GETINGE

Getinge Assured

AccuView Biological Test Pack

Test Pack with 5 Controls: 61301606714
Test Pack with 25 Controls: 61301606715

Product Lot #	Card Lot #	BI Lot #	Product Expiration Date:

Performance Characteristics:

When exposed to steam sterilization cycles, the chemical integrator printed on the Instant Readout Integrator Card will change from purple to green, indicating all critical parameters for sterilization have been met. The biological indicator (BI), when incubated, will demonstrate either growth or no growth.

Critical Parameters: (in a standard hospital steam sterilizer) 4 minutes at 132°C or 3 minutes at 135°C prevac cycle.

This is to certify that the Instant Readout Integrator Card Packaged inside the product listed above satisfies performance requirements after exposure to dry saturated steam when tested under the conditions described in ANSI/AAMI ST79. The chemical indicator within this product is classified as FDA cleared integrator.

The chemical integrator within this product is stable after exposure to steam and may be kept as a permanent report.

The AccuFast biological indicators packaged within this product are manufactured in compliance with EN 866, ISO 11138, US Pharmacopoeia, Italian Pharmacopoeia Edition XI, and all appropriate subsections.

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Indications for Use
The AccuView Biological Test Pack with Instant Readout Integrator is a single use device 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 visible indication that sterilizing conditions were met.

Color Change
Growth Medium: Purple to Yellow
Integrator Card: Purple to green
Process Indicator Label: Blue to black

Instructions for Use
1. Load the sterilizer as normal.
2. Place the biological test pack flat on the lowest shelf closest to the drain.
3. Process the load as recommended by the 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 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.

Test Pack: If either the Instant Readout Integrator Card or the Biological Indicator yields a failing result, the test pack has not been exposed to proper sterilization conditions.

Use of Controls
Five or twenty five AccuFast Biological indicators are supplied with each case of test packs for use as controls.

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°- 100° F (10°- 38°C) and 10 - 70% 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 record card, biological indicator label, test pack box and packaging labels.

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.