



Biological Indicator for Steam

1. Product description:

The Biological Indicator AC24(orange cap) is designed for monitoring of steam sterilization processes.

The presence of *Geobacillus.stearothermophilus*(ATCC7953) spores is detected by a visual color change (media turns yellow). The yellow color change indicates a sterilization process failure. The final readout of a negative result (media remains purple) is made after 24 hours of incubation.

2. Directions for use:

2.1 Identify the Biological Indicator by writing the sterilizer number, load number, and processing date on the label.

2.2 Pack the biological indicator along with materials to be sterilized in an appropriate package according to recommended sterilization practices. Place the package in those areas which you consider a priori most inaccessible for the sterilizing agent (steam). Generally, a problematic area is the center of the load or near the door.

2.3 Sterilize as usual.

2.4 After the sterilization process has finished, open the sterilizer door, wait five minutes and remove the biological indicator from the package. CAUTION! Wear safety glasses and gloves when removing the AC48 Biological Indicator from the sterilized package. WARNING! Do not crush or handle the biological indicator excessively, since this might cause the glass ampoule to burst.

2.5 Let the biological indicator cool until it reaches room temperature.

2.6 Check the chemical indicator on the label of the biological indicator. A color change to black indicates that the biological indicator has been exposed to steam. IMPORTANT: This color change does not evidence the process effectiveness to achieve sterility. If the chemical indicator color has not changed, it is necessary to check the sterilization process.

2.7 Press the cap to seal the tube. Then, break the ampoule contained within the biological indicator by an ampoule crusher.

2.8 Incubate the processed biological indicator and the indicator used as positive control for a maximum of 24 hours at $56\pm 2^\circ\text{C}$ for the readout.

Record the results and discard biological indicators immediately as explained below.

Do not reuse the sterilizer until the biological indicator test result is negative.

3. Warning:

3.1 Wear safety glasses and gloves when removing the biological indicator from the sterilizer.

3.2 Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst.

3.3 Wear safety glasses when crushing the biological indicator. Handle the biological indicator by the cap when crushing and tapping. Do not use your fingers to crush the glass ampule.

3.4 Do not roll the biological indicator between fingers to wet the spore strip.

3.5 Do not reuse the sterilizer until the biological indicator test result is negative.

3.6 Do not expose AC48 to EO, Dry Heat, Radiation or chemical agents or any sterilization process other than Steam sterilization.

4. Disposal:

Dispose of used Purtec biological indicators according to your healthcare facility's policy.

You may wish to autoclave any positive biological indicators at 121°C for at least 15 minutes, or at 132°C for 10 minutes in a gravity displacement steam sterilizer, or at 132°C for 4 minutes in a vacuum assisted steam sterilizer.

5. Storage and Shelf Life:

A. Store Purtec biological indicators under normal room conditions: $15\text{--}30^\circ\text{C}$ 30-80% relative humidity.

B. Do not store these biological indicators near sterilants or other chemicals. Do not freeze.

C. Purtec biological indicators have a 24 month shelf life.