

Standard Operating Procedures (SOP) Autoclave Challenge Testing

Potential Hazards

- Sharps exposure
- Heat burns
- Projectiles

PPE

- Lab coat
- Safety glasses/goggles
- Closed toe shoes
- Impervious gloves (e.g. nitrile gloves)
- Heat- insulating gloves (i.e. autoclave gloves)



Materials Required

- Autoclave Usage/ Disposal of Waste S.O.P.
- Biological indicator vial
- Autoclave bags
- Autoclave tape
- Incubator
- String
- Log Book
- Mock waste load contents (e.g. conical tubes, eppendorf tubes, bottles)

Procedures

PROCESSING INDICATORS

1. Turn on incubator located in MH 121-B by plugging unit into outlet. Allow equipment to warm up for 30 minutes before use.
2. Obtain B.I. (biological indicator) vials located in MH 121-B and mock waste load contents in biosafety conex box at CSA.
3. Identify the B.I. by noting the autoclave number and processing date on the label of the vial.



4. Begin preparing the simulated waste load by loading autoclave bag half- full with mock waste load contents and placing onto metal autoclave tray.
5. Tie a long string to the biological indicator vial and place the biological indicator into the middle of the load. The string will allow easy removal after autoclaving.
6. Add ½ cup (100 ml) of tap water to the inside of the autoclavable red biohazard bags. Do not fill the mock waste bag over half full or above its fill line (if present.)
7. Loosely tie the neck of the red biohazardous bag with autoclave tape leaving a hole approximately the size of your fist to allow steam to penetrate and pressure to escape.
 - The end of the string should be hanging out the neck.



8. Begin loading the autoclave by donning appropriate Personnel Protective Equipment (PPE) including laboratory coat, eye protection, impervious gloves (nitrile), heat- insulating gloves (autoclave gloves), and closed- toe shoes.
 - a. **CAUTION:** Autoclave gloves will absorb liquids that conduct heat energy, which may cause burns to the hands.
9. DO not overload; leave sufficient room for steam circulation. Mock waste bags should be placed in a vertical position to avoid spills.
10. Close the door and latch it completely.
11. Begin the autoclave process by choosing the appropriate program for the container and material being sterilized. Consult the autoclave program chart located on autoclave door for assistance in choosing the appropriate cycle.
12. Start your cycle (PRESS START BUTTON) and fill out the autoclave user log with requested information. A completed cycle takes a minimum of 75 minutes. Alternatively, check the Jelly Bean link to see status of machine:
 - a. <http://www.jellybeanmonitoring.com/fullerton.html>
13. When the cycle is complete, (indicated by the final LED in the progress display semicircle being illuminated), open the door.
14. While wearing general lab PPE with addition of autoclave gloves, fully open the autoclave door and leave open for AT LEAST 5 minutes before removing the biological indicator.
15. Carefully unload the contents of the autoclave, making sure to avoid getting the autoclave gloves wet since they would then lose their insulating properties.
16. Pull string to remove biological indicator.
17. Drain water from simulated waste load into the sink drain and return contents to biosafety conex box.

18. Incubate the biological indicator as soon as possible. Leave unit plugged in during entire incubation process.

INCUBATING PROCESS

19. Place the bottom of the biological indicator vial into the incubator's metal heating block at roughly a 45 degrees' angle.



20. Push the vial straight back. This crushes the vial and activates the indicator.



21. Push activated indicator down to firmly seat in the metal heating block. Be sure the cap remains above the metal block.



22. Obtain a non-sterilized B.I. vial and mark it with a "C". This is now the control vial that is to be incubated repeating steps 19-21.



23. All sterilized B.I. vials, including control vial, are to be incubated for 48 hours.

SPECIAL CONSIDERATIONS FOR DELAYED INCUBATION

1. Do not crush ampoule after sterilization.
2. Keep Ampoules at room temperature.
3. Can store up to 7 days.

INTERPRETATING STERILIZED INDICATOR RESULTS

1. Examine the biological indicator after 48 hours for any color change.
 - Appearance of a **yellow color** indicates bacterial growth and an **inadequate sterilization process**.

Failed Sterilization
Process



Successful Sterilization
Process



- No color change indicates an adequate sterilization process.

INTERPRETATING CONTROL INDICATOR RESULTS

1. Examine control indicator after 48 hours for color change.
 - Appearance of a yellow color is evidence for bacterial growth.

Failed control
Process



Successful control
Process



- A yellow color in the control vial demonstrates correct incubation, viability of spores and capability of the medium to promote rapid growth.

RECORDING RESULTS

*****Note: Procedure # corresponds with #'s in Diagram A (sample log sheet) *****

1. Record the **Department name**
2. Record the biological indicator manufacturing lot number (**BI Lot #**)
3. For **Sterilizer Process Type**, check "**Steam**"
4. For **Biological Indicator** product used, check "**3M Attest 1262 (48 hr readout)**".
5. Record the **Date** of sterilization and **Sterilizer** (autoclave) number.
6. Under **Load Contents/ Reference/ Patient information** write "**Mock Load**".
7. Record the **Well #** the **Test** (sterilized indicator), and the **Control** (control indicator) was placed into.
 - a. Well # is identified on top of incubator heating block
8. Record the time the biological indicator was placed in the incubator and your initials.
9. Record the time the biological indicator was removed from the incubator and your initials.
10. Under **Indicator Results**, record the results by circling the + (positive) representing a failed test, or the – (negative) representing a passed test.

11. Record the biological Control indicator test results by circling the + (positive) representing a passed control, or the – (negative) representing a failed control.
12. Record any **Action Taken** as a result of a sterilization process failure or incorrect incubation in the action take section.
 - a. Mandatory action taken for any failures or incorrect incubation is to notify biosafety officer (x8118)
13. For any other section not specified, leave blank.

DIAGRAM A

3M Attest™ Biological Indicator
 Process Monitor Documentation System

Facility/Dept. name: _____ BI Lot #: _____

Sterilizer Process Type: Steam

Chemical Indicator / Integrator: 3M Attest 1261 (24 hr readout)
 3M Attest 1262 (48 hr readout)

Load Information (Affix load label)						Lot No	Biological Indicator						
Date	Load	Sterilizer	Implant	PRH %	Load Contents / Patient / Reference		Well #	Incubation		Indicator Results (circle one)			
						Result	Test	Control	Time In/ Date/ Initials	Time Out/ Date/ Initials	24 hr.	48 hr.	Control
					"Mock Load"	Accept					+	+	+
						Reject					-	-	-
						Accept					+	+	+
						Reject					-	-	-
						Accept					+	+	+
						Reject					-	-	-
						Accept					+	+	+
						Reject					-	-	-
						Accept					+	+	+
						Reject					-	-	-

Action Taken: _____

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