3M™ Attest™ Rapid Readout Biological Indicator 1295

Product Description

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 (pink cap, referred to hereinafter as the 1295 BI) is a self-contained biological indicator specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490H (hereinafter referred to as the 490H Auto-reader). The 1295 BI is a single-use device.

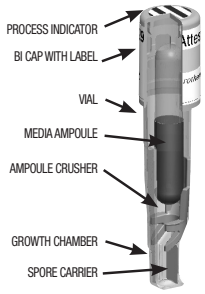


Figure 1: Design of the 3M™ Attest™ Rapid Readout Biological Indicator 1295

PROCESS INDICATOR

BI CAP WITH LABEL

VIAL

MEDIA AMPOULE

AMPOULE CRUSHER

GROWTH CHAMBER

SPORE CARRIER

A schematic illustrating the design of the 1295 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 pink cap. A chemical process indicator printed with stripes which change in color from blue towards pink upon exposure to vaporized hydrogen peroxide is located on the top of the cap.

The 1295 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 490H Auto-reader. The presence of fluorescence within the specified incubation time for the 1295 BI in the 490H Auto-reader indicates a sterilization process failure.

The 1295 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 sterilization process failure. Use of this indication method is optional and is typically restricted to special studies.

Readout Time

The rapid readout result has been correlated with a 7-day visual pH color change result following the FDA's Reduced Incubation Time protocol. The time to result is determined by the software version programmed on the 490H Auto-reader.

24-minute Fluorescent Result

1295 BIs incubated in a 490H Auto-reader having software version 4.0.0 or greater have a 24 minute reduced incubation time result that correlates to the 7 day (168 hours) visual readout result ≥ 97% of the time.

4-hour Fluorescent Result

1295 BIs incubated in a 490H Auto-reader having software versions less than 4.0.0 have a 4-hour reduced incubation time result that correlates to the 7 day (168 hours) visual readout result ≥ 97% of the time.

Due to the high reliability of the fluorescent result there is no advantage to incubating 1295 BIs after the fluorescent result has been determined by the 490H Auto-reader and recorded.

1295 BIs meet ANSI/AAMI/ISO 11138-1:2006/(R)2010 and EN/ISO 11138-1:2006.

Indications for Use

Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the following systems: AMSCO® V-PRO® 1 Low Temperature Sterilization System (Lumen cycle), AMSCO® V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization

System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles) systems, STERRAD® NX with AllClear™ Technology (Standard and Advanced cycles) and STERRAD® 100NX with AllClear™ Technology (Standard, Flex, Express and Duo 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 peroxide burns:

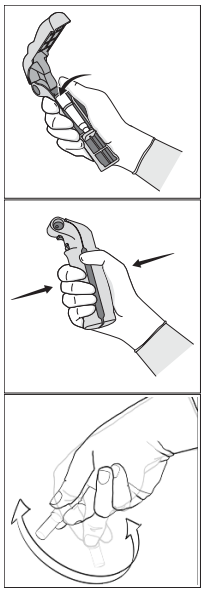
- Wear safety glasses and gloves when removing the 1295 BI from the sterilizer.
- Wear safety glasses and gloves when activating the 1295 BI.
- Handle the 1295 BI by the cap when crushing or flicking.

Residual hydrogen peroxide may be trapped within the 1295 BI if the media ampoule is damaged during the sterilization process. If a broken ampoule is observed after processing, avoid direct contact with the 1295 BI as it may result in hydrogen peroxide burns. Follow the disposal instructions provided at the end of this document.

Precautions
1. Do not use the 1295 BI to monitor sterilization cycles which it is not designed to challenge:
   a. Steam sterilization cycles;
   b. Dry heat sterilization cycles; or
   c. Ethylene oxide sterilization processes.
2. To reduce the risk associated with incorrect results:
   - Before sterilization, inspect 1295 BI to verify media ampoule is intact and process indicator stripes are blue. Do not use any 1295 BIs which have a broken media ampoule or process indicator stripes which are not blue.
   - Do not place tape or labels on 1295 BI prior to sterilization or incubation in the 490H Auto-reader.
   - Activate and incubate the 1295 BI within 1 hour after the completion of the sterilization cycle.
   - Do not incubate a 1295 BI if, after processing and before BI activation, it is observed to have a broken media ampoule. Retest the sterilizer with a new biological indicator.
   - After 1295 BI activation, ensure media has flowed to the spore growth chamber.
3. To ensure the product functions as intended throughout the labeled shelf life, store 1295 BIs in the resealable foil pouch until use.
4. The 1295 BI is not designed for use in STERRAD® test packs, including the STERRAD® 100NX® System DUO Test Pack.

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 sterilization load be monitored with a biological indicator.

Directions for Use
1. Remove 1295 BI from sealed foil pouch, then reseal foil pouch if other 1295 BIs remain in foil pouch. Do not place any labels or indicator tape on the vial or on the cap.
2. Place the 1295 BI in a sterilization pouch indicated for use in vaporized hydrogen peroxide sterilization processes. Seal the sterilization pouch.
3. Place the pouched BI in the most challenging area of the sterilizer, with the white side of the pouch facing up and the clear plastic side facing down. When there is adequate space in the loaded sterilizer chamber, place the pouched BI directly on the sterilizer chamber rack or shelf. 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, don safety glasses and gloves and remove the pouched BI from the sterilizer. Inspect the 1295 BI to verify the media ampoule is intact. If a chemical indicator was included in the pouch with 1295 BI, inspect the CI to assure the ink of the CI is not smeared or runny. If the BI media ampoule is intact and the ink of the CI (if included) appears typical remove the BI from the sterilization pouch and proceed to Step 6. If the media ampoule is broken or if the ink of the CI appears smeared or runny, leave them in the sterilization pouch and follow the disposal instructions. Retest the sterilizer using a new 1295 BI and CI (if included).
6. Check the process indicator on the top of the cap of the 1295 BI. A color change of the stripes from blue towards pink confirms that the 1295 BI has been exposed to the vaporized hydrogen peroxide sterilization process. This color change does not indicate that the process was sufficient to achieve sterility. If the process indicator is unchanged, check the sterilizer physical monitors.
7. Identify the 1295 BI by writing the load number, sterilizer, and processing date on the indicator label.



8. Activate the 1295 BI.

While wearing safety glasses and gloves, place the 1295 BI in an Attest™ Biological Indicator Activator. Close and squeeze the activator to close the 1295 BI cap and crush the media ampoule (see pictures at right). 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. Place the activated 1295 BI in a 490H Auto-reader incubation well which is color-coded pink and wait for the result. See the 490H Auto-reader Operator's Manual for further information related to its use.

NOTE:

Activate and incubate the 1295 BI within 1 hour of the completion of the sterilization cycle.

9. Each day that a processed 1295 BI is incubated, activate and incubate at least one non-processed 1295 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 490H Auto-reader.
10. Incubation and Reading:

    Incubate the positive control and processed 1295 BIs at 60 ± 2°C in a 490H Auto-reader. See the 490H Auto-reader Operator's Manual for the proper use of this equipment. The 490H Auto-reader will indicate a positive result as soon as it is obtained. The final negative 1295 BI reading is made at:
    - 24 minutes in 490H Auto-readers having software version 4.0.0 or greater
    - 4 hours in 490H Auto-readers having a software version less than 4.0.0.

    After the results are displayed and recorded, the 1295 BIs may be discarded.

Interpretation of Results

Fluorescent Result

The positive control (unprocessed) 1295 BI must provide a positive fluorescent result (+ symbol on the 490H Auto-reader LCD display). Processed 1295 BI results are not valid until the positive control reads fluorescent positive. If the positive control reads negative (- symbol on the LCD display), check the 490H Auto-reader Operator's Manual Troubleshooting Guide. Retest the 490H Auto-reader with a new positive control.

With processed 1295 BIs, a final negative reading (- symbol on the LCD display) indicates an acceptable sterilization process. A positive (+ symbol on the LCD display) result for a processed 1295 BI indicates a sterilization process failure. Act immediately on any positive results for processed BIs. Determine the cause of the positive BI following facility policies and procedures. 3M recommends retesting the sterilizer according to your facility policy before processing additional loads.

Optional Visual pH Color Change Result

The 1295 BI is normally discarded after the fluorescent result has been recorded. If, however, special studies are desired, 1295 BIs may be further incubated for a visual pH color change result. In the case of the positive control BI, a yellow color change of the growth media will appear within 24 hours. Any observation of a yellow color within the vial indicates a positive result.

In the case of a processed 1295 BI, a media color change from purple to yellow indicates a sterilization process failure. A negative pH color change result, i.e., media remains purple, can be assessed at 7 days. To avoid media dry-out, it is recommended that the 1295 BI be transferred to a humidified incubator operating at 60ºC after the fluorescent result has been recorded.

Storage

- Store 1295 BIs in the original resealable foil pouch under normal room conditions: 59-86ºF (15-30ºC).
- Do not store 1295 BIs near sterilants or other chemicals.

Disposal

Dispose of used 1295 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.

For processed BIs observed to have a broken media ampoule after the sterilization process, or if the ink of the CI appears smeared or runny (if included) leave the BI and CI in the sterilization pouch and place the pouch in packaging compatible with steam sterilization and steam sterilize per the parameters above.

For further information, please contact your local 3M representative or contact us at 3M.com and select your country.

Explanation of Symbols

REF Catalogue Number

Caution, see instructions for use

Do not use if package is damaged

Do not reuse

Use by date

LOT Batch code

Manufacturer

Date of manufacture

VH202 Product is designed for use with vaporized hydrogen peroxide sterilization processes

Made in the U.S.A. of
globally sourced materials by

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