3M™ Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack

Product Description

The 3M™ Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack is specifically designed to routinely challenge the ethylene oxide (EO) sterilization process when used in conjunction with the 3M™ Attest™ 290G Auto-reader or the 3M™ Attest™ Auto-reader 390G. This pack is designed to present a resistant challenge to the EO sterilization process as is the routine EO biological indicator syringe pack recommended by AAMI. Each pack contains a 3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO (green cap). Attest™ 1294 Rapid Readout Biological Indicator for EO controls are provided. The Attest™ 1294 Rapid Readout Biological Indicator for EO is a self-contained device consisting of a standardized, viable population of *Bacillus atrophaeus* spores specifically designed for the rapid, reliable monitoring of ethylene oxide (EO) sterilization processes when used in conjunction with the Attest™ 290G Auto-reader or the Attest™ Auto-reader 390G.

The Attest™ 1294 Rapid Readout Biological Indicator for EO detects sterilization process failures through the activity of a naturally occurring enzyme, beta-glucosidase, produced by the organism during the germination and outgrowth process. The Attest™ Auto-reader detects the activity of this enzyme by reading a fluorescent product produced by the enzymatic breakdown of a substrate in the media. Presence of this enzyme indicates a sterilization process failure. The final negative biological indicator result, indicating an acceptable sterilization process, is made after 4 hours of incubation. The Attest™ 1294 Rapid Readout Biological Indicator for EO may also be incubated for 7 days to obtain a visual pH color change. The biochemical activity of viable *Bacillus atrophaeus* produces acid by-products that cause the media to change from blue-green to yellow. This visual pH color change also indicates a sterilization process failure however, due to the high sensitivity of the 4-hour fluorescent result, there is no advantage to incubating the Attest™ 1294 Rapid Readout Biological Indicator for EO beyond 4 hours when sterilizer chamber relative humidity is ≥ 35%.

Considerations for Use

Low sterilizer chamber relative humidity may increase the fluorescent readout time beyond 4 hours. If sterilizer chamber relative humidity is less than 35% at the time of gas injection, or if your sterilizer does not monitor relative humidity, continue to incubate the BI for a pH color change result. Any positive result (fluorescent or pH color change) indicates a sterilization process failure.

Indications for Use

The 3M™ Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack is a routine test pack used to monitor ethylene oxide sterilization cycles when used in conjunction with the 3M™ Attest™ 290G Auto-reader or the 3M™ Attest™ Auto-reader 390G.

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 injury from flying debris due to a ruptured BI:

- Allow the BI 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 when crushing the biological indicator.
- Handle the biological indicator by the cap when crushing and tapping.
- Do not use your fingers to crush the glass ampoule.
- Do not roll the biological indicator between your fingers to wet the spore strip.

Precautions

Do not use Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack to monitor:

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

To ensure the test pack delivers the intended challenge:

- DO NOT open pack prior to sterilization;
- DO NOT reuse 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 an Attest™ 1298 Rapid Readout Biological Indicator for EO Test Pack be used to monitor every ethylene oxide sterilization load.

Directions for Use

1. Use an Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack to test loads containing wrapped telescopic instruments, plastic, rubber, metal instruments, and equipment. For testing container systems, place Attest™ 1294 Rapid Readout Biological Indicator for EO in the areas determined by product testing to be the most resistant.
2. Place the Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Pack 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 Test Pack Prior to BI Incubation:
   Aerate the test pack for the same amount of time as the other packs from the load. At the end of the aeration cycle, check to see that the external chemical indicator on the outside of the test pack has turned from red to green, which indicates the pack has been exposed to the EO sterilization process. The external chemical indicator will turn green and may be shades of olive green to brown depending upon the relative humidity conditions of the cycle. If the chemical indicator is unchanged, check the sterilization process. Remove the Attest™ 1294 Rapid Readout Biological Indicator for EO from the test pack. Dispose of the remaining test pack components according to the healthcare facility's policy.

   B. Removal of Test 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 external chemical indicator on the outside of the test pack has turned from red to green, which indicates the pack has been exposed to the EO sterilization process. The external chemical indicator will turn green and may be shades of olive green to brown depending upon the relative humidity conditions of the cycle. If the chemical indicator is unchanged, check the sterilization process. Remove the Attest™ 1294 Rapid Readout Biological Indicator for EO from the test pack. Return the remainder of the test pack to the load for aeration according to the health care 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 Attest™ 1294 Rapid Readout Biological Indicator for EO. A color change from red to green confirms that the biological indicator has been exposed to the EO 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.
6. Identify the vial by writing the sterilizer, load number, and processing date on the biological indicator label. Do not place another label or indicator tape on the biological indicator.
7. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.
8. While wearing safety glasses, press the biological indicator cap down. Crush the glass ampoule of the biological indicator in the crusher well of the Attest™ Auto-reader. Hold the biological indicator by the cap and tap on a hard surface until media wets strip at bottom of vial, and then place the biological indicator in an auto-reader incubation well. See Attest™ Auto-reader Operator's Manual for further details.
9. Crush, tap and incubate at least one non-sterilized Attest™ 1294 Rapid Readout Biological Indicator for EO (positive control) each day a processed indicator is incubated. This helps ensure:
   - 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 Attest™ Auto-reader components.

   Write a "C" and a date on the label of the positive control biological indicator. The positive control should be from the same lot number as the processed indicator.

   Incubation and reading of Attest™ 1294 Rapid Readout Biological Indicators for EO:
10. Incubate the positive control and processed indicator for 4 hours at 37 ± 2°C (99 ± 3°F) in a 3M™ Attest™ 290G Auto-reader or 3M™ Attest™ Auto-reader 390G. See the Auto-reader Operator's Manual for the proper use of this equipment. The auto-readers automatically take readings and may indicate a positive result in less than 4 hours. The final fluorescent negative biological indicator reading is made at 4 hours. If sterilizer chamber relative humidity is ≥ 35%, record the final reading and discard the processed indicator. If sterilizer chamber relative humidity is unknown or < 35%, continue to incubate the biological indicator for a pH color change result as low relative humidity may increase the fluorescent readout time beyond 4 hours. A humidified incubator will be required to avoid media dry out. The final negative reading (no color change) for a visual pH color change is made at 7 days.

    Interpretation of Results:

    Fluorescent Results

    The positive biological indicator control must provide a positive result [red light on the 3M™ Attest™ 290G Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390G]. If the positive biological indicator control reads negative [green light on the 3M™ Attest™ 290G Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390G], refer to the applicable 3M™ Attest™ Auto-reader Operator's Manual Troubleshooting section. Retest the auto-reader with a new positive biological indicator control. The results for the processed biological indicator are not valid until the positive biological indicator control reads positive.

    With a processed biological indicator, a positive [red light on the 3M™ Attest™ 290G Auto-reader or plus symbol (+) on the LCD display of the 3M™ Attest™ Auto-reader 390G] means a sterilization process failure has occurred. A negative [green light on the 3M™ Attest™ 290G Auto-reader or minus symbol (-) on the LCD display of the 3M™ Attest™ Auto-reader 390G] after 4 hours of incubation and chamber relative humidity ≥ 35% indicates an acceptable sterilization process.

    pH Color Change Results

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 7 days of incubation. The positive control indicator should show a color change from blue-green to yellow for the processed indicator results to be valid.

11. Immediately act on any positive biological indicator results. Always retest the sterilizer and do not use sterilizer for processing loads until the biological indicator results are negative.

Disposal

Dispose of used Attest™ rapid readout biological indicators according to your healthcare facility's policy. You may wish to sterilize any positive biological indicators prior to disposal.

Storage

- Best stored under normal room conditions: 15-30ºC (59-86ºF), 35-60% relative humidity.
- Do not store Attest™ 1298/1298F Rapid Readout Biological Indicator for EO Test Packs near sterilants or other chemicals.

Explanation of Symbols

REF Catalog 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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1-800-228-3957
3M.com/infectionprevention

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