PRODUCT SPECIFICATION

Product PN	***10496120***	**Mod. 984**
Description	**M-Enterococcus Broth – Ampoules 2ml, (50pk)**	**Rev. 02**

M-Enterococcus Broth – Ampoules



PRODUCT DESCRIPTION	AMP ENTEROCOCCUS 2ml, (50pk) M-enterococcus broth is a modified version of the improved media described by Slanetz and Bartley; the modification is the addition of 2,3,5-Triphenyl-tetrazolium chloride (TTC). Colonies produce a red color as a result of the precipitation of formazan following the reduction of TTC by bacteria. The media detects enterococci in 48 hours. Sodium azide inhibits the growth of gram-negative organisms.
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-enterococcus broth detects enterococci from water or other material in 48 hours.
MATERIALS	**Media:** M-enterococcus broth **Color:** Pale amber 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

Pale amber 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: 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.

Media Formulation:
Approximate formula* per liter of water

Enzymatic Digest of Casein	15 gm
Enzymatic Digest of Soybean Meal	5 gm
Yeast Extract	5 gm
Dextrose	2 gm
Potassium Phosphate	4 gm
Sodium Azide	0.4 gm
2,3,5 – Triphenyltetrazolium Chloride, 1%	10 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

9 months when stored properly

STERILIZATION

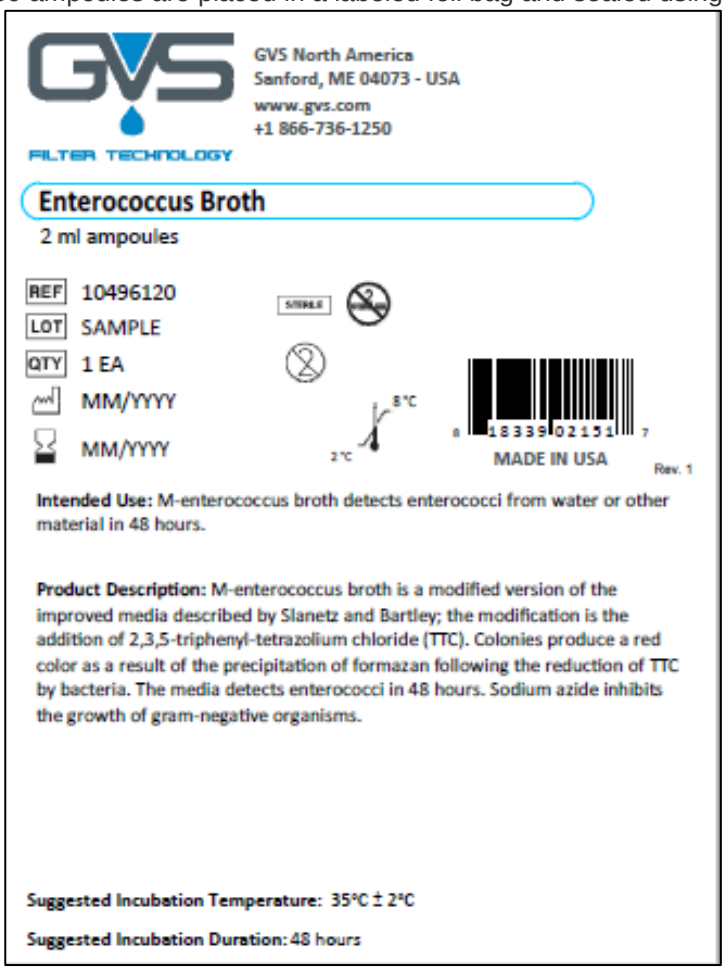
Product is sold sterilized.

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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 amber	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. faecalis* ATCC 19433	ISO 11133:2014
3	Negative Test Organism	*E. coli* ATCC 25922	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	Pale Amber	ISO 11133:2014
7	Colony Color	Pink to Red	ISO 11133:2014
8	Incubation	35°C ± 2°C for 18-48 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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Rev. 02

Description **M-Enterococcus Broth – Ampoules 2ml, (50pk)**

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.