**TRAINING UPDATE**

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|---|---|---|---|
| **Lab Location:** | SGMC & WOMC, GEC | **Date Distributed:** | 5/10/2021 |
| **Department:** | ALL | **Due Date:** | 6/30/2021 |

**DESCRIPTION OF PROCEDURE REVISION**

| **Name of procedure:** |
|---|
| **SOP: Centrifuge Use, Maintenance and Function Checks** (SGAH.QA868 v4) |
| **Description of change(s):** |
| • Header: Added FWMC<br>• Section 5: Updated maintenance steps, removed outdated information.<br><br>This SOP Update will be implemented on 5/26/21 |
| |

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

| | | |
|---|---|---|
| **Title** | **Centrifuge Use, Maintenance and Function Checks** | |
| **Prepared by** | Leslie Barrett | Date: 4/14/2014 |
| **Owner** | Cynthia Bowman-Gholston | Date: 4/14/2014 |

| **Laboratory Approval** | | |
|---|---|---|
| **Print Name and Title** | **Signature** | **Date** |
| *Refer to the electronic signature page for approval and approval dates.* | | |
| Local Issue Date: | Local Effective Date: | |

## TABLE OF CONTENTS



## 1. PURPOSE

This document sets forth the process for maintenance of centrifuges used in the laboratories, including speed, temperature, and timer checks.

## 2. SCOPE

This process applies to all departments in which centrifuges are used.

## 3. RESPONSIBILITY

- The **Technical Supervisor** is responsible for implementing this process in the department for which he/she is responsible.
- The **Technical Supervisor** or designated **CLIA General Supervisor** is responsible for review, approval, and documentation of the monthly performance records for equipment.

- The **Department Manager or Supervisor (non-Technical)** is responsible for implementing this policy in the applicable non-technical departments and ensuring the review and approval of the records for equipment.
- The **Department Supervisor and Group Lead** are responsible for:
  - Ensuring compliance with this process in his/her department or ensuring the procedures are performed by an approved outside vendor (if applicable).
  - Ensuring staff are trained in proper use and care of the equipment
  - Review of records as specified.
- A contracted company is responsible for:
  - Initial and annual preventive maintenance checks to assess proper functioning of rotors, electrical safety, electronics, mechanical, motor and speed.
  - Repairs as required
  - Maintaining or providing records of all routine checks and repairs.

## 4. DEFINITIONS

- **Airfuge:** a very high-speed centrifuge driven by compressed air.
- **External Tachometer:** an instrument used to measure rotational speed in revolutions per minute (RPM).
- **General Centrifuge**: a general-purpose centrifuge used most often to separate serum or plasma from whole blood.
- **Coagulation Centrifuge**: a centrifuge used to prepare platelet poor plasma for coagulation test procedures (platelet count <10,000/μL.)
- **Serofuge**: a centrifuge specifically designed for use in blood banking and other immunohematology testing procedures.
- **Relative Centrifugal Force (RCF):** the force exerted on a spun object, which is dependent on that object's speed of rotation and distance from the center of rotation.
- **Revolutions Per Minute (RPM):** the number of complete rotations that a centrifuge rotor completes in one minute at a defined operating setting.
- **Testing Centrifuge**: a centrifuge used in the testing process.

## 5. PROCEDURE

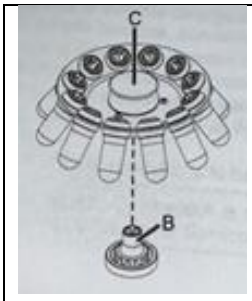
### Daily Maintenance

| Step | Action |
|---|---|
| 1 | Verify that the speed setting of the centrifuge matches the posted setting, as applicable. If incorrect, adjust and document on the maintenance log. |
| 2 | Visually inspect the centrifuge for cleanliness. Clean with a hospital-approved disinfectant wipe as needed to remove spills or contamination. Refer to the laboratory safety manual for appropriate precautions when broken glass is present in the centrifuge chamber. |

### Weekly Maintenance

| Step | Action |
|---|---|
| 1 | Clean the centrifuge:<br>• **Disconnect the power cord before cleaning.**<br>• Remove the rotor. This may require you to unscrew or unlock the rotor.<br>• Wipe the inside and outside of the centrifuge using a damp cloth (not dripping wet) and a small amount of dishwashing liquid or 70% alcohol. Use gauze and water to rinse away the detergent residue.<br>• Ensure the rotor and accessories dry completely after cleaning.<br>• Do not immerse the centrifuge in liquid or flood the centrifuge with liquid during the cleaning process. |
| 2 | Inspect the centrifuge and accessories for cracks. Hold the rotors under a light source and observe for cracks. Remove the centrifuge from service and notify a supervisor if cracks or damage are present. |
| 3 | Wipe the rubber seal around the centrifuge chamber with talcum powder. |

### Monthly Maintenance

| Step | Action |
|---|---|
| 1 | **Note: This step is required for Hettich 280 Centrifuge only.**<br>Disassemble the rotor. Wipe the motor shaft and rotor with a damp cloth and lightly grease with centrifuge grease or Vaseline.<br>  <br><br>B. Motor Shaft<br>C. Rotor |

**Contracted Maintenance Performed by an Outside Company**

| Step | Action |
|---|---|
| 1 | Speed Checks:<br>1. Speed checks are performed semi-annually by a contracted company.<br>2. Use an external tachometer to check centrifuge-operating speeds. (Do not use the built-in centrifuge tachometer for calibration purposes, if so equipped.)<br>3. Ensure that the external tachometer is maintained and calibrated according to the tachometer manufacturer's specifications.<br>4. Review test procedures to assure that centrifuges are checked at all speeds of intended use. If more than three speeds are required:<br>a. Check the lowest speed used for testing purposes<br>b. Check the highest speed used for testing purposes<br>c. Of the speeds used for testing purposes, check one setting between the highest and lowest speeds<br>d. It is not necessary to check additional speeds if the highest, lowest, and middle speeds are found accurate.<br>5. If the centrifuge specifications are defined as RCF units in the test procedure (gravities or g-force), refer to the attached nomogram to convert RPM to RCF (Appendix A.). Alternatively, a computerized or on-line calculator may be used to convert RPM to RCF.<br>6. If the centrifuge uses a built-in tachometer to set the required speed, record the centrifuge's indicated reading on the Centrifuge Functional Quality Control record (form supplied by the lab).<br>7. If there is no built-in tachometer, record the setting of the speed adjustment control and the measured external tachometer reading on the Centrifuge Functional Quality Control log. Compare the measured reading to the intended reading.<br>8. Tolerance limits must be defined, follow the manufacturer's specifications. If not defined a 10% tolerance may be used. If the centrifuge speed exceeds the acceptable speed range, take corrective action as appropriate. Document all corrective action.<br>9. Documentation<br>a. Record the results of all speed measurements, acceptable ranges and associated corrective action on the Centrifuge Functional Quality Control record. These records must be kept for the life of the equipment.<br>b. A copy of the record must be left at the laboratory.<br>c. The centrifuge must be labeled with:<br>i. Speed setting and/or RPM versus RCF for each speed of intended use<br>ii. Date calibrated or date due for next calibration<br>iii. Initials or signature of person performing the calibration |

| Step | Action |
|---|---|
| 2 | Timer Checks:<br>1. Timer checks are performed by a contracted company.<br>a. Every 6 months for blood bank and testing centrifuges.<br>b. At least annually for general centrifuges.<br>2. Choose a test time interval for which the centrifuge is commonly used. When more than three timer settings are used: check the lowest time and the highest time.<br>3. Start the centrifuge timer and the standard stopwatch (or other timer) simultaneously.<br>4. When the centrifuge timer stops, stop the standard stopwatch/timer.<br>5. Each laboratory must establish and document acceptable tolerance limits for centrifuge timer function based on the intended use of the centrifuge. Record the acceptable timer range on the Centrifuge Functional Quality Control record. If not defined by the manufacturer, a 5% tolerance may be used.<br>6. Take corrective action if the centrifuge time exceeds the acceptable timer range. Document all corrective action.<br>7. Documentation--Record the centrifuge timer interval and the standard stopwatch/timer reading on the appropriate log. |
| 3 | Annual maintenance (unless the manufacturer requires more frequently).<br>1. Check motor brushes and drive belts<br>2. Check lid safety interlock<br>3. Repair or replace defective items as necessary |

**Additional Testing for Specialized Centrifuges**

| Step | Action |
|---|---|
| 1 | Coagulation Centrifuges<br>Perform Platelet Poor Plasma Verification every 6 months. |

**Record Review**

| Step | Action |
|---|---|
| 1 | Maintenance checks performed by laboratory staff are reviewed weekly by the Group Lead, Supervisor or designee and monthly by the designated CLIA General Supervisor. |
| 2 | Maintenance checks performed by another company are reviewed upon receipt by the Supervisor, Manager or Director. Review must indicate if performance is acceptable or not, and include corrective action if appropriate. |

**Centrifugation Specifications**

| Step | Action |
|---|---|
| 1 | Specimens are centrifuged for a designated time at a relative centrifugal force (RCF) adequate to achieve either serum or plasma as indicated for testing. An RCF of 1000-1300* and a centrifugation time of 10 minutes will provide a specimen adequate for testing, higher RCF and shorter spin times are acceptable unless otherwise stated in the individual assay/test procedure. Centrifuges are checked and approved for RCF and Time prior to initial service date as applicable. Due to limitations of certain centrifuges and for standardization RCF is converted* to RPM. The approved centrifugation RPM and Time are clearly marked on the outside of each centrifuge. The approved centrifugation RPM and Time required to obtain platelet-poor plasma** must be determined for each centrifuge designated for that purpose and marked on the designated centrifuge.<br><br>**Note: Specific centrifugation requirements to preserve cellular components for microscopic review are outlined in appropriate test procedure(s) and clearly displayed on designated centrifuges.**<br><br>* Use of alternate centrifugation conditions (e.g., higher RCF and shorter spin time) may also provide acceptable performance.<br>** Citrate tubes should be centrifuged at a speed and time to consistently produce platelet-poor plasma (platelet count <10,000/uL) per CLSI Guidelines. |
| 2 | To ensure associate safety all tubes are centrifuged within their specified limitations as listed below.<br><br>RCF = Relative Centrifuge Force, g's<br>Many microcentrifuges only have settings for speed (revolutions per minute, RMP), not relative centrifugal force. Consequently, a formula for conversion is required to ensure the appropriate setting is used. The relationship between RPM and RCF is as follows:<br><br>$g = (1.118 \times 10^{-5}) R S^2$<br><br>Where g is the relative centrifugal force, R is the radius of the rotor in centimeters, and S is the speed of the centrifuge in RPM.<br><br>**Caution:** Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. BD Vacutainer® Plus Tubes will withstand up to 10,000 RCF in a balanced centrifuge. Always use appropriate carriers or inserts. |

| Step | Action |
|---|---|
| 3 | Centrifugation speed and time often are not critical factors in routine sample-handling procedures involving a benchtop microcentrifuge. Usually, as long as speed and time are sufficient to ensure that cells, debris or resin are pelleted effectively, it does not matter if the speed is faster or the time longer than necessary. |

## 6. RELATED DOCUMENTS

- Laboratory Safety Manual
- Retention Records and Materials, Laboratory policy
- Platelet Poor Plasma Verification, Coagulation procedure
- Serologic Centrifuge Maintenance and Function Checks, Blood Bank procedure
- Quest Diagnostics *Policy for Centrifuge Maintenance and Function Checks* (QDNQA702)
- Centrifuge Maintenance and Function Check Log (AG.F86)
- Centrifuge Functional Quality Control, Core Lab (AG.F365)

## 7. REFERENCES

1) Bermes, E.W. and D.S. Young. 2001. General Laboratory Techniques, Procedures, and Safety, pp 13-14. In *Teitz Fundamentals of Clinical Chemistry, 5th Edition*. Burtis, Carl A. and Edward R. Ashwood (eds). W.B. Saunders Company, Philadelphia, PA
2) National Committee for Clinical Laboratory Standards (NCCLS). *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard-Third Edition*. NCCLS document number H7-A3. National Committee for Clinical Laboratory Standards, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.
3) College of American Pathologists (CAP). 1999. *Laboratory Instrument Evaluation, Verification & Maintenance Manual*, 5th *Edition.* College of American Pathologists, Waukegan, Illinois.
4) Procedure for Centrifuge Maintenance and Function Checks, QDNQA702, v1.1, Local version D
5) Product insert, BD Vacutainer® Evacuated Blood Collection System, Becton, Dickinson and Company, 10/2007.

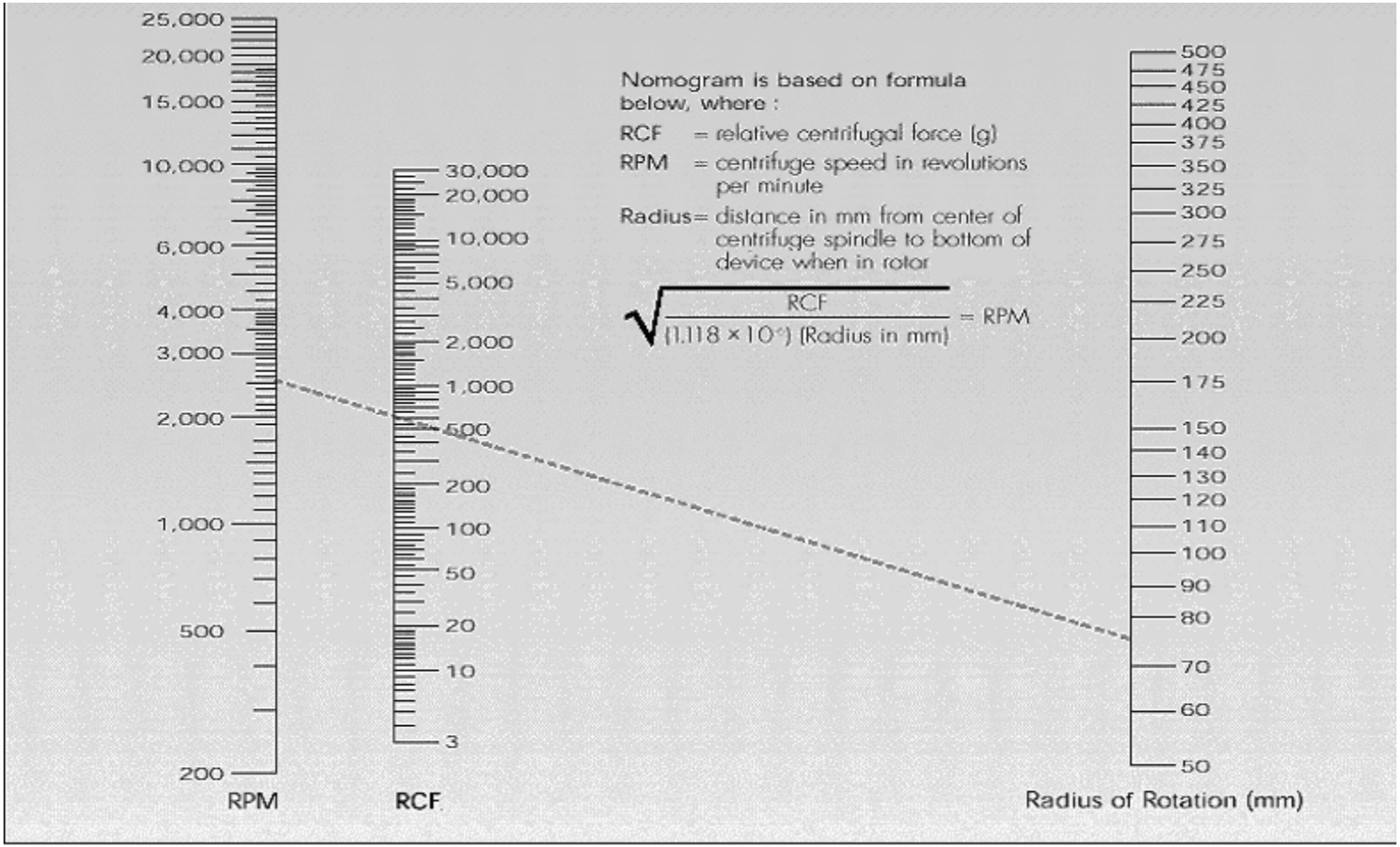
## 8. REVISION HISTORY

| Version | Date | Reason for Revision | Revised By | Approved By |
|---|---|---|---|---|
| | | Supersedes SOP GEC.L10.002, SGAH.L12.002, WAH.L12.002 | | |
| 0 | 2/22/17 | Header: add other sites<br>Section 3 & 5: replace Biomedical/Clinical Engineering with contracted company<br>Section 5: update log title<br>Section 6: add QC log | L Barrett | C Bowman-Gholston |
| 1 | 1/31/19 | Header: update parent facility<br>Section 5: change BB RPM and timer checks to semi-annual to match BB SOP | L Barrett | C Bowman-Gholston |
| 2 | 2/17/20 | Header: changed WAH to WOMC<br>Section 5: Updated format and wording for clarity. Added pictures for clarity. Eliminated sections that do not apply to AHC laboratories. | SCodina | C Bowman-Gholston |
| 3 | 5/6/21 | Header: Added FWMC<br>Section 5: Updated maintenance steps, removed outdated information. | D Collier | C Bowman-Gholston |

## 9. ADDENDA AND APPENDICES

A. Nomogram to convert RPM to RCF

## APPENDIX A




To convert maximum relative centrifugal force (RCF) to RPM: Determine centrifuge 's radius of rotation (in mm) by measuring distance from center of centrifuge spindle to bottom of device when inserted into rotor. Lay a ruler or draw a line from radius value in right-hand column value that corresponds to the device's maximum rated g-force. Then read the maximum value from column at left.