

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"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input type="checkbox"/> BSE/TSE, directive 2003/32/ <input type="checkbox"/> DEHP plasticizer Free and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> 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 1928">  <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 Label ID: s9999999, and 'MADE IN USA'.</p> </div> |

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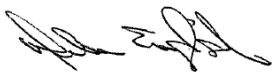
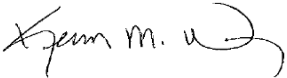
Rev. 02

| 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acceptance Requirement | | | Sampling Plan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Media Color – clear yellow | all | 100% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Cap/vial – no leaking containers | none | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| PERFORMANCE REQUIREMENTS | <table><tr><th colspan="3">Acceptance Requirement</th><th>Sampling Plan</th></tr><tr><td></td><td>Parameter</td><td>Specification</td><td>ISO 11133:2014</td></tr><tr><td>1</td><td>Test Organism</td><td><i>E. coli</i> ATCC 25922</td><td>ISO 11133:2014</td></tr><tr><td>2</td><td>Negative Test Organism</td><td><i>E. faecalis</i> ATCC 19433 Growth Inhibited</td><td>ISO 11133:2014</td></tr><tr><td>3</td><td>pH at 25°C</td><td>6.9 ± 0.2</td><td>ISO 11133:2014</td></tr><tr><td>4</td><td>Sterility</td><td>Zero Growth</td><td>ISO 11133:2014</td></tr><tr><td>5</td><td>Media Color</td><td>Yellow Clear</td><td>ISO 11133:2014</td></tr><tr><td>6</td><td>Colony Color</td><td>Fecal coliforms have growth and produce gas; non-fecal coliforms have growth but no gas</td><td>ISO 11133:2014</td></tr><tr><td>7</td><td>Incubation</td><td>44.5°C ±2°C for 24 hours</td><td>ISO 11133:2014</td></tr></table> | | | Acceptance Requirement | | | Sampling Plan | | Parameter | Specification | ISO 11133:2014 | 1 | Test Organism | <i>E. coli</i> ATCC 25922 | ISO 11133:2014 | 2 | Negative Test Organism | <i>E. faecalis</i> ATCC 19433 Growth Inhibited | ISO 11133:2014 | 3 | pH at 25°C | 6.9 ± 0.2 | ISO 11133:2014 | 4 | Sterility | Zero Growth | ISO 11133:2014 | 5 | Media Color | Yellow Clear | ISO 11133:2014 | 6 | Colony Color | Fecal coliforms have growth and produce gas; non-fecal coliforms have growth but no gas | ISO 11133:2014 | 7 | Incubation | 44.5°C ±2°C for 24 hours | ISO 11133:2014 |
| Acceptance Requirement | | | Sampling Plan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Parameter | Specification | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Test Organism | <i>E. coli</i> ATCC 25922 | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Negative Test Organism | <i>E. faecalis</i> ATCC 19433 Growth Inhibited | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | pH at 25°C | 6.9 ± 0.2 | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | Sterility | Zero Growth | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | Media Color | Yellow Clear | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | Colony Color | Fecal coliforms have growth and produce gas; non-fecal coliforms have growth but no gas | ISO 11133:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 | Incubation | 44.5°C ±2°C for 24 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  |

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CustomerApproval:

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.