility according ISO 10993-1 ☐ IMDS ☒ RoHS, directive 2002/95/CE ☐ BSE/TSE, directive 2003/32/ ☐ DEHP plasticizer Free and latex free ☐ Aging ☒ REACH 1907/2006/CE (hazardous substances regulation) ☐ Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☒ Conflict minerals

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PRODUCT CHARACTERISTIC	Self-contained swab device consisting of (1) a yellow capped swab and (2) a tube containing a purple-colored gel media.		
	Physical: Tube: 15 cm Swab: yellow capped swab		
	Incubation Temperature Range: 35°C ± 2°C Storage temperature Range: From 5°C to 25°C		
	Biological: Product is sold sterilized.		
	Toxicity: See SDS for further information.		
INSTRUCTIONS WARNINGS	Liquid media is temperature sensitive. Store at recommended temperature. DO NOT FREEZE.		
PRODUCT SHELF LIFE	12 months when stored properly		
STERILIZATION	Product is sold sterilized.		
PACKAGING AND LABELLING	25 devices placed in a box containing an insert. The box is labeled. Label contains: Item Description, item code, lot number, qty and Exp Date.		
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	Visual acceptance requirements apply when inspected under below conditions: Magnification: none Light type: normal room lighting		
	Liquid Media Acceptance Requirement		Sampling Plan
	1	Color – purple colored gel	all
	2	Tube appearance – no misshapen tube.	none
	3	Package contains swab & tube of purple-colored gel media	all
			100%

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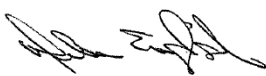
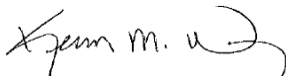
PERFORMANCE REQUIREMENTS

Liquid Media Acceptance Requirement			Sampling Plan
	Parameter	Specification	
1	Performance: qualitative	Color change: purple to yellow	ISO 11133:2014
2	Test Organisms, Positive control	<i>E. coli</i> NCTC 9001	ISO 11133:2014
3	Test Organisms, Negative control	<i>Streptococcus faecalis</i> NCTC 0775 <i>Proteus mirabilis</i> NCTC 11938 <i>Staphylococcus aureus</i> NCTC 8532	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color - Negative	purple	ISO 11133:2014
6	Media Color - Positive	yellow	ISO 11133:2014
7	Incubation	35°C ± 2°C for 18-24 hours	ISO 11133:2014

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)
11/18/2019	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

Customer Approval:

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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.