

GERMISAFE™

Self-Contained Biological Indicators For Steam Sterilization

- For use in all steam sterilization cycles
- Vials contain *Geobacillus stearothermophilus* spores
- Assists in compliance with guidelines and standards for sterilization monitoring
- Incubator with built-in vial crusher
- Test up to 14 sterilizers at one time
- Spore test as stated in provincial standards and guidelines



Starter Kits*



**Starter Kit includes self-contained biological indicator vials, incubator, log book and built-in vial crusher.*

Extras



When to Test?

- ☐ Whenever a new type of packaging material or tray is used
- ☐ After training new sterilization personnel
- ☐ After a sterilizer process failure is indicated by a failed (positive) BI+
- ☐ After a sterilizer has been repaired
- ☐ After any change in the sterilizer loading procedures
- ☐ During initial use of a new sterilizer
- ☐ After relocation of an existing sterilizer; and after electrical/power source failure

Common causes of steam sterilization failure

- ☐ Interrupting the sterilization cycle
- ☐ Incorrect cycle parameters (time & temperature)
- ☐ Mechanical failure
- ☐ Operator error
- ☐ Sterilizer overload

INSTRUCTIONS FOR USE

Sterilization

1. Record the sterilizer number, load number and processing date on the BI label.
2. Place one or more BI's inside an instrument tray, rigid container, peel pouch or process challenge device, e.g. AAMI challenge pack, whichever is representative of the load being processed.
3. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (i.e. the bottom shelf near the door, over the drain of a large sterilizer or in the middle shelf of a small sterilizer).
4. Process the load according to the sterilizer manufacturer's instructions.
5. Remove the BI and confirm the chemical indicator printed on the label has turned brown.

Caution: After processing, the BI is hot and under pressure. Always allow to cool for ten (10) minutes before crushing. Failure to do so could cause the glass ampule inside the BI vial to burst which may result in injury. For this reason, safety glasses should be worn when handling and crushing a processed BI.

Activation and Incubation

1. Activate the processed BI up to 8 hours after processing by crushing the inner glass media tube using a vial crusher.
2. Incubate at 55-60°C for 24 hours checking for spore growth (visual colour change from purple to yellow) at regular intervals (i.e. 8, 12 and 18 hours).

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No colour change in the purple media indicates proper sterilization.
2. Any positive (growth indicated by purple to yellow colour change) result, should be reported immediately to a Supervisor and the sterilizer taken out of service until resolved.
3. The stability of positive growth as indicated by a yellow colour change has been tested up to 48 hours.

Use of Controls

1. As a control, an unprocessed BI (from the same lot) should be crushed and incubated each time the sterilizer is tested.

To order GermiSafe or for more information, contact your Account Manager or Germiphene at 1.800.265.9931 | info@germiphene.com www.germiphene.com

INSTRUCTIONS FOR USE

Q. Can we check results of our Germi-Safe vials before 24 hours?

- A. Yes. 24 hours is required for complete incubation, however many failures occur with 8 hours. Once a failure is detected, there is no reason to continue incubating the BI. We recommend checking results periodically (e.g., 6, 12, and 18 hours).

Remember: the unprocessed Control BI should turn yellow, indicating spore growth. **Caution:** After processing, the BI is hot and under pressure. Always allow to cool for ten (10) minutes before crushing. Failure to do so could cause the glass ampule inside the BI vial to burst which may result in injury. For this reason, safety glasses should be worn when handling and crushing a processed BI.

Q. What is a Control and when should one be used?

- A. A Control is an unprocessed Germi-Safe vial. Each time the sterilizer is tested, an unprocessed (control) BI should be activated and incubated. The spores will grow and turn the growth media from purple to yellow, which demonstrates the spores inside were viable at the time of use and that the incubator temperature is appropriate.

Q. What should a user do if their unprocessed Control BI does not turn yellow?

- A. Check that the incubator is plugged in, has power and it set to 60°C. Be sure the vial has NOT expired, and is properly activated using plastic vial crusher. Also be sure the BI's have been properly stored prior to use. Room temperature and not exposed to the Steam sterilization process.

Q. What can cause the media to evaporate or turn brownish in colour during incubation?

- A. Media can evaporate or turn a brownish colour if left in the incubator for too long, usually a period beyond 72 hours. Media that has been incubated for 24 hours or less that starts to turn a brownish colour, can be an indication that the incubator temperature is too high. This "caramelizing" of the media does not necessarily indicate a sterilization failure, but indicates the media has been exposed to heat for too long.

Q. How should users dispose of the processed and unprocessed Germi-Safe vials?

- A. Dispose of the BI's as normal waste when no growth is observed e.g. passed test. However when growth is observed in failed test or unprocessed Control, these should be autoclaved at 250°F for 30 minutes prior to disposal.



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