

# Smart-Read® EZTest

## 10<sup>6</sup> BIOLOGICAL TEST PACK WITH INSTANT READOUT INTEGRATOR

Reorder No: SRSP6/25

### DIRECTIONS FOR USE

#### INDICATIONS FOR USE:

**Smart-Read® EZTest® Biological Test Pack with Instant Readout Integrator** is designed specifically for biological testing of 121°C and 134°C 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 Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.

#### COLOR CHANGE

Biological Media: Purple to Yellow

Smart-Read EZTest Label Chemical Indicator: Blue to Black

Record Card: Purple to Green.

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

Steam sterilization cycle functioning at 134°C for 3 minutes or longer. Steam sterilization cycle functioning at 121°C for 12 minutes or longer

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

121°C – 12 minutes; 134°C – 4.9 minutes

#### INSTRUCTIONS FOR USE

1. Load the sterilizer as normal.
2. Place the biological 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 10 minutes.
5. Open the pack and remove the **Smart-Read EZTest Indicator**. Activate and incubate in the **Smart-Well™ Incubator**. If sterilization failure occurs, **Smart-Read** may provide positive biological evidence of that failure in as soon as three to five hours of incubation. A positive test must be immediately confirmed by the operator visually observing the color change to yellow. To meet the USFDA/RIT protocol the biological indicator must be further incubated for a total of 10 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.

#### INCUBATION

**Smart-Read EZTest** biological indicators are designed to be used with the **Smart-Well** incubator which is 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 **Smart-Well** incubator. Slowly pull forward to break the glass ampoule and release the media. Tap the EZTest BI to remove any bubbles within the plastic tube. Then immediately place the exposed activated indicator in an incubator cell, 1-10. The "C" cell is intended for an unexposed positive control BI (see also Use of 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.

#### 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 and therefore, biological kill should be achieved. Record data on the Integrator Card.

#### Biological Indicator:

1. LEDs located in front of each cell display the current status of the cell: amber = test in progress; red = test positive; green = test negative. The appearance of a yellow color in the media indicates bacterial growth. No color change from purple indicates adequate sterilization. All incubation results MUST be visually confirmed by the operator.
2. Act on a yellow BI as soon as the color change is noted. Notify appropriate personnel. Always retest the sterilizer with several **Smart-Read EZTest** biological indicators throughout the test load. **Smart-Read EZTest** biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from Mesa Labs.
3. If sterilization failure occurs, **Smart-Read** may provide positive biological evidence of that failure in as soon as three to five hours of incubation. A positive test must be immediately confirmed by visually the operator observing the color change to yellow. To meet the USFDA/RIT protocol the biological indicator must be further incubated for a total of 10 hours.
4. A printout will be generated from the **Smart-Well** incubator containing results of incubation of **Smart-Read EZTest** BIs.

#### SAFETY PRECAUTIONS

**CAUTION:** the PCD 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% 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 **Smart-Read 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 **Smart-Read Biological Test Packs** are manufactured according to quality systems in compliance with ISO 11138. The INSTANT READOUT INTEGRATOR is compliant with the FDA requirements for chemical indicators.

Manufactured for:  
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