3M™ Attest™ Super Rapid Readout Biological Indicator 1492V

Product Description

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (brown cap, referred to hereinafter as the 1492V 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) dynamic-air-removal (pre-vacuum) steam sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490 (hereinafter referred to as the 490 Auto-reader). The 1492V BI is a single-use device.

A schematic illustrating the design of the 1492V BI is provided in Figure 1. The self-contained design includes a carrier with spores of *Geobacillus stearothermophilus* and a media ampoule containing bacteriological growth medium which meets the requirements for growth promoting ability specified in ANSI/AAMI/ISO 11138-1:2006/(R)2010. The spore carrier and media ampoule are contained in a plastic vial topped with a brown cap. A chemical process indicator which changes from pink to light brown upon exposure to steam is located on the top of the cap.

The 1492V 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 1 hour of incubation of the 1492V BI in the 490 Auto-reader indicates a steam sterilization process failure.

The 1492V 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 also indicates a steam sterilization process failure. Use of this indication method is optional and is typically restricted to special studies.

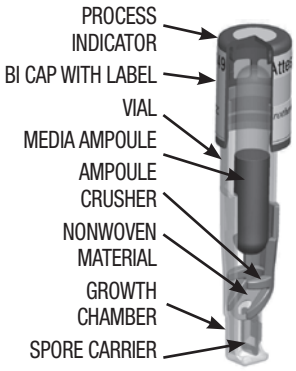

Figure 1: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V Design

Readout Times

The 1-hour super rapid readout and the optional 48-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. Processed indicators were examined at 48 hours and 7 days for detection of a visual pH color change. The 1-hour fluorescence change readings and the 48-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.

1-hour Fluorescence Change Result

1492V BIs have 1-hour reduced incubation time results that correlate to the 7-day (168 hours) visual readout result ≥ 97% of the time.

48-hour Visual pH Color Change Result

1492V BIs have 48-hour reduced incubation time results that correlate to the 7-day (168 hours) visual readout result ≥ 97% of the time.

Due to the high reliability of the 1-hour fluorescent result there is no advantage to incubating 1492V BIs beyond 1 hour.

1492V 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

United States

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

Outside the United States

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor 270°F (132°C) to 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles.

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 1492V BI to monitor sterilization cycles which it is not designed to challenge:
   a. Gravity-displacement steam sterilization cycles;
   b. 250°F (121°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles;
   c. Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.
2. After BI activation, ensure media has flowed to the spore growth chamber.
3. Do not place tape or labels on 1492V BI prior to sterilization or incubation in the 490 Auto-reader.

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 a biological indicator in an appropriate Process Challenge Device (PCD i.e., BI challenge test pack).

Directions for Use

1. Identify the 1492V BI by writing the load number, sterilizer, 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 1492V BI in a representative tray configuration or Process Challenge Device (PCD) as recommended by professional association guidelines or national standards for healthcare facility practice. Do not place the 1492V BI in direct contact with a chemical indicator as residue could transfer to the biological indicator and affect the result.
3. Place the PCD 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 PCD out of the sterilizer, and remove the 1492V BI.
6. Allow the 1492V BI to cool for 10 minutes prior to activation.
7. Check the process indicator on the top of the cap of the 1492V BI. A color change from pink to light brown confirms that the 1492V 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 brown (i.e., configured to incubate 1492V 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 that 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 1492V 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 1492V BI is incubated, activate and incubate at least one non-processed 1492V 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. The positive control BI 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 1492V BIs at 56 ± 2°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 1 hour. The 490 Auto-reader will indicate a positive result as soon as it is obtained. The final negative 1492V BI reading is made at 1 hour. After the results are displayed and recorded, the 1492V BIs may be discarded.

Interpretation of Results

Fluorescent Results

The positive control (unprocessed) 1492V BI must provide a positive fluorescent result (+ on the 490 Auto-reader LCD display). Processed 1492V 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 1 hour. If the positive control reads negative (- on the LCD display) at 1 hour, check the 490 Auto-reader Operator's Manual Troubleshooting Guide. Retest the 490 Auto-reader with a new positive control.

With processed 1492V BIs, a positive (+ on the LCD display) result indicates a sterilization process failure. A final negative processed 1492V BI reading (- on the LCD display) after 1 hour of incubation indicates an acceptable sterilization process.

Act immediately on any positive results for processed BIs. 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 1492V BI is normally discarded after the fluorescent result has been recorded. If, however, special studies are desired, 1492V 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 48 hours. Any observation of a yellow color within the vial indicates a positive result.

In the case of a processed 1492V 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 48 hours.

Storage/ Shelf Life

- Store 1492V BIs under normal room conditions: 59-86ºF (15-30ºC), 35-60% relative humidity (RH).
- Do not store 1492V BIs near sterilants or other chemicals.
- 1492V BIs have a shelf life of 21 months. The expiration date is indicated on the BI and packaging by an hourglass symbol followed by the year and month of expiration (e.g. year and month: 2014-11).

Disposal

Dispose of used 1492V BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 132°C (270°F) for 4 minutes or at 275°F (135°C) for 3 minutes in a dynamic-air-removal steam sterilizer prior to disposal.

Explanation of Symbols

Caution, see instructions for use

Do not reuse

Use by date

LOT Batch code

Manufacturer

EC REP Authorized representative for the European Community – This symbol is accompanied by the name and the address of the authorized representative in the European Community.

CE Mark of Conformity to European Directives. For France Only.

STEAM Product is designed for use with steam sterilization cycles.

REF Catalog Number – This symbol is accompanied by the catalog number relevant to the device bearing the symbol.

CE For France Only
Uniquement pour la France

Made in the U.S.A. by

3M Health Care

2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957
www.3M.com

EC REP **3M Deutschland GmbH**
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany

Issue Date: 2012-11
34-8710-4275-9