

Autoclave Safe Use and Validation Procedure

1. PURPOSE

- 1.1. This procedure provides guidelines for the safe operation and maintenance of autoclaves, as well as a process to assess an autoclave's efficiency and performance.

2. SCOPE

- 2.1. This Autoclave Safe Use and Validation Procedure applies to all individuals (employees, students, volunteers, visiting faculty, etc.) who operate, are responsible for or owns an autoclave or biological sterilizer. This procedure shall be used in conjunction with the autoclave manufacturer's manual and other required departmental / clinical procedures.

3. RESPONSIBILITIES

3.1. Autoclave owner (Department, Unit or Principal Investigator)

3.1.1. Has responsibility for ensuring autoclave users under their supervision:

- Adhere to all guidelines, procedures and regulations pertaining to the use of autoclaves.
- Are trained on the hazards associated with operation of an autoclave.
- Use the appropriate personal protective equipment (PPE) as required.
- Report hazardous material spills to Notre Dame Security Police (NDSP) (campus phone: 911 or non-campus phone: 631-5555) and report the incident through the [online Safety Incident Report](#).
- Maintain the autoclave as directed by manufacturer's specifications.

3.1.2. Selects biological indicator method for validation. See Appendix A for vendors and process options.

3.1.3. Ensures autoclave validations are completed monthly for each autoclave.

3.1.4. If validations repeatedly fail (see section 11.2), removes the autoclave from service until repaired.

3.1.5. Maintains log of autoclave usage (see Appendix B).

3.1.6. Maintains biological indicator validations and makes them available upon request.

3.2. Principal Investigators

3.2.1. Have overall responsibility for ensuring autoclave users under their supervision:

- Adhere to all guidelines, policies and regulations pertaining to the use of autoclaves.
- Complete all appropriate safety training and document the training.
- Are trained on the hazards associated with operation of an autoclave. All training shall be documented, retained, and made available upon request.
- Have appropriate PPE available and use as required in this procedure.

- Report hazardous material spills to NDSP (campus phone: 911 or non-campus phone: 631-5555) and report the incident through the [online Safety Incident Report](#).

3.3. Autoclave Operators (employees, students, volunteers, visiting faculty)

- 3.3.1. Comply with all guidelines outlined in this procedure.
- 3.3.2. Attend all appropriate safety training related to autoclave operation.
- 3.3.3. Notify the autoclave owner of any problems with an autoclave.
- 3.3.4. Notify the autoclave owner or PI of any injuries related to autoclave use.
- 3.3.5. Inform autoclave owner or RMS of any unsafe practices or conditions.
- 3.3.6. Complete recordkeeping requirements in this procedure.
- 3.3.7. Complete validation requirements in this procedure.
- 3.3.8. Notify the immediate supervisor when two consecutive validation failures occur.

3.4. Risk Management and Safety (RMS)

- 3.4.1. Conducts audits quarterly to review autoclave logs and other applicable documentation.
- 3.4.2. Ensures validations are being conducted and the results maintained according to the requirements in this procedure.
- 3.4.3. Notifies autoclave owner of any non-compliance and deficiencies identified during the review.

4. TRAINING

- 4.1. All autoclave users shall be trained on the proper use / operation prior to using any autoclaves.
- 4.2. Training consists of 2 components:
 - 4.2.1. complyND training (course name: RMS – Autoclave Safety Training)
 - 4.2.2. Lab Specific (hands-on) training
 - An experienced and knowledgeable person shall conduct the Lab Specific autoclave training.
 - Since autoclaves vary greatly from model to model, training shall cover the specifics of the exact autoclave model(s) the autoclave user will be using.
 - Lab Specific training shall be documented and records maintained so they are available upon request.

5. ASSOCIATED HAZARDS

- 5.1. Autoclaves are sterilizers using high pressure and high temperature steam to kill microorganisms and render biohazardous material inactive. The potential safety risks for the operators include:
 - 5.1.1. Heat burns from hot materials, superheated liquids, and autoclave chamber walls and door.

- 5.1.2. Steam burns from residual steam coming out from the autoclave and materials on completion of the cycle.
- 5.1.3. Hot fluid scalds from boiling liquids and spillage in autoclave.
- 5.1.4. Bodily injury if there is an explosion from autoclaving sealed containers.
- 5.1.5. Chemical exposure from autoclaving hazardous chemicals.
- 5.1.6. Fires and explosions from autoclaving hazardous chemicals.
- 5.1.7. Exposure to biological materials if load is not properly sterilized.

6. EMERGENCY MEDICAL PROCEDURES

- 6.1. Medical treatment shall be sought immediately for autoclave related injuries.
- 6.2. Dispatch shall be contacted by calling 911 from a campus phone or 574-631-5555 from a cell phone.
- 6.3. All injuries and exposures shall be reported to the immediate PI/Supervisor and documented in a [Safety Incident Report](#).

7. PERSONAL PROTECTIVE EQUIPMENT (PPE)

- 7.1. Always wear the following when operating an autoclave:
 - 7.1.1. Standard lab clothing (long pants, close-toed shoes).
 - 7.1.2. Safety glasses, lab coat, heat resistant gloves.

8. AUTOCLAVE BASICS AND OPERATION

- 8.1. The following materials shall never be autoclaved:
 - 8.1.1. Hazardous chemicals (flammables, reactives, corrosives, toxics) pose exposure to toxic fumes, fire and explosion risk when autoclaved.
 - 8.1.2. Items contaminated with chemicals and biologicals (including lab coats) pose chemical exposure, fire and explosion risks when autoclaved.
 - Biologically contaminated items, which are also chemically contaminated, shall be handled as hazardous waste.
 - See the [Hazardous Waste Procedure](#) for more information.
 - 8.1.3. Dried bleach, bleach associated materials, nitrocellulose materials pose chemical exposure, fire and explosion risks.
 - 8.1.4. Radioactive materials contaminated with biologicals pose radioactive exposure risk when autoclaved.
 - Biologically contaminated radioactive materials shall be handled as radioactive waste.
 - See the [Radiation Safety Manual](#) for more information.
- 8.2. Verify materials are able to be autoclaved safely.

- 8.2.1. Consult manufacturer's information to verify the materials will withstand autoclave cycles.
 - 8.2.2. Plastics shall be heat-resistant; e.g., polycarbonate (PC), PTFE ("Teflon") and most polypropylene (PP) items.
 - 8.2.3. Glass shall be heat-resistant borosilicate (Pyrex™ or Kimax™) and inspected for cracks.
- 8.3. Prepare and package materials appropriately.
- 8.3.1. Loose dry materials and small items shall be wrapped or bagged in steam-penetrable paper or loosely wrapped aluminum foil. Wrapping too tightly will impede steam penetration, decreasing efficiency of the sterilization process.
 - 8.3.2. All containers shall be covered with a loosened lid or steam-penetrable stopper to prevent pressure buildup.
 - 8.3.3. Containers/bottles of liquid shall be a maximum of $\frac{2}{3}$ filled, with caps loosened to allow for pressure changes. Maintain 1-2 inches of space between the bottles.
 - 8.3.4. Sharps shall be in a designated 'Sharps' container or tray.
 - 8.3.5. Items or baskets shall be tagged with autoclave tape.
 - 8.3.6. Water shall be added to containers / autoclave trays, as appropriate.
 - 8.3.7. Items shall be placed in containers to secure and contain spills.
 - Items shall be placed in a stainless steel or autoclavable plastic container/pan for their stability and ease of handling.
 - The pan shall be large enough to contain a total spill of the contents.
 - Bags shall not be tightly sealed to allow for steam penetration.
 - 8.3.8. Autoclave steam indicator tape shall be used in each autoclave load. It may be used to secure packages to indicate that those packages have been exposed to the proper levels of heat and moisture needed to achieve sterility.
 - 8.3.9. Biological indicator validation shall be completed monthly and shall be placed in the center of the load to verify full sterilization has been achieved.
- 8.4. Prior to loading the autoclave:
- 8.4.1. The inside of the autoclave chamber shall be checked for any items left by previous users.
 - 8.4.2. The drain strainer shall be checked for debris and cleaned, as needed.
 - 8.4.3. The door gaskets shall be inspected for deterioration and verified gasket is still intact and pliable.
- 8.5. Loading:
- 8.5.1. The autoclave shall be loaded according to the manufacturer's recommendations. DO NOT overload the autoclave.
 - 8.5.2. The autoclave door shall be fully closed and latched to prevent steam from escaping while the autoclave is running a cycle.
 - 8.5.3. The autoclave cycle settings shall be verified to ensure appropriate settings have been selected.

8.6. Unloading

- 8.6.1. The cycle shall be assessed to ensure it has completed and both temperature and pressure have returned to a safe range.
- 8.6.2. The proper PPE (Section 5) shall be donned when opening the autoclave door after a cycle. If sharps containers are present in load, cut- and heat-resistant gloves shall be used.
- 8.6.3. After the cycle ends, the door shall be opened slowly and used as a shield. Keep head, face, arms, and hands away from the opening.
- 8.6.4. After the cycle ends, autoclave users shall wait at least 10 minutes to remove autoclaved liquid load items.
- 8.6.5. Autoclaved liquids shall stand for at least a full hour before touching with ungloved hands. Be sure to let others in the area know that a heat hazard is present.

9. TYPES OF STERILIZATION INDICATORS

9.1. Biological Indicators

- 9.1.1. Contain spores from *Geobacillus stearothermophilus*, a microorganism that is inactivated when exposed to saturated steam for a minimum of 20 minutes.
- 9.1.2. Indicate if sterilization of *G. stearothermophilus* spores occurred.
- 9.1.3. Manufacturer's instructions shall be followed for proper use.

9.2. Chemical Indicators

9.2.1. Tape and Bag Indicators

- Tape indicators are adhesive-backed paper tape with heat sensitive, chemical indicator markings.
- Tape indicators change color or display diagonal stripes, the words "sterile" or "autoclaved" when exposed to temperatures at or above 121°C.
- Tape indicators are typically placed on the exterior of the waste load.
- Some autoclave bags have chemical indicator markings that appear when exposed to temperatures at or above 121°C.
- If the temperature sensitive tape or bags do not indicate that a temperature of at least 121°C was reached during the sterilization process, the load is not considered decontaminated. See 11.2 for what to do for validation failures.
- If tape or bag indicators fail on two consecutive loads, notify the autoclave owner.
- Tape and bag indicators are not designed nor intended to prove that organisms have actually been killed. They indicate that a temperature at or above 121°C has been achieved within the autoclave.
- IBC recommends that you DO NOT use autoclave tape as the only indicator of decontamination or sterilization.

9.2.2. Integrated Chemical Indicator Strips

- Integrated chemical indicator strips provide a limited validation of temperature and time by displaying a color change after exposure to normal autoclave operating temperatures at or above 121°C for several minutes.
- Chemical color change indicators can be placed within the waste load.

- If the chemical indicators fail on two consecutive loads, notify the autoclave owner.

10. VALIDATION PROCESS

10.1. General Process Overview

- 10.1.1. A typical load (bottles, cages, liquids, plates, etc.) shall be prepared as described in section 8.3 and loaded into the autoclave.
- 10.1.2. A biological indicator shall be placed within the load. A retrieval string/cord shall be used, as necessary.
- 10.1.3. The appropriate cycle settings shall be inputted and the cycle started.
- 10.1.4. The results shall be checked and recorded after the 48-hour incubation period.

10.2. Biological indicator validation shall be completed on a monthly basis.

10.3. Manufacturer's recommendations for placement of spore sample and incubation time shall be followed.

10.4. If mailing sample(s) for vendor verification, they shall be packaged and shipped per manufacturer's recommendations.

11. RESULTS OF VALIDATION

11.1. Pass

11.1.1. If the biological indicator does not exhibit growth and the chemical indicator tape / strips indicate temperatures were met, the validation passes and the information should be logged into the Autoclave Log Sheet (see Appendix B).

11.2. Fail

11.2.1. Failure has occurred when:

- the autoclaved biological indicator exhibits growth or
- the chemical indicator tape / strips do not indicate the proper temperature was met.

11.2.2. When the validation process fails, the validation process shall be repeated.

11.2.3. If the second validation indicator fails,

- the autoclave user shall notify the autoclave owner of the consecutive failures.
- The autoclave owner shall remove the autoclave from service and submit a repair request by a qualified technician.
 - The autoclave shall remain out of service until repairs have been completed and a validation test successfully passes.
 - A "Out of Service – Do Not Use" sign (see Appendix C for example) shall be posted on autoclave.

11.3. Validation results shall be maintained by the owner (Department or PI) and shall be made available upon request.

12. RECORDKEEPING

12.1. Autoclave log

12.1.1. Users shall maintain an autoclave log and available autoclave printouts for each use.

12.1.2. The log shall be maintained near the autoclave.

12.1.3. The following details shall be included:

- Date, time and operator's name
- Contact information: PI name and phone number
- Type of material sterilized/cycle
- Temperature, pressure, and length of time the load was sterilized.

12.1.4. Autoclave records shall be retained for at least 3 years.

12.2. Biological Indicator Test Results

12.2.1. Autoclave owner shall maintain all biological indicator test results and make them available during the quarterly audit and upon request.

12.2.2. Records shall indicate biological indicator manufacturer information, type of load tested, the validation test date, name and phone number of autoclave user conducting validation test.

12.2.3. Records shall be maintained either in the room with the autoclave or signage should be posted indicating the location of any records.

12.2.4. These results shall be maintained for 3 years.

12.3. Preventative Maintenance / Repair Records

12.3.1. Autoclave owner shall maintain all preventative maintenance / repair records and make them available during the quarterly audit and upon request.

12.3.2. Records shall indicate who performed the work, type of maintenance / repairs conducted, and the service date.

12.3.3. Records shall be maintained either in the room with the autoclave or signage should be posted indicating the location of any records.

12.3.4. These results shall be maintained for 3 years.

12.4. Quarterly Audits

12.4.1. RMS shall maintain audit reports per the [University Records Management and Archives Policy](#).

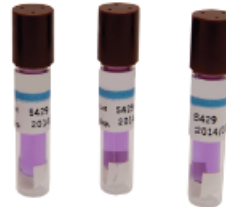
Appendix A – Vendors for Biological Indicators

1. Mesa Laboratories <http://sporetesting.mesalabs.com/>
 - 1.1. In Lab / Department Testing

Mesa Labs In-Office Spore Testing

Mesa Labs In-Office Spore Testing System

EZTest is an easy-to-use, in-office spore testing system for use in steam sterilization cycles. Simply place an ampoule in a normal sterilization cycle. After the cycle, crush the ampoule and then incubate. Results are available in 24 hours! Color changes from purple to yellow indicate sterilization cycle failure. EZTest Steam is a self-contained biological indicator for use in monitoring the efficacy of 121° C, 132° C, 134° C and 135° C steam sterilization cycles.



Contains *G. Stearothermophilus* Spores.

Each lot of EZTest is certified for population, species, D-value, z-value (where applicable), purity and expiry.

Interpreting Results:

If the spores are not destroyed during the sterilization cycle, then the growth media will change to yellow after incubation, which indicates a failed (positive) test result. If the sterilization cycle is successful and the spores are completely destroyed, then the growth media will remain purple after incubation, which indicates a passed (negative) test.

Use of Controls:

A positive control vial should always be used. Place an un-sterilized F7Test vial in the incubator along with the processed test vial. The control vial should change to yellow, indicating spore growth.

Incubation:

The Model 1410 incubator is used for incubation of EZTest self-contained biological indicators.

- Thirteen (13) individually numbered incubation cavities
- Integrated digital thermometer for easy temperature reference.
- Activation cavity for activating (crushing) EZTest vials.
- Fast warm up time



Item	Reorder Number	Package Configuration	Price
EZTest Steam	EZS/5	100 count	\$245.10
EZTest Steam <i>G. stearothermophilus</i>	EZS/525	25 count	\$ 96.24
1410 Incubator	I-1410	1	\$364.04

1.2. Mail-in Sample

Mesa Labs Mail-In Spore Testing

Mesa Labs Mail-In Spore Testing Services

Weekly Testing Service

- 52 tests with matching controls
- Individually barcoded envelopes
- Email test results

Monthly Testing Service

- 12 tests with matching controls
- Individually barcoded envelopes
- Email test results

Benefits of the Mesa Labs Mail-In Spore Testing Service

1. Complete Paperless System

- Email Test Results
 - Set up for the appropriate managers and office personnel
- Email Reminders-to-Test
 - Set up for the appropriate staff members
- Online Storage and Backup of Test Results
 - Easy access to your test result history 24 hours a day, 7 days a week

2. Notification and Compliance Support

- Failed test management - Prompt phone notification and support directly with the office
- Review the process for managing failed tests
- Review with staff members, managers, or doctors the process for monitoring and access to documentation on our secure website

3. Online Anytime Compliance Tracking (ACT) Dashboard

- Comprehensive review of test results data for your sterilizers
- Provide % of tests processed versus State Board required/recommended
- This data analysis and review will assist your office in quickly identifying trouble areas

Sterilization Record Keeping Wire-Bound Booklet

This sterilization log book is an essential component of your overall infection control program. Use this record keeping booklet to record mechanical parameters and chemical and biological test results. You can also document preventive maintenance and sterilizer repairs.



Services available for Steam/Autoclave, Chemical Vapor and Dry Heat Sterilizers.

Mesa Laboratories, Inc.
www.sporetesting.com
sporetesting@mesalabs.com



1-800-289-7781

2. 3M https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Attest-Biological-Indicator-Incubator-116/?N=5002385+3292874818&rt=rud

3M™ ATTEST™ STEAM INCUBATOR (56°C)

Intended Use

The 3M™ Attest™ Steam Incubator is designed and has been tested to be used with 3M™ Attest™ Biological Indicators (BI) 1261 and 1261P or 1262 and 1262P and allows rapid, reliable monitoring of steam sterilization processes. As a quick reference, the steam monitoring system is color-coded blue and brown, respectively. Use with other biological indicators may lead to incorrect results.

Each Attest™ incubator is pre-set at the appropriate temperature to promote growth of the test organism. The incubator's internal temperatures are rigidly controlled to 56°C +/- 2°C (133°F +/- 3°F) and automatically maintained. If a temperature measurement device is used to monitor the incubator, the sensor should be in contact with the metal heating block wall.

Appendix B – Sample Autoclave Log Sheet

AUTOCLAVE LOG SHEET

All loads containing biohazardous waste must be autoclaved at 121 C for a minimum of 30 minutes.

Autoclave Make/Model:				Location (Building/Room #):							
Lab/Facility Name:				Principal Investigator/Supervisor Name:							
Autoclave Owner:				Phone Number:							
Date	Contents	Cycle Number	Cycle Type	Sterilization Time (min)	Pressure (psi)	Max Temp Reached	Tape Result (Pass/Fail)	Chemical Integrator Result (Pass/Fail)	Biological Indicator Result (Pass/Fail)	Operator	Comments

Appendix C – Autoclave Out of Service – Do Not Use Sign

**OUT OF
SERVICE
DO NOT USE**