

3M™ Attest™ Rapid Readout Biological Indicator 1292E

Product Description

The 3M™ Attest™ Rapid Readout Biological Indicator 1292E (brown cap) is designed for the rapid, reliable monitoring of steam sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 290 or the 3M™ Attest™ Auto-reader 390. The Attest™ rapid readout biological indicator detects the activity of a naturally occurring *Geobacillus stearothermophilus* enzyme, alpha-glucosidase, which is one of the enzymes involved in spore outgrowth and normal vegetative cell function. The auto-reader detects the activity of a *Geobacillus stearothermophilus* enzyme by reading a fluorescent product produced by the enzymatic breakdown of a substrate contained in the media. Detection of the *Geobacillus stearothermophilus* enzyme indicates a sterilization process failure.

The final readout of a negative indicator result is made after 3 hours of incubation.

Monitoring Frequency

To improve the performance of the sterilization process, an Attest™ rapid readout biological indicator should be placed in an appropriate test tray or package and be used to monitor every load.

Indications

Use 3M™ Attest™ 1292E rapid readout biological indicators to monitor:

1. 121° - 134°C vacuum assisted steam sterilization cycles.
2. 121° - 123°C gravity steam sterilization cycles.

Contraindications

None.

WARNING

There is a glass ampoule inside the plastic vial of the biological indicator.

- Crushing or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.
- Wear safety glasses and gloves when removing the biological indicator from the sterilizer.
- Wear safety glasses when crushing the biological indicator.
- Handle the biological indicator by the cap when crushing and tapping.
- Do not use your fingers to crush the glass ampoule.
- Do not roll the biological indicator between fingers to wet the spore strip.

Precautions

Do not use the 3M™ Attest™ 1292E rapid readout biological indicators to monitor:

1. 132° - 135°C gravity steam sterilization cycles.
2. Dry heat, chemical vapor, ethylene oxide, or other low temperature sterilization processes.

Directions for Use

1. Identify the Attest™ rapid readout biological indicator by writing the sterilizer and load number, and processing date on the indicator label. Do not place another label or indicator tape on the Attest™ indicator vial or on the cap.
2. Place an Attest™ rapid readout biological indicator in an appropriate test package or tray according to recommended practices. Avoid placing the vial in direct contact with a chemical indicator which could transfer fluorescent residue to the biological indicator.
3. Place the test package or tray in a full load in the most challenging area for the sterilant which has been identified by prior testing. This is generally on the bottom shelf, near the door and over the drain.
4. Process the load as usual.
5. After completion of the cycle and while wearing safety glasses and gloves, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest™ biological indicator.

Note WARNING above

6. When the biological indicator is not contained in a test pack or any other heat absorbing packaging material, remove the biological indicator from the sterilizer and allow it to cool for an additional 10 minutes prior to crushing.
7. When the biological indicator is contained in a test pack or other heat absorbing packaging material, the test pack or any other heat absorbing packaging material should be removed from the sterilizer and opened up for 5 minutes to dissipate heat prior to removing the biological indicator. Then allow the biological indicator to cool outside the test pack for an additional 10 minutes prior to crushing.
8. Check the chemical indicator on the label of the biological indicator. A color change from rose to brown/black confirms that the biological indicator has been exposed to the steam sterilization process. This color change does not indicate that the process was sufficient to achieve sterility. If the chemical indicator is unchanged, check the sterilization process.
9. While wearing safety glasses, press cap down. Crush the glass ampoule of the biological indicator in the crusher well of the auto-reader. Hold the biological indicator by the cap and tap on a hard surface until media wets strip at bottom of the vial. Then incubate the biological indicator in an auto-reader incubation well configured to incubate brown cap Attest™ Rapid Readout Biological Indicators. See Attest™ Auto-reader Operator's Manual for further details.
10. Crush, tap and incubate at least one non-sterilized Attest™ rapid readout biological indicator (positive control) each day a sterilized indicator is incubated. Write a "C" and a date on the label. The positive control should be from the same lot number as the sterilized indicator.
11. Incubate the positive control and sterilized indicator for 3 hours at 60 ± 2°C in a 3M™ Attest™ 290 Auto-reader or a 3M™ Attest™ Auto-reader 390. See the applicable auto-reader Operator's Manual for the proper use of this equipment. The auto-readers automatically take readings and indicate a positive result as soon it is obtained. The final negative biological indicator reading is made at 3 hours. Discard processed indicator.

It is good practice to incubate a positive control for a visual color change. This helps ensure:

- correct incubation temperatures are met,
- viability of spores have not been altered due to improper storage temperature, humidity or proximity to chemicals,
- capability of media to promote rapid growth, and
- proper functioning of auto-reader components.

Interpretation of Results:

The positive (unprocessed) control biological indicator must provide a positive result [red light on the 3M™ Attest™ 290 Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390]. If the positive biological indicator control reads negative [green light on the 3M™ Attest™ 290 Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390], refer to the applicable auto-reader Operator’s Manual Troubleshooting section. Retest the auto-reader with a new positive control biological indicator. The processed biological indicator results are not valid until the positive biological indicator control reads positive.

With a processed biological indicator, a positive [red light on the 3M™ Attest™ 290 Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390] means a sterilization process failure has occurred. A negative [green light on the 3M™ Attest™ 290 Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390] after 3 hours of incubation indicates an acceptable sterilization process.

12. Immediately act on any positive biological indicator results. Always retest the sterilizer and do not use sterilizer for processing loads until the biological indicator results are negative.

Disposal

Dispose of used Attest™ rapid readout biological indicators according to your healthcare facility’s policy. You may wish to sterilize any positive biological indicators prior to disposal.

Storage

- Best stored in the original box under normal room conditions: 15-30°C (59-86°F) and 35-60% relative humidity.
- Do not store these biological indicators near sterilants or other chemicals.

Validation of Reduced Incubation Times /Confirmation of Readout Reliability:

A 7-day readout is optional and not intended to be routinely performed. The 7-day results may be used to initially validate the 3-hour readings. A humidified incubator will be required to avoid media dry out before 7 days. Indicators are examined daily for detection of a visual color change. The 3-hour fluorescent results are compared to the 7-day visual readings to determine the readout reliability of the indicator. Readout reliability of the Attest™ 1292E rapid readout biological indicator is determined using the sensitivity calculation under the following table.








**Attest™ 1292E Rapid Readout Biological Indicators
121°C Gravity Displacement, 121°C and 134°C Vacuum Assisted
Steam Sterilization Processes
Validation of Reduced Incubation Time - Readout Reliability Summary**

Sterilization Process	Incubation Temperature	# Tested	# Growth Positives at 168 hours	Fluorescence	
				# False Negatives at 3 hours	Sensitivity at 3 hours
121°C Gravity Displacement	60°C	1600	488	0	100%
121°C Vacuum Assisted	60°C	1737	531	0	100%
134°C Vacuum Assisted	60°C	2740	442	0	100%

$$\text{Sensitivity} = \frac{(\text{Number of Growth Positives after 168 hours}) - (\text{Number of False Negatives})}{\text{Number of Growth Positives after 168 Hours}} \times 100$$

The table shows that all the 7 day (i.e., 168 hours) growth visual positives were detected by fluorescence within 3 hours of incubation. This means no false negative indicators were detected after 3 hours of incubation. This also means that if there is no fluorescence at 3 hours, no growth positives will be detected if incubation continues. Based on the claimed ≥ 97% readout reliability of the 3-hour biological indicator results, there is no advantage to incubating the Attest™ 1292E rapid readout biological indicator beyond 3 hours.

Explanation of Symbols

-  Catalogue Number
-  Caution, see instructions for use
-  Do not reuse
-  Use by date
-  Batch code
-  Manufacturer
-  Date of manufacture

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