PRODUCT SPECIFICATION

Product PN *10496710*

Description Brilliant Green Bile Broth- Tubes

Mod. 984

Rev. 02

Brilliant Green Bile Broth - Tubes



PRODUCT DESCRIPTION	Tube BRILL GRN BILE 9ml (20/pk) Brilliant Green Bile Broth is an emerald green colored microbiology nutrient liquid media used to detect coliform bacteria in water, food, and dairy products. The media contains two inhibitors, oxgall and brilliant green dye, which inhibit gram-positive and selected gram-negative organisms. Lactose fermentation produces gas and is detected in the inverted Durham's tube. The formation of gas indicates the presence of fecal coliform.
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	Brilliant Green Bile Broth is used to detect coliform bacteria in water, food, and dairy products.
MATERIALS	**Media:** Brilliant Green Bile Broth **Color:** Emerald green nutrient liquid media **Tube and Durham tube**: Clear borosilicate glass **Cap**: Black phenolic with rubber liner **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	**Emerald green colored liquid media dispensed in borosilicate glass container.** **Physical:** **Dimensions:** Glass container (19 x 65mm) **Volume/container:** 9.0 ml +/- 0.5ml **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**	Store at recommended temperature.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	**1)** Twenty tubes are placed in box containing insert. **2)** Box is labeled. 

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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

Acceptance Requirement			Sampling Plan
1	Media Color – emerald green	all	100%
2	Cap/tube – no leaking containers	none	

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Positive Growth	Turbid to Highly Turbid & gas production in the Durham Tube	ISO 11133:2014
2	Test Organism	*E. coli* ATCC 25922	ISO 11133:2014
3	Negative Test Organism	*S. aureus* ATCC 25923 Growth Inhibited & no gas production	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	Green	ISO 11133:2014
7	Colony Color	Turbidity with Gas	ISO 11133:2014
8	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

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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.