



ProTest Self-Contained Biological Indicator

For use in **steam/EO** sterilization cycles.

Information Sheet

Storage: 60-80°F (15-27°C), 30-70% relative humidity. Protect from freezing, sterilants, and light. **Do not refrigerate.**

Description: ProTest is intended for use in the monitoring of saturated steam or ethylene oxide sterilization cycles. Each ProTest vial contains a spore disc inoculated with *Geobacillus stearothermophilus* (#7953) spores for steam sterilization and/or *Bacillus atrophaeus* (#9372) for EO sterilization and a culture medium encased in a glass ampoule with a pH indicator. The acid production associated with growth causes a change in color of the ProTest media to or toward yellow to facilitate the detection of growth.

Frequency of Testing: For the greatest control of sterilized goods, we recommend that 2 or more ProTest Biological Indicators be included with every load.

Precautions: Do not use damaged units. Do not use after expiration date. Since ProTest contains live cultures, units should be handled with care. Always wear gloves and safety glasses when removing units from the sterilizer and when activating the units. This is a single use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of non-sterile product.

Disposal: Prior to disposal or discard, sterilize by steam at 121°C for not less than 30 minutes.

INSTRUCTIONS FOR USE:

- A. Exposure:** Place one or more ProTest units in a horizontal position in the most difficult to sterilize locations. Run Cycle. Remove units and verify that the chemical indicator on the vial label has changed color.
CAUTION: After sterilization, handle unit with care. Contents of the ampoule are hot and under pressure. Failure to allow sufficient cooling time (10-15 minutes) may result in bursting of the ampoule. **Always wear appropriate safety gear (gloves and safety glasses) when handling sterilized units.**
- B. Activation:** After the Biological Indicator has cooled, crush the media ampoule by squeezing the sides of the plastic tube. The unit is properly activated when the media has been released from the ampoule and the spore disc is in contact with the released media.
- C. Incubation:** Place the processed unit(s) and one unprocessed (control) unit in a vertical position in an incubator at:
 - 1) 58-62°C for steam (*Geobacillus stearothermophilus*) for 24 hours.
 - 2) 30-35°C for EO, (*Bacillus atrophaeus*) for 48 hours.
- D. Monitoring:** Begin monitoring the incubated units after 12-18 hours. Record observations. All positive units should be recorded and disposed of immediately. **Do not continue to incubate positive units.** Final negative results can be made after 24 hours of incubation for steam, 48 hours for EO.
- E. Interpretation:**

Control: The control unit should exhibit turbidity and/or a color change to or toward yellow. If the control unit does not show signs of growth, consider the test invalid.

Test: A failed sterilization cycle is indicated by turbidity and/or a color change to or toward yellow. A test unit that retains its original color indicates that sterilization parameters have been met.