



UMD Autoclave Validation Program Standard

The ESSR Biosafety Office manages the Autoclave Validation Program for autoclaves used for the sterilization of biological waste.

Autoclaves used for biological waste sterilization should be tested monthly to confirm proper performance and support safe disposal of biological waste generated in laboratories.

The Autoclave Validation Program aims to:

- 1) Monitor the functionality of autoclaves used for biological waste sterilization
- 2) Provide a standardized method for validation across departments
- 3) Reduce costs for users by ESSR-provided validation materials

Autoclave validation testing may be performed using one of two methods below. Either method is acceptable for monthly validation testing as long as Biological Indicators (BI) are used and results are recorded.

Mail-Out BI Test: A BI strip is placed in the autoclave during a standard waste cycle. After the cycle, the strip is placed in the provided envelope and mailed to the testing service for processing. Results are available within about one week after the sample is mailed. Kits should be stored in a cool, dry location away from direct sunlight and chemical disinfecting agents.

In-House BI Test: An in-house BI vial may be used. After the autoclave cycle, the vial is incubated in a laboratory incubator following the manufacturer's instructions. The SOP for in-house BI test shall be sent to the Biosafety Office for review and approval. Results are typically available within 24 hours.

1. Roles and Responsibilities

1.1 Biosafety Office:

- 1) Procuring validation kits for each autoclave in this program
- 2) Distributing kits to departmental Points of Contact (POCs) or their designees
- 3) Monitoring monthly validation testing
- 4) Communicating with departments and POCs when issues arise
- 5) Assisting with troubleshooting when validation tests fail
- 6) Coordinating alternative waste sterilization options when necessary

1.2 Departments:

- 1) Identifying a POC for this program. Typically, the Departments' Compliance Officers take the responsibilities of POCs for this program.

- 2) Providing postage for mail-out BI tests. This can be done by supplying stamps or by providing an account number for use with the [UMD Mail Services](#).

2. Communication Expectations

It is the POCs' responsibility to ensure the monthly BI testing is conducted for autoclaves within their departments. On behalf of their departments, the POCs or their designees notify autoclave@umd.edu when:

- 1) An autoclave is slated for installation, relocation, or decommissioning
- 2) An autoclave is under repair or inactive
- 3) An autoclave is being used for biological waste sterilization
- 4) A validation test has failed
 - a. Provide context for failure, details of retest, and repair plans if applicable
- 5) Autoclave test kits are running low (less than 3 kits remain)
- 6) Planning to change the validation method

POCs subscribe to the autoclave@umd.edu [Google Calendar](#) for routine reminders and notifications:

- 1) Events can be created to mark the date of testing, mailing, receipt of results, etc.
- 2) Periods of inactivity or expected repair can be planned and recorded
- 3) The Biosafety team can mark kit expiration dates, reorder dates, and delivery dates

The Biosafety Office may follow up if:

- 1) There is an absence of testing for two consecutive months without email communication from POCs
- 2) A test has failed and no follow-up has been provided

3. Instructions for Failed Validation

- 1) POCs will receive an email notification from the testing lab indicating failure.
- 2) The POC or their designee shall mark unit as "Out of Service" with specific date and note on the "Out of Service" sign.
- 3) Investigate the cause of the failure and retest.
- 4) If retest successful, remove "Out of Service" designation and return to routine use.
- 5) If retest fails, maintain "Out of Service" sign, coordinate autoclave service/repairs, and contact autoclave@umd.edu to notify and discuss alternative waste management options.
- 6) After necessary service, retest to confirm return to working order.
- 7) Record updates throughout via the autoclave@umd.edu [Google Calendar](#).

Appendix: Mail-Out BI Test Instructions

Test strips can be processed in an autoclave with a typical load on a standard waste cycle or in an empty autoclave by following the instructions below.

1. Verify that the expiration date has not elapsed and the account number on the test pack matches the ID# on the autoclave unit, as shown on the label.
 - a. **This is critical for accurate tracking and data collection.** Each account number contains the building and room numbers where the autoclave is located, followed by the unique MD# for the unit (or serial number if no MD#).
 - b. Discard the expired kit as biological waste and email autoclave@umd.edu for replacement.
2. **Do not remove control strip** from envelope's right side. Remove test strip from envelope's left side and place strip into autoclave. **Do not open blue glassine pouch** containing test strip.
 - a. Test strips themselves are not considered hazardous, but ensure you are donning appropriate PPE for the hazards associated with the waste you are handling. This includes heat-resistant gloves in addition to standard lab attire, such as gloves, safety glasses, lab coat, long pants, and closed toed shoes.
3. Run autoclave on the standard waste cycle and document cycle details internally.
 - a. Include unit ID#, date, time, operator name, cycle name (or parameters), and load type, if applicable.
 - b. Record circumstances that may have interfered with the sterilization process, such as incorrect cycle parameters, cycle interruption, or interference of an object with the pressure seal.
4. Place the test strip back into the pre-addressed envelope, seal it, and mail via USPS. Any undeliverable test packets will be returned by USPS to the Biosafety Office in the Seneca Building.
5. Receive validation results via email and record.
6. Communicate testing details and results with the Biosafety team via events on the autoclave@umd.edu [Google Calendar](#).