



PRODUCT CHANGE NOTIFICATION

31 Jan 2017

Notification ID: CN-180106

Notification Type: Media Tube Growth Promotion Testing and Labeling Change

Dear Customer,

We would like to take this opportunity to notify you of changes that will be made to the growth promotion testing and labeling of Mesa Laboratories' TSB-BP16 growth media. As detailed in previous notifications, Mesa Labs is relocating manufacturing operations from its facility at 8607 Park Drive, Omaha, NE 68127 to a newly constructed facility at 625 Zoot Way, Bozeman, MT 59718.

Effective with the first lots to be released from the Mesa manufacturing facility located at 625 Zoot Way, the following changes are being implemented:

Change in Testing

Product release testing will be conducted to support the product's intended use. We will no longer perform growth promotion testing intended for general purpose media. Growth promotion testing will instead be performed using organisms specific to our biological indicator products. The change in testing will have no impact on the performance of the media for its intended purpose of incubating our biological indicators.

- The following organisms will be tested: *Geobacillus stearothermophilus* 7953, *Geobacillus stearothermophilus* 12980 and *Bacillus atrophaeus* 9372.
- Mesa will no longer test for the following organisms: *Escherichia coli* 25922, *Candida albicans* 10231, *Staphylococcus aureus* 25923 or *Bacillus subtilis* 6633.

Change in Labeling – Certificate of Conformance & Box Label

- The address has been changed to reflect the manufacture and distribution of this product from the new facility in Bozeman, MT.
- A part number and revision number has been added to the certificate.
- The instructions for use have been added to the certificate.
- Formatting changes have been made throughout, not considered changes to content, to align with formatting of other site documents
- Lot number will no longer be reported using the julian date. Instead, the prefix TSBP will be assigned, followed by a 3-digit sequential number. Example: TSBP-001
- The format of the expiration date format will be aligned with regulatory requirements (YYYY-MM-DD.)
- The statement "*Meets or Exceeds NCCLS & USP Tests for Growth Promotion and Sterility*" has been removed.



MesaLabs

As always, if you have any questions, please contact your Mesa Laboratories Representative.



Robert Bradley, Director of Production

31 Jan 2018

Date



Janis E. Smoke, Director of Quality & Regulatory Affairs

31 Jan 2018

Date

Tryptic Soy Broth

For Industrial Use Only

CERTIFICATE OF COMPLIANCE

Reorder No: TSB-BP16
Product Description: 16 x 100 mm tubes containing a proprietary formulation of soybean casein digest medium
Lot No.: TSBP-000
Manufacture Date: YEAR MONTH DAY
Expiration Date: YEAR MONTH DAY
Fill Level: 6.5 ± 0.5 mL

Growth promotion was performed using *Geobacillus stearothermophilus*, 7953⁽¹⁾ & 12980⁽¹⁾ and *Bacillus atrophaeus* 9372⁽¹⁾. Product was autoclaved to ensure sterility.

⁽¹⁾Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

Certified By: _____
Quality Representative Date

INSTRUCTIONS FOR USE

Test Laboratory:

- All testing should be performed in a clean, dust-free room and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rigid aseptic techniques to avoid “false positive” samples.
- Tubed media should be observed daily for growth after culturing and incubation:

Yellow = growth = non-sterile
Purple = no growth = sterile

Growth in tubes can be sub-cultured if identification of positive growth is desired. Recommended sub-culturing procedure techniques are available from Mesa Labs.

- Controls:
 - Positive:** One or more positive controls should be included in each test series. Yellow color and turbidity indicates that the medium possesses suitable growth promoting qualities. If positive control does not grow, do not use the lot. Contact Mesa Labs.
 - Negative:** One or two tubes incubated with test series. Absence of color change to yellow and/or turbidity indicates that the medium was sterile prior to sterility testing.

Storage and Disposal:

- Store at room temperature. Protect from light.
- This product has a shelf life which is clearly designated on each package. Rotate your stock accordingly.

NOTE: Do not use after expiration date printed on package. Dispose of unused culturing media by pouring liquid down drain and placing the tubes in the proper disposal receptacle.



Bozeman Manufacturing Facility

625 Zoot Way
Bozeman, MT 59718

T: 303/987-8000 ♦ F: 406/585-9219

www.mesalabs.com

Rev.1
Part No. 77021

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