PRODUCT SPECIFICATION

Product PN *10498402*

Mod. 984

Rev. 02

Description Swabcheck *E.coli* 4ml 125/pk

Swabcheck *E.coli*; 125/pk

PRODUCT DESCRIPTION	Swabcheck *E.coli*; 125/pk 125 vials/pack. Each vial contains 4 ml of liquid media and a swab.
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	Swabcheck *E.coli* is used for the detection of *E.coli* on surfaces. The presence of fluorescence using a UV light source confirms the presence of *E.coli.*
MATERIALS	**Liquid Media:** Swabcheck *E.coli* media **Liquid Media Color:** Yellow liquid **Swab Tube:** clear polypropylene **Screw Cap:** Yellow polyethylene with silicone washer **Swab:** white cotton **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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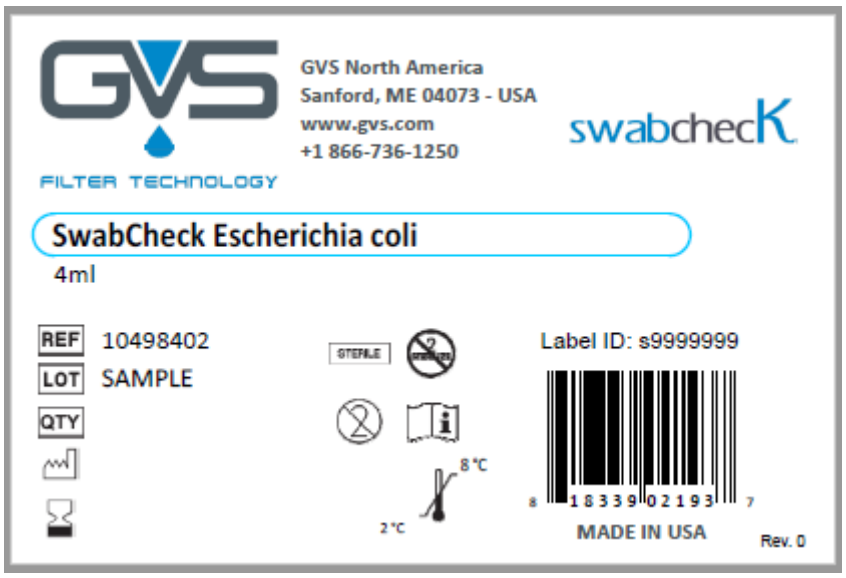
PRODUCT CHARACTERISTIC	**Yellow colored media dispensed in self standing, round bottomed capped plastic vials. The cotton swab is secured inside the screw cap** **Physical:** **Vial:** 12 x 84 mm **Cap:** 14 x 13.25 mm polyethylene with silicone washer **Swab:** 78mm long **Volume/tube:** 4.0 ml **Incubation Temperature Range:** 35ºC ± 2°C **Storage temperature Range:** From 2°C to 8°C **Biological:** Product is sold sterilized. **Toxicity:** See SDS for further information.
INSTRUCTIONS **WARNINGS**	Liquid media is temperature sensitive. Store at recommended temperature.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	**125 vials placed in a box containing an insert. The box is labeled and shrink-wrapped.** **LABEL:** 

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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	***Visual acceptance requirements apply when inspected under below conditions:*** **Magnification:** none **Light type:** normal room lighting

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	

PERFORMANCE REQUIREMENTS

Liquid Media Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	*E.coli* ATCC 25922	ISO 11133:2014
3	pH at 25°C	6.9 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Yellow	
6	Colony color	*E. coli* fluoresces under 366 nm UV light	ISO 11133:2014
7	Direct Inoculation	Turbid & fluoresce under UV	ISO 11133:2014
8	Incubation	35°C ±2°C for 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)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications	Kevin Wrigley/Director, Quality

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CustomerApproval:

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.