Incubation and reading of Attest™ 1294 Rapid Readout Biological Indicators for EO:

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.

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:

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

7. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.

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.

5. 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.

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 chemical indicator outside the test pack has turned from red to green, which indicates the pack has been exposed to the EO sterilization process.

- 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 outside 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 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.

- 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.

- 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.

- 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 test 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™ 1296 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 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 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 (95 ± 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 < 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.

- If sterilizer chamber relative humidity is ≥ 35%, record the final reading and discard the processed indicator. If sterilizer chamber relative humidity is < 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 produce 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 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 < 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.

pH Color Change Results

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.
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: 15-30°C (59-86°F), 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>意义</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog number</td>
<td>型号</td>
</tr>
<tr>
<td>Caution, see instructions for use</td>
<td>注意，参阅使用说明</td>
</tr>
<tr>
<td>Do not reuse</td>
<td>不可重复使用</td>
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<tr>
<td>Use by date</td>
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