3M™ Attest™ 1262/1262P

Biological Indicato (English)

PRODUCT DESCRIPTION: The 3M Attest 1262 Biological Indicator (brown cap) is designed for monitoring steam sterilization processes.
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.
MONITORING FREQUENCY: Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor every load. This presents an appropriate challenge and improves the performance of the sterilization process.
CONTRAINDICATIONS: None
WARNING:
There is a glass ampule inside the plastic vial of the biological indicator.
- Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst.
- Wear safety glasses and gloves when removing the biological indicator from the sterilizer.
- 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 ampule.
- Do not roll the biological indicator between fingers to wet the spore strip.

PRECAUTIONS:
Do not use the Attest 1262 Biological Indicators to monitor:
1. 132°C (270°F) gravity steam sterilization cycles, ≤ 3 minutes.
2. Dry heat, chemical vapor, ethylene oxide sterilizers, or other low temperature sterilization processes.

DIRECTIONS FOR USE:
1. Identify the Attest biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
2. Place an Attest biological indicator horizontal or cap up in an appropriate test tray or package according to recommended practices. Appropriate test trays or packages for loads containing:
   Fabric packs run at 121°C (250°F) for ≥ 30 minutes in a gravity sterilizer or at 132°C (270°F) for ≥ 4 minutes in a vacuum assisted cycle:
   • Attest 1262 biological indicator in an AAMI 16 towel pack.
   Wrapped metal instruments or hard goods run at 121°C (250°F) for ≥ 20 minutes in a gravity cycle:
   • Attest 1262 biological indicator in a wrapped hard goods item (e.g., instrument set) from the load. Include porous items if applicable.
   Wrapped metal instruments or hard goods run at 132°C (270°F) for ≥ 4 minutes in a vacuum assisted cycle:
   • Attest 1262 biological indicator in an AAMI 16 towel pack or in a wrapped hard goods item (i.e., instrument tray) from a load with porous items if applicable.
   Single wrapped metal instruments or hard goods run at 132°C (270°F) for ≥ 4 minutes in an express vacuum assisted cycle.
   • Attest 1262 biological indicator in a single wrapped instrument tray or hard goods from the load. Do not process items with lumens or porous materials in this cycle.
   Unwrapped metal instruments or hard goods with no porous items run at 121°C (250°F) for ≥ 15 minutes in a gravity cycle.
   • Attest 1262 biological indicator in an unwrapped hard goods item (e.g., instrument set) from a load.
   Unwrapped metal instruments or hard goods with no porous items run at 132°C (270°F) for ≥ 3 minutes in a vacuum assisted cycle.
   • Attest 1262 biological indicator in an unwrapped hard goods item (e.g., instrument tray) from the load. AAMI suggests placing a biological indicator in an empty instrument tray.
   Unwrapped metal instruments or hard goods with porous items run at 132°C (270°F) for ≥ 4 minutes in a vacuum assisted cycle.
   • Attest 1262 biological indicator in an unwrapped hard goods item (e.g., instrument tray) from the load. Include porous items.
   Container systems run at 121°C (250°F) in gravity cycles and 132°C (270°F) in a vacuum assisted cycles:
   • Attest 1262 biological indicators in the areas determined by product testing to be the most resistant.
   Table top gravity sterilizers that run from 121°C/132°C (250°F/270°F) with a come-up time of ≥ 2 minutes.
   • Attest 1262 biological indicators in a test tray or package that is representative of the load and creates the greatest challenge. Include porous items if applicable.
3. Place the test tray or package 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.
4. Process the load as usual.
5. After the completion of the cycle and while wearing safety glasses and gloves, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest biological indicator.
   Note WARNINGS above
6. When the biological indicator is not contained in a test package or an other heat absorbing packaging material, remove the biological indicator from the sterilizer and allow to cool for an additional 10 minutes prior to crushing.
7. When the biological indicator is contained in a test pack or other heat absorbing packaging material, the test pack or any other heat absorbing packaging material should be removed from the sterilizer and opened up 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.
8. Check the chemical indicator on the label of the biological indicator. A color change from rose to brown confirms that the biological indicator 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.
9. While wearing safety glasses, crush and incubate the biological indicator at 56 ± 2°C (133 ± 3°F).

Attest Incubator	**Attest Incubator**
120 volt (North American Usage)	**240 volt (International Usage)**
Model 116 (14 indicators)	Model 118 (14 indicators)
Model 126 (28 indicators)	Model 128 (28 indicators)
Top tier of Model 130 (14 indicators)	Top tier of Model 131 (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.
10. 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.
11. Write a "C" and a date on the label of the positive control indicator. Crush and incubate the control at 56 ± 2°C (133 ± 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
12. Incubate processed and control biological indicators for 48 hours at 56 ± 2°C (133 ± 3°F).

Incubation Times:

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

13. 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.
14. Record the sterilized 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 results are negative.

DISPOSAL: Dispose of used Attest biological indicators according to your healthcare facility's policy. You may wish to autoclave any positive biological indicators at 121°C/250°F for at least 15 minutes, or at 132°C/270°F for 10 minutes in a gravity displacement steam sterilizer, or at 132°C/270°F for 4 minutes in a vacuum assisted steam sterilizer.
STORAGE AND SHELF LIFE:
A. Store Attest biological indicators under normal room conditions: 15-30°C (59-86°F), 35-60% relative humidity.
B. Do not store these biological indicators near sterilants or other chemicals.
C. Attest biological indicators have a 24 month shelf life.

LOT 2010-10 AZ • The lot in a box and the hourglass symbols are symbols that represent lot number and expiration date. The hourglass is followed by a year and month which represent the expiration date (year and month: 2010-10). The entire line after the hourglass represents the lot number (2010-10 AZ).

Made in U.S.A. by

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