PRODUCT SPECIFICATION

Product PN *10496109*

Mod. 984

Rev. 02

Description Wallerstein Differential Broth- Ampoules

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PRODUCT DESCRIPTION	AMP WL-DIFFERENTIAL 2ml, (50pk) WL (Wallerstein Laboratory) Differential Broth is a selective medium used for the isolation and enumeration of bacteria associated with breweries and industrial fermentation. Most yeasts and molds are inhibited by the addition of cycloheximide, facilitating the isolation of bacteria.
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	WL (Wallerstein Laboratory) Differential Broth is used to detect bacteria present in breweries and industrial fermentation. To obtain reliable counts of bacteria growing in a mixed culture with yeast, both WL Differential broth and WL Nutrient Broth should be used. The atmosphere, temperature, and duration of incubation will vary depending on the nature of the sample and the bacteria of interest.
MATERIALS	**Media:** WL Differential Broth **Color:** Blue 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

Blue 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: Organism dependent --*L. plantarum* 35°C ±2°C; *S. cerevisiae at* 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	4.0 gm
Pancreatic Digest of Casein	5.0 gm
Dextrose	50.0 gm
Monopotassium Phosphate	0.55 gm
Potassium Chloride	0.425 gm
Calcium Chloride	0.125 gm
Magnesium Sulfate	0.125 gm
Ferric Chloride	0.0025 gm
Manganese Sulfate	0.0025 gm
Bromocresol Green	0.022 gm
Cyclohexamide	0.004 gm

** Adjusted and/or supplemented as required to meet performance requirements*
pH 5.5 ± 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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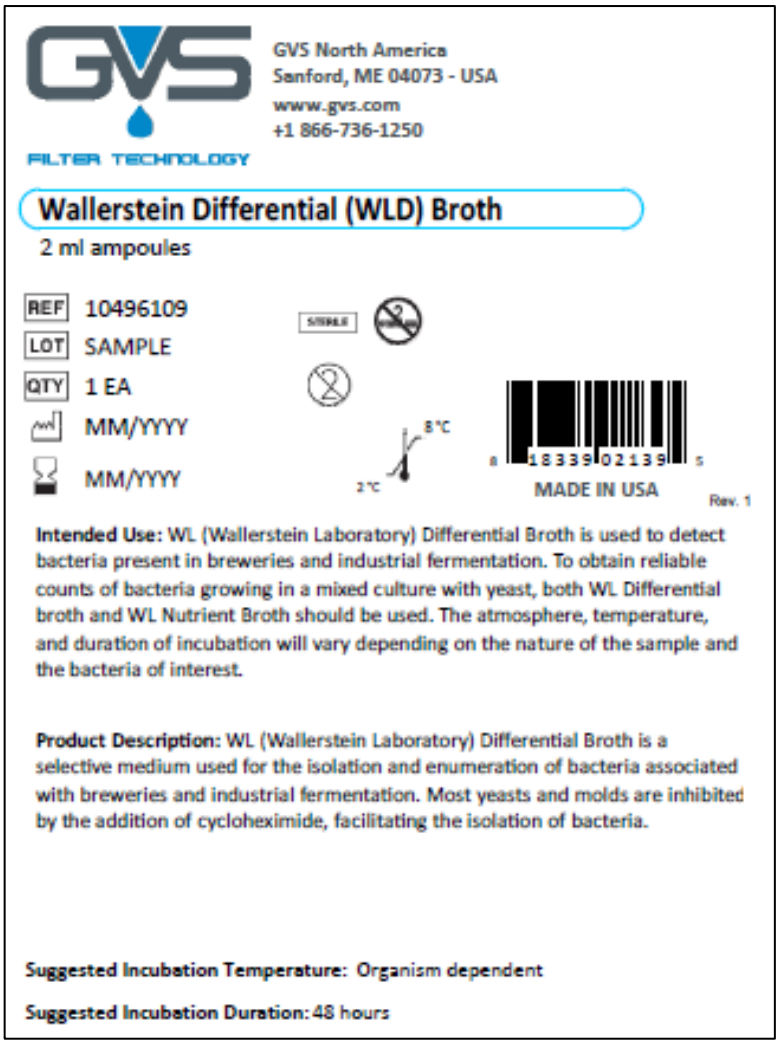
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Description **Wallerstein Differential Broth- Ampoules**

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 – green - blue	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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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	*L. plantarum* ATCC 8014	ISO 11133:2014
3	Negative Test Organism	*S. cerivisiae* ATTC 4098	ISO 11133:2014
4	pH at 25°C	5.5 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Green -Blue	ISO 11133:2014
7	Colony Color	Organism Dependent	ISO 11133:2014
8	Incubation	25°C ±2°C, 35°C ±2°C for at least 48 hours (Organism Dependent)	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 **Wallerstein Differential 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.