PRODUCT SPECIFICATION

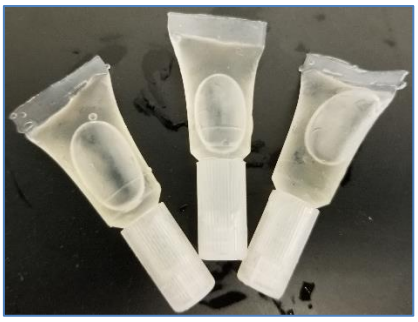
Product PN *10496119*

Mod. 984

Rev. 02

Description Pseudomonas Isolation Broth- Ampoules

Pseudomonas Isolation Broth- Ampoules



PRODUCT DESCRIPTION	AMP PSEUDOMONAS 2ml, (50pk) *Pseudomonas aeruginosa* is characterized by the production of pyocyanin (a blue green, water soluble, non-fluorescent, phenazine pigment) which is stimulated by the inclusion of magnesium chloride and potassium sulfate in the Pseudomonas Isolation Broth. Irgasan, an antimicrobial agent, selectively inhibits gram-positive and gram-negative bacteria other than pseudomonads. Glycerol both serves as an energy source and helps in the promotion of pyocyanin.
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	Pseudomonas Isolation Broth is used for the isolation of Pseudomonas and differentiating *P. aeruginosa* from other pseudomonads based on pigment formation.
MATERIALS	**Media:** Pseudomonas Isolation Broth **Color:** Pale brown 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 brown 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 — 20 gm Magnesium Chloride — 1.4 gm Potassium Sulfate — 10 gm Irgasan — 0.25 gm Glycerol — 20 ml ** 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.

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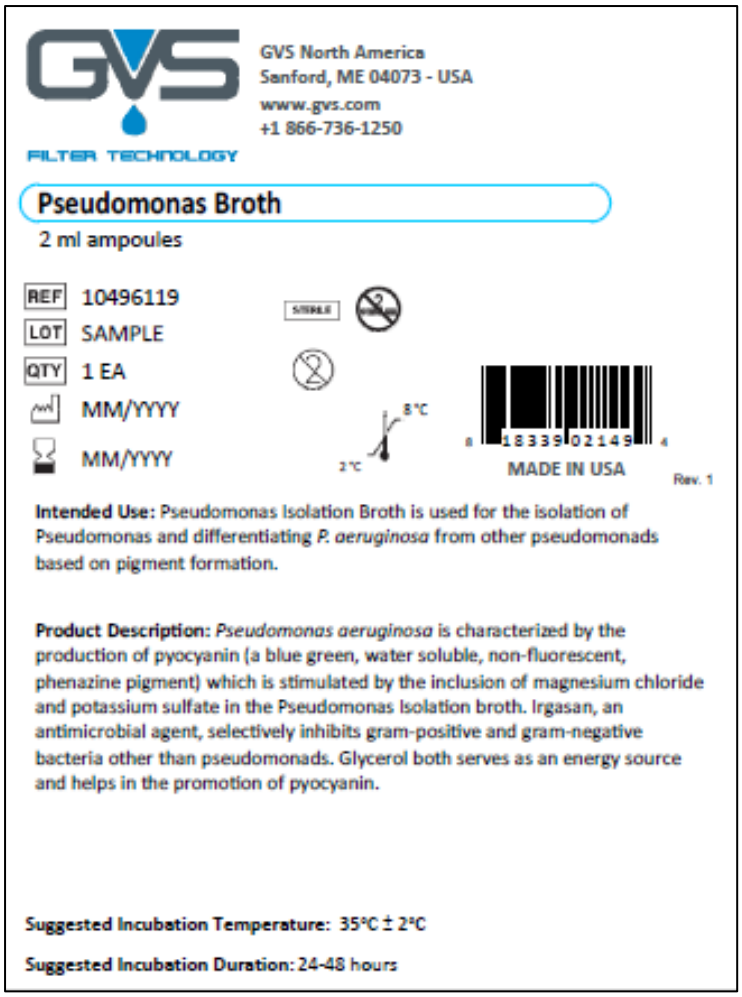
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PACKAGING AND LABELLING

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

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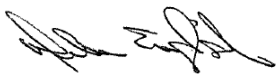
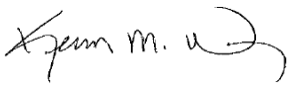
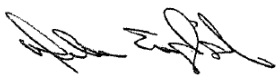
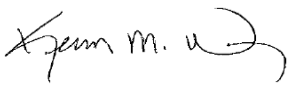
Description Pseudomonas Isolation Broth- Ampoules

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	*Positive Test Organism*	*Ps. aeruginosa ATCC 10145*	ISO 11133:2014
3	Negative Test Organism	*E. coli* ATCC 25922	ISO 11133:2014
4	pH at 25°C	7.0 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Pale Brown	ISO 11133:2014
7	Colony Color	Organism Dependent. *Ps. aeruginosa* – blue to blue green	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 
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 *10496119*

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Description **Pseudomonas Isolation 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.