PRODUCT SPECIFICATION

Product PN *10496102*

Mod. 984

Rev. 02

Description M-TGE Total Count Broth - Ampoules

M-TGE Total Count Broth - Ampoules



PRODUCT DESCRIPTION	AMP M-TGE Total Count 2ml, (50pk) M-TGE Broth; also known as membrane Tryptone Glucose Extract Broth, Plate Count Broth, or Standard Methods Broth; is used for detection and enumeration of total aerobic bacteria. Bacteria produce a range of different colored and sized colonies. The product is made in accordance with the American Public Health Association (APHA) formulation.
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-TGE Broth is used for the non-selective development and enumeration of aerobic bacteria from dairy, water, food, or other products of sanitary concern.
MATERIALS	**Media:** M-TGE Broth **Color:** 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

PRODUCT SPECIFICATION

Product PN *10496102*

Mod. 984

Rev. 02

Description **M-TGE Total Count Broth - Ampoules**

PRODUCT CHARACTERISTIC	**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:** 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** Enzymatic Digest of Casein — 10.0 gm Beef Extract — 6.0 gm Dextrose — 2.0 gm ** Adjusted and/or supplemented as required to meet performance requirements* *pH 7.0 ± 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.

PRODUCT SPECIFICATION

Product PN *10496102*

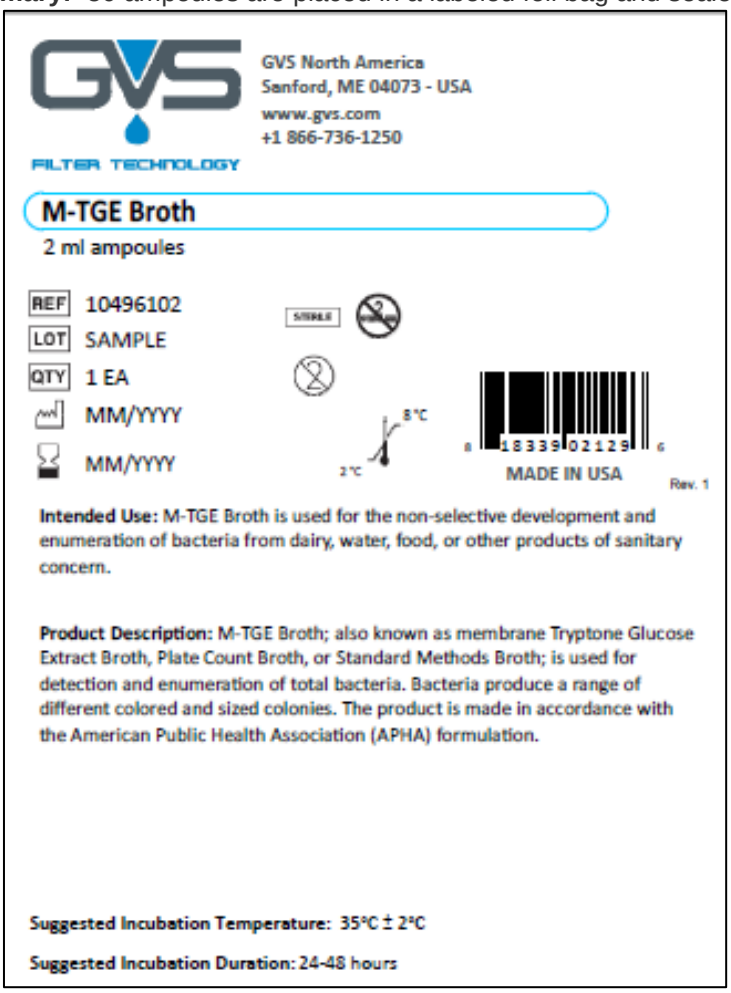
Mod. 984

Rev. 02

Description M-TGE Total Count Broth - Ampoules

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

PRODUCT SPECIFICATION

Product PN *10496102*

Mod. 984

Rev. 02

Description M-TGE Total Count Broth - Ampoules

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	pH at 25°C	7.0 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Amber	ISO 11133:2014
6	Colony Color	Organism Dependent	ISO 11133:2014
7	Incubation	35°C ±2°C for 24- 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:

PRODUCT SPECIFICATION

Product PN *10496102*

Mod. 984

Rev. 02

Description **M-TGE Total Count Broth - Ampoules**

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.