TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	2/28/2017
Department:	Core & Processing staff	**Due Date:**	3/21/2017
		Implementation:	**3/21/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Centrifuge Use, Maintenance and Function Checks SGAH.QA868 v1

Note: this has been converted to a system SOP

Centrifuge Functional Quality Control, Core Lab AG.F365.0

Description of change(s):

SOP:

Section 3 & 5: replace Biomedical/Clinical Engineering with contracted company

Section 5: update log title

Section 6: add QC log

FORM: New log to document centrifuge speed and timer checks *(form has already been implemented)*

This revised SOP will be implemented on March 21, 2017

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:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

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1. PURPOSE

This document sets forth the process for maintenance of centrifuges used in Quest Diagnostics 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 department(s) for which he/she is/are responsible and ensuring the review and approval of the records documenting the performance of these requirements at established frequency.
- 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.
  - ~~Notifying Clinical Engineering department of any additions or deletions of equipment~~
- ~~Biomedical/Clinical Engineering staff are~~ 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.

Form revised 3/31/00

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.)
- **Immunohematology/Blood Bank Centrifuge**: a centrifuge specifically designed for use in blood banking and other immunohematology testing procedures.
- **Optimal Spin Time:** that time necessary to yield definite agglutination of a 1+ positive sample, while showing no agglutination in a negative sample.
- **Refrigerated Centrifuge**: a centrifuge where the rotator area is cooled by mechanical refrigeration.
- **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

A. Maintenance – performed by Laboratory staff

1) Each day of use (a record of the performance of each of these tasks must exist):
   a) Verify the actual (speed) setting matches the posted setting, as applicable. If incorrect, adjust and document on the Maintenance Log.
   b) The centrifuge must be visually inspected for cleanliness and cleaned as necessary.
   c) The centrifuge exterior and interior should be cleaned immediately upon any detection of spillage or contamination using a cleaning solution as recommended by the manufacturer.
      - Adhere to appropriate safety precautions when removing broken glass from the centrifuge chamber. Refer to Laboratory Safety manual.
      - Appropriate safety precautions must be maintained when cleaning up any biohazardous materials. Refer to Laboratory Safety manual.

2) At least monthly, unless the manufacturer requires more frequently (a record of the performance of each of these tasks must exist):

a) Clean the centrifuge chamber using a cleaning solution recommended by the centrifuge manufacturer
b) Clean tube shields, cups, or carriers
c) Examine rubber cushions and replace if worn, where applicable
d) Wash gaskets and check for wear and/or defects
e) Check the cover latch to ensure that there is no air leakage (for the prevention of aerosols)

3) Perform any other centrifuge maintenance and function checks specific to your particular equipment as frequently as required by the manufacturer.

4) Documentation**:**
   a) Initial and date daily, monthly and annual procedures on the Maintenance Log. These records must be kept near the instrument (accessible to anyone using the instrument).

B. Centrifuge Speed Checks

1) General and Testing Centrifuges – performed by a contracted company ~~Biomedical/Clinical Engineering~~

   a) Use an external tachometer to check centrifuge-operating speeds. (Do not use the built-in centrifuge tachometer for calibration purposes, if so equipped.)
   b) Ensure that the external tachometer is maintained and calibrated according to the tachometer manufacturer's specifications.
   c) Review test procedures to assure that centrifuges are checked at all speeds of intended use. If more than three speeds are required:
      - Check the lowest speed used for testing purposes
      - Check the highest speed used for testing purposes
      - Of the speeds used for testing purposes, check one setting between the highest and lowest speeds
   d) It is not necessary to check additional speeds if the highest, lowest, and middle speeds are found accurate.
   e) 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.
   f) 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 ~~centrifuge calibration~~ record (form supplied by the lab).
   g) 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. ~~centrifuge calibration record and~~ Compare the measured reading to the intended reading.
   h) Tolerance limits must be defined, follow the manufacturer's specifications. If not defined a 10% tolerance may be used.

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2) Frequency
   a) Check RPMs of general centrifuges at least annually at speed(s) of intended use.
   b) Check RPMs of testing and refrigerated centrifuges at least every 6 months at speed(s) of intended use (in RCF).

3) Corrective Action
   a) If the centrifuge speed exceeds the acceptable speed range, take corrective action as appropriate. Document all corrective action.

4) Documentation
   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.
   b) A copy of the record must be left at the laboratory.
   c) The centrifuge must be labeled with:
      - Speed setting and/or RPM versus RCF for each speed of intended use
      - Date calibrated or date due for next calibration
      - Initials or signature of person performing the calibration

5) Coagulation Centrifuges – performed by Core Lab staff
   a) Perform quality control per procedure Platelet Poor Plasma Verification.
   b) Document results and label centrifuge as above in 4) c).

6) Blood Bank Centrifuges - performed by Blood Bank staff
   a) Check RPMs of blood banking centrifuges at least quarterly using an external tachometer.
   b) Calibrate to establish the optimal spin time for a 1+ macroscopic agglutination before initial use and after adjustments, repairs, or implementation of new techniques.
      - Refer to the Blood Bank procedure, Serologic Centrifuge Maintenance and Function Checks.
      - Post the optimal spin time(s) on all blood bank centrifuges used for interpreting agglutination reactions.
      - Calibration must be performed annually and after repairs.

C. Centrifuge Timer Checks - performed by contracted company ~~Biomedical/Clinical Engineering~~

1) 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.

2) Start the centrifuge timer and the standard stopwatch (or other timer) simultaneously.

3) When the centrifuge timer stops, stop the standard stopwatch/timer.

4) 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.

5) Frequency
Verify timer accuracy at least every 6 months for testing centrifuges and annually for general centrifuges.
Blood Bank centrifuge timers must be checked quarterly.

6) Corrective Action
   a) If the centrifuge timer exceeds the acceptable timer range, take corrective action as appropriate.
   b) Document all corrective action

7) Documentation
Record the centrifuge timer interval and the standard stopwatch/timer reading on the appropriate log.

D. Annual maintenance (unless the manufacturer requires more frequently) - performed by contracted company ~~Clinical Engineering~~

1) Check motor brushes and drive belts

2) Check lid safety interlock

3) Repair or replace defective items as necessary

E. Record review

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 ~~Biomedical/Clinical Engineering~~ 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.

F. Centrifugation Specifications

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. **Note: Specific centrifugation requirements to preserve cellular components for microscopic review are outlined in appropriate test procedure(s) and clearly displayed on designated centrifuges.**

2) To ensure associate safety all tubes are centrifuged within their specified limitations as listed below.

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.

* Use of alternate centrifugation conditions (e.g., higher RCF and shorter spin time) may also provide acceptable performance.
RCF = Relative Centrifuge Force, g's
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:

$$g = (1.118 \times 10^{-5}) R S^2$$

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.

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.

** Citrate tubes should be centrifuged at a speed and time to consistently produce platelet-poor plasma (platelet count <10,000/uL) per CLSI Guidelines.

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.

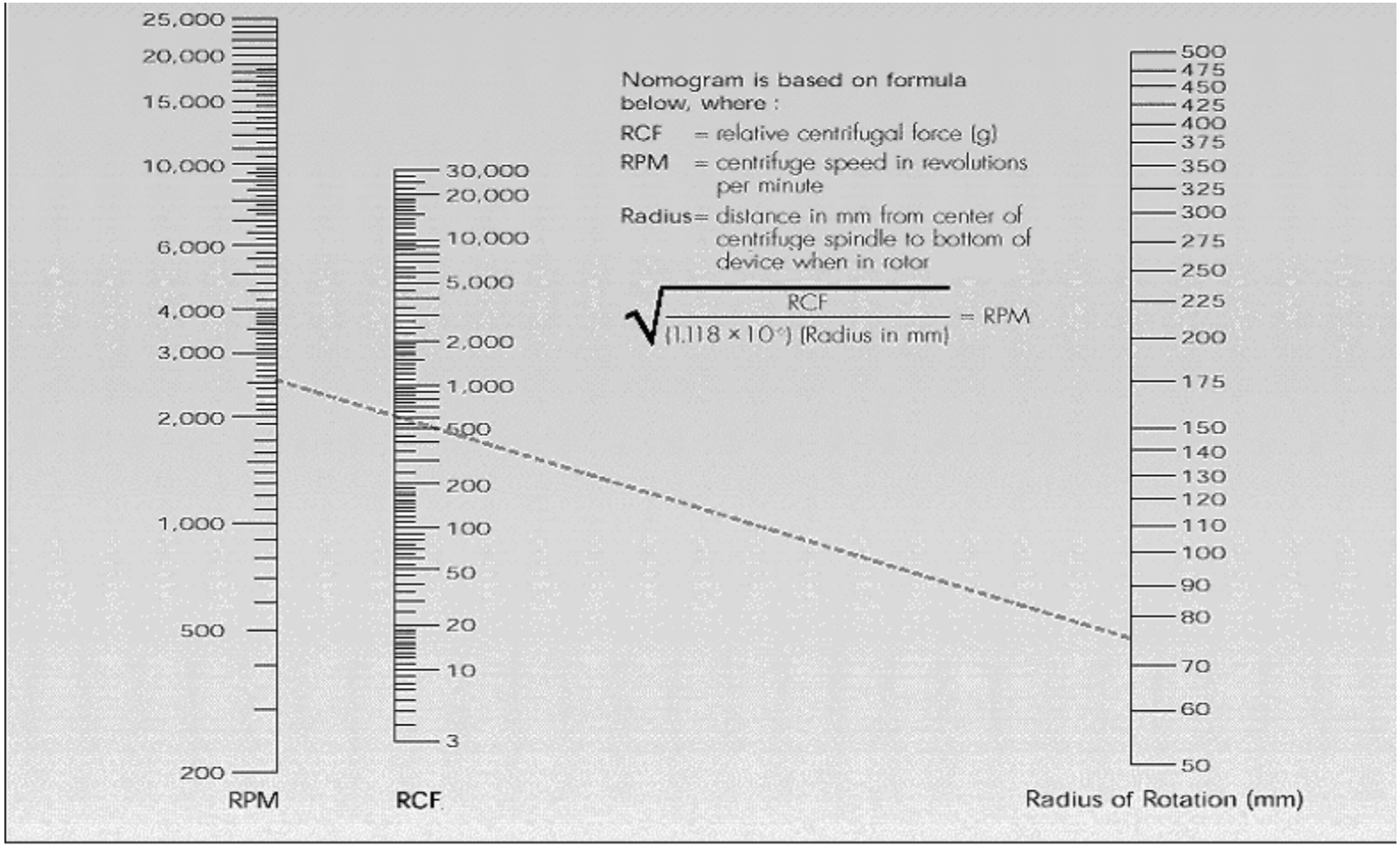
8. REVISION HISTORY

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 Section 3 & 5: replace Biomedical/Clinical Engineering with contracted company Section 5: update log title Section 6: add QC log	L Barrett	C Bowman

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.

Core Lab Centrifuge Functional Quality Control

Section 1: To Be Completed by BioMedical Engineering

Date	Equipment Description	Serial Number	Speed Setting (RPM)	Speed Obtained (RPM)	Acceptable Range (RPM) 5% difference	Timer Setting	Timer Obtained	Acceptable Range (5% difference)	Timer Setting	Timer Obtained	Acceptable Range (5% difference)	Interp (S or U)	Tech

Interpretation: S=Satisfactory U=Unsatisfactory, corrective action required, DO NOT USE equipment with unsatisfactory performance

Stopwatch Identification_____

Stopwatch checked against telephone time through 30 seconds, OK _____ (Acceptable Range = 27-33 seconds)

Tachometer Identification_____ Tachometer field calibrated to 60Hz, OK_____

Section 2: Review

1 Verify that work has been performed and all blanks on the form are filled in.
2 Verify that all RPM and timer checks are within acceptable range.
3 Remove from service any equipment with unsatisfactory performance.

Reviewed by:_____ Date: _____

Section 3: Comments