3M™ Attest™
Rapid 5 Steam-Plus Test Pack 41382/41382F

GB

Product Description

The 3M™ Attest™ 41382 Rapid 5 Steam-Plus Test 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 is the standard 16 towel pack recommended by AAMI. Each test pack has a process indicator on the pack label that changes from yellow to brown or darker when exposed to steam. Each pack contains a 3M™ Attest™ 1292 Rapid Readout Biological Indicator (brown cap), a record keeping sheet, and a 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator. Attest™ biological indicator controls are provided. The test pack is a single use device.

AAMI recommends that steam sterilization loads containing an implant be monitored with a process challenge device containing a biological indicator and an integrating indicator. Comply™ SteriGage™ Steam Chemical Integrators are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140-1:2014. Comply™ SteriGage™ Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature. The Comply™ SteriGage™ Steam Chemical Integrator offers an immediate Accept/Reject reading that allows for implant load early release in emergency situations as defined in AAMI ST-79.

3M™ Attest™ 1292 Rapid Readout Biological Indicators comply with the requirements of ISO 11138-1:2006 and ISO 11138-3:2006. The 3M™ Attest™ 1292 Rapid Readout Biological Indicator is a dual readout biological indicator system specifically designed for rapid and reliable monitoring of steam sterilization process when used in conjunction with the 3M™ Attest™ 290 Auto-reader or the 3M™ Attest™ Auto-reader 390. When steam processed, the chemical indicator on the Attest™ vial label changes from rose to brown/black. The Attest™ 1292 Rapid Readout Biological Indicator detects the presence of *Geobacillus stearothermophilus* by detecting the activity of alpha-glucosidase, an enzyme present within the organism. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. This creates a fluorescence change, which is detected by the auto-reader. A fluorescence change indicates a steam sterilization process failure.

The Attest™ 1292 Rapid Readout Biological Indicator also detects the presence of *G. stearothermophilus* organisms by a visual color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces acid by-products that cause the media to change color from purple to yellow. A visual pH color change also indicates a steam sterilization process failure. Due to the high sensitivity of the 3-hour fluorescent results, however, there is no advantage to incubating the Attest™ 1292 Rapid Readout Biological Indicator beyond 3 hours.

Indications for Use

Use the 3M™ Attest™ 41382 Rapid 5 Steam-Plus Test Pack to monitor:

1. 121°C (250°F) gravity steam sterilization cycles;
2. 132°C (270°F) vacuum assisted steam sterilization cycles.

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 and tapping.
- Do not use your fingers to crush the glass ampoule.
- Do not roll the biological indicator between fingers to wet the spore strip.

Precautions

DO NOT use the 3M™ Attest™ 41382 Rapid 5 Steam-Plus Test Pack to monitor sterilization cycles which it is not designed to challenge:

1. 121°C (250°F) gravity steam sterilization cycles <30 minutes;
2. 121°C (250°F) vacuum assisted steam sterilization cycles;
3. 132°C (270°F) gravity steam sterilization cycles;
4. 132°C (270°F) vacuum assisted steam sterilization cycle <4 minutes.
5. Dry heat, chemical vapor, ethylene oxide, 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 every steam sterilization load be monitored with an appropriate biological indicator.

Directions for Use

1. Use the Attest™ Rapid 5 Steam-Plus Test Pack to monitor 121°C (250°F) gravity steam sterilization cycles ≥ 30 minutes and 132°C (270°F) vacuum assisted steam sterilization cycle ≥ 4 minutes.
2. Place an Attest™ Rapid 5 Steam-Plus Test 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, fully open the sterilizer door for a minimum of 5 minutes prior to removing the test pack.
5. While wearing thermal resistant gloves, retrieve the test pack. Check to see that the external process indicator on the outside of the test pack has changed 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™ biological indicator.
7. Check the Comply™ SteriGage™ Steam Chemical Integrator. A dark color in the ACCEPT window of the chemical integrator confirms that the inside of the pack has been exposed to sufficient steam sterilization conditions. If the dark color has not entered the ACCEPT window, a REJECT result is indicated. This indicates the inside of the pack was not exposed to sufficient steam sterilization conditions. Check the sterilization process.
8. Check the chemical indicator on the label of the Attest™ biological indicator. A color change from rose to brown/black confirms that the biological indicator has been exposed to the steam process. This color change does not indicate that the process was sufficient to achieve sterility.
9. Identify the Attest™ biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
10. For a permanent record, fill out the required information on the record-keeping sheet. Record the biological indicator result when it is available.
11. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.
12. While wearing safety glasses, press the biological indicator cap down. Crush the glass ampoule of the biological indicator in the crusher well of the auto-reader. Hold the biological indicator by the cap and tap on a hard surface, but not on the auto-reader, until the media wets the strip at bottom of the vial. Then place the biological indicator in an auto-reader incubation well configured to incubate Attest™ 1292 Rapid Readout Biological Indicators. See Attest™ Auto-reader Operator's Manual for further details.
13. Each day that a processed Attest™ 1292 Rapid Readout Biological Indicator is incubated, crush, tap and incubate at least one non-processed Attest™ 1292 Rapid Readout Biological Indicator to use as a positive control. Write a "C" (for "control") and the date on the label. The positive control biological indicator should be from the same manufacturing date and lot number as the processed biological indicator.
14. Incubate the positive control and sterilized Attest™ 1292 Rapid Readout Biological Indicators for 3 hours at 60 ± 2°C (140 ± 3°F) in a 3M™ Attest™ 290 Auto-reader or a 3M™ Attest™ Auto-reader 390. See the applicable auto-reader Operator's Manual for the proper use of this equipment. The auto-readers automatically take readings and indicate a positive result as soon it is obtained. The final fluorescent negative biological indicator reading is made at 3 hours. After the final reading is obtained the biological indicators may be discarded.

Interpretation of Results:

Fluorescent Result

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

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

pH Color Change Result (Optional)

The appearance of a yellow color in the processed indicator demonstrates bacterial growth and a sterilization process failure. No color change (i.e. media remains purple) indicates an adequate sterilization process. A final negative result is made after 48 hours of incubation. The positive control indicator should show a color change from purple to yellow for the processed indicator results to be valid.

15. Biological indicators can be discarded after the results are provided by the Auto-reader, however:

It is a good practice to incubate a positive control for a visual color change each day a sterilized biological indicator is processed. This helps ensure:

- correct incubation temperatures are met,
- viability of spores have 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.

The positive control indicator should show a yellow color change of the growth media within 48 hours.

16. Record the processed and control biological indicator results. Act on any positive test result as soon as it is noted. Always retest the sterilizer and do not use the sterilizer until three consecutive biological indicator results are negative.

Disposal

Dispose of used Attest™ biological indicators according to your healthcare facility's policy. You may wish to sterilize any positive biological indicators at 121°C (250°F) for ≥30 minutes in a gravity-displacement steam sterilizer or at 132°C (270°F) for ≥4 minutes in a vacuum- assisted steam sterilizer.

Storage/ Shelf Life

- Best stored under normal room conditions: 15-30ºC (59-86ºF) and 35-60% relative humidity.
- Store away from direct sunlight. Do not store near sterilants or other chemicals.
- Attest™ 41382 Rapid 5 Steam-Plus Test Packs have a 2-year shelf life from the date of manufacture. The expiration date is indicated on the test pack and packaging by the 4-digit year and 2-digit month of expiration
  (e.g. ⧖ 2017-05).
- All of the information to the right of the lot-in-a-box and hourglass symbols indicates the lot number
  (e.g., LOT ⧖ 2017-05AD). The lot number of the test pack matches the lot number of the 1292 BI inside the pack.
- After use, the Comply™ SteriGage™ Steam Chemical Integrator will not change visually within 6 months when stored at above conditions.

Explanation of Symbols

⚠ Caution, see instructions for use

Do not reuse

⧖ Use by date

LOT Batch code

Manufacturer

STEAM Product is designed for use with steam sterilization cycles.

REF Catalogue Number

Made in U.S.A. by

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