

**KCMC Biotechnology  
Laboratory**

**STANDARD  
OPERATING  
PROCEDURE**

**Effective Date**  
24 Jan 2007

**SOP-Number**  
EQP.007

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**Date**  
24 January 2007

**Title: AUTOCLAVE OPERATION AND MAINTENANCE**

**Author/Date: Anne Morrissey/October 2006**

**Approvals/Date:**

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**John A. Crump, MB, ChB, Laboratory Director**

\_\_\_\_\_  
**Anne Morrissey, MS, MT(ASCP)SM, Microbiology Lab Supervisor**

**This SOP has been read and understood by:**

<b>Name</b>	<b>Date</b>
<b>Signatures on original copy filed in office.</b>	
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<b>Annual Review</b>	
<b>By</b>	<b>Date</b>

# KCMC Biotechnology Laboratory

## STANDARD OPERATING PROCEDURE

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Title: **AUTOCLAVE OPERATION AND MAINTENANCE**

### Document History:

Version Number	Reason for Changes	Date

### Copies distributed to:

Name	Date

**Title: AUTOCLAVE OPERATION AND MAINTENANCE**

**PURPOSE**

Procedures for safe operation of the autoclave for sterilization of liquids, solids and infectious waste, quality control and maintenance.

**PRINCIPLE**

An autoclave uses pressurized steam to decontaminate liquids, solids and infectious waste. The effectiveness depends on the temperature achieved, time, and the direct steam content with infectious agents. Due to the pressure and high temperatures produced, all operations must be in accordance with manufacturer's instructions to ensure safety of users.

**SCOPE**

This Standard Operating Procedure applies to all personnel in the Biotechnology Laboratory who have been trained and are competent in the operation of the autoclave.

**WHAT CAN AND CANNOT BE AUTOCLAVED**

<b>CAN BE AUTOCLAVED</b>	<b>CANNOT BE AUTOCLAVED</b>
<ul style="list-style-type: none"><li>• <b>Cultures of infectious agents</b></li><li>• <b>Laboratory infectious waste</b></li><li>• <b>Solutions requiring sterility</b></li><li>• <b>Human blood and body fluids</b></li><li>• <b>Materials contaminated with secretions from humans or animals</b></li></ul>	<ul style="list-style-type: none"><li>• <b>Toxic, flammable, reactive or volatile chemicals</b></li><li>• <b>Radioisotopes</b></li></ul>

**SAFETY PRECAUTIONS**

- Use standard precautions when handling infectious waste materials to prevent exposure to bloodborne pathogens. Wear gloves when handling autoclave waste bags.
- Do not operate the autoclave unless trained in the proper use.
- When sterilizing liquids use only pyrex containers with caps loosened to allow for steam escape.
- Arrange items so that steam can circulate evenly - do not overload.
- Use only the "liquids" cycle when sterilizing liquids.
- On completion of cycle, open door one half inch to allow residual steam to escape.
- Use heat resistant gloves to remove hot items on to a cart or other conveyance. Do not carry hot items out of the room.

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### **QUALITY CONTROL - STERITAPE**

**Frequency:** Each load.

**Control:** Temperature sensitive autoclave tape (Steritape).

**Procedure:** Place a 1-2 inch piece of tape to the innermost item in the sterilizer or on the innermost side of a waste disposal bag.

**Acceptable Results:** Development of black stripes on the tape after completion of sterilization.

**Corrective Actions for Unacceptable Results:**

1. Add a biological indicator to the load and resterilize the items. (see section below QUALITY CONTROL – BIOLOGICAL INDICATORS)
2. If no black stripes appear assume the optimal sterilization temperature has not been reached and retain the items pending outcome of the biological indicator test.
3. If the result of the biological indicator test is, unacceptable arrange for items to be sterilized at KCMC.
4. Consult Operations Manual for troubleshooting solutions.
5. Arrange for repair if needed.

**Documentation:**

1. Complete a QC DEVIATION form to document problem and describe corrective actions.
2. Submit form to Biotechnology Lab Manager for review.

### **QUALITY CONTROL – BIOLOGICAL INDICATORS**

**Frequency:** Once per month.

**Control:** Sterikon Biological Indicator (Jencons Cat# 503-309)

**Procedure:**

1. Place one biological indicator ampule in the autoclave with the load to be sterilized preferably in the center of the loaded materials.
2. Run the autoclave at the desired setting.
3. Remove the ampule and place in a 56° C heating block.
4. Place an ampule that has not been autoclaved in the heat block.
5. Examine ampules at 24 and 48 hours for a color change from purple to yellow.

**Acceptable Results:**

1. No change of color from purple to yellow.

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**Corrective Action for Unacceptable Results:**

1. Arrange for items to be sterilized at KCMC.
2. Consult Operations Manual for troubleshooting solutions.
3. Arrange for repair if needed.
4. Retest biological indicator after troubleshooting or repair.

**Documentation:**

1. Record results of biological indicator tests on AUTOCLAVE QC – BIOLOGICAL INDICATOR record sheet.
2. Review QC results monthly.
3. Complete a QC DEVIATION form to document problem, and describe corrective actions for unacceptable results; submit form to Biotechnology Lab Manager for review.

**MAINTENANCE**

**Each Use** – Clean door and lid seal with clean soft cloth.

**Weekly**

1. Remove basket and other containers from the autoclave.
2. Clean the inside and the baskets with mild detergent solution and soft cloth (never use brush or scouring cloth as they will damage).
3. Empty the boiler chamber and clean the electrode with a clean soft cloth.
4. When indicated, carry out the cleaning program, empty the reservoir and refill with distilled water.

**Monthly:**

1. Release the safety valve by pulling out the external ring. Wear gloves and safety glasses to avoid splashes.
2. Remove basket and the plate under basket and check for buildup of

**Every 150 cycles** – Replace the exhaust air filter. Autoclave display will instruct at the appropriate time.

**Title: AUTOCLAVE OPERATION AND MAINTENANCE****AUTOCLAVE OPERATION****Materials/Equipment**

Systec Autoclave

Gloves for removing hot items

Temperature sensitive sterilization indicator tape

**Loading Items**

1. Check that the caps on containers of liquids are loosened slightly. Tightly closed containers may explode.
2. Do not mix liquids with solids, or liquids with waste. The items should be of the same type i.e. liquid, solid or waste.
3. Place materials in a perforated tray or wire basket.
4. Affix a piece of temperature sensitive autoclave tape to the objects in the middle of the load.
5. Distribute items evenly so that the steam can circulate around them. Overloading results in inadequate sterilization.

**Sterilizing Cycles**

There are 5 program cycles available for sterilizing materials:

PROGRAM	USE	TEMP °C	STERILIZATION TIME
1	SOLIDS (glassware, instruments)	134	7 min
2	SOLID WASTE	121	20 min
3	LIQUID WASTE	121	20 min
4	LIQUIDS IN VESSELS	121	15 min
5	LIQUIDS	121	15 min

**Operation**

1. Switch on the autoclave using the green main switch.
2. Press the SEL CYCLE key to scroll through the program cycles.
3. Select the program cycle appropriate for the materials being sterilized (use only programs 3,4, or 5 for liquids).
4. Press the PARAMETERS key.
5. Check that the autoclave is properly loaded.
6. Check the water level in the reservoir chamber and fill if necessary.
7. Close and lock the autoclave door.

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8. Press the START key.
9. The program will start and the LED "START" will light.
10. If necessary, a program may be stopped at any time by pressing the START/STOP key.

**Unloading**

1. Once the cycle is complete the autoclave will end the program.
2. Wait for the LED to display "END".
3. Turn the central lock counterclockwise. This activates the lid switch and the steam exhaust valve so that any pressure inside the chamber is released.
4. The LED "DOOR" will blink and "PRESS UP" will appear in the display. Activate the key to release the door lock.
5. Turn the lock counterclockwise to open the door.
6. Allow sufficient time for items to cool. DO NOT transport hot liquids.
7. Close off water supply and air lines.
8. Switch off the autoclave.

**REFERENCES**

Operating Manual, Systec, The Autoclave Company, Wetttenberg, Germany. May, 2002.  
Package Insert, Sterikon Biological Indicators.

**APPENDIX A – AUTOCLAVE STERILITY CHECKS**

**APPENDIX B – AUTOCLAVE MAINTENANCE RECORD**