



STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR CENTRIFUGE OPERATION AND MAINTENANCE

CHAPTER: 3-Equipment

SOP #: SF-3-04.02

SUPERSEDES SOP #: N/A

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1. REVISION

1.1. Significant revisions incorporated in this version include:

- 1.1.1. Added the vendor Technical Alternatives, Inc. and its contact number to Section 7. Removed the contact number located throughout the body of the SOP.
- 1.1.2. Edited Sections 5.2 and 6.2 to specify that bleach is made fresh daily whenever it is required.

2. PURPOSE

2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) to maintain and operate centrifuges in a manner which complies with all appropriate regulatory and protocol specific requirements; as well as to ensure that all personnel are consistently using centrifuges as required.

3. PRINCIPLE

3.1. A centrifuge is a piece of equipment driven by an electric motor, which puts an object in rotation around a fixed axis, applying a force perpendicular to the axis. The centrifuge works using the sedimentation principle, where the centripetal acceleration causes denser substances to separate out along the radial direction (the bottom of the tube). Likewise, lighter objects will tend to move to the top of the tube; (or, if on a rotating plate, move to the center). Settings for the centrifuges specifically referenced in this SOP can be input in either rpm's (revolutions per minute) or xG's (relative force of gravity which is a function of the speed and radius of the rotor) therefore, manual calculations are not required.

4. SCOPE

4.1. This SOP applies to personnel operating and maintaining the centrifuges used in the SSF. It defines the process for the operation of and the documentation of maintenance for the centrifuges. Centrifuge settings are defined in protocols and other documents, not this SOP. The centrifuges are capable of providing ambient and/or refrigerated environments. Since the SSF utilizes ambient temperature only, no temperature verifications are performed. For use at

temperatures other than ambient requiring accuracy/precision, temperature verification must be performed and documented by the user.

5. MATERIALS

- 5.1. 70% Ethanol
- 5.2. 10% Bleach (prepared fresh daily at point of use)
- 5.3. Warm Soap solution (dilute mixture of general use soap and water)
- 5.4. Standard lab mechanical balance

6. PROCEDURE

6.1. Centrifuging has a high potential for aerosol formation. All procedures involving this operation are performed carefully to minimize the creation of aerosols.

6.2. Any spills and accidents which result in potential exposure to infectious materials are immediately reported to the laboratory director and the Institutional Biosafety Officer. Spills are cleaned up using 10% bleach (prepared fresh daily at point of use). Medical evaluation and treatment are provided by Occupational Health Services. Refer to SOP SF-1-7 Personnel Safety for further information.

6.3. OPERATION - Sorvall Legend Micro 21 centrifuge (Ambient only)

- 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 ON (located in the back, on bottom right).
- 6.3.3. Press the open button to release the lid.
- 6.3.4. The nominal values of the last run are displayed.
- 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. Select desired rcf (xg)/rpm using arrow keys.
- 6.3.7. Using the arrow keys near the SPEED control, scroll to the desired speed.
- 6.3.8. Set the run time by using the arrows to scroll to desired time.
- 6.3.9. When parameters are set, put plastic lid on, close the outer lid, and push the start/stop button to begin the run.
- 6.3.10. When the centrifuge has completed the run and the digital rcf (xg)/rpm display for rotor speed displays 0, push the open button to release the lid.
- 6.3.11. If a centrifuge fails to function as defined above, record on SSF Centrifuge Maintenance Log (Appendix A), Comments section, and notify SSF Management. If unable to resolve, contact Technical Alternatives, Inc. or another approved service vendor for repair. Proceed per SF-1-10 SOP for Out of Specification Condition Notification and Management.

6.4. OPERATION - Eppendorf Model Centrifuge 5810R (-9°C to 40°C)

DISCLAIMER: This centrifuge is not routinely checked for temperature accuracy. If a temperature other than ambient is desired, it will be necessary to have a calibration check on temperature performed beforehand.

- 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 (blue switch located on side panel on bottom right).

- 6.4.2.1. Be sure that the stand-by button on the front control panel () is not red. If it is, press the button to remove the centrifuge from stand-by mode.
- 6.4.3. Press the open button to release the lid.
- 6.4.4. Add specimen(s) symmetrically to the buckets making sure to balance each tube against an equivalent tube in the opposite bucket.
- 6.4.5. The nominal values of the last run are displayed.
- 6.4.6. Using the arrow keys after pressing the ‘temp’ control, adjust the temperature to the desired setting.
- 6.4.7. The desired temperature can be reached more quickly if the ‘fast temp’ is pressed.
- 6.4.8. Using the arrow keys after pressing the ‘speed’ control, scroll to the desired rcf (xg)/rpm using the arrow keys.
- 6.4.9. Set the run time by using the arrow keys after pressing the ‘time’ button.
- 6.4.10. If necessary, set the braking time by pressing the ‘time’ button twice until the  symbol for braking level (brake) appears. Select braking level 0 to 9. **CLARIFICATION: Braking level (brake) 0 corresponds to free deceleration. The device only shows the symbol above when levels 0 to 8 have been set.**
- 6.4.11. When parameters are set, push the start/stop button to begin the run.
- 6.4.12. When the centrifuge has completed the run and the digital RPM display for rotor speed displays 0, push the open button to release the lid.
- 6.4.13. If a centrifuge fails to function as defined above, record on Appendix A, Comments section, and notify SSF Management. If unable to resolve, contact Technical Alternatives, Inc. or another approved service vendor for repair. Proceed per SF-1-10 SOP for Out of Specification Condition Notification and Management.

6.5. CLEANING (monthly)

- 6.5.1. Clean the outside of the centrifuge with a mild soap solution.
- 6.5.2. Remove buckets and clean with 10% bleach solution.
- 6.5.3. Wipe the interior rotor chamber of the centrifuge with a cloth dampened with warm soapy water, wipe clean and then wipe again with a cloth dampened with 70% Ethanol.
- 6.5.4. Clean more frequently, as needed, due to spillage for decontamination purposes.
- 6.5.5. Document completion on Appendix A.

6.6. FUNCTION VERIFICATION AND MAINTENANCE

6.6.1. Routine

- 6.6.1.1. Centrifuge certification and preventative maintenance will be done annually at minimum by a qualified and approved service vendor (e.g., Technical Alternatives, Inc.).
- 6.6.1.2. PM includes, but is not limited to, cleaning and lubrication, power supply check, rotor inspection, and speed/time verifications and calibrations as necessary.
 - 6.6.1.2.1. For speed and time verifications and calibrations, collect “As Found” and “As Left” data from the service technician. These values may be recorded on the PM documentation left by the technician.
- 6.6.1.3. Each check must include the testing of at least three documented test points against an NIST traceable device applicable to the parameter being tested. The

points chosen must be reasonably dispersed across the range of values that are applicable to the SSF. For example, a speed check for the Eppendorf Model Centrifuge 5810R might include 1000, 2000, and 3000 rpm as test points. Likewise, 5, 10, and 30 minutes might be the test points for a time check.

- 6.6.1.4. The variation for each parameter check should be within $\pm 30\%$ of the actual value (i.e., the reading on the NIST traceable device) to be acceptable.
- 6.6.2. Non-Routine
 - 6.6.2.1. If there are any equipment malfunctions, consult the user's manual. If still unable to resolve, notify SSF Management. Contact Technical Alternatives, Inc., or another approved service vendor, for repair. Complete an OOS Response Form per SF-1-10.
- 6.6.3. Service vendor will provide documentation of the work being completed and any adjustments/repairs made. Attach the documentation to Appendix A.

6.7. CALIBRATION

- 6.7.1. If the parameter variations defined in Section 6.6.1.4 are found by the vendor to be unacceptable, the centrifuge will be calibrated by the service vendor. The service vendor will provide documentation of the work being completed and any adjustments/repairs made. Be sure to collect "As Found" and "As Left" data. Attach the documentation to Appendix A.
- 6.7.2. If calibration was necessary, notify SSF management and proceed per SF-1-10 SOP for Out of Specification Condition Notification and Management.

7. REFERENCES

- 7.1. Eppendorf Centrifuge 5810 R Operating Manual (located on the SSF Shared Drive)
- 7.2. Sorvall Legend Micro 17/17R 21/21R Instructions for use Manual (located in SSF Management Office)
- 7.3. Technical Alternatives, Inc.: (734) 971-1372

8. DOCUMENTATION

- 8.1. Maintenance logs are submitted for review by SSF Management and maintained per SF-1-6 Controlled Document Management SOP.
- 8.2. Records of annual centrifuge calibration are maintained per SF-1-6.
- 8.3. OOS results are documented as defined in SF-1-10 SOP for OOS Response and Management.
- 8.4. Deviations are managed per the SF-1-9 Deviation Management SOP.

9. APPENDICES

- 9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:
 - APPENDIX A – SSF Centrifuge Maintenance Log (1 Page)

SSF Centrifuge Maintenance Log

Year:	Centrifuge Model / Serial Number:
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	Date	Clean Exterior (√)	Clean Interior (√)	Clean Buckets (√)	Initials
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					

Comments/Corrective Actions (Note any equipment malfunctions and non-routine maintenance here and attach documentation):

Attach vendor certification/documentation for annual PM and calibrations*
(PM includes, but is not limited to, cleaning and lubrication, power supply check, rotor inspection, and speed/time verifications and calibrations as necessary. “As Found” and “As Left” documentation should be provided for verifications and calibrations).
**If any parameter of the calibration checks fails to fall within acceptable criteria (within 30% of actual value), initiate OOS report per SF-1-10 SOP for Out of Specification Response and Management.*

Reviewed by: _____ **Date:** _____