



Raven Labs

a division of Mesa Labs

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Instructions for Use

ProAMP Self-Contained Biological Indicator with Negative Controls

For **steam sterilization cycles** only. Store in a refrigerator at 2-8°C. **Industrial Use Only. DO NOT FREEZE.**

Description: ProAMP is intended for use in the monitoring of saturated steam sterilization cycles. Each ProAMP ampoule contains a spore suspension of ***Geobacillus stearothermophilus*** (#7953) within a growth medium also containing Bromocresol Purple to function as a pH indicator. The acid production associated with growth causes a change in color from purple to or toward yellow.

Frequency of Testing: For greatest control of sterilized goods we recommend that ProAMP Biological Indicators be included with every load.

Precautions: Do not use damaged ampoules. Do not use after expiration date. Since ProAMP contains live cultures, ampoules should be handled with care. ProAMP is not intended for flash sterilization processes. 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. 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: Sterilize all positive and expired units prior to disposal.

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Please see **Negative Control Insert** for suggested use of Negative Controls

Exposure: Place one or more ProAMP Biological Indicators in the most difficult location to sterilize, usually near the drain or suspended in a volume of liquid. Run cycle.

Caution: After sterilization, handle ampoules 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.

Incubation: Place the processed ampoule in an incubator at 55-60°C. Mark a control ampoule as such and incubate along with processed ampoules to ensure spore viability. Raven recommends an incubation time of 48 hours.

Monitoring: Examine the ProAMP ampoules daily during incubation. Record observations. All positive ampoules should be recorded and then disposed of immediately.

Interpretation:

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

Test: A failed sterilization cycle is indicated by a change in color to or toward yellow. A test ampoule that retains its purple color indicates an adequate sterilization cycle.

Survival Time (in minutes) = not less than (labeled D-value) x [(log 10 labeled spore count) – 2]*

Kill Time (in minutes) = not more than (labeled D-value) x [(log 10 labeled spore count) + 4]*

*These equations are taken from USP 31

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