



This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-3.

Product Name: Instant Biological Indicator (IBI)

For use in Monitoring: Steam

LOT IBI-1901 (Kit)

REF ISCS-06

2020-10-01 (YYYY-MM-DD)

Indicator Solution

LOT 191002-1

REF IS-5ML

2020-10-02 (YYYY-MM-DD)

2019-10-02

Quantity 1

Biological Tablet

LOT 191001-1

2019-10-01

2020-10-01 (YYYY-MM-DD)

Resistance Characteristics

Steam 121°C:

Survival: 5 minutes

Kill: 15 minutes

Self-Contained Biological Indicator (SCBI)

LOT S736-2

REF DT-06

2021-07-31 (YYYY-MM-DD)

2019-07-31

Quantity 25

Population: 1.4×10^6 per 6 mm disc

Resistance Characteristics

Steam 121°C: 1.5 minutes

Survival

6.3 minutes

Kill

15.2 minutes

z value: 7.6 °C

Based on *D* value determinations at 118°C, 121°C and 130°C

The *D* value(s) were determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.

Recovery

Biological Tablet

After exposure to the sterilization process, remove the adhesive strip to access the Biological Tablet. Add 1-3 drops of Indicator Solution to the Tablet. Within 30 seconds, observe and record the color of the Tablet. Biological Tablets which are positive will transition to a shade of red. Biological Tablets which are negative will remain off white, yellow or light pink in color. Negative Biological Tablets indicate the cycle/process was effective.

SCBI (Optional)

After exposure and removal of the Biological tablet and Base, activate the SCBI by depressing the cap until an audible click is heard and the media ampule breaks. Ensure the Spore Disc is immersed in the growth medium. Incubate at 55°-65°C for a minimum of 10 hours. Incubate an unexposed SCBI which has been activated as a Positive Control.

Examine SCBIs for growth as frequently as possible. SCBIs which are positive for growth of *Geobacillus stearothermophilus* will transition from Purple to Yellow and/or display a cream-colored sediment. If the Positive Control does not yield a Yellow color and/or turbidity, the test is not valid and the incubation conditions should be verified.



SCBIs which are negative for growth will remain clear and Purple in color. Negative SCBIs (Clear and Purple after incubation) indicate the cycle/process was effective.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

Storage and Shelf Life

	Room Temperature (15°-30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	Kit is labeled with the shorter expiration date of the components with individual expiry periods: the Indicator Solution, Biological Tablet, Media Ampule and the Spore Disc.		

Disposal:

IBI: Autoclave, steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

Indicator Solution: Discard as general waste.

Quality Approval

Date