PRODUCT SPECIFICATION

Product PN *10496106*

Mod. 984

Rev. 02

Description **Preservative Resistant Media- Ampoules**



Preservative Resistant Media- Ampoules

PRODUCT DESCRIPTION	AMP PRY 2ml, (50pk) Preservative Resistant Yeast (PRY) media is a low pH selective medium made with weak acid. Weak acids are commonly used in the food industry as preservatives, but some species of yeast are resistant to these preservatives. *Zygosaccharomyces* species are resistant to weak acid preservatives and are tolerant of many other stressful environments. Mannitol is the energy source; yeast extract provides essential nutrients.
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	Preservative Resistant Yeast (PRY) media is designed to selectively isolate and enumerate preservative resistant food spoilage yeasts, such as *Zygosaccharomyces bailii*.
MATERIALS	**Media:** PRY Broth **Color:** Pale yellow 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 yellow 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:** 25°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 Yeast Extract 10.0 gm Mannitol 10.0 gm Glacial Acetic Acid 10.0 ml ** Adjusted and/or supplemented as required to meet performance requirements* *pH 3.6 ± 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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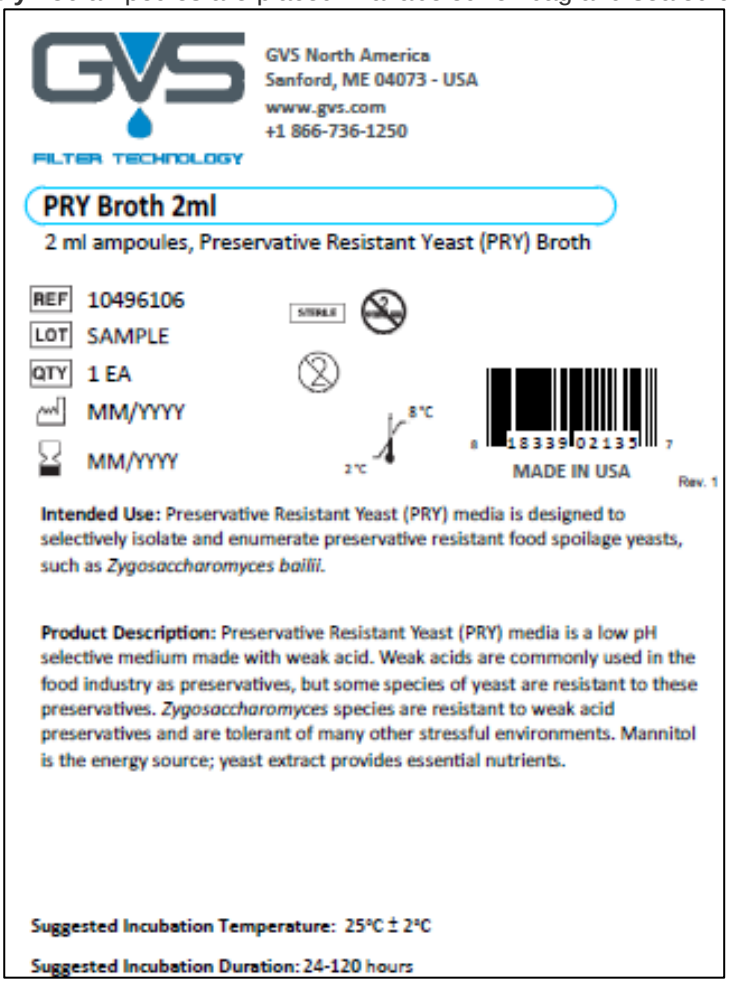
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PACKAGING AND LABELLING

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

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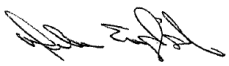
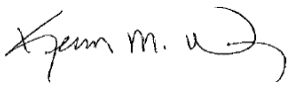
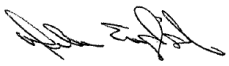
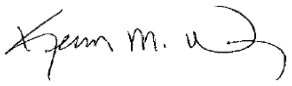
Rev. 02

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	*Z.bailii* ATCC 58445	ISO 11133:2014
3	pH at 25°C	3.6 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Pale Yellow, Clear	ISO 11133:2014
6	Colony Color	Organism Dependent	ISO 11133:2014
7	Incubation	25°C ±2°C for 24-120 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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Mod. 984

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Description **Preservative Resistant Media- 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.