EZTest®

BIOLOGICAL TEST PACK WITH INSTANT READOUT INTEGRATOR

REF STP25

DIRECTIONS FOR USE

INDICATIONS FOR USE

EZTest® Biological Test Pack is designed specifically for biological testing of 132°C (270°F) pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator (EZTest®) containing 10^5 *Geobacillus stearothermophilus* inside a small package of porous and nonporous materials, simulating the biological indicator test packs defined by ANSI/AAMI ST79. Also, in the middle of the pack is a Chemical Integrator Record Card. When used as directed, the Record Card Chemical Integrator gives visible indication that sterilizing conditions were met.

COLOR CHANGE

Biological Media: Purple to Yellow
Biological Vial Chemical Indicator: Blue to Black
Record Card: Purple to Green.

CRITICAL PARAMETERS *(in a standard hospital steam sterilizer)*

Steam sterilization cycle functioning at 132°C for 3 minutes or longer

RECORD CARD STATED VALUES *(As determined in a steam sterilization resistometer.)*

132°C – 5 minutes

INSTRUCTIONS FOR USE

1. Load the sterilizer as normal
2. Place the test pack flat on the lowest shelf near the door.
3. Process the load, normal cycle.
4. Remove the pack from the sterilizer and allow to cool at room temperature for 15 minutes.
5. Open the pack and remove the biological indicator. Incubate at 55° – 60°C for 24 hours.
6. Remove and examine the Instant Readout Integrator Card.
7. When the chemical integrator - "PASS" – 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.
8. Incubate Biological Indicators for 24 hours at 55° – 60°C for final sterilization verification.

INCUBATION

Any microbiological incubator that is adjusted for 55 - 60°C will satisfy the incubation conditions for the EZTest®. To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampule. Place the activated indicator in the indicator rack and incubate immediately.

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.

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" - 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 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*:** Biological indicators are supplied with each case (25) of test packs for use as positive controls. Activate and incubate an unexposed control indicator with every sixth test pack run. Examine the positive indicator at 18 and 24 hours. The yellow color is evidence of bacterial growth and verifies viable biological indicator use. Record the results. Dispose of indicators as instructed above.

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) 10-70% Relative Humidity. Do not store near sterilants or other chemicals.

EXPIRY DATE

The expiry date is printed on the product packaging.

LOT NUMBER

A unique identification code, LOT, is printed on each record card, biological indicator label, and boxing/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 EZTest® Biological Test Pack is equivalent in function and performance to the standard AAMI Challenge Test Pack as outlined in the ANSI/AAMI ST79. All biological indicators used in the EZTest® Biological Test Packs are manufactured according to quality systems in compliance ANSI/AAMI/ISO 11138.

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