PRODUCT SPECIFICATION

Product PN *10496125*

Mod. 984

Rev. 02

Description KF Streptococcus Ampoules

KF Streptococcus Ampoules



PRODUCT DESCRIPTION	AMP Streptococcus 2ml, (50pk) KF-Streptococcus Broth is a purple colored nutrient broth used for detecting enterococci in water. Maltose and lactose are the fermentable carbohydrates. Sodium azide selects for Gram-positive bacteria. Bromcresol purple is the indicator dye. TTC (2, 3, 5 triphenyltetrazolium chloride) results in pink to red color colonies when it is reduced to insoluble formazan by metabolizing cells.
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	KF-Streptococcus Broth is a selective medium for the isolation and enumeration of fecal streptococci in water.
MATERIALS	**Media:** KF Streptococcus Broth **Color:** Purple 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	**Purple 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

Peptone	10.0 gm
Yeast Extract	10.0 gm
Sodium Chloride	5.0 gm
Sodium glycerophosphate	10.0 gm
Maltose	20.0 gm
Lactose	1.0 gm
Sodium Azide	0.4 gm
Bromocresol Purple	0.015 gm
TTC 1% solution	10.0 ml

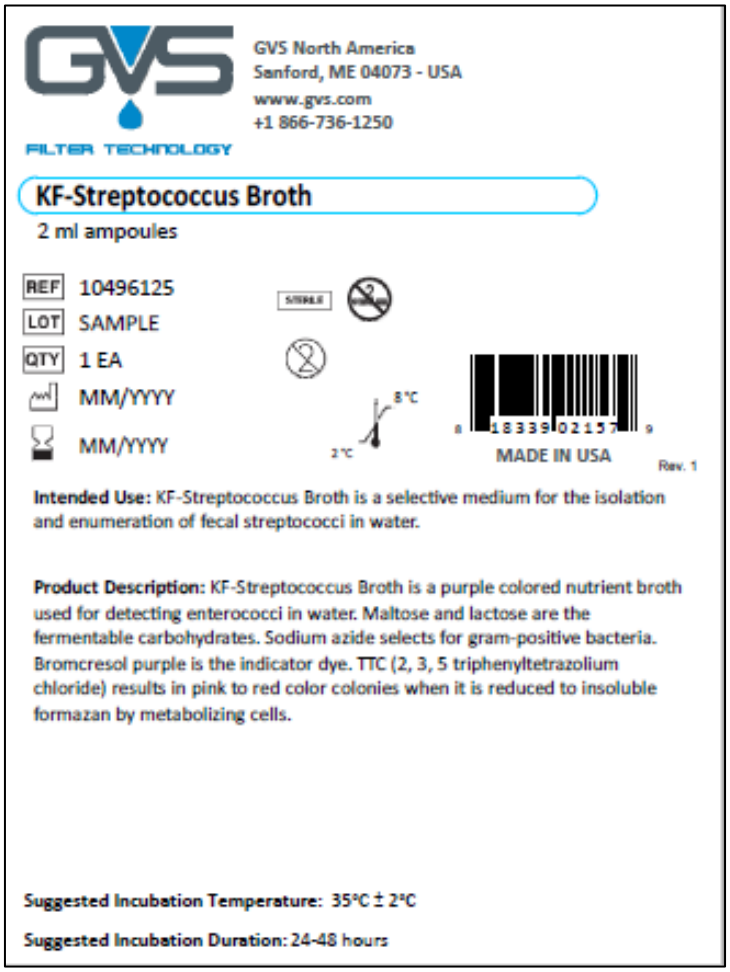
** Adjusted and/or supplemented as required to meet performance requirements*
pH: 7.2 ± 0.2

INSTRUCTIONS **WARNINGS**	Product is temperature 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 – purple	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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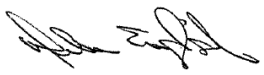
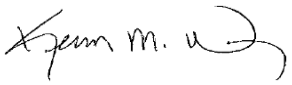
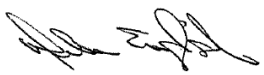
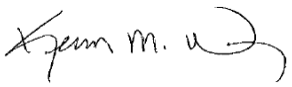
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PERFORMANCE REQUIREMENTS

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 Growth Inhibited	ISO 11133:2014
4	pH at 25°C	7.2 ± 0.2	ISO 11133:2014
5	Shelf Life when store at 5°C	9 Months	ISO 11133:2014
6	Sterility	Zero Growth	ISO 11133:2014
7	Media Color	Purple, clear	ISO 11133:2014
8	Colony Color	Pink to red, sometimes with yellow zones	ISO 11133:2014
9	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:

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Description KF Streptococcus 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.