PRODUCT SPECIFICATION

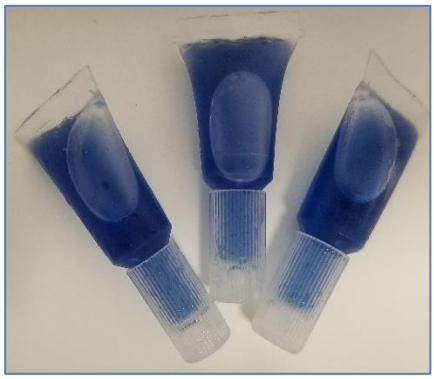
Product PN *10496124*

Mod. 984

Rev. 02

Description M-FC Broth - Ampoules

M-FC Broth - Ampoules



PRODUCT DESCRIPTION	AMP M-FC 2ml, (50pk) M-FC (Membrane-Fecal Coliform) allows the development of fecal coliforms at elevated 44.5°C temperature. Bile salts inhibit non-enteric bacteria. Aniline blue indicates the ability of fecal coliforms to ferment lactose to acid by-products that causes a pH drop in the medium. Other organisms form grey to cream 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-FC Broth is used for the detection and enumeration of fecal coliforms at elevated temperatures (44.5°C) using the membrane filtration technique.
MATERIALS	**Media:** M-FC broth **Color:** Blue 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

Blue 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: 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.

Media Formulation:
Approximate formula* per liter of water

Tryptose	10 gm
Peptone	5.0 gm
Yeast Extract	3.0 gm
Sodium Chloride	5.0 gm
Lactose	12.5 gm
Bile Salts	1.5 gm
Aniline Blue	0.1 gm

** Adjusted and/or supplemented as required to meet performance requirements*
pH: 7.4 ± 0.2

INSTRUCTIONS

WARNINGS

Product is temperature sensitive.
Store at recommended temperature.

PRODUCT SHELF LIFE

12 months when stored properly

STERILIZATION

Product is sold sterilized.

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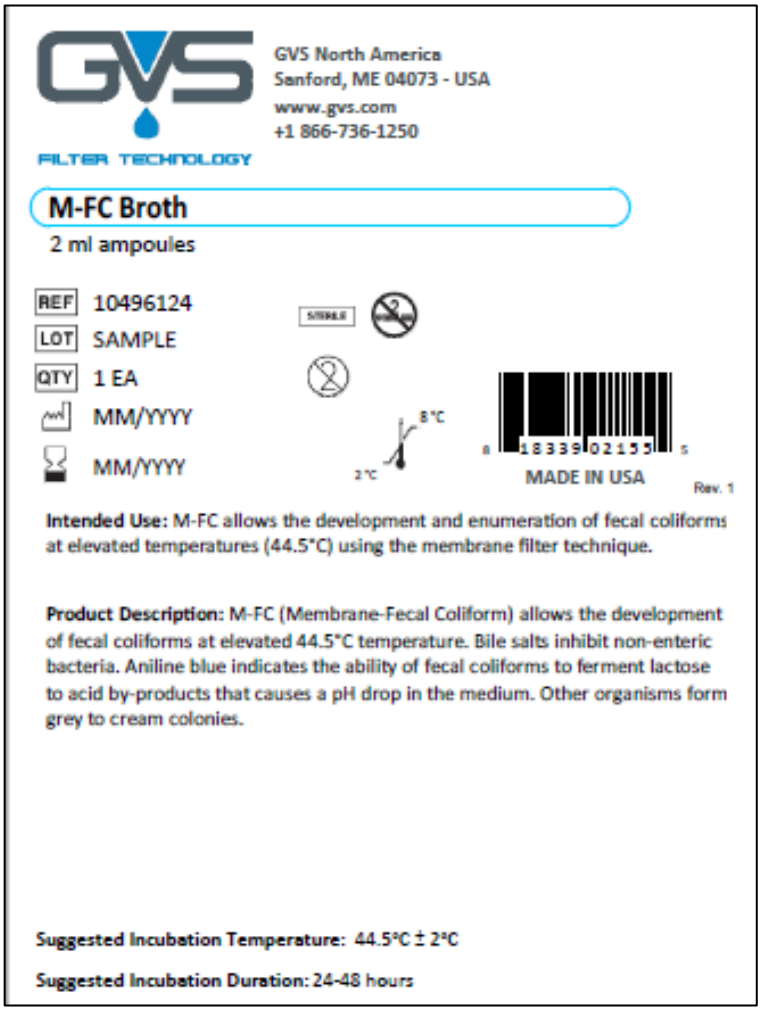
PACKAGING AND LABELLING

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 – blue	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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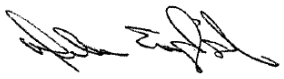
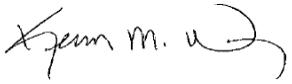
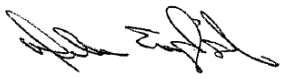
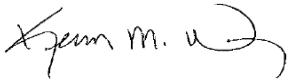
PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Positive 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	7.4 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Blue, Clear	ISO 11133:2014
7	Colony Color	Fecal coliforms are blue in color, all others are gray to cream.	ISO 11133:2014
8	Incubation	44.5°C for 22-26 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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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.