

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

Product Description

The 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V is specifically designed for routinely challenging and conducting qualification testing of 270°F (132°C) and 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization processes in healthcare facilities. The challenge pack consists of multiple layers of medical index cards, some of which are die-cut to contain the biological indicator. The stacked cards are wrapped with a sterilization wrap. Each challenge pack has a process indicator on the pack label that changes from yellow to brown or darker when exposed to steam. This convenient disposable challenge pack presents a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). The challenge pack is a single use device.

Each challenge pack contains a 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (brown cap), hereinafter referred to as a 1492V BI, and a record keeping sheet. When steam processed, the process indicator bar printed on the record keeping sheet turns from yellow to brown or darker and the process indicator on the top of the 1492V BI cap changes color from pink to light brown or darker. The 1492V BI is a self-contained dual readout biological indicator specifically designed for rapid and reliable monitoring of the steam sterilization process when used in conjunction with the 3M™ Attest™ Auto-reader 490, hereinafter referred to as the 490 Auto-reader. 3M™ Attest™ 1492V biological indicator controls are provided with the challenge packs.

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.

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 $\geq 97\%$ 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 $\geq 97\%$ 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 Steam Challenge Pack 1496V 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 contained in the challenge pack 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 Steam Challenge Pack 1496V 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. To avoid the risk of serious injury or death from flying debris due to a ruptured ampoule:

- Allow the biological indicator 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 when activating the biological indicator.
- Handle the BI by the cap when crushing and flicking.
- Do not use your fingers to crush the glass ampoule.

Precautions

1. To ensure the challenge pack delivers the intended challenge:
 - DO NOT OPEN challenge pack prior to sterilization;
 - DO NOT reuse challenge pack.
2. DO NOT use the challenge pack 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. 270°F (132°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles having exposure times <4 minutes or 275°F (135°C) dynamic-air-removal (pre-vacuum) steam sterilization cycles having exposure times <3 minutes;
 - d. Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.
3. After 1492V BI activation, ensure media has flowed to the spore growth chamber.

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 (i.e., BI challenge test pack).

Directions for Use

1. Place an Attest™ Super Rapid Readout Steam Challenge Pack 1496V flat, with the label side up, in a full load in the most challenging area for the sterilant to reach. This is generally on the bottom shelf, over the drain. Do not place objects (i.e., another pack) on top of the challenge pack. This will create too great of a challenge for air removal and steam penetration.
2. Process the load according to established procedures.
3. After completion of the cycle, while wearing heat resistant gloves, retrieve the challenge pack.
4. Check to see that the external process indicator on the outside of the challenge pack has changed from yellow to brown or darker. Open the challenge pack and allow the 1492V BI to cool outside the challenge pack for 10 minutes prior to activation.
5. Remove the record keeping card from inside the challenge pack. Check the chemical indicator bar on the record keeping card. A color change from yellow to brown or darker confirms the pack has been exposed to the steam process.
6. Check the process indicator on the top of the 1492V BI cap. A color change from pink to light brown or darker confirms that the biological indicator 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.
7. Identify the processed 1492V BI by writing the sterilizer, load number, and processing date on the indicator label. Do not place another label or indicator tape on the biological indicator.
8. For a permanent record, fill out the required information on the record keeping card. Record the 1492V BI result when available.
9. Discard the challenge pack. Using the challenge pack more than once will invalidate subsequent test results.

10. To activate the 1492V BI, place it in a 490 Auto-reader incubation well which is color-coded brown (i.e., configured to incubate 1492V BIs). While wearing safety glasses, 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.

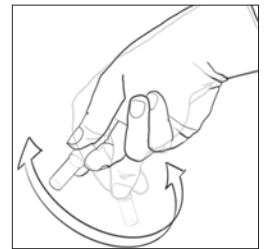
11. Each day that a processed 1492V BI is incubated, activate and incubate at least one non-processed 1492V BI to use as a positive control. Follow the activation instructions provided in Step 10 above. Write a "C" (for "control") and the date on the BI label. The positive control should be from the 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.

12. Incubation and Reading:

Incubate the positive control and steam processed 1492V 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 1492V BI results are available within 1 hour. The 490 Auto-reader will display 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 (- on the LCD display) result for the processed 1492V BI 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 qualification testing yields satisfactory results (typically three consecutive cycles with negative BI results and three consecutive cycles with passing Bowie-Dick test results).

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

- Best stored under normal room conditions: 59-86°F (15-30°C), 35-60% relative humidity (RH).
- Store away from direct sunlight. Do not store challenge packs near sterilants or other chemicals.


Disposal

Dispose of used 1492V BIs according to your health care facility policy. You may wish to steam sterilize any positive biological indicators at 270°F (132°C) 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

 Batch code


 Manufacturer

 Date of manufacture

 Product is designed for use with steam sterilization cycles.

 Catalogue Number

Made in U.S.A. by

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