



PRODUCT CHANGE NOTIFICATION

14 Sep 2018

Notification ID: CN-180902

Notification Type: Specification Change

Dear Customer,

We would like to take this opportunity to notify you of a specification change to the following Mesa catalog numbers:

- 3-4100 Spore Strips, *Geobacillus stearothermophilus* Log 4
- 3-5100 Spore Strips, *Geobacillus stearothermophilus* Log 5
- 3-1000 Spore Strips, *Geobacillus stearothermophilus* Log 5
- 3-6100 Spore Strips, *Geobacillus stearothermophilus* Log 6
- 5-5100T Spore Strips, Combined Log 6/5 Test
- 5-1000C Spore Strips, Combined Log 6/5 Control
- 5-1000T Spore Strips, Combined Log 6/5 Test


Effective immediately (starting with the next lots to be released on or after the date of this notification), the shelf life of these catalog items has been reduced to 18 months from the current 24 months. A review of stability data to date revealed that our current shelf life claim of 24 months is at the limit of the capability of the GST spores to perform as per the label claim. The change has been made to reduce the risk to the end user of using a biological indicator that has drifted outside the acceptable limits for population and/or resistance performance.

The expiration date for any lots which have been distributed prior to the date of this notification remain as recorded on approved labeling. Lots distributed with 24-month expiration dates will be monitored for stability through 24 months per Mesa's approved procedure, QC-301 *Stability Program*.

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


Robert Bradley, Director – Manufacturing

14 Sep 2018
Date


Janis E. Smoke, Director – Quality & Regulatory Affairs

14 Sep 2018
Date