InstaTRU™ Instant Biological Indicators (IBI) For Monitoring Steam Processes

True Indicating Codes: IBI-S

Product Description

InstaTRU™ Instant Biological Indicator Kits for monitoring Steam processes consist of:

- A polypropylene vial
- Tablet manufactured *Geobacillus stearothermophilus 7953* spores with proprietary materials extracted from *Geobacillus stearothermophilus* spores contained within the white silicone base with foam insert
- One bottle of Indicator Solution and trays for viewing results

Physical Properties

Process	Steam at 121°C, 132°C and 135°C
Dimensions	52 mm x 13.5 mm
Packaging	50 Indicators per box

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more InstaTRU™ Instant Biological Indicator be included with every load.

Indications for Use

The True Indicating InstaTRU TM Instant Biological Indicator for Steam (IBI-05) 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-05 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.

IBI-S can be used for routine monitoring of the efficacy of steam sterilization processes, qualification testing where applicable, product testing, and for releasing processed loads (reference K251559).

Instructions for Use

The following instructions provide necessary information for an end user to understand how to use the InstTRU™ Instant Biological Indicator. Always refer to the directions which are provided with the product and adhere to any and all warnings and cautions.

Exposure: 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.

TRUE INDICATING PRODUCTS
946 Kane St. Suite A, Toledo, OH, 43612
United States
@: info@trueindicating.com
www.trueindicating.com

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

Slowly remove the vented cap from the vial to access the Biological Tablet. Scissors may be utilized to aid in accessing the Biological Tablet. 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.

Transfer the tablet from the vented cap and foam to a plastic tray included in the kit, and add 1-3 drops of Indicator Solution onto the Tablet.

NOTE: No gloves are necessary as the Instant Biological Indicator and Indicator Solution have been evaluated and do not contain any irritants to the skin. Aseptic transfer is not required. Adding more than 3 drops will not impact the test in any way.

After 20 seconds, record the color of the Tablet and then discard immediately per the disposal instructions outlined on the Certificate of Analysis. Results are valid for up to 5 minutes from adding Indicator Solution. Repeat process for one Instant Biological Indicator which has not been exposed as a Positive Control.

Tablet Interpretation: Processed InstaTRU™ Instant Biological Indicator: 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.

Negative Result = PASS

Positive Result = FAIL

Positive Control: The Biological Tablet should transition to red within 20 seconds. If the Biological Tablet does not transition to red, the test is considered invalid. Ensure the Instant Biological Indicator evaluated as the Positive Control had not been processed and that the Indicator Solution has not reached its expiration date. 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.

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

Disposal

Autoclave InstaTRU™ Instant Biological Indicator for not less than 30 minutes at 121°C, or per validated disposal cycle prior to discard. Indicator Solution and Packaging: Discard as general waste.

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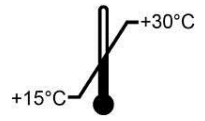
Performance Characteristics

Population	≥ 1.0 x 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 *D* value at 132°C ± 0.5°C ≥10 seconds *D* value at 135°C ± 0.5°C ≥8 seconds 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 121°C, 132°C and 135°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 IBIs result in growth at the certified survival time Kill Time: All IBIs 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.		

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