PRODUCT SPECIFICATION

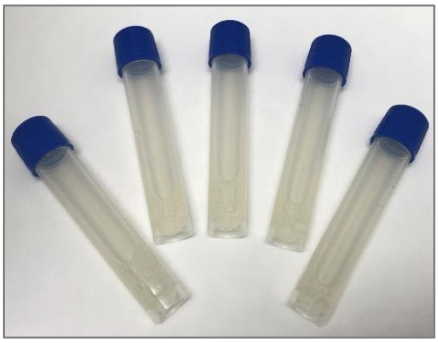
Product PN *10496192*

Mod. 984

Rev. 02

Description MI Broth-Vials

MI Broth-Vials



PRODUCT DESCRIPTION	Vial MI 2ml (50pk) MI Broth detects the presence of coliform bacteria by the production of b-galactosidase, which cleaves the substrate MUGal to produce 4-methylumbelliferone, which fluoresces on exposure to UV light. Non-coliforms do not produce this enzyme and therefore do not fluoresce on the medium. *Escherichia coli* is detected by the compound IBDG. The b-glucuronidase produced by *Escherichia coli* cleaves the substrate to produce a blue indigo colour in the colonies. As *Escherichia coli* is also a total coliform, and also produces b-galactosidase, it will also fluoresce. The antibiotic Cefsulodin is present to inhibit the growth of gram-positive bacteria and some non-coliform gram-negative bacteria that can cause false positive reactions.
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	MI Broth is used for the detection of Total Coliforms and *E.coli* in water testing.
MATERIALS	**Media:** MI Broth **Color:** Pale yellow nutrient liquid **Vial**: polypropylene **Cap:** blue 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

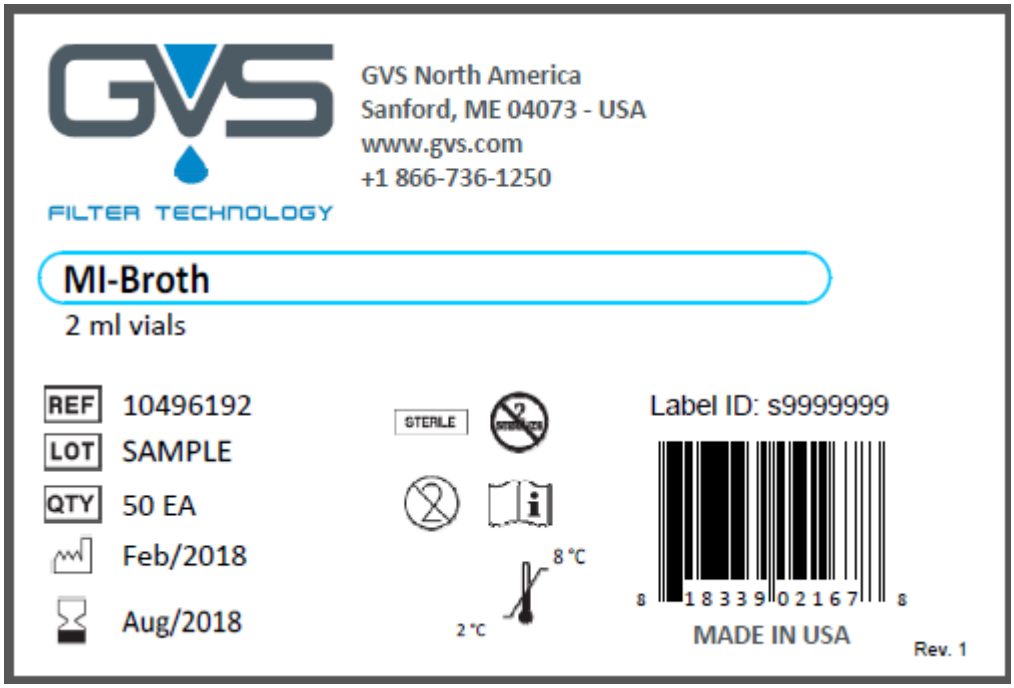
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Description **MI Broth-Vials**

PRODUCT CHARACTERISTIC	**Pale yellow colored liquid media dispensed in plastic vials and capped.** **Physical/Mechanical:** **Dimensions:** Vial (12.5 mm x 72); **Volume/vial:** 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.
INSTRUCTIONS **WARNINGS**	Product is temperature sensitive. Store at recommended temperature.
PRODUCT SHELF LIFE	6 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	**1)** 50 vials are placed in a box containing an insert. **2)** Label box and shrink wrap. 

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Description MI Broth-Vials

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 –clear to pale yellow	all	100%
2	Vial/cap appearance – no misshapen or leaking vials	none	

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 *E.aerogenes* ATCC 13048	ISO 11133:2014
3	Negative Test Organism	*Ps. aeruginosa* ATCC 10145	ISO 11133:2014
4	pH at 25°C	6.95 ± 0.2	ISO 11133:2014
5	Shelf Life when store at 4°C	6 Months	ISO 11133:2014
6	Sterility	Zero Growth	ISO 11133:2014
7	Media Color	Clear to Pale Yellow	ISO 11133:2014
8	Colony Color	*E.coli* shows blue colonies with blue fluorescence. Other coliforms are yellow to clear with blue-white fluorescence	ISO 11133:2014
9	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:

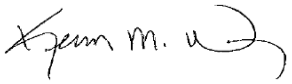
PRODUCT SPECIFICATION

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Description MI Broth-Vials

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 

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.