

3M™ Attest™ Super Rapid Readout Biological Indicator 1491

Product Description

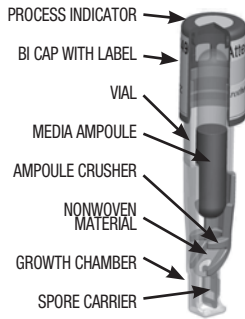


Figure 1: 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 Design

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 (blue cap, referred to hereinafter as the 1491 BI) is a self-contained biological indicator specifically designed for rapid and reliable qualification testing and routine monitoring of 270°F (132°C) and 275°F (135°C) gravity-displacement steam sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490 (hereinafter referred to as the 490 Auto-reader).

A schematic illustrating the design of the 1491 BI is provided in Figure 1. The self-contained design includes a spore carrier with spores of *Geobacillus stearothermophilus* (formerly known as *Bacillus stearothermophilus*) and a media ampoule containing bacteriological media which meets the requirements for growth promoting ability. The spore carrier and media ampoule are contained in a plastic vial topped with a blue cap. A chemical process indicator which changes from pink to light brown or darker upon exposure to steam is located on the top of the cap.

The 1491 BI utilizes the α -glucosidase enzyme system, which is generated naturally within growing cells of *Geobacillus stearothermophilus*. The α -glucosidase in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate, 4-methylumbelliferyl α -D-glucoside (MUG). The resultant fluorescent by-product, 4-methylumbelliferone (MU) is detected in the 490 Auto-reader. The presence of fluorescence within 30 minutes of incubation of the 1491 BI in the 490 Auto-reader indicates a steam sterilization process failure.

The 1491 BI can also indicate the presence of *G. stearothermophilus* organisms by a visual pH color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces metabolic by-products that cause the media to change color from purple to yellow which would also indicate a steam sterilization process failure. Use of this indication method is optional and is typically restricted to special studies.

Readout Times

The 30-minute super rapid readout and the optional 24-hour visual pH color change incubation times have been correlated with a 7-day incubation period (at 56±2°C) following the FDA's Reduced Incubation Time protocol. Sterilized indicators were examined at 24 hours, 48 hours, and 7 days for detection of a visual pH color change. The 30-minute fluorescence change readings and the 24-hour visual pH color change readings were compared to the 7-day visual pH color change readings to determine the readout time of the indicator.

30-minute Fluorescence Change Result

1491 BIs have 30-minute reduced incubation time results that correlate to the 7-day (168 hours) visual readout result \geq 97% of the time.

24-hour Visual pH Color Change Result

1491 BIs have 24-hour reduced incubation time results that correlate to the 7-day (168 hours) visual readout result \geq 97% of the time.

Due to the high reliability of the 30-minute fluorescent result there is no advantage to incubating 1491 BIs beyond 30 minutes.

1491 BIs meet ANSI/AAMI/ISO 11138-1:2006/(R)2010, ANSI/AAMI/ISO 11138-3:2006/(R)2010 and EN/ISO 11138-1:2006, EN/ISO 11138-3:2006.

Indications for Use

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ Auto-reader 490 to monitor the cycles below.

Sterilization Type	Temperature	Time
Gravity Displacement Immediate-Use Steam Sterilization Cycle (Flash)	270°F (132°C)	3 minutes
	270°F (132°C)	10 minutes
	275°F (135°C)	3 minutes
	275°F (135°C)	10 minutes

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 provides a final fluorescent result in 30 minutes. An optional visual pH color change result is observed in 24 hours.

Contraindications

None

Warnings

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

- Allow the BI to cool for the recommended time period before activating. Activating or excessive handling of the BI before cooling may cause the glass ampoule to burst.
- Wear safety glasses and gloves when removing the BI from the sterilizer.
- Wear safety glasses when activating the BI.
- Handle the BI by the cap when crushing or flicking.
- Do not use your fingers to crush the glass ampoule.

Precautions

1. DO NOT use the 1491 BI to monitor sterilization cycles which it is not designed to challenge:
 - a. 275°F (135°C), 270°F (132°C) and/or 250°F (121°C) dynamic-air-removal (prevacuum) steam sterilization cycles.
 - b. 250°F (121°C) gravity-displacement steam sterilization cycles.

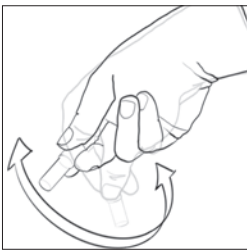
- c. Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.
2. The sterilizer must have a 1.5 minute come-up time to kill the 1491 BI in 3 minutes. If the come-up time is < 1.5 minutes, extend the cycle exposure time to 4 minutes to achieve consistent kill.
3. After activation, ensure media has flowed to the spore growth chamber.

Monitoring Frequency:

Follow facility Policies and Procedures which should specify a BI 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 BI.

Directions for Use

1. Identify the 1491 BI by writing the sterilizer, 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 1491 BI in a representative tray configuration as recommended by professional association guidelines or national standards for healthcare facility practice. Do not place the 1491 BI in direct contact with a chemical indicator as residue could transfer to the biological indicator and affect the result.
3. Place the representative tray in the most challenging area of the sterilizer. This is typically on the bottom shelf, over the drain, however, the sterilizer manufacturer should be consulted to identify the area of the chamber least favorable to sterilization.
4. Process the load according to recommended practices.
5. After completion of the cycle, take the representative tray out of the sterilizer, and remove the 1491 BI.
6. Allow the 1491 BI to cool for 10 minutes prior to activation.
7. Check the process indicator on the top of the cap of the 1491 BI. A color change from pink to light brown or darker confirms that the 1491 BI has been exposed to the steam process. This color change does not indicate that the steam process was sufficient to achieve sterility. If the process indicator is unchanged, check the sterilizer physical monitors.



8. To activate the biological indicator, place it in a 490 Auto-reader incubation well which is color-coded blue (i.e. configured to incubate 1491 BIs). Press the cap of the BI down firmly to close the cap and crush the glass ampoule. Immediately remove the BI and flick it (see picture at right). Visually verify the media has flowed into the growth chamber at the bottom of the vial. If the media hasn't filled the growth chamber, hold the BI by the cap and flick it until media fills the growth chamber. Return the activated 1491 BI to the incubation well and wait for the result. See the 490 Auto-reader Operator's Manual for further information related to its use.
9. Each day that a processed 1491 BI is incubated, activate and incubate at least one non-processed 1491 BI to use as a positive control. Follow the activation instructions provided in Step 8 above. Write a "C" (for "control") and the date on the BI label. The positive control should be from the same lot code as the processed biological indicator. It is a good practice to use a positive control each day a processed 1491 BI is incubated. This helps confirm:
 - 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 the 490 Auto-reader.
10. Incubation and Reading:
Incubate the positive control and steam processed 1491 BIs at $56 \pm 2^\circ\text{C}$ in a 490 Auto-reader. See the 490 Auto-reader Operator's Manual for the proper use of this equipment. Positive results are available within 30 minutes. The 490 Auto-reader will indicate a positive result as soon as it is obtained. The final negative 1491 BI reading is made at 30 minutes. After the results are displayed and recorded, the 1491 BIs may be discarded.

Interpretation of Results:

Fluorescent Results

The positive control (unprocessed) 1491 BI must provide a positive fluorescent result (+ on the 490 Auto-reader LCD Display). Processed 1491 BI results are not valid until the positive control reads fluorescent positive. The positive control should read positive (+ on the LCD Display) at or before 30 minutes. If the positive control reads negative (- on the LCD Display) at 30 minutes, check the 490 Auto-reader Operator's Manual Troubleshooting Guide. Retest the 490 Auto-reader with a new positive control.

With processed 1491 BIs, a positive (+ on the LCD Display) result indicates a sterilization process failure. A final negative processed 1491 BI reading for a fluorescence change (- on the LCD Display) after 30 minutes of incubation indicates an acceptable sterilization process.

Act immediately on any positive BI results. Determine the cause of the positive BI following facility policies and procedures. Always retest the sterilizer and do not use sterilizer for processing loads until three consecutive BI results are negative.

Optional Visual pH Color Change Result

The 1491 BI is normally discarded after the fluorescent result has been recorded. If, however, special studies are desired, 1491 BIs may be further incubated for a visual pH color change result. After activation and during incubation, the white Nonwoven Material will absorb the bromocresol purple indicator, the pH-sensitive indicator dye in the growth media, and appear blue. In the case of the positive control BI a yellow color change of the growth media and/or Nonwoven Material will appear within 24 hours. Any observation of a yellow color within the vial indicates a positive result.

In the case of a processed 1491 BI, a media and/or Nonwoven Material color change from purple to yellow indicates a sterilization process failure. A negative pH color change result, i.e. media and Nonwoven Material remain purple/blue, can be assessed at 24 hours.

Storage

- Best stored in original box under normal room conditions: 59-86°F (15-30°C), 35-60% relative humidity (RH).
- Do not store 1491 BIs near sterilants or other chemicals.

Disposal

Dispose of used 1491 BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 121°C/250°F for at least 30 minutes, or at 132°C/270°F for 10 minutes in a gravity displacement steam sterilizer, or at 132°C/270°F for 4 minutes in a dynamic-air-removal steam sterilizer prior to disposal.

Explanation of Symbols

 Catalogue Number


 Caution, see instructions for use

 Do not reuse

 Use by date

 Batch code

 Manufacturer

 Date of manufacture

 Product is designed for use with steam sterilization cycles.

Made in U.S.A. by

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