

# 3M™ Attest™ 1294 Rapid Readout Biological Indicator

## Product Description

The 3M™ Attest™ 1294 Rapid Readout Biological Indicator (green cap) is specifically designed for the rapid, reliable monitoring of ethylene oxide (EO) sterilization processes when used in conjunction with either the 3M™ Attest™ 290G Auto-reader or the 3M™ Attest™ Auto-reader 390G. The Attest™ rapid readout biological indicator detects the activity of a naturally occurring *Bacillus atrophaeus* enzyme, beta-glucosidase, which is one of the enzymes involved in spore outgrowth and normal vegetative cell function. The Auto-reader detects the activity of a *B. atrophaeus* enzyme by reading a fluorescent product produced by the enzymatic breakdown of a substrate in the media. Detection of the enzyme indicates a sterilization process failure. The final fluorescent readout of a negative indicator result is made after 4 hours of incubation. The 4-hour fluorescent readout has been validated and is routinely verified at standard ethylene oxide test conditions (54°C ± 1°C, 600 ± 30 mg/l ethylene oxide, and 60% ± 10% relative humidity).

## Considerations for Use

Low sterilizer chamber relative humidity may increase the fluorescent readout time beyond 4 hours. If sterilizer chamber relative humidity is less than 35% at the time of gas injection, or if your sterilizer does not monitor relative humidity, continue to incubate the BI for a pH color change result. Any positive result (fluorescent or pH color change) indicates a sterilization process failure.

## 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 ethylene oxide sterilization load be monitored with a biological indicator.

## Indications

Use 3M™ Attest™ 1294 rapid readout biological indicators to monitor ethylene oxide sterilization cycles only.

## Contraindications

None.

## WARNINGS:

- Butyl, neoprene, or nitrile gloves should be worn when removing the biological indicator from the load prior to the completion of aeration.
- 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™ 1294 rapid readout biological indicators to monitor:

1. Steam sterilization cycles.
2. Dry heat, chemical vapor, or other low temperature sterilization processes.

## Directions for Use

1. Identify the Attest™ rapid readout biological indicator by writing the sterilizer number, load number, and processing date on the indicator label. Do not place another label or indicator tape on the biological 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 biological indicator in direct contact with a chemical indicator which could transfer fluorescent residue to the biological indicator. Appropriate test packages or trays for loads containing:

### Wrapped telescopic instruments, plastic, rubber, metal instruments, and equipment

- Attest™ 1294 rapid readout biological indicator in an AAMI routine test pack\*.
  - \*AAMI Routine Test Pack
    - Place one Attest™ rapid readout biological indicator into the barrel of a plastic syringe with the cap of the biological indicator facing the syringe tip and the bottom facing the plunger.
    - Remove the tip guard of the syringe.
    - Place the syringe between the folds of one cotton surgical towel.
    - Place a chemical indicator beside the syringe.
    - Place the surgical towel in one peel pouch or wrapper.

### Container systems

- Attest™ 1294 rapid readout biological indicator in the area(s) determined by product testing to be the most resistant.
3. Place the test package or tray in a full load in the most challenging area for the sterilant. This is generally in the center of the load.
  4. Process the load as usual.
  5. After sterilization, two options exist:
    - A. Aeration of Test Pack Prior to BI Incubation:

Aerate the BI test pack for the same amount of time as the other packs from the load. At the end of the aeration cycle, remove the biological and chemical indicators from the test pack. Dispose of the remaining test pack components according to the healthcare facility's policy.
    - B. Removal of Biological Indicator from Test Pack Prior to Aeration:

Open the sterilizer door according to the manufacturer's instructions: transfer the load to the aerator and retrieve the test pack. (If a sterilizer with aeration capability is used, follow the manufacturer's instructions for opening the door and remove the test pack prior to the aeration cycle.) Remove the biological and chemical indicators from the test pack. Return the remainder of the test pack to the load for aeration according to the health care facility's policies. When it is necessary to handle items that are not fully aerated, butyl, neoprene, or nitrile gloves should be worn. The breathing zone of personnel should be monitored to verify the safety of the practices followed.
  6. Check the chemical indicator on the label of the biological indicator. A color change to green confirms that the biological indicator has been exposed to the EO 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.
  7. 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, and then place the biological indicator in an auto-reader incubation well. See Attest™ Auto-reader Operator's Manual for further details.

8. 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. Incubating a positive control helps ensure:
  - correct incubation temperatures are met;
  - viability of spores has 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.
9. Incubate the positive control and processed indicator for 4 hours at 37 ± 2°C (99 ± 3°F) and read the results in the 3M™ Attest™ 290G Auto-reader or 3M™ Attest™ Auto-reader 390G. See the 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 4 hours. The final fluorescent negative biological indicator reading is made at 4 hours. If sterilizer chamber relative humidity is ≥ 35%, record the final reading and discard the processed indicator. If sterilizer chamber relative humidity is unknown or < 35%, continue to incubate the biological indicator for a pH color change result as low relative humidity may increase the fluorescent readout time beyond 4 hours. A humidified incubator will be required to avoid media dry out.

**Interpretation of Results:**

Fluorescent Results

The positive biological indicator control must provide a positive result [red light on the 3M™ Attest™ 290G Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390G]. If the positive biological indicator control reads negative [green light on the 3M™ Attest™ 290G Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390G], refer to the applicable 3M™ Attest™ Auto-reader Operator’s Manual Troubleshooting section. Retest the auto-reader with a new positive biological indicator control. The sterilized 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™ 290G Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390G] means a sterilization process failure has occurred. A negative [green light on the 3M™ Attest™ 290G Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390G] after 4 hours of incubation and chamber relative humidity ≥ 35% indicate an acceptable sterilization process.

pH Color Change Results

The appearance of a yellow color in the processed indicator demonstrates bacterial growth and a sterilization process failure. No color change indicates an adequate sterilization process. A final negative result is made after 7 days of incubation. The positive control indicator should show a color change from blue-green to yellow for the processed indicator results to be valid.

10. 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).
- Do not store these biological indicators near sterilants or other chemicals.

**Validation of Reduced Incubation Time (Readout Reliability Data)**

The 7-day results may be used to validate the 4-hour readings or in cases of unknown or low (<35%) chamber relative humidity. 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. After exposure to standard EO test conditions, the 4-hour fluorescent results are compared to the 7-day visual readings to determine the readout reliability of the indicator. Readout reliability of the Attest™ 1294 rapid readout biological indicator is determined using the sensitivity calculation in the following table.

**Attest™ 1294 Rapid Readout Biological Indicators**  
**600 mg EO/l (100% EO), 54°C, 60% RH**  
**Validation of Reduced Incubation Time (Readout Reliability Summary)**

Sterilization Process	Incubation Temperature	Growth		Fluorescence	
		# Tested	# Growth Positives 168 hours	# False Negatives 4 hours	Sensitivity
54°C	37°C (99°F)	600	307	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 4 hours of incubation. This means no false negative indicators were detected after 4 hours of incubation. Based on the claimed ≥ 97% readout reliability of the 4-hour biological indicator results, there is no advantage to incubating the Attest™ 1294 rapid readout biological indicator beyond 4 hours when sterilizer chamber relative humidity is greater than or equal to 35%.

**Explanation of Symbols**

 Catalogue Number

 Caution, see instructions for use

 Do not reuse

 Use by date

 Batch code

 Manufacturer

 Date of manufacture

Made in U.S.A. by

 **3M Health Care**

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1-800-228-3957

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