



Mesa Biological Indicators

ProTest EO and EZTest Gas Self-Contained Biological Indicators (SCBI)

This document refers to ProTest EO SCBIs of *Bacillus atrophaeus*, reference #9372, made by Mesa's Omaha, Nebraska Manufacturing Facility in comparison to Mesa's equivalent replacement product EZTest Gas SCBIs of *Bacillus atrophaeus*, reference #9372, made by Mesa's Bozeman, Montana Manufacturing Facility.

General Characteristics:

ProTest EO	Specifications	EZTest Gas
		
Omaha, NE	Manufacturing Location	Bozeman, MT
PT-1-6-25 or PT-1-6-100	Catalog #(s)	EZG/625 or EZG/6
1.0x10 ⁶ – 4.0x10 ⁶	Population Range	1.0x10 ⁶ – 5.0x10 ⁶
10.5mm x 45.0mm	Dimension (Width x Height)¹	10.5mm x 48.9mm
25ct or 100ct	Packaging Configurations	25ct or 100ct
Green	Cap Color	Red
9372	Cell Line Number	9372
2.5-5.8 minutes	D-value Range²	2.5-5.8 minutes
18 months	Shelf-Life	24 months
30-39°C	Incubation Temperature	35-39°C
48 hours	Incubation Time	48 hours
I 1410	Compatible Mesa Incubator	I 1410
Green to Yellow	Media Color Change	Red-Orange to Yellow
Cream to Brown	Chemical Indicator	Blue to Brown
USP, ISO 11138-1, ISO 11138-2	Compliance	USP, ISO 11138-1, ISO 11138-2
1921058	FDA Registration Number	3026-231
K041784	FDA 510(k)	K930683

¹The width dimension is measured at the widest point.

²The D-value range is established with Oxyfume 2000 blend EO gas.

Product Comparison

Product Lot Comparison:

Product Characteristic	ProTest EO			EZTest Gas		
	Lot Number			Lot Number		
	PT-353	PT-429	PT-499	G-178	G-187	G-196
Population Per Strip	2.1x10 ⁶	4.0x10 ⁶	2.0x10 ⁶	2.9x10 ⁶	2.9x10 ⁶	2.7x10 ⁶
Ethylene Oxide (EO) D-value 600mg/L, 54°C, 60%RH In Minutes	3.3	2.9	3.1	3.5	3.9	3.2
EO Survival Time In Minutes	14.3	13.3	13.3	15.65	17.46	14.30
EO Kill Time In Minutes	34.1	30.7	31.9	36.73	40.97	33.66

Based on a product comparison and review of best practices, the EZTest Gas SCBIs manufactured by Mesa's Bozeman, Montana facility are equivalent to ProTest EO 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.

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

During Transition

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

Post Transition

Ordering Information	
Telephone	303-987-8000 Ext. 10040
Fax	406-585-9219
Email	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.