PRODUCT SPECIFICATION

Product PN *10496103*

Mod. 984

Rev. 02

Description M-Endo Coliform Broth - Ampoules

M-Endo Coliform Broth - Ampoules



PRODUCT DESCRIPTION	AMP M-ENDO 2ml, (50pk) M-Endo is a red colored microbiology nutrient media used to detect total coliform bacteria. Lactose fermenting organisms form aldehydes, which react with Schiff's reagent (basic fuchsin and sodium sulfite) and form red colored colonies. *Escherichia coli* colonies develop a green metallic sheen. Lactose non-fermenting bacteria form clear colorless colonies.
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	M-Endo coliform broth is used for the enumeration of coliforms in water (such as drinking, surface, recreational and purified water) by the membrane filtration method. It is used to differentiate lactose from non-lactose fermenting intestinal organisms and as a presumptive test for coliforms.
MATERIALS	**Media:** m-endo coliform broth **Color:** Red nutrient liquid **Ampoules**: polypropylene **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

Pink-red colored liquid media dispensed in plastic ampoules.

Physical:
Ampoule Dimensions: 57.9 mm x 8.4mm (at cap)/22 mm (at seal)
Volume/ampoule: 2 - 2.4 ml

Incubation Temperature Range: 35°C ± 2°C
Storage temperature Range: From 2°C to 8°C

Biological:
Product is sold sterilized.
Toxicity: See SDS for further information.

Media Formulation:
Approximate formula* per liter of water

Lactose	12.5 gm
Tryptose	10.0 gm
Enzymatic digest of Casein	5.0 gm
Enzymatic digest of Animal Tissue	5.0 gm
Sodium chloride	5.0 gm
Dipotassium phosphate	4.375 gm
Monopotassium phosphate	1.375 gm
Sodium Sulfite	2.1 gm
Yeast Extract	1.5 gm
Basic Fuchsin	1.05 gm
Sodium deoxycholate	0.1 gm
Sodium lauryl sulfate	0.05 gm
Nondenatured ethanol	20 ml

** Adjusted and/or supplemented as required to meet performance requirements*
pH 7.2 ± 0.2

INSTRUCTIONS WARNINGS

Product is temperature and light sensitive.
Store at recommended temperature protected from light.

PRODUCT SHELF LIFE

12 months when stored properly

STERILIZATION

Product is sold sterilized.

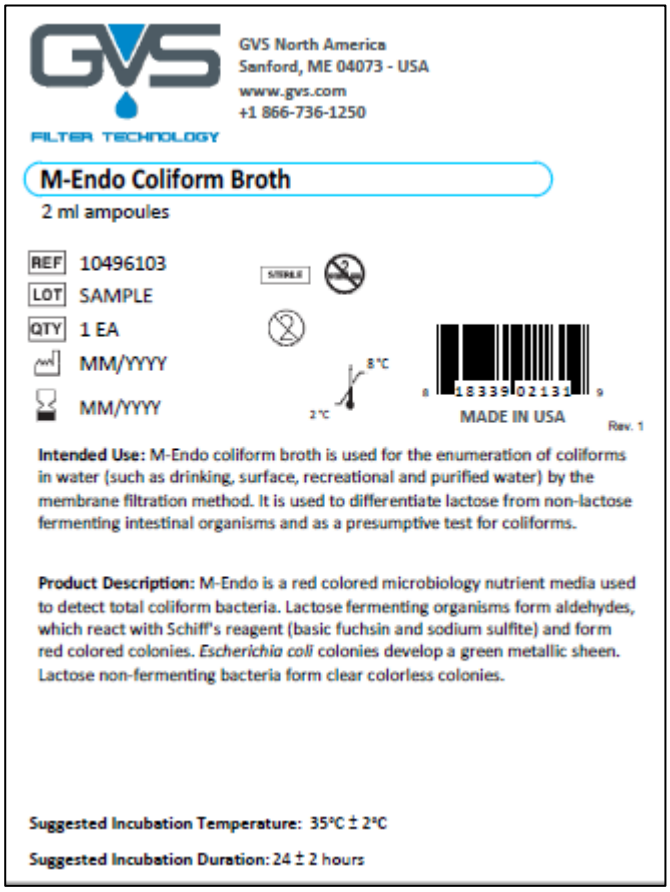
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PACKAGING AND LABELLING	**Primary:** 50 ampoules are placed in a labeled foil bag and sealed using a heat sealer. 
CERTIFICATE OF COMPLIANCE	With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality 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 – pale pink to red	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	*E.coli* ATCC 25922	ISO 11133:2014
3	Negative Test Organism	*Ps. aeruginosa ATCC 10145*	ISO 11133:2014
4	pH at 25°C	7.2 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Pink	ISO 11133:2014
7	Colony Color	Coliforms are pink to dark red with green metallic sheen	ISO 11133:2014
8	Incubation	35°C ±2°C for 22-24 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
7/28/2021	1	Update description, label, ampoule dimension & add media formulation	Debra English/Manager Biochemistry Applications	Kevin Wrigley/Director, Quality

CustomerApproval:

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Description	**M-Endo Coliform Broth - Ampoules**	**Rev. 02**

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.