



## Instructions for Use

### US Healthcare Intended Use:

**Smart-Read EZTest** is a Self-contained Biological Indicator (SCBI) intended for use in determining the efficacy of steam sterilization processes. The SCBI may be used in the following steam sterilization cycles:

Cycle Type	Cycle Temperature	Cycle Exposure Time
Gravity	121°C	30 minutes
Gravity	132°C	10 minutes
Flash Gravity	132°C	3 minutes*
Pre-Vac	132°C	4 minutes
Pre-Vac	135°C	3 minutes

\*Unwrapped nonporous devices only.

**Smart-Read EZTest** has a validated reduced incubation time of 10 hours.

**NOTE:** Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

#### A. Exposure:

1. Remove an appropriate number of “single use” **Smart-Read** units from the box.
2. Identify the indicators by labeling pertinent process information.
3. Place a **Smart-Read** biological indicator in a suitable test pack which is representative of the load (e.g. a linen pack for the load of linen, a tray of instruments for metal goods may be used).
4. Place this test pack in the most challenging location of the sterilizer, generally on the bottom shelf near the door over the drain.  
NOTE: If a test pack is not being used, the **Smart-Read** unit should be oriented in a horizontal position during load processing.
5. Process the load as usual.
6. Remove from the sterilizer and allow the pack to cool for a sufficient time to cool the indicator, at least 10 minutes. NOTE: Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.
7. Retrieve the **Smart-Read** biological indicators from the test load.
8. The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes unexposed from exposed units. NOTE: a black chemical indicator color does not indicate acceptable sterilization.

#### B. 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 air 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).

#### C. Interpretation:

1. 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 incubation 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 as early 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. Notify appropriate personnel. **Smart-Read** biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from Mesa Labs.
5. The recommended incubation time is 10 hours (meets the USFDA/RIT protocol).
6. A printout containing test results will be generated from the Smart-Well incubator printer. Review and sign the printed report and store it in the Smart-Well Record Book.
7. Dispose of all used **Smart-Read** biological indicators in accordance with your institution’s policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

#### Use of Controls:

- A. As a positive growth control, place an activated, unsterilized **Smart-Read EZTest** biological indicator in the “C” cell of the Smart-Well incubator once per day.
- B. 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 incubation cycle. The appearance of a yellow color indicates bacterial growth. A yellow BI is the desired result for the positive control.
- C. If the positive control does not grow, do not use the units from this package. Contact Mesa Labs.

#### Storage:

- A. Store **Smart-Read** biological indicators at room temperature. Do not desiccate.
- B. Do not store these indicators near sterilants or other chemicals.
- C. **Smart-Read** biological indicators have a shelf life which is clearly designated on each box. Rotate your stock accordingly.

NOTE: Do not use **Smart-Read** biological indicators after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.