3M™ Attest™ 1278/1278F EO Pack

Product Description

The 3M™ Attest™ 1278/1278F EO pack is specifically designed to routinely challenge ethylene oxide (E0) sterilization processes. This convenient disposable pack is designed to be as resistant as the routine EO biological indicator test pack recommended by AAMI.

Each pack contains a 3M™ Attest™ 1264 Biological Indicator (green cap). The chemical indicator on the Attest™ biological indicator label and the chemical indicator dot on the pack turn from red to green when EO processed. Attest™ biological indicator controls are provided.

The presence of *Bacillus atrophaeus* 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 green) is made after 48 hours of incubation.

Indications for Use

Use the Attest™ 1264 Biological Indicators to monitor EO sterilization cycles.

Contraindications

None.

Warnings

Butyl, neoprene, or nitrile gloves should be worn when removing the biological indicator test pack from the load prior to the completion of aeration.

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:

- 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

To ensure the test pack delivers the intended challenge:

- DO NOT open pack prior to sterilization;
- DO NOT reuse test pack.

Do not use the Attest™ 1278/1278F EO Pack to monitor sterilization cycles which it is not designed to challenge:

1. Steam sterilization cycles;
2. Dry heat, chemical vapor, or other low temperature sterilization processes.

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 an Attest™ biological indicator be used to monitor every ethylene oxide sterilization load.

Directions for Use

1. Use an Attest™ EO pack to test loads containing wrapped telescopic instruments, plastic, rubber, metal instruments, and equipment.
2. Place the EO pack in a full load in the most challenging area for the sterilant. This is generally in the center of the load.
3. Process the load as usual.
4. After sterilization two options exist:

   a. Aeration of EO pack prior to incubation

   Aerate the other packs from the load for the same amount of time as the test pack. At the end of the aeration cycle, check to see that the chemical indicator dot on the test pack turned from red to green which indicates the pack has been exposed to the EO sterilization process. If the chemical indicator dot is unchanged, check the sterilization process. Remove the biological indicator from the test pack. Dispose of the remaining test pack components according to the healthcare facility's policy.

   b. Removal of biological indicators from EO pack prior to aeration

   Open the sterilizer door according to the manufacturer's instructions; transfer the load to the aerator and retrieve the test pack. If a sterilizer with aeration capability is used, follow the manufacturer's instructions for opening the door and remove the test pack prior to the aeration cycle. Check to see that the chemical indicator dot on the test pack turned from red to green which indicates the pack has been exposed to the EO sterilization process. If the chemical indicator dot is unchanged, check the sterilization process. Remove the biological indicator from the test pack. Return the remainder of the test pack to the load for aeration according to the healthcare facility's policy. When it is necessary to handle items that are not fully aerated, butyl, neoprene, or nitrile gloves should be worn. The breathing zone of personnel should be monitored to verify the safety of the practices followed.
5. Check the chemical indicator on the label of the biological indicator. A color change from red to green indicates the pack has been exposed to the EO sterilization process. The color change does not indicate that the process was sufficient to achieve sterility. If the chemical indicator on the label is unchanged, check the sterilization process.
6. Identify the Attest™ biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
7. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.
8. Incubate the biological indicator at 37 ± 2°C (99 ± 3°F).

Attest™ Incubator 110/120 volt (North American Usage)	**Attest™ Incubator 220/240 volt (International Usage)**
Model 127 (28 indicators)	Model 129 (28 indicators)

   a. 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.
9. Incubate at least one non-processed Attest™ biological indicator (positive control) each day a processed indicator is incubated. The positive control indicator should be from the same lot code as the processed indicator.

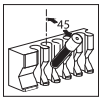

Figure 1

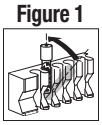
Figure 2

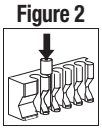
Figure 3

10. Write a “C” and a date on the label of the positive control indicator. Crush and incubate the control at 37 ± 2°C (99 ± 3°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

11. Incubate the processed and control biological indicators for 48 hours at 37 ± 2°C (99 ± 3°F) for a visual color change readout. Examine the indicators for early detection of positive results (media turns yellow) at convenient time intervals such as 18 and 24 hours. The final negative reading (media remains green) is made after 48 hours of incubation.

    The **positive control** should show a yellow color change in the media. If the positive control remains green, check the incubator temperature and storage conditions. Retest the incubator with a new positive control. The processed indicator results are not valid until the positive control shows a yellow color change.

    With a **processed indicator,** a visual color change to yellow indicates bacterial growth and a sterilization process failure. No color change (media remains green) after 48 hours of incubation indicates an adequate sterilization process.

12. 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 the biological indicator test results are negative.

Storage

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

Disposal

Dispose of used™ Attest™ biological indicators according to your healthcare facility’s policy. You may wish to steam sterilize 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

REF Catalogue Number

Caution, see instructions for use

Do not reuse

Use by date

LOT Batch code

Manufacturer

Date of manufacture

Made in U.S.A. by

3M Health Care

2510 Conway Ave.
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3M.com/infectionprevention

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