



## PRODUCT CHANGE NOTIFICATION

05 August 2018

**Notification ID:** CN-180604

**Notification Type:** Product Manufacturing and Labeling Change

Dear Customer,

We would like to take this opportunity to notify you of labeling and manufacturing changes that have been made to Apex catalog numbers. This change notification applies to the following Mesa catalog numbers:

- **HMV-091** Apex VPHP Disc *G. stearothermophilus* 12980
- **KCD-404** Apex VPHP Disc *G. stearothermophilus* 12980
- **NAS-152** Apex VPHP Disc *G. stearothermophilus* 7953
- **GRS-090** Apex VPHP Disc *B. atrophaeus* 9372

### Manufacturing and Labeling Changes

The primary packaging and labeling of **HMV-091**, **KCD-404**, **NAS-152**, and **GRS-090** has been automated. Until now, primary packaging and labeling was done entirely manually and occurred in a number of steps: printing of Tyvek sheets; sealing of pouches on three sides; insertion of inoculated, dried carriers into the pouches; sealing of the fourth side; and cutting into individual units. These steps are now performed in a custom QuickPouch machine, manufactured expressly for this purpose by Adaptive Manufacturing Technologies. The new equipment was fully qualified according to an approved IQ/OQ protocol. The process performance qualification for these products is currently underway using this machine. A summary of the process performance qualification, including protocol numbers and results of the equipment qualification, will be posted to <https://biologicalindicators.mesalabs.com/birelocation/> as soon as it is available.

Use of the new equipment required the following changes to the primary labeling. Examples of the revised primary labels are attached.

- The fonts have been changed, including color. All printing is now black ink only.
- The manufacturer's name has been added to align with the requirements of ISO 11138-1:2017.

No other changes to the manufacturing process have been made, including to preparation of spore crops, dilutions, inoculation or drying of discs, secondary packaging, or levels of inspection.

### Labeling Changes


The lot numbering schemes for these Apex products have been changed. The changes have been made to align the numbering with that of other Mesa products. The new schemes are as follows:

- **HMV-091** lot numbers are now AH- followed by three-digit sequentially assigned numbers. *For example, AH-123.*

- **KCD-404** lot numbers are now AK- followed by three-digit sequentially assigned numbers. *For example, AK-123.*
- **NAS-152** lot numbers are now AN- followed by three-digit sequentially assigned numbers. *For example, AN-123.*
- **GRS-090** lot numbers are now AG- followed by three-digit sequentially assigned numbers. *For example, AG-123.*

The changes will be effective with the first lots released from our facility located at 625 Zoot Way, Bozeman MT 59718.

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

  
Robert Bradley, Director – Manufacturing 06 Aug 2018  
Date

  
Janis E. Smoke, Director – Quality & Regulatory Affairs 07 Aug 2018  
Date

**Attachment 1**  
Examples of revised primary labeling




**CN-180604**

**Attachment 1**

**Examples of revised primary labeling**


**HMV-091 primary labeling**

**Apex VPHP Disc**  
*G. stearo*thermophilus  
12980  
LOT: AH-XXX  
EXP:YYYY-MM-DD  
MesaLabs




**KCD-404 primary labeling**

**Apex VPHP Disc**  
*G. stearo*thermophilus  
12980  
LOT: AK-XXX  
EXP:YYYY-MM-DD  
MesaLabs



**NAS-152 primary labeling**

**Apex VPHP Disc**  
*G. stearo*thermophilus  
7953  
LOT: AN-XXX  
EXP:YYYY-MM-DD  
MesaLabs



**GRS-090 primary labeling**

**Apex VPHP Disc**  
*B. atrophaeus*  
9372  
LOT: AG-XXX  
EXP:YYYY-MM-DD  
MesaLabs

