

Product PN 10496714

Mod. 984

Description EC Broth, with Durham tubes - Vials

Rev. 02

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PRODUCT DESCRIPTION	<p>Tube EC w/Durham 9ml (20/pk)</p> <p>EC Broth contains casein peptone as a source of nutrients. Lactose provides the carbohydrate fermented by coliform bacteria and <i>E. coli</i>. In addition, lactose-positive bacteria metabolize lactose with gas formation. Gram-positive bacteria are inhibited by the mixture of bile salts.</p>
MANUFACTURER NAME	<p>GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSLs@gvs.com - Website: www.gvs.com</p>
INTENDED USE / APPLICATION	<p>EC Broth with Durham Tube is for the detection of fecal coliforms in water and waste water at 44.5°C</p>
MATERIALS	<p>Media: EC Broth</p> <p>Color: Clear yellow</p> <p>Tube and Durham tube: Clear borosilicate glass</p> <p>Cap: Black phenolic with rubber liner</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> ☐ 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

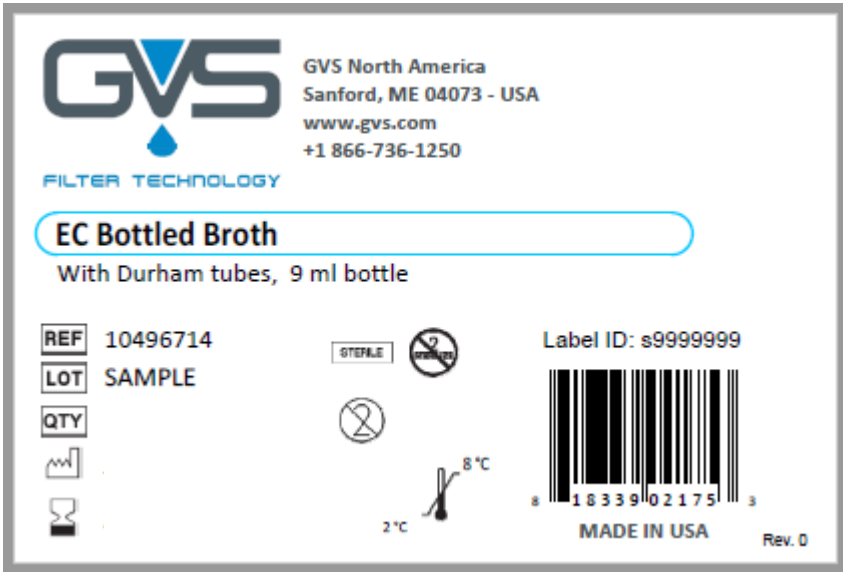
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PRODUCT CHARACTERISTIC	<p>Clear yellow colored liquid media dispensed in borosilicate glass container.</p> <p>Physical: Dimensions: Glass vial -- 19 x 65mm Durham Tube --9 x 30 mm Volume/container: 9.0 ml +/- 0.5ml Incubation Temperature Range: From 42.5°C to 46.5°C Storage temperature Range: From 2°C to 8°C</p> <p>Biological: Product is sold sterilized. Toxicity: See SDS for further information.</p>
INSTRUCTIONS WARNINGS	<p>Product is temperature sensitive. Store at recommended temperature. .</p>
PRODUCT SHELF LIFE	<p>12 months when stored properly</p>
STERILIZATION	<p>Product is sold sterilized</p>
PACKAGING AND LABELLING	<ol style="list-style-type: none"> Twenty tubes are placed in a box containing a foam insert Box is labeled and shrink-wrapped. <div data-bbox="507 1361 1353 1930">  <p>The label features the GVS logo and 'FILTER TECHNOLOGY' text. It specifies 'EC Bottled Broth' with 'Durham tubes, 9 ml bottle'. Key information includes: REF 10496714, LOT SAMPLE, QTY, a 'STERILE' icon, a 'NO OPEN FLAME' icon, a temperature range icon showing 2°C to 8°C, a barcode with the number 1833902175, Label ID: s9999999, and 'MADE IN USA'. The revision is noted as 'Rev. 0'.</p> </div>

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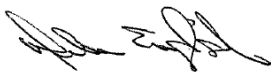
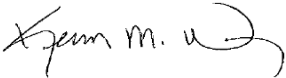
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CERTIFICATE OF COMPLIANCE	With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.																																						
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions: Magnification: none Light type: normal room lighting</p> <table><tr><th colspan="3">Acceptance Requirement</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Media Color – clear yellow</td><td>all</td><td rowspan="2">100%</td></tr><tr><td>2</td><td>Cap/vial – no leaking containers</td><td>none</td></tr></table>			Acceptance Requirement			Sampling Plan	1	Media Color – clear yellow	all	100%	2	Cap/vial – no leaking containers	none																									
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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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Customer Approval:

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.