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: Instant 20s Indicator

Quantity: 25 Instant 20s Indicators, 1 bottle Indicator Solution, 25 plastic viewing cups, 1 pair disposable tweezers

LOT IBI-2201 (Kit) REF ISCS-05 2023-02-01 (YYYY-MM-DD)

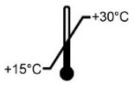
Indicator Solution

LOT 220101-01 2022-01-01

Biological Tablet

LOT 220101-02 2022-01-01

Performance Characteristics		
D value	Survival	Kill
Steam 121°C: 2.0 minutes	6.0 minutes	18.0 minutes
Steam 132°C: 0.3 minutes	0.9 minutes	2.7 minutes
Steam 135°C: 0.1 minutes	0.3 minutes	0.9 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: 11.4°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 20s Indicator.		

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	13 Months from Date of Manufacture		Single Use Only
Disposal	Autoclave Instant 20s Indicator, steam at 121˚C for not less than 30 minutes or incinerate (standard microbial waste; non-pathogenic species). Indicator Solution: Discard as general waste.		

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Quality Approval

February 28, 2022
Date

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Instructions For Use

Important: The following instructions provide necessary information for an end user to understand how to use for the Instant 20s Indicator. Always refer to the directions which are provided with the product and adhere to any and all warnings and cautions.

WARNING:

- The Instant 20s Indicator could be hot from steam exposure and should be handled with care post-exposure.
- Exposure to temperatures above 138°C could impact the integrity of the product.
- Store the Instant 20s Indicators and Indicator Solution at 15°C - 30°C. Failure to do so could damage the solution by exposing to elevated temperatures above 30°C and cause false-negative results.

Common Steps: Instant 20s Indicators may be utilized to monitor steam sterilization processes efficacy at stated values of 121°C for 30 minutes (Gravity Cycle), 132°C for 4 minutes (Pre-Vacuum), and 135°C for 3 minutes (Pre-Vacuum). The Instant 20s Indicators are ideal for monitoring non-liquid steam sterilization cycles within full, partial, or empty chambers. The Instant 20s Indicators can be exposed with mixed loads (porous and non-porous), porous only loads or non-porous only loads.

Exposure: The Instant 20s Indicator may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or the Instant 20s 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 exposure, remove Instant 20s Indicator and/or product from sterilizer. Instant 20s Indicators may be held at room temperature for up to 72 hours' post-exposure prior to activation without any impact to their performance of providing the efficacy of a sterilization cycle. If the processed Instant 20s Indicators are not activated within 72 hours of exposure, the Instant 20s Indicator should be discarded and the cycle should be repeated.

Result: Efficacy of the cycle can be determined in 20 seconds or less using the Biological Tablet and Indicator Solution which will determine the viability of enzymes derived from *Geobacillus stearothermophilus* post-sterilization.

Slowly remove the red base from the clear vial to access the Biological Tablet. The Biological Tablet is inside the red base on top of the foam plug insert.

Allow the Tablet to remain in the base or transfer to a plastic cup for easier viewing of the Tablet and add 1-3 drops of Indicator Solution onto the Tablet.

After 20 seconds, record the color of the Tablet and then discard immediately per the disposal instructions outlined on the Certificate of Analysis. Repeat process for one Instant 20s Indicator which has not been exposed as a Positive Control.

 Negative Result  Positive Result

Tablet Interpretation: Processed Instant 20s Indicator: If the Tablet remains the initial off-white/yellow color for 20 seconds, the cycle was effective. This indicates a **Negative** result meaning all enzymes from *Geobacillus stearothermophilus* have been deactivated within the Instant 20s Indicator.

If the Tablet turns a red color any time during or at 20 seconds, the cycle was not effective. This indicates a **Positive** result, meaning enzymes from *Geobacillus stearothermophilus* are still active within the Instant 20s Indicator. The cycle must be investigated, and the load must be exposed again using an additional Instant 20s Indicator.

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 20s 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 Tablet result to be visually determined within 20 seconds of adding the Indicator Solution to the Tablet.

Do NOT view the color of the tablet after 20 seconds of adding the Indicator Solution. A secondary reaction may occur which is unrelated to the Biological Tablet enzyme's viability. If more than 20 seconds has passed and the result was not visually determined, the test is invalid. Discard the Tablet and conduct another Positive Control test again.

Storage: Store in original box at room temperature conditions: 15-30°C, 20-80% relative humidity.