TRUE INDICATING PRODUCTS

Certificate of Analysis

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

Product Name: InstaTRU™ Instant Biological Indicator (IBI) for Steam

Quantity: 50 IBIs, 1 bottle Indicator Solution

LOT (Kit)

REF IBI-S

(YYYY-MM-DD)

Indicator Solution

LOT

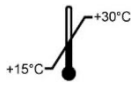
REF IS-5ML

Quantity: 1

Biological Tablet

LOT

Performance Characteristics		
Biological Tablet Population:	x 10^5 per tablet	
Steam – Tablet D value	Tablet Survival	Tablet Kill
121°C: minutes	minutes	minutes
132°C: minutes	minutes	minutes
135°C: minutes	minutes	minutes
The *D* value was determined per the fraction negative method and is reproducible only when exposed 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.		
z Value: °C	Based on D Value determinations at 121°C, 132°C, and 135°C	
Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the Instant Biological Indicator for Steam (IBI).		

Storage, Shelf Life and Disposal			
	Temperature (15°- 30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	20 Months from Date of Manufacture		Single Use Only
Disposal	Autoclave IBI, 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

InstaTRU™ Instant Biological Indicators (IBI) for Steam
Product Code: IBI-S, For Monitoring Steam Processes

Indications for Use

The True Indicating InstaTRU TM Instant Biological Indicator for Steam (IBI-S) is a Biological Indicator inoculated with a minimum of 10^5 viable *Geobacillus stearothermophilus* bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization processes and for releasing monitoring processed loads, providing visual confirmation in 20 seconds. The IBI-S by itself is not recommended and should not be used for qualification testing purposes (a BI within a Process Challenge Device (PCD) is recommended). Gravity-displacement Steam Sterilization Cycles: 121 ºC for 30 minutes, 132 ºC for 25 minutes, 132 ºC for 15 minutes, 132 ºC for 10 minutes, 132 ºC for 3 minutes; Dynamic-air-removal Steam Sterilization Cycles: 132 ºC for 4 minutes and 135 ºC for 3 minutes.

WARNING! The Instant Biological Indicator could be hot from steam exposure and should be handled with care post-exposure. Exposure to temperatures above 138°C could impact on the integrity of the product. Store the Instant Biological Indicator and Indicator Solution at 15°C - 30°C, 20 – 80% RH. Failure to do so could damage the Indicator Solution by exposing it to elevated temperatures above 40°C and cause false-negative results.

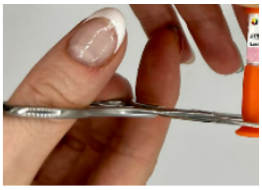
Instructions for Use

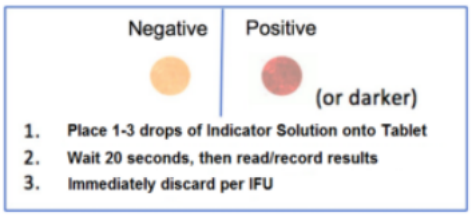
Exposure: The InstaTRU™ Instant Biological Indicators (IBI) can be used for routine monitoring of the efficacy of steam sterilization processes, qualification testing where applicable, product testing, and for releasing processed loads. **Note: Sensitivity and Specificity were determined to be greater than 95% based on non-clinical validation testing**. The IBI may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or Instant Biological Indicator in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove the Instant Biological Indicator and/or product from the sterilizer. Instant Biological Indicators may be held at room temperature for up to 72 hours post-exposure prior to activation without any impact to performance. If the processed Instant Biological Indicators are not activated within 72 hours of exposure, the cycle should be repeated.

Instant Result: Success of the sterilization cycle can be determined in 20 seconds or less using the biological tablet of the Instant Biological Indicator which provides a direct correlation to sterilization results of *Geobacillus stearothermophilus*.

1. Slowly remove the vented cap off the clear vial to access the Biological Tablet (scissors may be utilized).





2. If scissors are used, cut the bottom of the vented cap just above the widest portion as the Biological Tablet is inside the vented cap on top of the foam plug insert.

3. Obtain the Indicator Solution which came with the specific lot of Instant Biological Indicators and apply 1 - 3 drops of solution onto the indicator tablet. Adding more than 3 drops will not impact the test in any way.

Interpretation:

If the biological tablet remains its initial off-white/yellow color for 20 seconds, the sterilization cycle was successful. This indicates a **negative** result meaning all *Geobacillus stearothermophilus* spores have been deactivated within the Instant Biological Indicator. If the biological tablet turns a red color within 20 seconds, the sterilization exposure was unsuccessful. This indicates a **positive** result meaning *Geobacillus stearothermophilus* spores are still active within the Instant Biological Indicator and the test is considered invalid. The cycle must be investigated, and the load must be exposed again using an additional Instant Biological Indicator.

Result – White to Off-White to shades of Peach **= PASS**

Positive Result - Shades of Light Pink to Red **= FAIL**

Negative

It is critical for the biological tablet result to be visually determined within 20 seconds from adding the Indicator Solution to the tablet. A secondary reaction can occur which is unrelated to the primary reaction directly related to spore outgrowth of *G. stearothermophilus*. If 20 seconds have passed and the result was not visually determined, the test is still valid for up to 5 minutes from adding Indicator Solution after which a tan/peach color can develop also signifying a negative result. Do not determine the result after 5 minutes of adding Indicator Solution to a tablet to avoid misinterpretation, instead discard the tablet/incubate the SCBI using traditional incubation, or expose another IBI.

Optional - Traditional Use - Instant Biological Indicator – Self-Contained Biological Indicator (SCBI).

NOTE: The use of the SCBI is not required and is only offered as a secondary verification if deemed necessary.

Activation: Depress the vial wall inward towards the glass ampule in a downward motion until an audible click is heard and the glass media ampule contained within the plastic vial is crushed. Ensure that the disc is immersed in the growth medium. Activate one Instant Biological Indicator which has not been exposed in a sterilization process as a Positive Control if necessary.

Incubation: Place the processed, activated Instant Biological Indicator and a Positive Control in a vertical position in any standard incubator at 55°C to 65°C for a minimum of 10 hours. Examine the Instant Biological Indicator and record observations. **Interpretation**: Control - Biological Indicator: The Positive Control should exhibit a color change to Yellow and/or demonstrate turbidity. If the Positive Control as does not show signs of growth, consider the test invalid. **Test Biological Indicator**: A passing sterilization cycle is indicated by no signs of turbidity and the Purple color remaining and not transitioning to Yellow. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow. **NOTE: The End-Point Color Stability is seven (7) days post-steam exposure for both the Biological Tablet and SCBI Media.**

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators- Part 1:General requirements
ISO 11138-3 sterilization of healthcare products—Biological indicators – Part 3 Biological indicators for moist heat sterilization processes.
USP <55> Biological Indicators— Resistance Performance Tests
True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the recommended methodology. USP Biological/Official Monographs

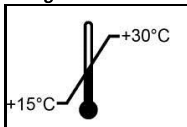
Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

Performance Characteristics

Population	≥ 1.0×10^5
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	D value at 121°C ± 0.5°C ≥ 1.5 minutes The Steam D value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. z value ≥ 10°C Determined based on three temperatures in the range of 110°C to 138°C. True Indicating typically utilizes D values determined at 110°C, 121°C and 130°C for z value calculation.
Post-Market Criteria	Population: 50% to 300% of certified population D value: ± 20% of the certified D value Survival Time: All SCBIs result in growth at the certified survival time Kill Time: All SCBIs result in no growth at the certified kill time

Storage and Shelf Life

	15°C to 30°C		Protect from heat, radioactive sources and sterilizing agents
	20% to 80% Relative Humidity		Do not freeze
Shelf Life	The shelf life of the Instant Biological Indicator is based on the shorter of two individual components (the media ampoule and inoculated carrier and Indicator Solution), which have independent expiration periods. This is usually 20 months from the date of manufacture. The Indicator Solution has a 20-month shelf life and can be purchased separately if necessary.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Instant Biological Indicator. Do not use damaged Instant Biological Indicators or Instant Biological Indicators which demonstrate a red tablet post-indicator solution, turbidity or have transitioned to a Yellow color from incubating the optional SCBI test. Do not use after expiration date. The Instant Biological Indicators contain live cultures and should		

	be handled with care.