



PRODUCT CHANGE NOTIFICATION

17 Sep 2018

Notification ID: CN-180905

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 EZTest-H2O2 Log 6. This change notification applies to the following Mesa catalog numbers:

- EZH/6
- EZH/61

Testing Change

Historically Mesa utilized a STERRAD® 100S to develop the resistance claim for each lot of EZTest-H2O2. Due its advanced age, Mesa has chosen to decommission that piece of equipment and purchased a NewForge H2O2 resistometer that was installed and fully qualified for use at our 625 Zoot Way facility.

Due to the change in test equipment, the test conditions will also be changed. The test condition changes are being implemented to more closely mirror test conditions that are being developed at the AAMI/ISO level for biological indicators intended for use in hydrogen peroxide sterilization processes. The changes are as follows:

Test Equipment	STERRAD® 100S	NewForge H2O2 Resistometer
Exposure Temperature	45°C	50°C
Exposure Concentration	2.0 mg/L	2.3 mg/L

To support this change Mesa captured data on three lots of EZTest-H2O2 tested in both test systems. A summary is provided below.

Lot	STERRAD® 100S D-value (2.0 mg/L)	NewForge Resistometer D-value (2.3 mg/L)	Percent difference
H-199	2.39 min	2.14 min	- 10.5 %
H-202	1.80 min	2.07 min	+ 15.0 %
H-203	1.89 min	2.17 min	+ 14.8 %

While there are differences in the resistance values produced by the two pieces of test equipment, they fall within the industry recognized allowable variance limit of +/-20% of the label claim.

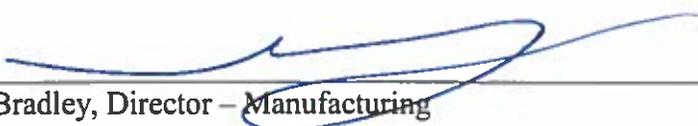
As they were historically, the test parameters will be reported on the certificates of analysis provided with each lot. Sample certificates are attached to this notification.

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.

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

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.

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

Attachments: Sample certificates of analysis for each catalog number

EZTest®

BIOLOGICAL INDICATOR CERTIFICATE OF ANALYSIS FOR INDUSTRIAL USE ONLY

Reorder No: EZH/6

Geobacillus stearothermophilus 7953⁽¹⁾

Indicator for Hydrogen Peroxide Sterilization.

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Lot No: **H-000** Manufacture Date: YYYY-MM-DD

Expiration Date: YYYY-MM-DD

Heat Shocked Population: 0.0 x 10⁶ Spores / Unit

Carrier size: Approximately 7.16 mm diameter

Assayed Resistance: Hydrogen Peroxide Vapor at 50°C, 2.3 mg/L

D-Value⁽²⁾

0.0 Min

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's quality standards.

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

⁽²⁾ Resistance was determined in a BIER vessel and calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.

Certified by:

Quality Representative

Date



Bozeman Manufacturing Facility
625 Zoot Way
Bozeman, MT 59718
T: 303/987-8000 ♦ F: 406/585-9219
www.mesalabs.com

EZTest®

Hydrogen peroxide

Monitoring Frequency:

For optimum control of sterilized goods, we recommend that an **EZTest** biological indicator be used to monitor every sterilizer load. Monitoring use is the responsibility of each institution or end user.

INSTRUCTIONS FOR USE

NOTE: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

A. Exposure:

1. Remove an appropriate number of **EZTest** units from the box.
2. Identify the indicators by labeling pertinent process information.
3. It is recommended that duplicate BI's be used per cycle.
4. Place **EZTest** biological indicators in a horizontal position with representative materials to be sterilized.
5. These materials should be located in the "worst case" (least lethal location) in the load.
6. Select the appropriate cycle and process the load.
7. Remove from the sterilizer.
8. Retrieve the **EZTest** biological indicator from the test load.

B. Incubation:

Any microbiological incubator that is adjusted for 55 to 60°C will satisfy the incubation conditions for the **EZTest**. To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

C. Interpretation:

1. Examine the indicator at regular intervals for any color change (i.e. 12, 18, and 24 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
2. Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate quality personnel (i.e. Infection Control). Always retest the sterilizer with several **EZTest** biological indicators throughout the test load. **EZTest** biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from Mesa Labs.
3. The incubation time is 24 hours. (Meets the US FDA CDRH RIT protocol)
4. Record the results.
5. Dispose of all used **EZTest** biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

D. Use of Controls:

1. As a positive growth control, place an activated, unsterilized **EZTest** biological indicator in each incubator on a daily basis.
2. Examine the positive indicator at regular intervals (i.e. 12, 18, and 24 hours). The yellow color is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of as mentioned above.
3. If the positive control does not grow, do not use the units from this box. Contact Mesa Labs.

E. Storage:

1. Store **EZTest** biological indicators at room temperature and away from light sources. Do not desiccate.
2. Do not store these indicators near sterilants or other chemicals.
3. **EZTest** biological indicators have 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 expired indicators by autoclaving at 121°C for not less than 30 minutes.

Rev.1
Part No.77086

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