

Getinge Assured

AccuFast Biological Test Pack

Indications for Use

The Getinge Assure AccuFast Biological Test Pack with Instant Readout Integrator is designed specifically for biological testing of 4 minutes at 132°C (270°F) and 3 minutes at 135°C (275°F) in pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing *Geobacillus Stearothermophilus* inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by ANSI/AAMI ST79. When used as directed, the Instant Readout Integrator Record Card gives instant visual indication that all critical parameters for sterilization were met.

Color Change

BI Indicator Strip: Blue to Black

BI Growth Medium: Purple to Yellow

Integrator Card: Purple to green

Instructions for Use

1. Load the sterilizer as normal.
2. Place the biological test pack at on the lowest shelf closest to the drain.
3. Process the load as recommended by the device manufacturer.
4. Remove the pack from the sterilizer and allow to cool.
5. Open the pack and remove the AccuFast biological indicator. Activate and incubate in the Getinge Incubator. If sterilization failure occurs, biological indicator may provide positive biological evidence of that failure in as soon as 3 to 5 hours of incubation. A positive test can be immediately confirmed by the operator visually observing the color change to yellow. To meet the USFDA/RIT protocol, the recommended incubation time is 10 hours.
6. Remove and examine the Instant Readout Integrator Card.
7. When the chemical integrator changes color from purple to green, it indicates correct exposure conditions of temperature, time and steam. Biological spores should be killed under the same exposure conditions.

Incubation

AccuFast biological indicators are designed to be used with a Getinge Incubator either a 1410 or a 1710 which is calibrated to maintain 60°C ± 2°C (140° ± 36°F). To activate the media, place the indicator in an upright position in the crushing chamber located on the Getinge Incubator. Slowly pull forward to break the glass ampoule and release the media. Immediately place the exposed activated indicator in an incubator cell, 1-10. If using the 1710 incubator, the "C" cell is intended for an unexposed positive control BI.

Interpretation

Instant Readout Integrator Card: An Integrator Card printed with a chemical integrator is contained within the Process Challenge Device (PCD) to demonstrate that the PCD was exposed to proper sterilization conditions of steam, time and temperature. If the chemical integrator is purple it has not been exposed to the proper conditions. If the indicator is green (endpoint), the pack has been exposed to proper sterilization conditions. Record data on the Integrator Card.

Biological Indicator:

1. If using the 1710 incubator, the LEDs 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 cycle.
2. The appearance of a yellow media color indicates a positive test (sterilization failure). No media color change, negative test, indicates adequate sterilization.
3. Biological growth from sterilization failures may be detected in as soon 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 your facilities policy. Notify appropriate personnel. AccuFast biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request.
5. The recommended incubation time is 10 hours (meets USFDA/RIT protocol).
6. If using the 1710 incubator, a printout will be generated from the Getinge Incubator containing results of incubation of AccuFast BIs.

Use of Controls

- As a positive growth control, place an activated, unsterilized AccuFast biological indicator in the Getinge Incubator with the same BI lot number and run in accordance to hospital protocol.
- When using the 1710, the LEDs located in 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.
- If the positive control does not grow, do not use the units from this box. Contact your Getinge representative.

Disposal

Dispose of all used biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 121°C (250°F) for no less than 30 minutes.

Safety Precautions

CAUTION: the test pack will be hot and should be opened carefully to avoid thermal injury.

Storage

Store at normal room temperature 50° - 86°F (10° - 30°C) and 10 - 60% R.H. Do not store near sterilants or other chemicals.

Expiry Date

The expiry date is printed on the product packaging. Do not use after expiration date listed on the packs.

LOT Number

A unique identification code, LOT is printed on each indicator label and packaging labels.

Interfering Substances or Conditions

There are no known interfering substances or conditions that could affect the intended use of the indicator or adversely affect the indicator performance.

Release of Toxic Substances

The indicator releases no known toxic substances in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

Declaration of Conformity

The Instant Readout Integrator Card is classified as an FDA Integrator. BI's are manufactured in compliance with Mesa laboratories, Bozeman Manufacturing facility's quality standards, USP and ISO 11138 guidelines and all appropriate subsections.