




Biological Indicator Spore Testing Procedure

- Biological indicator spore testing must be performed monthly according to the Department of Health Services on all autoclaves used for sterilizing medical instruments.
- Without biological indicator testing, adequacy/ efficacy of the sterilization process cannot be assumed.
- Ampules containing *Bacillus stearothermophilus* are used for this testing, due to its resistance to heat, to measure biological performance.
- These ampules for in office testing may be purchased from MesaLabs at: <https://sterilizermonitoring.mesalabs.com/mtc/Products/List?cid=2> or from different vendor. Make sure you are purchasing biological spore indicators and not just heat test strips. You can search “biological indicator” on the internet and find results.
- OPTIONS:
 - **In Office:** If perform your testing in office, you will purchase the ampules from a vendor AND have to process the test ampule, incubate, read and record the results every month. The charge to you is approximately \$94 for 25 vials (one year supply) and the incubator is a one-time cost of about \$229.
 - **Mail-In Testing Services:** 12 tests are \$84 and the spore indicator is processed and mailed to the lab. Test results are sent via email in 24 hours and your office is called if results fail. There are reminders to run reports. There is no charge for processing the tests but a one-time process and shipping cost of \$8.95 year. The tests require only one postage stamp to mail in.
- Offices that use MesaLabs for spore testing will receive a 10% discount if they tell them they are a provider for CenCal Health. Contact:
 - David Keil
Account Manager

1-800-289-7786 x32
dkeil@MesaLabs.com
<http://sporetesting.mesalabs.com/>

QUESTIONS and ANSWERS

- How many ampules will be needed per year? Most ampules have a shelf life of 48 months. You will need one ampule per autoclave per month as well as one control. If a provider has one autoclave they will need 24 ampules total per year (1 ampule per month + 1 control ampules x 12 = 24).
- How do I keep track of results? A log should be created and kept by the provider to record the date of testing and results (see example below). This log will be checked during Facility Site Audits to ensure that this biological indicator testing is being conducted quarterly.
- How do I do the testing? If you purchase your own ampules and do all the incubating, reading and recording yourself, there should be a set of instructions included with the ampules. Follow instructions and protocols that comes with your specific ampules.

Procedure

1. Every month perform the autoclave biological spore test.
2. Place vial in the center of the bag, or autoclave (if autoclave strictly used for sterilizing instruments).
3. Process the load using normal operating procedures.
4. Follow any instructions provided by the testing supplier.
5. If doing in house testing, incubate *at incubation temperature* for 24-48 hours (see specific protocol included with ampules).
6. Incubate a control vial that has not been autoclaved, media should turn yellow to indicate growth. If the control vial remains purple (colors may vary by test kit), there may be a problem with the batch of indicator vials and the test may not be valid. Repeat the run, and if the result is the same obtain a new set of test vials. Return the waste to the bin and re-run with a new batch of vials.
7. If the test vial media is purple after incubating 72 hours, sterilization is successful, there was no growth.
8. If the media turns yellow, the bacteria grew and sterilization failed.
 - a. Review the run chart to see if the physical conditions (time, temperature) were met. If they were, discontinue using the autoclave, return the waste to a biological waste bin, and contact the service provider to get the autoclave repaired.
 - c. Retest after the repairs are completed.
9. Record all results and retain in the Autoclave logbook (see example below).

Loading Autoclave

- Ensure material is acceptable for autoclaving
- Separate Similar Loads
- Load material to ensure steam penetration
- Ensure all containers & bags are well vented

Unloading Autoclave

- Wait until chamber pressure gauge reaches 0 before opening the door
- Open door slightly to allow any remaining steam to dissipate
- Verify heat sensitive tape has changed color. This indicates that proper temperature has been achieved on the package surface. It does not indicate sterility of the inner contents.

Safety Considerations

- Use caution when opening the autoclave door. Allow superheated steam to exit.
- Use caution when handling a bag in case sharp objects have been inadvertently placed in the bag. Never lift a bag from the bottom of the bag to load the chamber. Handle the bag from the top.
- Glassware may crack or shatter if cold liquid comes in contact with this superheated glassware. If glass breaks in the autoclave, use tongs, forceps, and other mechanical means to recover fragments.

Autoclave Testing

- All autoclaves should be regularly monitored for effectiveness in three areas: mechanical, thermal, and biological performance.
- Autoclave indicator tape indicates that the outside of the container came to temperature, it does not reflect time or conditions inside the load and does not prove effective decontamination.
- General mechanical maintenance will be conducted on an annual basis or as recommended by the manufacture
- Autoclaves should be tested monthly with a spore indicator for biological effectiveness and the results documented by user.
 - Spore indicators should be placed at the slowest point of heating (e.g. the center of the load)

Safety Maintenance

- A safety check should be completed prior to each use. (e.g. door closes and seals properly, rack is in place, correct settings are being used, the interior is clean)

Record Keeping

- Daily Autoclave Log is maintained and each load recorded.
 - o The use of an autoclave logbook is recommended for each autoclave. Prior to autoclaving any items, users fill in all required information. (Users Name, cycle time, cycle setting, time in/out, verification of results)

Autoclave Q and A's

What is an autoclave?

An autoclave, or steam sterilizer, is an insulated pressure chamber in which saturated steam is used to elevate the temperature. Autoclaves are found in research, diagnostic and microbiology laboratories, health centers and other places that require high-level disinfection.

How does an autoclave work?

An autoclave uses pressurized steam to decontaminate infectious waste. Laboratory autoclaves normally operate at a temperature of 273°F (121°C), a pressure of 15 pounds per square inch (psi) and a minimum cycle time of 30 minutes. The effectiveness of an autoclave depends on the time, temperature and direct steam contact with infectious agents. Other factors that influence treatment efficiency include waste density, physical state and size and organic content.

How do I use the autoclave?

- Autoclaves come in many different styles. Therefore, always follow the manufacturer's instructions when using the autoclave and ask your supervisor if you have questions.
- There are different autoclave and exhaust cycles for liquids and solids.
- Loosely close the bag or vessel; do not tie the bag or seal the vessel tightly before autoclaving. Sealed containers can explode.

NOTE: All autoclaves should be validated by spore testing: Monthly for healthcare use, weekly or daily for dental depending on the frequency of autoclaving. Sites that rarely perform autoclaving, (2-3 times per year) can do spore testing with each time they use the autoclave to assure sterility.