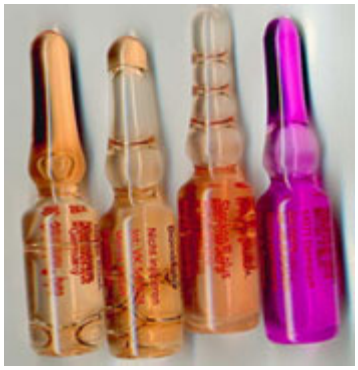
Sterikon© plus Bioindicator Troubleshooting Guide

Before autoclaving, the color of Sterikon plus Bioindicator is purple to deep pink. If the ampules show a differnt color, they are **not suitable** for use and **must** be discarded.

After incubation (without autoclaving) controls (3 examples) show growth and color change to orange/yellow. A slight turbidity might be visible when growth occurs.



After autoclaving (121°C, 15 min) and incubation (60°C, 48h) ampules (1 example) show no growth and no color change, Sterikon plus Bioindicator remains purple/deep pink.

Storage

Q: How long can the indicator be stored without refrigeration?

A: The indicator can withstand short periods without refrigeration to allow for standard ground shipment from the warehouse to the customer. However, it should be refrigerated promptly upon arrival.

Q: What is the proper storage temperature for the indicator?

A: The indicator should be stored refrigerated between +2 and +8°C until use.

Q: What should be done if the indicator hasn't been stored refrigerated?

A: It is recommended that the indicator be discarded if it hasn't been stored at the proper temperature.

Q: How long can the indicators be used after the expiration date?

A: The indicators should **not** be used and promptly discarded after the expiration date on the box.

Use

Q: How can the performance of Sterikon plus bioindicator be verified?

A: We recommend adapting the EMD Chemicals QC procedures to your lab environment. When incubating ampules at 35°C for 48 hours, all the ampules remain reddish-violet in color. When incubating ampules at 60°C for 24 hours, all the ampules turn yellow-orange in color. Additionally, we test performance by bringing them to room temperature and then transferring them into an oil bath set at 121 ± 0.5°C. After 6 minutes, remove half of the ampules. After 15 minutes, remove the other half of the ampules. Add more ampules to the oil and remove them after 10 minutes. Cool down all of the ampules immediately after removing from the oil by flushing with running water, and incubate them for 24 hours at 60°C. The ampules that were treated for 6 minutes must turn yellow-orange. The ampules

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that were treated for 10 minutes can be either yellow-orange or reddish-violet. The ampules that were treated for 15 minutes must remain reddish-violet.

We do not recommend verifying the spore population nor the D-value, as these tests do not generally reproduce the results reported on the Certificate of Analysis. Population verification is difficult because spores tend to stick to the charged walls of the glass ampule. D-value verification is difficult because it is only reproducible under the exact conditions under which it was determined. The other tests described previously are more representative of the proper performance of Sterikon plus bioindicator.

Q: What if the indicator is yellow before being placed in the autoclave?

A: The indicator should **not** be used and promptly discarded. This is an indication that the ampoules have been subjected to elevated storage temperatures. This is a failure due to improper storage conditions.

Q: What if the indicator is yellow upon removal from the autoclave?

A: This could occur with extreme operating conditions such as excessive temperature (>125°C) or excessive autoclave cycle time. A thorough investigation of the equipment should be conducted.

Q: Under what autoclave operating conditions can the indicator be used?

A: The indicator is designed for a steam autoclave operating at 121°C ± 0.5°C for a cycle time of 15 minutes. The ampoules should not be used at other operating temperatures.

Q: Where should the indicator(s) be placed in the load?

A: The indicator(s) should be placed at the most difficult location for steam to penetrate into the load.

Q: What is the proper incubation temperature and time?

A: The ampoules should be incubated at 60 ± 2°C for up to 48 hours. Results are usually known after 24 hours. However, final evaluation should be made after 48 hours.

Q: Are there any problems if the incubation period must be extended to 7 days?

A: No, although results will be available after 48 hours.

Q: What does it mean if the indicator(s) turns yellow after incubation?

A: The control ampoule (not autoclaved) should always turn yellow after incubation. If the autoclaved ampoules turn yellow and/or show turbidity then the autoclave cycle has failed.

Q: What is a failed autoclave cycle?

A: This is when the product being autoclaved hasn't reached 121°C or did not remain at 121°C for 15 minutes. The product should be autoclaved again after a thorough investigation of the operating conditions and the equipment.

Q: Why would a cycle fail yet the probe reached 121°C for 15 minutes?

A: This is a common problem using a drain probe to indicate temperature in the autoclave. The temperature has reached 121°C at the drain probe, however temperatures in the middle of the load may not have reached this temperature. Using a load probe eliminates this problem as the actual load temperature is used for monitoring the process. If a load probe is not available, then the cycle time has to be lengthened to compensate for the amount of time it takes for the load to reach 121°C.

Disposal and Safety

Q: How should the ampoules be disposed?

A: Sterilize all ampoules at 123°C for at least 15 minutes before discarding with normal glassware waste. Do not break the ampoules to remove the contents before discarding.

Q: How should a broken ampoule be cleaned up?

A: While wearing protective gloves, the area should be sprayed with a disinfectant solution then wiped up. The entire area should then be thoroughly cleaned with the disinfectant solution. The broken glass should be properly discarded.

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