

KCMC Biotechnology Laboratory	STANDARD OPERATING PROCEDURE	Effective Date 27 August 2006	SOP-Number EQP.005
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Title: CENTRIFUGE CALIBRATION			

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This SOP has been read and understood by:

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Annual Review	
By	Date

**KCMC Biotechnology
Laboratory**

**STANDARD
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PROCEDURE**

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Document History:

Version Number	Reason for Changes	Date

Copies distributed to:

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PRINCIPLE:

To ensure the centrifuges are: 1) providing accurate rotation speeds when compared to a National Institute of Standards and Technology (NIST) traceable tachometer, 2) the timer is verified when compared to a NIST traceable timer and 3) if there is a refrigeration feature, that the temperatures are verified when compared to a NIST traceable thermometer.

SCOPE

This Standard Operating Procedure applies to the calibration of Biotechnology Laboratory centrifuges by technical personnel that have been trained and assigned to perform the calibration.

FREQUENCY: As a minimum, the manufacturers' guidelines should be followed. All three elements of centrifuge calibration verification that apply must be done at least once a year, when a malfunction is suspected or after maintenance effecting function.

EQUIPMENT AND MATERIALS:

Equipment:

NIST traceable thermometer (Certified)

NIST traceable stopwatch (Certified)

NIST traceable tachometer (Certified)

Centrifuge to be verified (Test), identified by a unique assigned number

Two balanced tubes -- one containing glycerin and closed with a stopper containing a hole in which the probe from the NIST traceable thermometer can be inserted

Materials:

Centrifuge Calibration Verification Record Sheets containing the following information:

- Unique centrifuge number
- Centrifuge location
- Date of calibration
- Technician initials
- Test centrifuge readings
- Certified centrifuge readings
- Differences between test and certified readings
- Acceptable or unacceptable outcome
- Actions taken to correct unacceptable outcome
- Supervisor review

NIST certificate for timer*

NIST certificate for tachometer*

NIST certificate for thermometer*

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***Certification Procedure:** Each NIST timer, thermometer or tachometer comes with a period of time for which it is certified. Following this time or an accident that causes the instrument to malfunction, it must be sent to a service center qualified to recertify its accuracy or replaced. This is to be done yearly after the initial purchase certification has expired.

SAFETY PRECAUTIONS

Centrifuges used in the laboratory are to be considered contaminated and should be handled wearing gloves and a laboratory coat and/or thoroughly disinfected before performing calibration verification procedures.

VERIFICATION OF ROTATION SPEED PROCEDURE

1. Place a small section of black and white reflective tape that comes with the tachometer on the center spindle of the Test centrifuge. In order to measure the rotation speed, there must be a viewing port in the top cover that will allow the tachometer line of sight to the reflective tape.
2. To ensure the most accurate reading is obtained it is necessary to simulate normal usage. Place a normal well-balanced load using specimen covers into the centrifuge.
3. Start the centrifuge and allow to come to equilibrium at a normal operating speed.
4. Use the tachometer through the viewing port above the reflective tape to take a rotation rate reading.
5. Record the rotation speed indicated by the centrifuge either by the dial setting or by a built in tachometer on the Centrifuge Calibration Verification Record Sheet.
6. Record the reading from the Certified tachometer on the Record Sheet.
7. Calculate the difference between the two rotation readings and record. Indicate whether the Test centrifuge difference is low with a minus sign or high with a plus sign.
8. Assess the acceptability of the difference using the criteria specified later in this procedure (see Acceptable Criteria). If acceptable, label the centrifuge with the date, the tech and the signed difference and proceed to step (12).
9. If the difference is NOT acceptable, repeat the process. If the setting on the centrifuge can be adjusted to achieve the correct rotation rate, then mark the corrected setting with the verified rotation rate.
10. If one is not able to obtain the correct rotation rate, then remove the centrifuge from use, record the failure on the Centrifuge Calibration Verification Record Sheet, notify the supervisor and obtain an alternate, acceptable and uniquely numbered centrifuge.
11. Ensure all fields of the Centrifuge Calibration Verification Record Sheet are complete and filed in the Centrifuge Log Notebook. (See **appendix I** for an example sheet)

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12. Repeat the process for all speeds used in test procedures.

VERIFICATION OF REFRIGERATION TEMPERATURE PROCEDURE

1. Place the balanced tubes, one of which contains glycerin and is stoppered, into the specimen carriers of the centrifuge.
2. Set the centrifuge refrigeration setting to the temperature called for in the procedure.
3. Insert the NIST traceable thermometer probe into the glycerin. If the temperature is not within a few degrees of the desired refrigerated temperature, then allow the glycerin to equilibrate in a closed centrifuge until the temperature is close to the desired refrigerated temperature.
4. When the temperature is equilibrated, remove the thermometer probe and close the carriage covers.
5. Close and start the centrifuge for five minutes at the speed called for in the procedure or at the highest speed normally used.
6. When the centrifuge stops, remove the carriage cover and immediately place the probe of the NIST traceable thermometer into the glycerin tube.
7. Record the temperature of the centrifuge refrigeration setting and the certified thermometer, as accurately as possible, on the Centrifuge Calibration Verification Record Sheet.
8. Calculate the difference between the two temperatures and record. Indicate whether the centrifuge difference is low with a minus sign or high with a plus sign.
9. Assess the acceptability of the difference using the criteria specified later in this procedure (see Acceptable Criteria). If acceptable, label the centrifuge with the date, the tech and the signed difference and proceed to step (13).
10. If the difference is NOT acceptable, repeat the process. If the setting on the centrifuge can be adjusted to achieve the correct temperature, then mark the corrected setting with the verified temperature.
11. If one is not able to obtain the correct temperature, then remove the centrifuge from use, record the failure on the Centrifuge Calibration Verification Record Sheet, notify the supervisor and obtain an alternate, acceptable and uniquely numbered centrifuge.
12. Ensure all fields of the Centrifuge Calibration Verification Record Sheet are complete and filed in the Centrifuge Log Notebook. (See **appendix I** for an example sheet)
13. Repeat the process for all temperatures used in the test procedures.

VERIFICATION OF TIMER PROCEDURE

1. Set the centrifuge timer at a setting frequently used in procedures, and start the NIST timer simultaneously.

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2. Stop the NIST timer at the same time as the centrifuge timer ends.
3. Record both times of the NIST timer and the centrifuge timer setting, as accurately as possible, on the Centrifuge Calibration Verification Record Sheet.
4. Calculate the difference between the two times and record. If there is a difference between the stopwatch and the timer, indicate whether the centrifuge timer difference is short with a minus sign or long with a plus sign.
5. Assess the acceptability of the difference using the criteria specified later in this procedure (see Acceptable Criteria). If acceptable, label the timer with the date, the tech and the signed difference and proceed to step (10).
6. If the difference is NOT acceptable, repeat the process. If the setting on the centrifuge can be adjusted to reliably achieve the correct timing, then mark the corrected setting with the verified time.
7. If one is not able to obtain the correct timing, then remove the centrifuge from use, record the failure on the Centrifuge Calibration Verification Record Sheet, notify the supervisor and obtain an alternate, acceptable and uniquely numbered centrifuge.
8. A verified external timer can be used in place of the centrifuge timer. The centrifuge timer must be clearly labeled that it is not in use.
9. Ensure all fields of the Centrifuge Calibration Verification Record Sheet are complete and filed in the Centrifuge Log Notebook. Note all actions taken on Record sheet. (See **appendix I** for an example sheet)
10. Repeat the process for all times used in the test procedures.

ACCEPTABLE CRITERIA:

Verification of rotation speed:

The acceptable difference between the Test centrifuge and the Certified tachometer is $\pm 5\%$.

Verification of refrigeration temperature

The acceptable difference between the Test thermometer and the Certified thermometer is ± 2 degrees Centigrade.

Verification of timer

Acceptable difference between the Test timer and the Certified timer is $\pm 2\%$

PROCEDURE NOTES:

1. Unacceptable centrifuges may be cleaned or serviced and retested. If unable to repair discard.
2. Calibration records should indicate dates of removal, return to service or if centrifuge is discarded.

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3. All Centrifuge Calibration Verification Record sheets should remain on file as a record, even after the centrifuge has been removed permanently from service.
4. Centrifuges at time of calibration verification should be inspected for wear, lubricated as needed and cleaned.

REFERENCE

Kurt, Michael. Centrifuge Calibration Procedure. *The Johns Hopkins Hospital Core Lab Procedure Notebook*, Department of Pathology, Division of Clinical Chemistry, 2001, Johns Hopkins Hospital, Baltimore, MD.

APPENDIX:

Appendix A – Centrifuge Calibration Verification Record Sheet