

Getinge Assured

Biological Indicators

Indicators (50/box): 61301606636
Indicators (100/box): 61301606637

Geobacillus stearothermophilus 7953(1)

Biological Indicator for: Steam sterilization

Culture: Getinge Assure AccuFast Media, 58-62°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Lot No: **SR-**

Manufacture Date:

Expiration Date:

Heat Shocked Population: $\times 10^5$ Spores / Unit

Carrier Size: 1/4" x 3/4" (6 mm x 19 mm)

Assayed Resistance:	D-Value ⁽²⁾	Survival	Kill
Steam 121° C		(3)	(3) min
Steam 132° C		(4)	(4) min
Steam 134° C		(4)	(4) min
Steam 135° C		(4)	(4) min

Z-value: ° C

D-value reproducible only when exposed in an AAMI BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

⁽²⁾ D-value calculated using the Limited-Holcomb-Spearman-Karber method.

⁽³⁾ Survival/Kill values are calculated according to a formula in USP and ISO 11138.

Manufacturer uses a D-value rounded to four decimal places in this calculation.

⁽⁴⁾ Empirically derived data.

Certified By

Date

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AccuFast Biological Indicator

Indications for Use

Getinge AccuFast Biological Indicator is a Self-contained Biological indicator (SCBI) intended for use in determining the efficacy of steam sterilization processes. The SCBI may be used in the following steam sterilization cycles:

Cycle Type	Cycle Temperature	Cycle Exposure Time
Gravity	121°C	30 minutes
Gravity	132°C	10 minutes*
IUSS	132/135°C	4 minutes
Pre-Vac	132°C	4 minutes
Pre-Vac	135°C	3 minutes

*Unwrapped nonporous/porous devices only.

NOTE: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

Instructions for Use

1. Remove an appropriate number of "single use" Getinge AccuFast Biological units from the box.
2. Identify the indicators by labeling pertinent process information.
3. Place a Getinge AccuFast Biological indicator in a suitable test pack which is representative of the load (e.g. a linen pack for the load of linen, a tray of instruments for metal goods may be used).
4. Place this test pack in the most challenging location of the sterilizer, generally on the bottom shelf nearest to the drain.
NOTE: If a test pack is not being used, the Getinge AccuFast Biological unit should be oriented in a horizontal position during load processing.
5. Process the load as recommended by the device manufacturer's IFU.
6. Remove from the sterilizer and allow the pack to cool for a sufficient time to cool the indicator, at least 10 minutes. NOTE: Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.
7. Retrieve the AccuFast biological indicators from the test load.
8. The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes unexposed from exposed units.
NOTE: a black chemical indicator color does not indicate acceptable sterilization.

Incubation

Getinge AccuFast biological indicators are designed to be used with the Getinge incubators which are calibrated to maintain 60°C ± 2°C. To activate the media, place the indicator in an upright position in the crushing chamber located on the Getinge 1700/1710/1410 incubator. Slowly pull forward to break the glass ampoule and release the media. Tap the AccuFast BI to remove any air bubbles within the plastic tube. Then immediately place the exposed activated indicator in an incubation cell. The "C" cell on the 1710 Incubator is intended for an unexposed control BI (see also Use of Controls). In the 1410 Incubator place the processed or control biological indicator into the left side of the activation cavity.

Interpretation

1. On the 1710 Incubator the LED's located in front of each cell display the current status of the cell: Amber = testing BI, Red = detection of yellow BI, Green = BI still purple at end of incubation cycle.
2. The appearance of a yellow media color indicates a positive test (sterilization failure). If the media remains purple / no media color change it indicates a negative test, (adequate sterilization).
3. Biological growth from sterilization failures may be detected as early as 3 to 5 hours. The positive test can be immediately confirmed by visually observing the yellow color change.
4. Act on a positive test as soon as it is observed per the facilities policy. AccuFast biological indicators can be sub-cultured if desired after the identification of positive growth. Recommended sub-culturing procedure techniques are available upon request.
5. The recommended incubation time is 10 hours (meets the USFDA/CDRH/RIT protocol).
6. When using the 1710 Incubator a printout containing test results will be generated from the incubator printer. Review and sign the printed report and store it in the Record Book.
7. Dispose of all used AccuFast biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

Use of Controls

- A. As a positive growth control, place an activated, unsterilized AccuFast biological indicator in the "C" cell of the 1710 incubator per hospital protocol.
- B. When using the 1710, the LEDs located in the front of the Control cell displays the current status of the cell: amber - Test in progress, green - test positive and red - test negative. The appearance of a yellow color indicates biological growth. A yellow BI is the desired result for the positive control.
- C. If the control does not grow, do not use the units from this package.

Storage

- A. Store AccuFast biological indicators at room temperature. Do not desiccate.
- B. Do not store these indicators near sterilants or other chemicals.
- C. AccuFast biological indicators have a shelf life which is clearly designated on each box. Rotate your stock accordingly. NOTE: Do not use AccuFast biological indicators after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.