3M™ Attest™ 1262-S Biological Indicator for Steam
3M™ Attest™ Incubator

Product Profile

For Industrial and Pharmaceutical Applications

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Product Description

3M™ Attest™ 1262-S Biological Indicator for Steam

3M Attest 1262-S

The 3M™ Attest™ 1262-S Biological Indicator is a reliable and convenient biological indicator for validating and monitoring industrial and pharmaceutical steam sterilization processes. The Attest 1262-S may be used as a component of the quality system for a steam sterilization process that ensures that medical devices or biologics are processed per the manufacturer's specifications and comply with the requirements of national and international sterilization standards. The Attest 1262-S should be used with appropriate testing, verification, and documentation by the end user.

The Attest 1262-S is a self-contained biological indicator. This design reduces testing time and eliminates the potential for cross-contamination associated with the culturing of conventional spore strips. The Attest 1262-S design is comprised of a paper carrier inoculated with a standardized population of *Geobacillus stearothermophilus* ATCC® 7953 spores, a glass ampoule containing recovery medium which includes a pH indicator dye, a plastic cap with filter, and a plastic vial. (See Figure 1) The biological indicator has a chemical process indicator on the label that will change from rose to brown upon exposure to the steam sterilization process. The recovery media will produce a pH color change from purple to yellow if viable spores are present and incubation conditions are correct.

The Attest 1262-S is recommended for 132ºC (270ºF) vacuum-assisted and 121ºC (250ºF) gravity steam sterilization processes. The Attest 1262-S could also be used to monitor other steam sterilization processes, such as 134ºC (273ºF), with appropriate testing and validation by the end user. The suitability of the Attest 1262-S for monitoring any steam sterilization process must be verified and documented by the end user.

The Attest 1262-S is verified with a readout or Reduced Incubation Time (RIT) of 48 hours under specific test conditions. The Attest 1264-S can be incubated for up to 7 days with specific action to prevent media dry-out. A change in media color from purple to yellow indicates a positive biological indicator result.

The Attest 1262-S may be incubated in a 3M Model 126 Incubator, or any microbiological incubator providing the appropriate incubation temperature [56ºC ± 2ºC (133ºF ± 3ºF)].

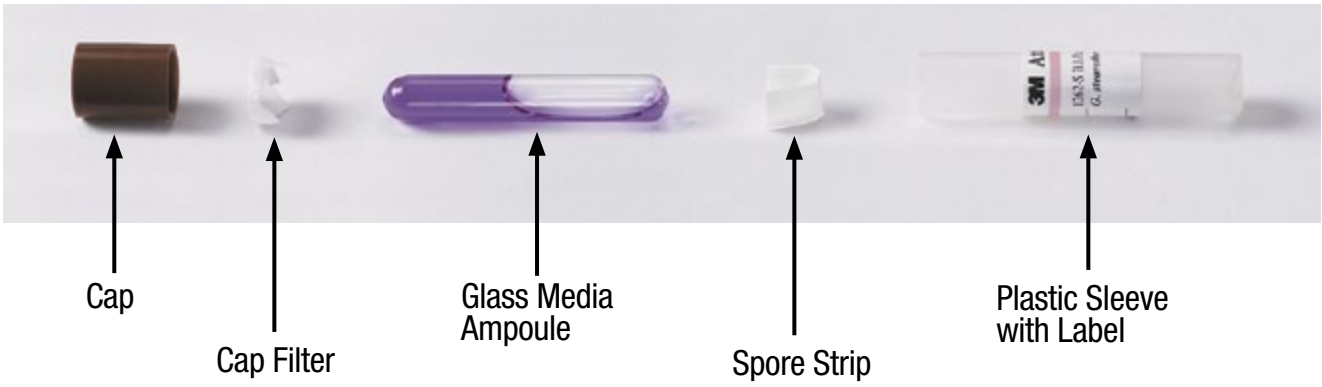

Figure 1 - 3M Attest 1262-S Components

3M Model 126 Incubator

The Attest 1262-S has not been tested or validated for monitoring sterilization processes other than steam, such as ethylene oxide, dry heat, radiation, hydrogen peroxide, or other chemical or low temperature processes.

The Attest 1262-S is available in cases containing 2 boxes of 300 biological indicators (600 biological indicators per case).

Regulatory Status

The Attest 1262-S is compliant with ISO 11138-1:2006[1] and ISO 11138-3:2006[2] (ANSI/AAMI/ISO 11138-1:2006[3] and ANSI/AAMI/ISO 11138-3:2006[4]). Key product design and performance specifications for the Attest 1262-S are provided in this Product Profile.

The 3M Attest 1262-S, when used to monitor industrial and pharmaceutical sterilization processes, is not regulated by the U.S. FDA as a medical device. The 3M Attest 1262-S is equivalent to the 3M Attest 1262 Biological Indicator for Steam, which is a Pre-Amendment Device.

Product Specification and Performance Information

The following sections describe the key performance specifications of the Attest 1262-S system, in some cases comparing them to the biological indicator requirements described in ***ISO 11138-3 (2006) Sterilization of health care products – Biological indicators for moist heat sterilization processes***.

Population Specification	
3M Attest 1262-S	$1.0 \times 10^6 – 9.9 \times 10^6$ cfu/strip
ISO 11138-3:2006 – Moist heat BIs	1.0×10^5 cfu/strip minimum

Table 1- Population

Method: The method used for determination of viable population of the Attest 1262-S involves maceration of multiple strips to separate the spores from the paper carrier, followed by serial dilutions, plating, colony counting, and dilution calculations to determine the population. Population test results are very dependent upon the methodology used to determine those results. The test method used to confirm the population of any lot of Attest 1262-S must be identical to the method used by 3M to determine the population stated on the certification. The 3M method is described in ***3M Technical Bulletin 05-000002, 3M Attest 1262-S – Population Test Procedure***, available upon request (In the U.S., all the 3M Sterilization Technical Helpline at 1-800-441-1922, Option 2 or through your local 3M office).

Rationale: The population range for Attest 1262-S is narrower than the population range specified for steam biological indicators in ISO 11138-3. The intent of this narrower specification is to provide a less variable indicator.

D-value Specification	
3M Attest 1262-S	1.5 – 3.0 minutes
ISO 11138-3:2006 – Moist heat BIs	1.5 minutes minimum

Table 2 - D-value

Method: The D-value for Attest 1262-S is determined using a Fraction Negative methodology. All exposures are completed at 121ºC (250ºF)

The test method used to confirm the D-value of any lot of Attest 1262-S must be identical to the method used by 3M to determine the D-value stated on the certification. The specific 3M method is described in ***3M Technical Bulletin 05-000005, 3M Attest 1262-S D-value Test Method***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through you local 3M office).

Rationale: The D-value specification for Attest 1262-S is narrower than the range specified in for steam biological indicators in ISO 11138-3:2006. The intent of this specification is to provide a less variable indicator.

Survival and Kill

The survival and kill values of the Attest 1262-S are based on the calculations specified in ISO 11138-1:2006. The formulas are:

Survival Time = ($\log_{10}$ population – 2) x D-value

Kill Time = ($\log_{10}$ population + 4) x D-value

These tests are conducted in a resistometer at 121ºC (250ºF). The actual calculated test times for each lot are reported on the Quality Certificate that accompanies each lot.

z-Value

The z-value specification for Attest 1262-S is based on the requirement specified in ISO 11138-3:2006. The specification for Attest 1262-S:

z-Value: ≥ 6ºC

Readout (Reduced Incubation) Time

The reference incubation time for biological indicators is generally considered to be seven days (168 hours). Incubation times of less than seven days, i.e., the "readout" or reduced incubation times (RIT) therefore need to be validated by appropriate testing. RIT testing is performed to establish the shortest incubation time necessary to ensure a high degree of confidence for detecting a positive biological indicator response.

Sensitivity is the statistic used to calculate the RIT. With the Attest 1262-S, sensitivity is a measure of the accuracy of the 48 hour readout to indicate spore survival following an steam sterilization process failure or exposure in a sub-lethal cycle, as compared to the indicator response at 168 hours. The minimum incubation time for a reliable readout will have a very small number of false negatives and consequently a very high sensitivity.

$$\text{Sensitivity} = \frac{(\#\text{ Growth Positives after 7 days} - \#\text{ False Negatives}) \times 100}{\#\text{ Growth Positives after 7 days}}$$

Note: A false negative is defined as a biological indicator showing a negative response at 48 hours incubation time and a positive response at 7 days incubation time.

The Attest 1262-S is routinely verified with a reduced incubation time (RIT) of 48 hours under a specific 3M test plan targeting a minimum sensitivity of 95%.

The test plan used by 3M is a sequential attribute-sampling plan designed to have certain operating characteristics that assure the RIT requirements are met on a consistent basis. Each crop of *Geobacillus stearothermophilus* spores is tested for RIT using this procedure. Generally, a minimum of 400 Attest 1262-S units are tested for each spore crop. While a spore crop may produce multiple lots of Attest 1262-S, each individual product lot is traceable to the RIT test data for that pertinent spore crop. The test method limits are set so that there is a 5% probability that a lot which has 95% or better RIT is rejected (producer's risk, i.e., reject a good lot), and a 10% probability of failing to reject a bad lot (defined by the test plan as 90% RIT, i.e., consumer's risk).

The specific 3M method for verifying the Reduced Incubation Time for Attest 1262-S is described in ***3M Technical Bulletin 05-000017, 3M Attest 1262-S Reduced Incubation Time Verification Procedure***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through your local 3M office.)

Instructions for Use

The following information is provided with the Attest 1262-S biological indicators and provides specific use instructions.

Identification and Expiration Date: Each biological indicator will be labeled with a lot code that also provides the expiration date information. The format of this code is noted below:

YYYY-MM XX

Y denotes the Year the product will expire;
M denotes the Month the product will expire (last day of that month);
"XX" is a 3M lot specific code.

For example:

2014-03 JK

represents a product with production code JK that will expire on March 31, 2014.

All of the information to the right of the "lot in a box" symbol represents the lot number (e.g. 2015-11AZ). The expiration date is indicated by the hourglass symbol followed by the year and month of expiration (e.g. year and month: 2015-11). Biological indicators that are beyond their expiration date should not be used. The entire lot code (8 characters) must be used to describe or document the product lot. Biological indicators that are beyond their expiration date should not be used.

Inspection: Damaged biological indicators may produce erroneous results. Indicators can be damaged in shipping, or in handling (e.g. during placement into, or extraction from, product or PCDs; damage by pallet handling before or after processing). Careful inspection of the biological indicator both before and after processing (before crushing the ampoule) is critical. (Note: Please follow safety precautions described in WARNING section when inspecting indicators that have been exposed to the sterilization process).

Carefully inspect each biological indicator for:

Missing or damaged components (e.g. cap filter, spore strip, media ampoule, plastic sleeve).

The integrity of the glass ampoule is critical. Inspect for any signs of breakage including wet spore strip, yellow media, wet or dried residual media inside vial, or apparent lack of media in the ampoule.

Any damaged or suspect biological indicators should be discarded. Any results obtained from damaged biological indicators should be considered suspect.

Positive Control Tests: Positive controls (unprocessed indicators) should be tested to ensure that storage or handling has not inadvertently affected the viability of the indicator organisms or the ability of the recovery media to promote bacterial growth. Positive controls also verify that incubation conditions are appropriate.

Test at least one positive control from the same biological indicator lot for each sterilizer load monitored. Verify that the color of the chemical indicator on the biological indicator label is rose (unprocessed color). To test the positive controls, crack the glass ampoule (note WARNING section below) and ensure that the growth media completely wets the spore strip. Incubate the positive controls at 56ºC ± 2ºC (133ºF ± 3ºF) with the processed indicators, for up to 48 hours. The media color must change from purple to yellow (yellow indicates a positive biological indicator) within 48 hours. Do not continue to incubate indicators that have turned positive. Failure of the positive control test may invalidate the processed indicator results.

Incubation and Interpretation of Processed Indicators:
WARNING: There is a glass ampoule inside the plastic vial of the biological indicator.

- 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 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 ampoule.

Remove the processed indicator from the sterilizer and, if applicable, its holder or PCD. Allow the indicator to cool.

Verify that the color of the chemical indicator on the biological indicator label has changed from rose (unprocessed color) to brown (processed color). Carefully inspect the biological indicator for any sign of damage, including a wet spore strip, dried or residual media, or lack of media in the vial. Discard any damaged indicators. Crack the glass ampoule (note WARNING section above) and ensure that the growth media completely wets the spore strip. Immediately incubate the processed indicators at 56ºC ± 2ºC (133ºF ± 3ºF), for the incubation time validated by the end-user. A media color change from purple to yellow indicates a positive biological indicator. Do not continue to incubate indicators that have turned positive.

Product Handling Information

Storage: Store Attest 1262-S biological indicators between 15-30ºC (59-86ºF) and 35% - 60% relative humidity (RH). Do not store near sterilants or other chemicals.

Disposal: Dispose of biological indicators per your facility procedure. You may wish to autoclave biological indicators at 121ºC/250ºF for at least 30 minutes.

References

1. *Sterilization of health care products --- Biological indicators – Part 1: General requirements.* International Organization for Standardization; 2006. ISO 11138-1.

2. *Sterilization of health care products --- Biological indicators – Part 3: Biological indicators for moist heat sterilization processes.* International Organization for Standardization; 2006. ISO 11138-3.

3. *Sterilization of health care products --- Biological indicators – Part 1: General requirements.* Association for the Advancement of Medical Instrumentation; 2006. ANSI/AAMI/ISO 11138-1.

4. *Sterilization of health care products --- Biological indicators – Part 3: Biological indicators for moist heat sterilization processes.* Association for the Advancement of Medical Instrumentation; 2006. ANSI/AAMI/ISO 11138-3.

Call us at Customer Service to place an order: 800-742-1994 (U.S.). Visit our website: **www.3M.com/medicalspecialties** for product and services information, news about conferences we will be attending, new product highlights or to make a direct inquiry

To have a sales representative contact you, or to request samples, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or for international inquiries, please contact your local country representative. Our 3M Medical Specialties subsidiary contacts are listed below.

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