

Steam Biological Test Pack with Instant Readout Integrator

BI 103/INT

Indications for Use

The Steam Biological Test Pack with Instant Readout Integrator is a steam sterilization monitor designed specifically for biological testing of pre-vacuum steam sterilizers operating at 134°C for 3 minutes or longer. The Instant Readout Integrator Card gives the operator a prediction of the biological test outcome.

Color Change

- **BI Process Indicator Label:** Blue to black
- **BI Growth Medium:** Purple to yellow
- **Integrator Card:** Purple to green

Directions for Use

1. Load the sterilizer as normal.
2. Place the biological test pack in the most challenging area of the sterilizer.
3. Process the load as recommended by manufacturer.
4. Remove the pack from the sterilizer and allow to cool.
5. Open the pack and remove the biological indicator.
6. Remove and examine the Instant Readout Integrator Card.
7. When the chemical integrator 'PASS IF GREEN' changes color from purple to green, it indicates correct exposure condition of temperature, time and steam. Biological spores should be killed under the same exposure conditions.

Incubation

To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the indicator rack and incubate immediately. Incubate biological indicators for 24 hours at 55°–60°C.

Interpretation

- **Instant Readout Integrator Card:** An Integrator card printed with a chemical integrator is contained within the test pack to demonstrate that the test pack was exposed to proper sterilization conditions of steam, time and temperature. If the chemical integrator 'PASS IF GREEN' is purple, it has not been exposed to the proper conditions. If the indicator is green, the pack has been exposed to proper sterilization conditions and therefore, biological kill should be achieved. Record the appropriate data on the Integrator card.
- **Biological Indicator:** During incubation, examine the biological indicator at regular intervals (i.e. 8, 12, 18, 24 hours) for signs of color change. If indicator growth media changes to yellow, the biological spores have survived and the load is not sterile. If the indicator growth media remains purple, the spores were exposed to proper sterilization conditions.

Use of Controls Five EZTest® 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 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 10°-38°C, 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 packs.

LOT Number

A unique identification code, [LOT], is printed on each indicator 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

BI's are manufactured in compliance with Mesa laboratories, Bozeman Manufacturing facility's quality standards, USP and ISO 11138 guidelines and all appropriate subsections.

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SteriTec Products Mfg. Co., Inc.
Member of the Getinge Group
74 Inverness Drive East
Englewood, CO 80112 USA

www.getinge.com/steritec