



## Mesa Biological Indicators

### ProTest H<sub>2</sub>O<sub>2</sub> and ExpoSure Self-Contained Biological Indicators (SCBI)

This document refers to ProTest H<sub>2</sub>O<sub>2</sub> SCBIs of *Geobacillus stearothermophilus*, reference #7953, made by Mesa's Omaha, Nebraska Manufacturing Facility in comparison to Mesa's equivalent replacement product ExpoSure SCBIs of *Geobacillus stearothermophilus*, reference #7953, also made by Mesa's Omaha, Nebraska Manufacturing Facility.

### General Characteristics:

ProTest H <sub>2</sub> O <sub>2</sub>	Specifications	ExpoSure
		
Omaha, NE	<b>Manufacturing Location</b>	Bozeman, MT
PTH-3-6-25 or PTH-3-6-100	<b>Catalog #(s)</b>	EXPO/6
1.0x10 <sup>6</sup> – 4.0x10 <sup>6</sup>	<b>Population Range</b>	1.0x10 <sup>6</sup> – 4.0x10 <sup>6</sup>
10.5mm x 45.0mm	<b>Dimension (Width x Height)<sup>1</sup></b>	10.5mm x 52.3mm
25ct or 100ct	<b>Packaging Configurations</b>	30ct
Blue	<b>Cap Color</b>	White
7953	<b>Cell Line Number</b>	7953
≥1.0 seconds	<b>D-value Range</b>	0.75-6.0 seconds
18 months	<b>Shelf-Life</b>	12 months
58-62°C	<b>Incubation Temperature</b>	55-60°C
24 hours	<b>Incubation Time</b>	24 hours
I 1410	<b>Compatible Mesa Incubator</b>	I 1410
Purple to Yellow	<b>Media Color Change</b>	Purple to Yellow
Red to Blue	<b>Chemical Indicator</b>	Red to Blue
USP, ISO 11138-1	<b>Compliance</b>	USP, ISO 11138-1
1921058	<b>FDA Registration Number</b>	1921058
NA	<b>FDA 510(k)</b>	K140589

<sup>1</sup>The width dimension is measured at the widest point.

# Product Comparison

## Product Lot Comparison:

Product Characteristic	ProTest H <sub>2</sub> O <sub>2</sub>			ExpoSure		
	Lot Number			Lot Number		
	PT-435	PT-466	PT-504	ES-0006	ES-0007	ES-0008
<b>Population Per Strip</b>	2.5x10 <sup>6</sup>	2.6x10 <sup>6</sup>	2.0x10 <sup>6</sup>	2.1x10 <sup>6</sup>	3.6x10 <sup>6</sup>	2.1x10 <sup>6</sup>
<b>H<sub>2</sub>O<sub>2</sub> D-value 3.0mg/L at 50°C In Seconds</b>	2.0	7.4	9.6	Not Certified	Not Certified	Not Certified
<b>H<sub>2</sub>O<sub>2</sub> D-value 2.5mg/L at 50°C In Seconds</b>	Not Certified	Not Certified	Not Certified	2.28	2.28	2.25

Based on a product comparison and review of best practices, the ExpoSure SCBIs manufactured by Mesa's Omaha, Nebraska facility are equivalent to ProTest H<sub>2</sub>O<sub>2</sub> SCBIs manufactured by Mesa's Omaha, Nebraska facility and offers the following advantage:

- FDA approved and 510(k) notified for use in following STERRAD® Models and Cycles
  - o STERRAD® 50
  - o STERRAD® 100S
  - o STERRAD® 200
  - o STERRAD® NX (Standard & Advanced)
  - o STERRAD® 100NX (STANDARD, FLEX, DUO and EXPRESS)

We acknowledge that some customers may need to perform a validation on the Mesa equivalent product. If you anticipate you will need product to validate this change please contact our Customer Service group to be put on our list for validation shipments.

The ordering information associated with these products, during and post transition, shall be as follows:

### During Transition

Ordering Information	
<b>Telephone</b>	303-987-8000 Ext. 10030
<b>Fax</b>	402-593-0995
<b>Email</b>	bicustomerservice@mesalabs.com

### Post Transition

Ordering Information	
<b>Telephone</b>	303-987-8000 Ext. 10040
<b>Fax</b>	406-585-9219
<b>Email</b>	bozcustserv@mesalabs.com

We understand that our clients have different needs based upon their quality system requirements or standard operating procedures. Because of this, if there is something specific that is required, such as completion of specific forms or documents, samples, etc... please do not hesitate to let us know.

Thank you for being a valued customer and we look forward to continuing to serve you.

If you have any questions, please don't hesitate to contact us.