

3M™ Attest™ 1276/1276F Steam Pack

Product Description

The 3M™ Attest™ 1276/1276F Steam Pack is specifically designed to routinely challenge the steam sterilization process in healthcare facilities. This convenient disposable pack is designed to present a resistant challenge to the sterilization process as was the standard 16 towel pack recommended by AAMI. Each pack contains a 3M™ Attest™ 1262 Biological Indicator (brown cap) and a record keeping sheet with a chemical indicator. When steam processed, the process indicator on the pack label and the chemical indicator strip on the record keeping sheet change from yellow to brown or darker, and the chemical indicator on the Attest™ vial changes from rose to brown/black. Attest™ biological indicator controls are provided. The presence of *Geobacillus stearothermophilus* spores is detected by a visual color change (media turns yellow). The yellow color change indicates a sterilization process failure. The final readout of a negative result (media remains purple) is made after 48 hours of incubation.

Indications for Use

Use the Attest™ 1276 Biological Indicator Steam Pack to monitor:

1. 250°F (121°C) gravity steam sterilization cycles \geq 30 minutes.
2. 270°F (132°C) vacuum assisted steam sterilization cycles \geq 4 minutes.

Contraindications

None.

Warnings

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

- Allow the biological indicator to cool for the recommended time period before crushing. 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 test pack from the sterilizer.
- Wear safety glasses when crushing the biological indicator.
- Handle the biological indicator by the cap when crushing.
- Do not use your fingers to crush the glass ampoule.

Precautions

Do not open pack prior to sterilization.

Do not use the Attest™ 1276 steam pack to monitor:

1. 250°F (121°C) gravity steam sterilization cycles < 30 minutes.
2. 270°F (132°C) vacuum assisted steam sterilization cycle < 4 minutes.
3. 270°F (132°C) gravity steam sterilization cycles.
4. Dry heat, chemical vapor, ethylene oxide, or other low temperature sterilization processes.

Directions for Use

1. Use an Attest™ steam pack to test loads containing fabric packs or wrapped metal instruments or hard goods run at 250°F (121°C) for \geq 30 minutes in a gravity cycle, or 270°F (132°C) for \geq 4 minutes in a vacuum assisted cycle. For testing container systems, place Attest™ 1262 biological indicators in the areas determined by product testing to be the most resistant.
2. Place an Attest™ steam pack, with the label side up, in a full load in the most challenging area for the sterilant. This is generally on the bottom shelf, near the door and over the drain.
3. Process the load as usual.
4. After the completion of the cycle and while wearing safety glasses and heat resistant gloves, retrieve the Attest™ steam pack.
5. Check to see that the external process indicator on the outside of the test pack has turned from yellow to brown or darker. Open up the test pack for 5 minutes to dissipate heat prior to removing the biological indicator. Then allow the biological indicator to cool outside the test pack for an additional 10 minutes prior to crushing.
6. Slip the coil off the Attest™ indicator.
7. Check the chemical indicator strip on the record keeping card and on the label of the biological indicator. A color change from rose to brown/black on the biological indicator and yellow to brown or darker on the strip confirms that the pack has been exposed to the steam 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.
8. Identify the Attest™ biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
9. For a permanent record, fill out the required information on the record keeping sheet and record the biological indicator result when it is available.
10. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.
11. While wearing safety glasses, crush and incubate the biological indicator at $56 \pm 2^\circ\text{C}$ ($133 \pm 3^\circ\text{F}$).

**Attest™ Incubator 120 volt
(North American Usage)**

Model 116 (14 indicators)

**Attest™ Incubator 240 volt
(International Usage)**

Model 118 (14 indicators)



- a. While wearing safety glasses, position indicator in metal block (see Figure 1). Place bottom of the indicator into the incubator's metal heating block so that the indicator is at an angle of approximately 45°.
 - b. Push the indicator straight back (see Figure 2). This crushes the media ampule and activates the indicator. Be sure that the cap will remain above the metal block when the indicator is pushed back.
 - c. Push the activated indicator down to seat it in the metal heating block. (See Figure 3). Be sure that the cap remains above the metal block when seated in the incubator.
12. Incubate at least one unprocessed Attest™ biological indicator (positive control) each day a processed indicator is incubated. The positive control indicator should be from the same manufacturing date and lot number as the processed indicator in the incubator.
 13. Write a "C" and a date on the label of the positive control indicator. Crush and incubate the control at $56 \pm 2^\circ\text{C}$ ($133 \pm 3^\circ\text{F}$). The purpose of the positive control is to ensure:
 - correct incubation conditions
 - viability of indicators (incorrect storage conditions could adversely affect even those indicators which are within their stated shelf life)
 - capability of media to promote rapid growth
 14. Incubate processed and control biological indicators for 48 hours at $56 \pm 2^\circ\text{C}$ ($133 \pm 3^\circ\text{F}$).

Incubation Times:

Early Detection	12 hours
	18 hours
	24 hours
Final Detection	48 hours

15. 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 48 hours of incubation. The positive control indicator should show a yellow color change for the processed indicator results to be valid.
16. Record the processed and control biological indicator results. Act on any positive test as soon as the first evidence of growth is noted. Always retest the sterilizer and do not use the sterilizer until biological indicator test results are negative.

Storage

- Best stored under normal room conditions: 59-86°F (15-30°C), 35-60% relative humidity.
- Do not store these biological indicators near sterilants or other chemicals.

Disposal

Dispose of used Attest™ biological indicators according to your healthcare facility's policy. You may wish to autoclave any positive biological indicators at 250°F/121°C for at least 15 minutes, or at 270°F/132°C for 10 minutes in a gravity displacement steam sterilizer, or at 270°F/132°C for 4 minutes in a vacuum assisted steam sterilizer.

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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3M.com/infectionprevention

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