3M™ Attest™ 1291 Rapid Readout Biological Indicator

Product Description

The 3M™ Attest™ 1291 Rapid Readout Biological Indicator (blue cap) is a dual readout biological indicator system specifically designed for rapid and reliable monitoring of the 270°F (132°C), gravity steam sterilization process when used in conjunction with either the 3M™ Attest™ 290 Auto-reader or the 3M™ Attest™ Auto-reader 390. The sterilizer must have a 1.5 minute come-up time to kill the 3M™ Attest™ 1291 Rapid Readout Biological Indicator in 3 minutes. If the come-up time is < 1.5 minutes, extend the cycle time to 4 minutes to achieve consistent kill.

The 3M™ Attest™ 1291 Rapid Readout Biological Indicator detects the presence of *Geobacillus stearothermophilus* by detecting the activity of alpha-glucosidase, an enzyme present within the organism. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. This creates a fluorescence change, which is detected by the auto-reader. A fluorescence change indicates a steam sterilization process failure.

The 3M™ Attest™ 1291 Rapid Readout Biological Indicator also detects the presence of *G. stearothermophilus* organisms by a visual color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces acid by-products that cause the media to change color from purple to yellow. A visual pH color change also indicates a steam sterilization process failure. Due to the high sensitivity of the 1-hour fluorescent results, however, there is no advantage to incubating the Attest™ 1291 Rapid Readout Biological Indicator beyond 1 hour.

Indications for Use

Use the 3M™ Attest™ 1291 Rapid Readout Biological Indicator to monitor 132°C (270°F) gravity steam sterilization cycles.

Contraindications

None.

Warnings

There is a glass ampoule inside the plastic vial of the biological indicator. To avoid the risk of serious injury from flying debris due to a ruptured biological indicator:

- Allow the biological indicator to cool for the recommended time period before crushing. Crushing or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.
- Wear safety glasses and heat-resistant 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™ 1291 Rapid Readout Biological Indicator to monitor sterilization cycles which it is not designed to challenge:

1. 132°C (270°F) or 121°C (250°F) vacuum-assisted steam sterilization cycles.
2. 121°C (250°F) gravity steam sterilization cycles.
3. Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.

Monitoring Frequency

Follow facility Policies and Procedures which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and standards. As a best practice and to provide optimal patient safety, 3M recommends that every steam sterilization load be monitored with an appropriate biological indicator.

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 vial or on the cap.
2. Place the Attest™ rapid readout biological indicator in an appropriate process challenge device according to recommended practices. Do not place the Attest™ rapid readout biological indicator in direct contact with a chemical indicator. Fluorescent residue could transfer to the rapid readout biological indicator and affect the result.Appropriate process challenge devices for specific loads containing:
   A. Unwrapped metal instruments or hard goods run at 132°C (270°F) for ≥3 minutes in a gravity displacement cycle:
      - Place an Attest™ rapid readout biological indicator in an unwrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray.

   B. Unwrapped metal instruments or hard goods with porous items run at 132°C (270°F) for ≥10 minutes in a gravity displacement cycle:
      - Place an Attest™ rapid readout biological indicator in an unwrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray but include porous items if applicable.

   C. Wrapped metal instruments or hard goods run at 132°C (270°F) for ≥10 minutes in a gravity displacement cycle:
      - Place an Attest™ rapid readout biological indicator in a wrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray, include porous items if applicable.

   D. Container systems run at 132°C (270°F) in a gravity displacement cycle:
      - Place an Attest™ rapid readout biological indicator in the area determined by product testing to provide the greatest challenge to the sterilization process.

   E. Patient Care trays run at 132°C (270°F) for ≥ 3 minutes a gravity displacement cycle:
      - Place an Attest™ rapid readout biological indicator in a tray or container of medical devices that is going directly to patient use to ensure that the medical devices are properly sterilized. Follow aseptic techniques when retrieving the Attest™ rapid readout biological indicator from the tray or container for incubation.
3. Place the process challenge device in the most challenging area for the sterilant. This is typically on the bottom shelf, near the door and over the drain.
4. Process the load according to recommended practices.
5. After completion of the cycle, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest™ rapid readout biological indicator.
6. When the Attest™ rapid readout biological indicator is not contained in a test pack or other heat absorbing packaging material, remove the Attest™ rapid readout biological indicator from the sterilizer and allow to cool for an additional 10 minutes prior to crushing.
7. When the Attest™ rapid readout 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 throughput chemical indicator (CI) on the label of the Attest™ rapid readout biological indicator. A color change from rose to brown/black confirms that the biological indicator has been exposed to the steam sterilization process. This CI color change does not indicate that the sterilization process was sufficient to achieve sterility. If the chemical indicator is unchanged, check the sterilization process monitoring controls and investigate placement of the biological indicator in the sterilizer.
9. While wearing safety glasses, press the 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, and then place the biological indicator in an auto-reader incubation well configured to incubate Attest™ 1291 Rapid Readout Biological Indicators. See Attest™ Auto-reader Operator's Manual for further details.
10. Each day that a processed Attest™ 1291 Rapid Readout Biological Indicator is incubated, crush, tap and incubate at least one non-processed Attest™ 1291 Rapid Readout Biological Indicator to use as a positive control. Write a "C" (for "control") and the date on the label. The positive control should be from the same manufacturing date and lot number as the processed biological indicator. Incubating a positive control 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 Attest™ Auto-reader.

11.Incubation and Reading:

Incubate the positive control and processed Attest™ 1291 Rapid Readout Biological Indicators for 1 hour at 60 ± 2°C (140 ± 3°F) 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 may indicate a positive result in less than 1 hour. The final fluorescent negative biological indicator reading is made at 1 hour. After the final reading is obtained the processed biological indicator may be discarded.

The processed biological indicator and the positive control may also be further incubated at 60°C for a visual pH color change result. Examine the biological indicator for early detection of positive results (i.e., media turns yellow) at convenient time intervals such as 6, 12 and 18 hours. The final negative reading (media remains purple) for a visual pH color change is made at 24 hours. The positive control should show a yellow color change of the growth media within 24 hours.

Interpretation of Results:

Fluorescent Result

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 1 hour of incubation indicates an acceptable sterilization process.

pH Color Change Result (Optional)

The appearance of a yellow color in the processed indicator demonstrates bacterial growth and a sterilization process failure. No color change (i.e. media remains purple) indicates an adequate sterilization process. A final negative result is made after 24 hours of incubation. The positive control indicator should show a color change from purple to yellow for the processed indicator results to be valid.

12. Immediately act on any positive biological indicator results. Always retest the sterilizer and do not use sterilizer for processing loads until three consecutive 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 at 132°C/270°F for 10 minutes in a gravity- displacement steam sterilizer prior to disposal.

Storage

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

Validation of Reduced Incubation Time (Readout Reliability Data)

The 1-hour and 24-hour incubation times have been correlated with a 7-day incubation period. Sterilized indicators were examined daily for detection of a visual pH color change. The 1-hour fluorescence change reading and the 24-hour visual pH color change readings were compared to the 7-day visual pH color change readings to determine the readout reliability of the indicator. Readout reliability of the Attest™ 1291 rapid readout biological indicator was determined using the sensitivity calculation described below:

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

Attest™ 1291 Rapid Readout Biological Indicators
132°C (270°F) Gravity Displacement Steam Sterilization Process
Validation of Reduced Incubation Time - Readout Reliability Summary

Sterilization Process	Incubation Temperature	# Tested	# Growth Positives at 168 hours	Growth		Fluorescence	
				# False Negatives at 24 hours	Sensitivity at 24 hours	# False Negatives at 60 minutes	Sensitivity at 60 minutes
132°C (270°F) Gravity Displacement	60°C (140°F)	880	533	13	97.6%	0	100%

These data demonstrate that ≥ 97% of the 7-day (i.e. 168 hours) growth visual positives were detected by fluorescence within 1 hour of incubation and by the visual pH color within 24 hours of incubation. The 3M™ Attest™ 1291 Rapid Readout Biological Indicator therefore meets readout reliability of ≥97% for the 1-hour fluorescence results and the 24-hour visual color change results.

Explanation of Symbols

REF Catalogue Number

 Caution, see instructions for use

 Do not reuse

 Use by date

LOT Batch code

 Manufacturer

 Date of manufacture

Made in U.S.A. by
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957
3M.com/infectionprevention

Issue Date: 2016-02
34-8719-0529-4