



MesaLabs

**PRODUCT CHANGE NOTIFICATION**

June 20, 2017

**Notification ID:** CN-170601

**Notification Type:** Product Specification Change

Dear Customer,

We would like to take this opportunity to notify you of a change that was made to the negative control unit that is part of the following SterilAmp II product configurations:

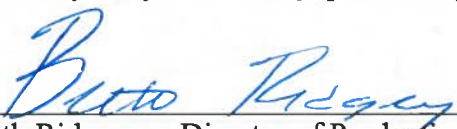
- SterilAmp II (SA/3, SA/4, SA/5, SA/6)
- SterilAmp II 18 mm (SA18/6, SA18/NC50)
- SterilAmp II '5230' (SASU/6, SASU/6B, SASU/650)
- SterilAmp II Negative Control (SANC)
- SterilAmp II '5230' (SASUNC)
- SterilAmp II Negative Control 18 mm (SANC18)


This change was implemented with lot SA-555 and first released on 04Mar2016.


Prior to this change, the SterilAmp II negative control unit included a glass bead denoting the absence of spores in the media. Through internal testing, it was determined this bead was causing the media color to not 'degrade' at the same rate as the biological indicator (BI); therefore, a deeper color remained after exposure in the same cycle. To prevent confusion for the end-user when comparing the color of the BI and the negative control ampoule, a stainless-steel bead was tested and showed significant improvement from the original glass bead. This change did not adversely affect the performance, handling or storage of the finished product.

Per Mesa Laboratories, Inc., Bozeman Manufacturing Facility's procedure, a Minor change is defined as a "change that is aesthetic, does not impact performance in any way, and does not impact customer's use of the product", and a customer notification for minor changes can occur at any time. You are receiving this notification retroactively as a courtesy to provide rationale for the change and the time frame for doing so.

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

  
Beth Ridgeway, Director of Production

  
Date

  
Janis E. Smoke, Director of Quality & Regulatory Affairs

  
Date