PRODUCT SPECIFICATION

Product PN *10496709*

Mod. 984

Rev. 02

Description EC Media with MUG – Bottled Broth

EC Media with MUG – Bottled Broth



PRODUCT DESCRIPTION	Tube EC-MUG 9ml (20/pk) EC Broth with MUG **-** The presence of fluorescence using a long-wave UV light source confirms the presence of *Escherichia coli* and no further confirmation is required. MUG detects anaerogenic strains, which may not be detected in the conventional procedure. Lactose is a source of energy. Casein peptone provides additional nutrients. The mixture of bile salts is inhibiting for gram-positive bacteria, particularly bacilli and fecal streptococci. The substrate 4-methylumbelliferyl-b-D-glucuronide is hydrolyzed by an enzyme, b-glucuronidase, possessed by most *Escherichia coli* and a few strains of *Salmonella*, *Shigella* and *Yersinia*, to produce a fluorescent end product, 4-methylumbelliferone.
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	EC Broth with MUG is a selective broth to detect coliforms and *E. coli* from food and water samples. If *E.coli* is present, the broth will fluoresce.
MATERIALS	**Media:** EC media with MUG **Color:** Yellow liquid **Tube and Durham tube**: Clear borosilicate glass **Cap**: Black phenolic with rubber liner **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

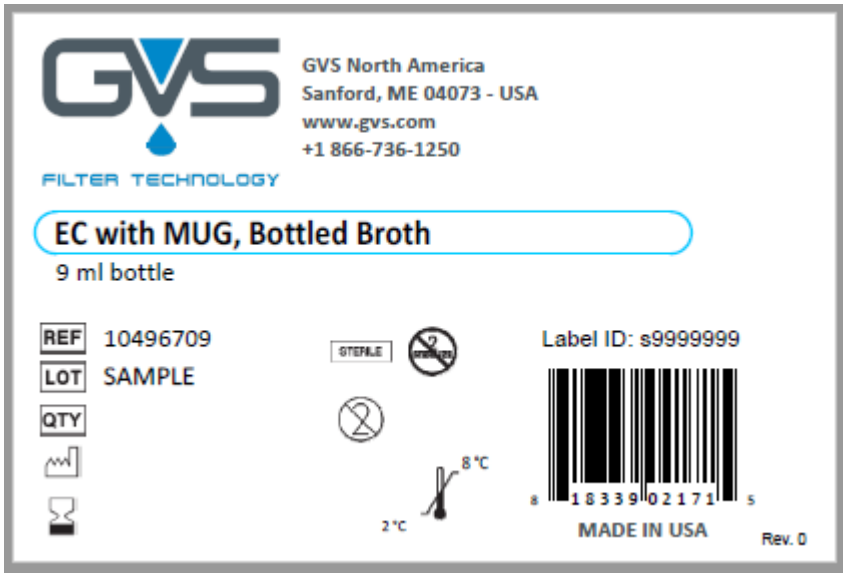
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PRODUCT CHARACTERISTIC	**Yellow colored liquid media dispensed in borosilicate glass container.** **Physical:** **Dimensions:** Glass vial -- 19 x 65mm Durham Tube –9 x 30 mm **Volume/container:** 9.0 ml +/- 0.5ml **Incubation Temperature Range:** 44.5°C ±2°C **Storage temperature Range:** From 2°C to 8°C **Biological:** Product is sold sterilized. **Toxicity:** See SDS for further information.
INSTRUCTIONS **WARNINGS**	Product is temperature sensitive. Store at recommended temperature.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	**1)** Twenty tubes are placed in a box containing an insert **2)** Box is labeled and shrink-wrapped. 

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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

Acceptance Requirement			Sampling Plan
1	Color – yellow	all	100%
2	Cap/vial – no leaking containers	none	

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Positive Growth	Turbid to Highly Turbid with gas production	ISO 11133:2014
2	Test Organism	*E. coli* ATCC 25922	ISO 11133:2014
3	Negative Test Organism	*E.aerogenes* ATCC 13048 Does not flouresce	ISO 11133:2014
4	pH at 25°C	6.9 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Yellow Clear	ISO 11133:2014
7	Colony Color	Fecal coliforms produce gas, *E. coli* will also fluoresce under UV light.	ISO 11133:2014
8	Incubation	44.5°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.