

Product PN 10496851

Mod. 984

Description MI Bottled Broth

Rev. 02

MI Bottled Broth



PRODUCT DESCRIPTION	BRO MI 50 ml (1/pk) MI Agar 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. <i>Escherichia coli</i> is detected by the compound IBDG. The b-glucuronidase produced by <i>Escherichia coli</i> cleaves the substrate to produce a blue indigo colour in the colonies. As <i>Escherichia coli</i> 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 <i>E.coli</i> in water testing.
MATERIALS	Media: MI Broth
	Color: Pale yellow nutrient liquid
	Bottle: Clear soda lime glass Cap: Black plastic
	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 glass bottles and sealed with cap Physical/Mechanical: Dimensions: Bottle (39 mm x 94 mm) with black cap Volume/ampoule: 48-52 ml Incubation Temperature Range: From 33°C to 37°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. Store at recommended temperature.
PRODUCT SHELF LIFE	6 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	1) Sealing band applied around cap and bottle junction 2) Label bottle. GVS North America Sanford, ME 04073 - USA www.gvs.com +1 866-736-1250 MI Bottled Broth 50 ml bottle REF 10496851 OT SAMPLE OTY 100 EA Jan/2018 Sample Secondary (for shipping): Another barcode label is applied to outside of box, with reference to the cumulative quantity.



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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

		Sampling Plan	
1	Color – pale yellow	all	1000/
2	Bottle/cap appearance – no cracks	none	100%

PERFORMANCE REQUIREMENTS

	Acceptance Re	equirement	Sampling Plan
	Parameter	Specification	ISO 11133:2014
1	Recovery (measured against control)	≥ 85 %	ISO 11133:2014
2	Test Organism	E. coli ATCC 25922 K. 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	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Clear to Pale Yellow	ISO 11133:2014
7	Colony Color	E. coli shows blue colonies with blue fluorescence. Other coliforms are yellow to clear with blue-white fluorescence	ISO 11133:2014
8	Incubation	33-37°C for 18-25 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)
11/20/19	0	Initial release	Debra English/Manager Biochemistry Applications	Kevin Wrigley/Director, Quality Ham M. W



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CustomerApproval:

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.