PRODUCT CHANGE NOTIFICATION

19Jun2019
Notification ID: CN-190508
Notification Type: Product Testing Change

Dear Customer,

We would like to take this opportunity to notify you of a testing change that has been made to the following Mesa catalog items.

- SGMSU/6

Testing Change
Historically Mesa performed USP calculated survival and kill testing on SGMSU/6 as a means to confirm the D-value. Due to the wide fractional zone for Mesa’s *Bacillus subtilis* ‘5230’ spores on paper carriers the USP calculated survival / kill test is not an appropriate method for confirming D-value. Beginning with lot B5230-160 Mesa will no longer perform USP calculated survival and kill testing.

To support this change Mesa will be removing the USP calculated survival and kill times from the certificate for SGMSU/6 and replacing it with the empirically derived survival and kill times.

This change will also impact the following catalog numbers that listed a reference D-value established using the SGMSU/6 product configuration:

- SU1X25/6
- SU2X10/6

The two items listed above will no longer list the USP calculated survival and kill times on their respective certificates of analysis.

See Attachment 1 for examples of certificates with the changes.

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

Robert Bradley  
Sr. Director – Bozeman Operations

Nicole Dewald  
Manager – Quality Assurance

19Jun2019
Date

Mesa Laboratories, Inc. – 625 Zoot Way Bozeman, MT 59718 – phone 406.585.9535
## MESASTRIP CERTIFICATE OF ANALYSIS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Survival</th>
<th>Kill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam (115°C)</td>
<td>0.0</td>
<td>04:00</td>
<td>00:00</td>
</tr>
<tr>
<td>Steam (118°C)</td>
<td>0.0</td>
<td>00:00</td>
<td>00:00</td>
</tr>
<tr>
<td>Steam (121°C)</td>
<td>0.0</td>
<td>00:00</td>
<td>00:00</td>
</tr>
<tr>
<td>Z-value</td>
<td>00.0°C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Users are manufactured in compliance with Mesa Laboratories, Inc’s Sterling Manufacturing Facility’s standard, ISO and ISO 1385 stds and all appropriate subcommittee with the exception of manufacturing tolerance determined by reference of the survival kill response characteristic. Empirical survival kill is reported manual.

### Quality Assurance

Mesa Laboratories, Inc. — 625 Zoot Way Bozeman MT 59718 — phone 406 585 9535

---

## MESASTRIP INSTRUCTIONS FOR USE

### Sterilization:
1. Place medical strips inside representative materials to be sterilized. Package or wrap in cloth.
2. Layout test to verify each package is to be ascertained. Identify net packages to be sterilized.
3. After netting, place test strips inside netting with plastic or sealed in plastic bags as POUCH.

### Test Label:
1. Label each netted package. Label each package with the following:
   - **MESASTRIP**: Name/Method
   - **Date/Time**

2. These test strips shall be inserted into the sterilization autoclave for sterilization at 121°C for 15 minutes.

### Storage and Disposal:
- Store unopened sterilization strips at room temperature.
- Do not expose sterilization strips to extreme conditions. Do not store
- Sterilization strips should be used within 12 months of manufacture.

### Note:
Do not use after exposure. Do not package. Do not re-use sterilized material bymanufacturer at 121°C for less than 15 minutes.

---

**LEGAL DISCLAIMER:** No warranty is given as to the fitness of such equipment for any sterilization or autoclaving equipment. Use of the equipment shall be at the user's own risk. This product is not a substitute for standard sterilization procedures. Users are advised to follow the manufacturer's instructions for use.

---

**CONFIDENTIALITY AND DISCLOSURE:** This information is confidential and proprietary. Any unauthorized disclosure or reproduction is strictly prohibited.
**Certificate of Analysis**

**Reactor No.:** SU11X2:58

**Expiry Date:** YYYYMMDD

**Lot No.:** BL25O-8888

**Biological Indicator for:** Low Temperature Steam Sterilization

**Culture:** Soybean casein digest broth

**Heat Shocked Population:** 0.8 x 10^5 Spores / Unit

**Carrier Size:** 1 x 25 mm

**Assayed Resistance:**

- **S-value (115°C):** 0.06 min.
- **S-value (118°C):** 0.00 min.
- **S-value (121°C):** 0.00 min.
- **Z-value:** 0.06°C

**Certiﬁed by:** Quality Assurance

---

**STORAGE & DISPOSAL: Class 6.2, limited quantities and only in original packaging.**

**Hazard:** Do not use after expiration date or to package or sterilize with limited packaging.

**NOTICE:** Do not use after expiration date or to package or sterilize with limited packaging.

---

**Instructions for Use:**

1. **Face up:** Ensure indicator arms are in view before use.
2. **Labeled:** This indicator is to be used with a label indicating its contents.
3. **Sticker:** Attach the label to the package.
4. **Temperature:** Ensure the package is stored at or below the indicated temperature.
5. **Expiration Date:** Ensure the package is not past its expiration date.
6. **Indications:** Use within 30 minutes of exposure.

---

**NOTE:** Do not use after expiration date or to package or sterilize with limited packaging.

---

**A L S O **

**LEGAL DISCLAIMER:**

- **Class 7, limited quantities and only in original packaging.**
- **Hazard:** Do not use after expiration date or to package or sterilize with limited packaging.
- **NOTICE:** Do not use after expiration date or to package or sterilize with limited packaging.

---

**A L S O **

**LEGAL DISCLAIMER:**

- **Class 7, limited quantities and only in original packaging.**
- **Hazard:** Do not use after expiration date or to package or sterilize with limited packaging.
- **NOTICE:** Do not use after expiration date or to package or sterilize with limited packaging.

---

**LEGAL DISCLAIMER:**

- **Class 7, limited quantities and only in original packaging.**
- **Hazard:** Do not use after expiration date or to package or sterilize with limited packaging.
- **NOTICE:** Do not use after expiration date or to package or sterilize with limited packaging.