Unit Procedure

Centrifuge Operation and Maintenance

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Department: Processing Laboratory

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1. OBJECTIVE

This procedure describes the process for Operation, Maintenance and Calibration of Refrigerated Centrifuge during clinical studies processed in laboratories managed through the Indiana Clinical and Translational Science Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This Standard Operating Procedure (SOP) is applicable for the Operation, Maintenance and Calibration of Refrigerated Centrifuge during clinical studies processed in laboratories managed through the CTSL.

3. RESPONSIBILITIES

The clinical and laboratory staff is responsible for appropriately operating and maintaining centrifuges in a safe and compliant manner.

4. DEFINITIONS

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	PL: Processing Laboratory
Rpm: Rotations Per Minute	Ref: Relative Centrifugal Force
SOP: Standard Operating Procedure	

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 "Document Control and Management"
5.2. CTSI-CRC-CLN-030 "Handling of SOP Deviations"
5.3. IU EHS Policies and Procedures: https://protect.iu.edu/environmental-health/
5.4. CTSI-CRC-PL-105 Out of Specification Condition and Notification Management
5.5. CTSI-CRC-PL-123 Contamination and Spill Clean-up Procedure

6. PROCEDURE

6.1. Operation of **Sorvall Legend X1R**.

6.1.1. Ensure that the power cord is plugged into a wall receptacle that provides the correct voltage.
6.1.2. Press the power switch to turn unit on. Switch is located on the back of unit in bottom left corner when facing the front.
6.1.3. Press the open button to release the lid.
6.1.4. Ensure that the correct rotor and buckets are installed for the specimens that will be centrifuged.
6.1.4.1. Refer to the centrifuge's manual for instructions on preparing and installing the rotor.
6.1.5. Add specimen(s) symmetrically to the buckets making sure to balance each tube against an equivalent tube in the opposite bucket.
6.1.6. Setting centrifuge speed:
6.1.6.1. Choose xg or rpm, per specimen processing instructions, by pressing the up/down button next to the "Speed" button and activate light next to "xg" or "rpm" as applicable.
6.1.6.2. Press "Speed" button.
6.1.6.3. Enter speed value on numeric keypad and press "Enter"
6.1.7. Setting centrifuge time:
6.1.7.1. Choose timer countdown to start "at speed" or "at start" by pressing the up/down button next to the "Time" button and activate light next to "at speed" or "at start", as applicable. **NOTE: Setting should always be set to "at speed" unless otherwise directed by protocol specific instructions.**
6.1.7.2. Press "Time" button.
6.1.7.3. Enter time value on numeric keypad and press "Enter". Be sure to enter time value as MM:SS.
6.1.8. Setting centrifuge temperature:
6.1.8.1. Choose air or sample temperature detection by pressing the up/down button next to the "Temp" button and activate light next to "air" or "sample" as applicable. **NOTE: Setting should always be set to "air" unless otherwise directed by protocol specific instructions.**
6.1.8.2. Press "Temp" button.
6.1.8.3. Enter temperature value on numeric keypad and press "Enter".
6.1.8.3.1. For samples requiring cold centrifuge, set temperature to 4°C.
6.1.8.3.2. For samples requiring room temperature centrifuge, set temperature to 24°C.
6.1.9. When parameters are set, push the START button to begin the run.
6.1.10. When the centrifuge has completed the run and the digital display shows "END OF RUN", push the open button to release the lid and retrieve specimens.

6.2. Operation of **Eppendorf Centrifuge Model 5702R**

6.2.1. Ensure that the power cord is plugged into a wall receptacle that provides the correct voltage.
6.2.2. Press the power button to turn unit on. Button is located on front panel and is backlit. Red indicates unit is off and green indicates unit is powered on.
6.2.3. Press the open button to release the lid.
6.2.4. Ensure that the correct rotor and buckets are installed for the specimens that will be centrifuged.
6.2.4.1. Refer to the appropriate manual for instructions on preparing and installing the rotor.
6.2.5. Add specimen(s) symmetrically to the buckets making sure to balance each tube against an equivalent tube in the opposite bucket.
6.2.6. Setting centrifuge speed:
6.2.6.1. Choose xg (rcf) or rpm, per specimen processing instructions, by pressing the SPEED control knob until the desired value ("rcf" or "rpm") appears on the display.
6.2.6.2. Rotate the SPEED control knob until the desired speed value appears on the display.
6.2.7. Setting centrifuge time:
6.2.7.1. Rotate the TIME control knob until the desired time value appears on the display.
6.2.7.2. Choose timer countdown to start "at speed" or "at start" by opening the lid of the centrifuge then pressing and holding the TIME control knob until the symbol for "at speed" or "at start" appears on the display next to the time value. **NOTE: Setting should always be set to "at speed" unless otherwise directed by protocol specific instructions.**
6.2.8. Setting centrifuge temperature:
6.2.8.1. Using the arrow keys on either side of the word 'temp' printed on the control panel, adjust the temperature to the desired setting.
6.2.8.1.1. For samples requiring cold centrifuge, set temperature to 4°C.
6.2.8.1.2. For samples requiring room temperature centrifuge, set temperature to 24°C.
6.2.8.2. 4°C can be reached quickly by closing lid and pressing the "fast temp" button. Centrifuge will spin until target temp is reached or "stop" button is pressed.
6.2.9. When parameters are set, push the TIME knob to begin the run.
6.2.10. When the centrifuge has completed the run and the digital display for rotor speed and time shows 0, push the open button to release the lid.

6.3. Operation of **Eppendorf Centrifuge Model 5810R**

6.3.1. Ensure that the power cord is plugged into a wall receptacle that provides the correct voltage.
6.3.2. Press the power switch to turn unit on. Switch is located on right side of unit near front panel.
6.3.3. Press the open button to release the lid.
6.3.4. Ensure that the correct rotor and buckets are installed for the specimens that will be centrifuged.
6.3.4.1. Refer to the appropriate manual for instructions on preparing and installing the rotor.
6.3.5. Add specimen(s) symmetrically to the buckets making sure to balance each tube against an equivalent tube in the opposite bucket.
6.3.6. Setting centrifuge speed:
6.3.6.1. Choose xg (rcf) or rpm, per specimen processing instructions, by pressing the SPEED button until the desired indicator appears on the display.
6.3.6.1.1. Rcf (xg) is indicated with an asterisk (*) and will appear to the left of the speed value (number) on the display.
6.3.6.1.2. Rpms are indicated with no (blank) indicator left of the speed value (number).
6.3.6.1.3. A third value, "rad", is not used and must not be selected.
6.3.6.2. While the speed value on the display is blinking, enter the speed value by pressing the up/down arrow buttons until the desired value appears on the display.
6.3.7. Setting centrifuge time:
6.3.7.1. Press the TIME button.
6.3.7.2. While the TIME value on the display is blinking, enter the time by pressing the up/down arrow buttons until the desired value appears on the display.
6.3.8. Setting centrifuge temperature:
6.3.8.1. Press the TEMP button.
6.3.8.2. While the TEMP value on the display is blinking, enter the temp by pressing the up/down arrow buttons until the desired value appears on the display.
6.3.8.2.1. For samples requiring cold centrifuge, set temperature to 4°C.
6.3.8.2.2. For samples requiring room temperature centrifuge, set temperature to 24°C.
6.3.8.3. 4°C can be reached quickly by closing lid and pressing the "fast temp" or "fast cool" button. Centrifuge will spin until target temp is reached or "stop" button is pressed.
6.3.9. When parameters are set, push the "start" or "start/stop" button to begin the run.

6.3.10. When the centrifuge has completed the run and the digital display for rotor speed and time shows 0, push the open button to release the lid.

6.4. Operation of **Beckman Coulter Models Allegra, JR-6, GS-6R, and GS-6KR**

6.4.1. Ensure that the power cord is plugged into a wall receptacle that provides the correct voltage.

6.4.2. Press the power switch to ON.

6.4.3. Move manual lock lever, located just under the front edge of the lid, to the left (UNLOCK)

6.4.4. Press Door switch to open position then lift the door up.

6.4.5. Ensure that the correct rotor and buckets are installed for the specimens that will be centrifuged.

6.4.5.1. Refer to the appropriate manual for instructions on preparing and installing the rotor.

6.4.6. Add specimen(s) symmetrically to the buckets making sure to balance each tube against an equivalent tube in the opposite bucket.

6.4.7. Setting centrifuge speed:

6.4.7.1. Press and hold the ACCU-SET button.

6.4.7.2. Rotate the SPEED dial to the selected speed until the desired value appears on the display.

6.4.7.3. Release the ACCU-SET button.

6.4.7.4. These models can only be set to rpms. Please refer to rpm to g conversion chart posted on the centrifuge.

6.4.8. Setting centrifuge temperature:

6.4.8.1. Set the TEMPERATURE knob to the required run temperature.

6.4.8.1.1. For samples requiring cold centrifuge, set temperature to approximately 4°C.

6.4.8.1.2. For samples requiring room temperature centrifuge, set temperature to approximately 24°C.

6.4.8.2. Verify actual interior temperature of centrifuge by observing the temperature gauge located on the left side of the control panel.

6.4.9. Setting centrifuge time and starting centrifuge:

6.4.9.1. After closing the lid and prior to startup of centrifuge, ensure manual lock lever has been switched to the right (locked position).

6.4.9.2. Turn the TIME control to the required run time.

6.4.9.3. Centrifuge will begin to start run.

6.4.9.3.1. Observe the speed display to verify start up and target speed has been reached.

6.4.9.3.2. If speed display shows four "8"s, centrifuge has detected an error and is either not running or in the process of stopping the current run.

6.4.9.3.2.1. Attempt to restart unit after verifying that the buckets are balanced correctly, reclosing the lid firmly and ensure manual lock lever has been switched to the right (locked position).

6.4.9.3.2.2. If centrifuge continues to display an error, contact CTSL management.

6.4.10. When the centrifuge has completed its run and the speed display shows 0, move the manual lock lever to the left (UNLOCK).

6.4.11. Press the DOOR switch and lift the lid to the full open position.

6.5. Routine Maintenance: The following tasks should be done monthly and recorded on each centrifuge's CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log.

6.5.1. Clean the outside of the centrifuge with a mild soap solution or commercial cleaner.

6.5.2. Remove buckets and clean with 10% bleach solution or dispatch.

6.5.3. Wipe the interior rotor chamber of the centrifuge with a cloth dampened with 10% bleach solution or dispatch.

6.5.4. Clean more frequently, as needed, due to spillage for decontamination purposes.

6.6. Preventative maintenance procedures shall be performed by a qualified and approved service provider as needed. PMs are not required but if performed, document date of service and vendor on page 1 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log and attach vendor's service record.

6.7. Calibration verification of temperature, speed and time shall be performed annually at a minimum by CTSL staff.

6.7.1. Record all results of the following procedure on page 2 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log.

6.7.2. Calibration verification of temperature, speed and time can be performed by hospital support when necessary.

6.7.2.1. Hospital support will be requested to utilize page 2 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log for documenting the results and follow the procedure outlined in steps 6.7.3 through 6.7.5.

6.7.2.2. Alternatively, documentation provided by hospital support may be acceptable if all requirements of this SOP are met. Attach verification documentation to page 2 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log.

6.7.3. Perform the verification of temperature calibration using an NIST thermometer and verify the accuracy of the following temp settings: 20°C, 10°C and 4°C.

6.7.3.1. Temperature measurements must be taken while the centrifuge is spinning and temp verification be performed concurrently with the speed and/or time verification process.

6.7.3.2. Be sure to secure the thermometer probe in such a way as to ensure it will not be struck by the centrifuge rotor.

6.7.3.3. Allow sufficient time for the centrifuge to reach target temperature before taking reading from NIST thermometer.

6.7.3.4. Acceptable criteria for all target temperatures is ±2°C.

6.7.4. Perform the verification of speed calibration using an NIST tachometer and verify the accuracy of the following speed settings: 1000 rcf (g), 2000 rcf (g) and 4000 rcf (g).

6.7.4.1. Speed verification should be performed concurrently with the time verification process when possible.

6.7.4.2. If centrifuge's maximum speed is less than 4000 rcf (g), document the centrifuge's max speed in the appropriate box on page 2 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log.

6.7.4.3. Refer to the tachometer instructions for operation of instrument.

6.7.4.4. If a centrifuge model can only be set to rpms, use same numerical values as for rcf (g) and add footnote to page 2 of CTSI-CRC-PL-LG607 Centrifuge Maintenance and Calibration Log indicating speed settings and tachometer recordings are in rpms.

6.7.4.5. Acceptable criteria for all speed settings is ±100 rcf (g) (or ±100 rpms as applicable – see step 6.6.4.4)

6.7.5. Perform the verification of timer calibration using an NIST timer and verify the accuracy of the following time settings: 5 min, 10 min and 20 min.

6.7.5.1. Time verification should be performed concurrently with the speed verification process when possible.

6.7.5.2. Acceptable criteria:

6.7.5.2.1. Digital displays - ±1 minute

6.7.5.2.2. Analog displays - ±3 minutes

6.7.6. If the results fail to meet acceptance criteria above, proceed as follows:

6.7.6.1. Place an out of service sign on the centrifuge and initiate an OOS investigation per CTSI-CRC-PL-105 Out of Specification Condition and Notification Management

6.7.6.2. Notify CTSL Management to have the unit repaired or replaced.

6.7.7. If repair or relocation of a centrifuge is required or performed, calibration verification should be repeated prior to placing unit back in operation and regardless of when the next scheduled verification is to occur.

7. REFERENCES – all manuals retained in CTSL.

7.1. Beckman Coulter Allegra, JR-6, GS-6R, and GS-6KR Instruction Manuals

7.2. Eppendorf 5702/5702 R/ 5702RH Instruction Manual

7.3. Eppendorf 5804/5804R/5810/5810R Instruction Manual
7.4. Sorvall Legend X1R Instruction Manual

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	23 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-012
Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2; Updated link in 5.3; Added operation instructions for Sorvall centrifuge (section 6.1); All other centrifuge operating instructions updated for clarity and accuracy; Centrifuge calibration verification process (section 6.7) updated for clarity and accuracy, including updated parameters that reflect the different settings and characteristics of the various centrifuges that are in service