

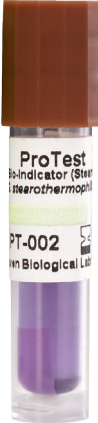

# Product Comparison

## Mesa Biological Indicators

### ProTest Steam and EZTest Steam Self-Contained Biological Indicators (SCBI)

This document refers to ProTest Steam SCBIs of *Geobacillus stearothermophilus*, reference #7953, made by Mesa's Omaha, Nebraska Manufacturing Facility in comparison to Mesa's equivalent replacement product EZTest Steam SCBIs of *Geobacillus stearothermophilus*, reference #7953, made by Mesa's Bozeman, Montana Manufacturing Facility.

### General Characteristics:

ProTest Steam	Specifications	EZTest Steam
		
Omaha, NE	<b>Manufacturing Location</b>	Bozeman, MT
PT-3-6-25 or PT-3-6-100	<b>Catalog #(s)</b>	EZS/625 or EZS/6
1.0x10 <sup>6</sup> – 4.0x10 <sup>6</sup>	<b>Population Range</b>	1.0x10 <sup>6</sup> – 5.0x10 <sup>6</sup>
PT-3-5-25 or PT-3-5-100	<b>Catalog #(s)</b>	EZS/525 or EZS/5
1.0x10 <sup>5</sup> – 4.0x10 <sup>5</sup>	<b>Population Range</b>	1.0x10 <sup>5</sup> – 5.0x10 <sup>5</sup>
10.5mm x 45.0mm	<b>Dimension (Width x Height)*</b>	10.5mm x 48.9mm
25ct or 100ct	<b>Packaging Configurations</b>	25ct or 100ct
Brown	<b>Cap Color</b>	Brown
7953	<b>Cell Line Number</b>	7953
1.5-3.0 minutes	<b>D-value Range</b>	≥ 1.5-minutes
18 months	<b>Shelf-Life</b>	24 months
55-60°C or 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
Cream to Black	<b>Chemical Indicator</b>	Blue to Black
USP, ISO 11138-1, ISO 11138-3	<b>Compliance</b>	USP, ISO 11138-1, ISO 11138-3
1921058	<b>FDA Registration Number</b>	3026-231
K041386 & K082756	<b>FDA 510(k)</b>	K930682 & K963841

\*The width dimension is measured at the widest point.

# Product Comparison

## Product Lot Comparison:

Product Characteristic	ProSpore Steam			EZTest Steam		
	Lot Number			Lot Number		
	PT-458	PT-481	PT-492	S-468	S-477	S-488
<b>Population Per Strip</b>	2.0x10 <sup>6</sup>	1.9x10 <sup>6</sup>	1.3x10 <sup>6</sup>	2.5x10 <sup>6</sup>	1.8x10 <sup>6</sup>	2.1x10 <sup>6</sup>
<b>Steam D-value at 121°C In Minutes</b>	1.8	2.0	1.8	1.8	2.0	2.2
<b>Steam Survival Time at 121°C In Minutes</b>	7.7	8.6	7.4	7.8	8.4	9.5
<b>Steam Kill Time at 121°C In Minutes</b>	18.5	20.6	18.2	18.4	20.2	22.7
<b>Steam D-value at 132°C In Minutes</b>	0.50	0.52	0.51	0.5	0.6	0.6
<b>Steam Survival Time at 132°C In Minutes</b>	2.2	2.2	2.1	2.2	2.6	2.6
<b>Steam Kill Time at 132°C In Minutes</b>	5.2	5.3	5.2	5.2	6.2	6.2
<b>Steam D-value at 134°C In Minutes</b>	0.25	0.32	0.20	0.4	0.5	0.5
<b>Steam Survival Time at 134°C In Minutes</b>	1.1	1.4	0.8	1.8	2.1	2.2
<b>Steam Kill Time at 134°C In Minutes</b>	2.6	3.3	2.0	4.2	5.1	5.2
<b>Steam D-value at 135°C In Minutes</b>	0.19	0.21	0.16	0.4	0.5	0.4
<b>Steam Survival Time at 135°C In Minutes</b>	0.8	0.9	0.7	1.8	2.1	1.7
<b>Steam Kill Time at 135°C In Minutes</b>	2.0	2.2	1.6	4.2	5.1	4.1
<b>Steam z-value</b>	Determined based on D-values at 118°C, 121°C and 124°C			Determined based on D-values at 121°C, 124°C, and 127°C		
	11.8°C	10.3°C	12.8°C	17.3°C	19.0°C	15.7°C

Based on a product comparison and review of best practices, the EZTest SCBIs manufactured by Mesa's Bozeman, Montana facility are equivalent to ProTest SCBIs manufactured by Mesa's Omaha, Nebraska facility and offers the following advantage:

- 24 month expiration period

We acknowledge that some customers may need to perform a validation on the Bozeman manufacturing facility's 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.

# Product Comparison

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.