

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Innova 43 Incubator		
Document ID: HSL_EQ_029	Version 1.0	Page 1 of 15

Released by/Date Effective:

Author Name	Title	Signature/Date

Approver Name	Title	Signature/Date

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1. PURPOSE

- 1.1. The purpose of this procedure is to describe the general use and maintenance of the Innova 43 Incubator.

2. SCOPE

- 2.1. This procedure applies to the HPV Serology Laboratory located at the Advanced Technology Research Facility, Room C2007.

3. REFERENCES

- 3.1. HSL_EQ_029.01: Use and Maintenance of the Innova 43 Incubator
- 3.2. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility
- 3.3. HSL_GL_002: Equipment Qualification and Calibration in the HPV Serology Laboratory
- 3.4. HSL_GL_003: Good Documentation Practices for the HPV Serology Laboratory
- 3.5. HSL_GL_004: Laboratory Notebook Control and Use for the HPV Serology Laboratory
- 3.6. HSL_GL_005: Signature and Initial Identification System
- 3.7. HSL_GL_006: Reagent Preparation for the HPV Serology Laboratory
- 3.8. HSL_GL_007: Reagent and Chemical Expiry in the HPV Serology Laboratory
- 3.9. HSL_GL_008: Laboratory Flow and Gowning Procedures for the HPV Serology Laboratory
- 3.10. HSL_GL_009: HPV Serology Laboratory BSL-2 Procedures
- 3.11. HSL_GL_010: Control and Request of Documents in the HPV Serology Laboratory

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as analyst, is responsible for reviewing and following this procedure.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

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5. REAGENTS, CHEMICALS AND EQUIPMENT

- 5.1. Cavicide (Warehouse, Cat # 79300360)
- 5.2. Ster-ahol (VWR, Cat # 14003-358 or equivalent)
- 5.3. Wypalls paper towel (Warehouse, Cat # 79300335 or equivalent)

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 6.2. Refer to the respective SDS when working with any chemicals.
- 6.3. Refer to "HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility" regarding waste disposal processes at the ATRF.

7. DEFINITIONS

Term	Definition
ATRF	Advanced Technology Research Facility
FME	Facilities, Maintenance and Engineering
HPV	Human Papillomavirus
HSL	HPV Serology Laboratory
SDS	Safety Data Sheets
SOP	Standard Operating Procedure
Type II water	Pure/Analytical Grade, used for standard applications

8. GENERAL OPERATION

- 8.1. The incubator should be allowed to reach the proper temperature prior to beginning an incubation.
 - 8.1.1. The incubator can run at temperatures between 5°C above room temperature and up to 80°C.
- 8.2. The spill pan/water reservoir should be filled with Type II water when humidity is required for the materials being incubated.
- 8.3. The plate shaker should not be run without a platform installed.
- 8.4. The incubator is not explosion proof and should not be used with flammable substances or used to grow organisms that produce flammable by-products.
- 8.5. The incubator can be operated in four ways.

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- 8.5.1. **Continuous mode** will run at a set speed and temperature, until the user stops the instrument.
- 8.5.2. **Timed Mode** will run at a set speed, time and temperature for a period of up to 99.9 hours, after which the incubator will shut off.
- 8.5.3. Using the **programmable controller**, the incubator can be set for multiple temperatures and speeds over an extended period of time.
- 8.5.4. Using a **computer**, the instrument can be controlled over an interface.
- 8.6. A visual and/or audible alarm will sound, to alert users of the following conditions.
 - Note:** Refer to Attachment 5: Alarm Descriptions, for more details on proper response to alarms.
 - 8.6.1. The end of a timed run.
 - 8.6.2. Deviations from speed set point.
 - 8.6.3. Deviations from temperature set point.
 - 8.6.4. Power failure.
 - 8.6.5. Lid open.
- 8.7. To view or change the instrument settings, refer to the summary screen. The summary screen will display the actual and set points for speed, the chamber temperature, elapsed time if using a program and humidity if in use.
- 8.8. Use the **PROG** screen to program steps for the shaker. The resident software for the Innova 43 Shaker can store up to 4 programs, each having as many as 15 steps. Each step can be programmed in 1 minute increments.
 - 8.8.1. To enter the programming mode, use the control knob to select the **PROG** screen. In the **PROG** screen, you can **Run** a program, create a **New** program, **Edit** a program or turn **Off** a program.
- 8.9. To create a new program, perform the following steps.
 - 8.9.1. Use the control knob to highlight the mode of Program 1, then click the control knob in. The selected field will begin to flash.
 - 8.9.2. Turn the control knob until the field says **New**.
 - 8.9.3. Click the control knob in to select this mode.
 - 8.9.4. The screen for Program 1 - Step - 01 will open.

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- 8.9.5. Turn the control knob to highlight the time setting, then click it in. The field will flash.
- 8.9.6. Turn the control knob until the desired running duration for this step (00:01 min – 99:59 h) appears.
- 8.9.7. Click the control knob in to save the setting.
- 8.9.8. Turn the control knob to highlight the °C temperature setting, then click it in. The field will flash.
- 8.9.9. Turn the control knob to set the temperature desired for the set time period.
- 8.9.10. When the desired value appears, click the control knob in to save the setting.
- 8.9.11. Turn the control knob to highlight the rpm setting, then click it in. The field will flash.
- 8.9.12. Turn the control knob to select the desired shaking speed for this time period.
- 8.9.13. Click the control knob in to save the setting. Continue to program as many as 15 steps in the same pattern.
- 8.10. Use the **Run** mode to turn a specific program on. Only 1 program can run at a time. When you change the mode to **Run**, the screen will show the **Run** icon.

9. MAINTENANCE

- 9.1. All spills should be cleaned up immediately using cavicide.
- 9.2. As Needed Maintenance
 - 9.2.1. If your unit is equipped with the factory installed humidity sensor, you may choose to use the spill pan as a water reservoir to reduce evaporation and raise the humidity level in the chamber.
 - 9.2.2. To fill the spill pan/water reservoir, open the lid and temporarily remove the platform.
 - 9.2.3. Make sure the drain valve is closed.
 - 9.2.4. Slowly fill the pan/reservoir with no more than 3 L of Type II water.

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9.2.5. **Note:** At a 37 °C set point, the chamber loses approximately 500 mL/hr from the pan. At a 25 °C set point, and placed in a 25 °C room, the chamber achieves a relative humidity equilibrium that is approximately 15 % above the ambient humidity.

9.2.6. To drain the spill pan/water reservoir, attach the quick-connect drain fitting. Direct it to a container or drain and allow the water to gravity drain. When the reservoir is empty, detach the fitting. The spill pan/water reservoir drain is located in the front, left side of the unit, under the humidity tray.

9.3. Quarterly Maintenance

9.3.1. Spray the internal unit with Cavicide and let it sit for at least 3 minutes prior to being wiped with a clean low-lint wipe.

9.3.2. Spray the internal unit with Ster-ahol and wipe with a clean low-lint wipe.

9.3.3. If a fill pan is being utilized, spray the fill pan with Cavicide and let it sit for at least 3 minutes prior to being wiped with a clean low-lint wipe.

9.3.4. Spray the window and door with Cavicide and let it sit for at least 3 minutes prior to being wiped with a clean low-lint wipe.

9.3.5. Spray the window and door with Ster-ahol and wipe with a clean low-lint wipe.

9.3.6. Document maintenance performed on HSL_EQ_029.01: Use and Maintenance of the Innova 43 Incubator.

9.4. Annual Calibration

9.4.1. Facilities, Maintenance and Engineering (FME) or a contracted vendor will calibrate the incubators every year as required, for routine use.

9.4.2. The incubator should be re-calibrated if they are moved more than 10 feet.

9.4.3. The incubators should be assessed for recalibration after repair, damage, or if physical, or electronic changes occur that could impact the operation, range, accuracy, or tolerance of the equipment.

9.4.3.1. This can be determined by the Scientific Manager or designees.

10. ATTACHMENTS

10.1. Attachment 1: Operating Controls

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- 10.2. Attachment 2: Display Operation
- 10.3. Attachment 3: Display Icons
- 10.4. Attachment 4: Troubleshooting Guide
- 10.5. Attachment 5: Alarm Descriptions

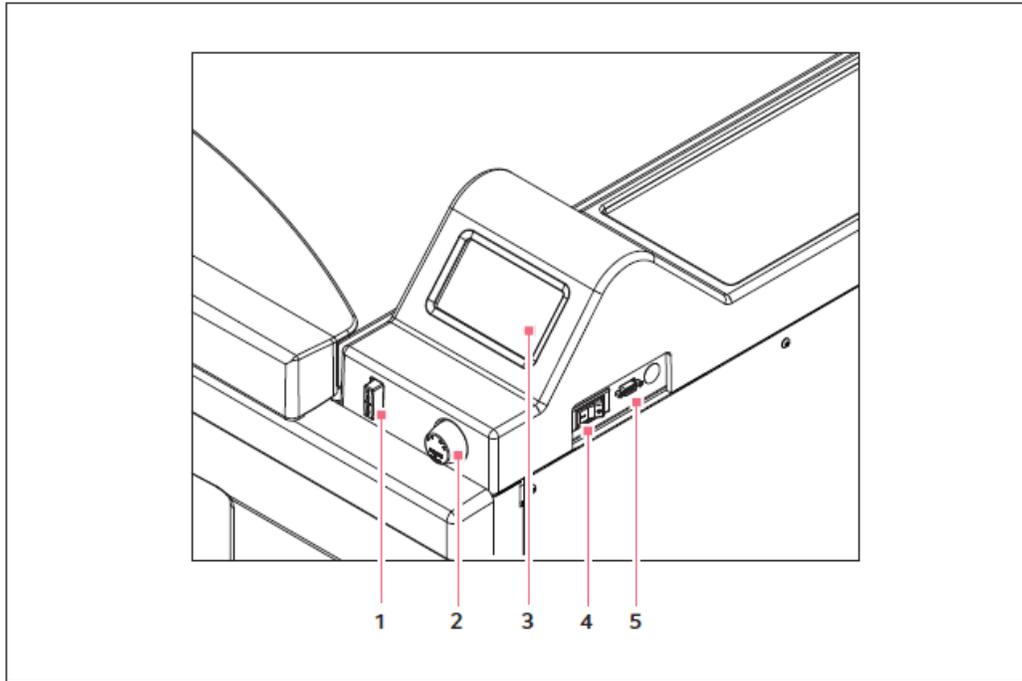
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Attachment 1: Operating Controls



- | | |
|-----------------------------------|----------------|
| 1 START/STOP switch (for shaking) | 4 Power switch |
| 2 Control knob | 5 RS-232 port |
| 3 Display | |

START/STOP switch	<ul style="list-style-type: none"> Used to start or stop the drive Activates timer when timed run is desired If the unit is stopped and restarted, the timer automatically returns to the beginning of a run
Control knob	<ul style="list-style-type: none"> Used to change screens Used to select operating conditions Used to change operating conditions
RS-232 port	<ul style="list-style-type: none"> Read out parameter values Controls operational functions using computer applications Used to connect to BioCommand SFI
Power switch	<ul style="list-style-type: none"> Circuit breaker Turns power on and off to the 43/43R Shaker

Attachment 2: Display Operation

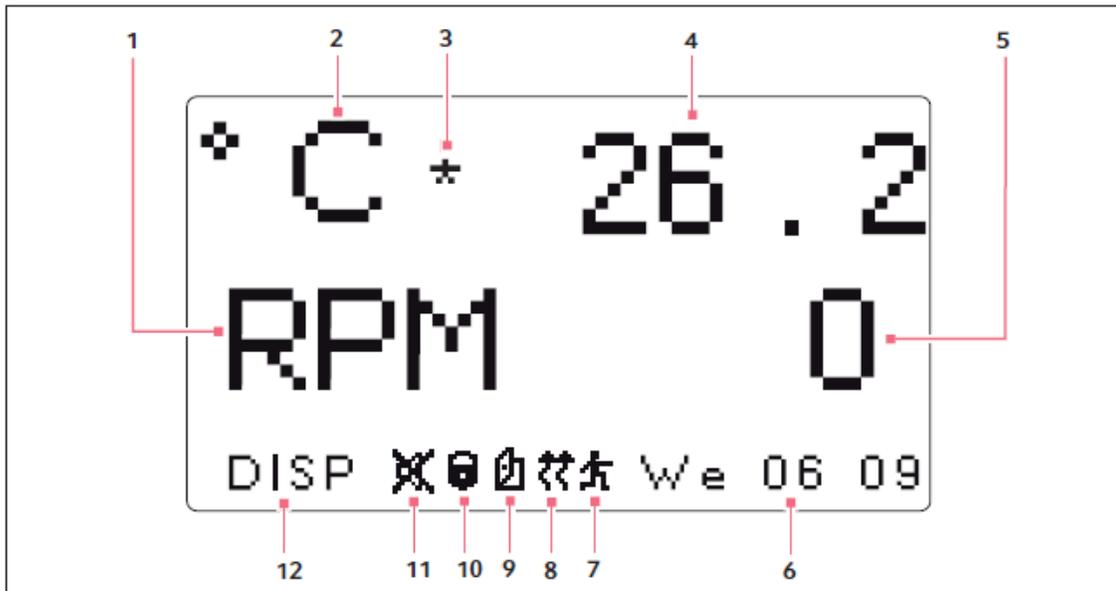


Fig. 5-1: Display screen

- | | |
|---|---|
| <p>1 Speed
Parameter</p> <p>2 Temperature
Parameter</p> <p>3 Temperature offset
Icon appears to the right of °C if the temperature offset feature is being used</p> <p>4 Temperature
Temperature parameter value</p> <p>5 Speed
Speed parameter value</p> <p>6 Day and 24-hour time</p> | <p>7 Program running
Icon appears when user-defined program is running</p> <p>8 Heater on
Icon appears when heater is on</p> <p>9 Lid open
Icon appears when lid is open</p> <p>10 Parameters locked
Icon appears when the possibility to make manual or programmed parameter changes is disabled (locked), controlled by settings in the <i>SET</i> screen</p> <p>11 Audible alarms muted
Icon appears when audible alarms are muted</p> <p>12 Screen name</p> |
|---|---|

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Attachment 3: Display Icons

Icon	Explanation	Location
	<ul style="list-style-type: none"> • Appears when audible alarms are muted 	<ul style="list-style-type: none"> • Bottom of screen • Visible in any screen except Program subscreens
	<ul style="list-style-type: none"> • Appears when the possibility to make manual or programmed parameter changes has been disabled (locked) • Controlled by settings on the <i>SET</i> screen 	<ul style="list-style-type: none"> • Bottom of screen • Visible in any screen except Program subscreens
	<ul style="list-style-type: none"> • Appears when the shaker lid is open 	<ul style="list-style-type: none"> • Bottom of screen • Visible in any screen except Program subscreens
	<ul style="list-style-type: none"> • Appears when the heater is on 	<ul style="list-style-type: none"> • Bottom of screen • Visible in any screen except Program subscreens
	<ul style="list-style-type: none"> • Appears when a user-defined program is running 	<ul style="list-style-type: none"> • Bottom of screen • Visible in any screen except Program subscreens
	<ul style="list-style-type: none"> • Appears to the right of °C if the temperature offset feature is being used 	<ul style="list-style-type: none"> • To the right of °C • Visible whenever the temperature is on screen

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Attachment 4: Troubleshooting Guide

Symptom	Cause	Solution
<p>Shaker does not run</p>	<ul style="list-style-type: none"> • Power cord is not plugged in 	<ul style="list-style-type: none"> ▶ Plug in power cord to working mains/power outlet
	<ul style="list-style-type: none"> • Lid is ajar 	<ul style="list-style-type: none"> ▶ Ensure lid is closed firmly
	<ul style="list-style-type: none"> • Defective main board • On/Off switch is broken • Lid switch is broken • Defective display board • Jammed shaking mechanism • Defective motor • Drive belt out of alignment or worn 	<ul style="list-style-type: none"> ▶ Call for service
	<ul style="list-style-type: none"> • Shaking speed has been set to 0 by program running or by computer interface 	<ul style="list-style-type: none"> ▶ Reset shaking speed (see <i>Changing setpoint values in the summary screen on p. 39</i>)
	<ul style="list-style-type: none"> • Improperly installed fuse 	<ul style="list-style-type: none"> ▶ Remove and reinstall fuse
	<p>Shaker runs slowly and/or there is no speed indication</p>	<ul style="list-style-type: none"> • Improperly installed fuse • Fuse is burned out
<ul style="list-style-type: none"> • Incorrect speed calibration 		<ul style="list-style-type: none"> ▶ Recalibrate shaking speed (see <i>Calibrating speed on p. 44</i>)
<ul style="list-style-type: none"> • Defective main board • Defective motor • Drive belt out of alignment or worn 		<ul style="list-style-type: none"> ▶ Call for service

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Symptom	Cause	Solution
Shaker does not run at set speed	<ul style="list-style-type: none"> Shaker is running in Program mode (look for Run icon in display) Shaker speed has been changed by RS-232 command or computer interface 	▶ Check display
	<ul style="list-style-type: none"> Shaker is overloaded and/or you are using baffled flasks 	▶ Remove some contents and balance load
	<ul style="list-style-type: none"> Defective motor Drive belt out of alignment or worn 	▶ Call for service
	<ul style="list-style-type: none"> Speed not calibrated correctly 	▶ Check speed calibration (see <i>Calibrating speed on p. 44</i>)
Excessive operating noise	<ul style="list-style-type: none"> Load out of balance 	▶ Unload all contents and reload
	<ul style="list-style-type: none"> Loose components in platform, subplatform, and/or drive assembly 	▶ Call for service
Shaker does not reach set temperature	<ul style="list-style-type: none"> Shaker is running in Program mode (look for Run icon in display) Shaker speed has been changed by RS-232 command/ computer interface Line voltage is too low 	▶ Check display
	<ul style="list-style-type: none"> Heater fuse blown Compressor fuse blown 	▶ Replace fuse
	<ul style="list-style-type: none"> Compressor over-pressure switch activated Defective heater Defective refrigeration system Defective heater Defective refrigeration system 	▶ Call for service
	<ul style="list-style-type: none"> Ambient temperature too high or too low 	▶ Adjust the room temperature
	<ul style="list-style-type: none"> Lid is not completely closed (even though Open Lid icon may not appear on display) 	▶ Open and reclose it firmly
	<ul style="list-style-type: none"> Frequency on line voltage is set incorrectly 	▶ Reset line voltage frequency
	<ul style="list-style-type: none"> Incorrect temperature indication 	▶ See <i>Incorrect temperature indication</i> section of this table

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Symptom	Cause	Solution
Incorrect temperature indication	<ul style="list-style-type: none"> • Temperature Offset has been programmed 	<ul style="list-style-type: none"> ▶ Look for Offset icon in display
	<ul style="list-style-type: none"> • Defective RTD assembly • Defective main board • Defective humidity probe or broken contact 	<ul style="list-style-type: none"> ▶ Call for service
Incorrect relative humidity %	<ul style="list-style-type: none"> • Defective humidity probe • Broken contact 	<ul style="list-style-type: none"> ▶ Call for service
Photosynthetic GRO lamp does not work	<ul style="list-style-type: none"> • Shaker is running in Program mode (look for Run icon in display), and program calls for GRO lamp to be off • GRO lamp mode has been changed by RS-232 command/ computer interface 	<ul style="list-style-type: none"> ▶ Check display
	<ul style="list-style-type: none"> • Bulb is burned out • Fuse is burned out 	<ul style="list-style-type: none"> ▶ Replace
		<ul style="list-style-type: none"> ▶ Check switch settings ▶ Check cable connections ▶ Check ballast voltage
UV germicidal lamp does not work	<ul style="list-style-type: none"> • Shaker is running in Program mode (look for Run icon in display), and program calls for UV lamp to be off • UV lamp mode has been changed by RS-232 command/ computer interface 	<ul style="list-style-type: none"> ▶ Check display
	<ul style="list-style-type: none"> • UV lamp is burned out • Fuse is burned out 	<ul style="list-style-type: none"> ▶ Replace
		<ul style="list-style-type: none"> ▶ Check switch settings ▶ Check cable connections ▶ Check ballast voltage

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Attachment 5: Alarm Descriptions

Indication	Description
TEMP	<ul style="list-style-type: none"> Indicates that the temperature has deviated more than ± 1 °C from setpoint after achieving control temperature range. After lid is opened, alarm will be disabled for 5 min while chamber recovers to setpoint.
RPM	<ul style="list-style-type: none"> Indicates that the speed has deviated more than ± 5 rpm from setpoint after achieving operating speed setpoint. After lid is opened, alarm will be disabled for 5 min while chamber recovers to setpoint.
POWER	<ul style="list-style-type: none"> Indicates that the unit is powering up (both at normal power-up and after power interruption); will flash until the control knob is moved.
HRS	<ul style="list-style-type: none"> Indicates when timed run is completed.

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11. REVISION HISTORY

Revision Start Date	Version #	Changes	Reasons
20Sep17	New	Create new SOP for the use and maintenance of the Innova 43 Incubator.	New SOP.

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Equipment ID:	Calibration Date:	Calibration Due Date:
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Date	Initials	Disinfectant(s) Used/ Lot Number	Activity Performed
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:
		<input type="checkbox"/> N/A <input type="checkbox"/> Cavicide, Lot #: <input type="checkbox"/> N/A <input type="checkbox"/> Ster-ahol, Lot #:	<input type="checkbox"/> Clean Incubator <input type="checkbox"/> Incubation: <input type="checkbox"/> Fill Pan/ Reservoir <input type="checkbox"/> Other:

Comments:

N/A

Review By/Date:	
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