**Centrifuge Calibration Verification - SOP**

**Background Information**

As a minimum, the centrifuge manufacturer’s guidelines for maintenance and calibration should be followed. All three elements of centrifuge calibration verification (verification of rotation speed, timer and centrifuge temperature) that apply must be done when the centrifuge is initially placed in service, annually thereafter, and when a malfunction is suspected or after maintenance effecting function.

**Policy**

The laboratory has processes and procedures to effectively ensure that centrifuges are maintained and calibrated to ensure accuracy and precision are preserved.

**Purpose**

This procedure provides instructions and guidelines for the use of centrifuges. Accurate rotation of speed, timer verification and temperature control (as applicable) in a laboratory environment must meet the National Institute of Standards and Technology (NIST) Principles.

**Pre-analytic Procedure**

1. Centrifuges must receive regular maintenance checks on a six-month schedule, or as recommended by the manufacturer. This check includes oiling the bearings and checking brushes and timing.
2. Centrifuges must be calibrated annually for speed and every six months for time.
3. Cleaning should be performed as needed for usage in specific laboratory areas.
4. Unacceptable centrifuges may be cleaned or serviced and retested. If unable to repair, they should be taken out of service.

**Analytic Procedure**

Supplies:

1. NIST traceable thermometer (certified) or equivalent (if applicable).
2. NIST traceable stopwatch (certified) or equivalent.
3. NIST traceable tachometer (certified) or equivalent.
4. Centrifuge to be verified (referred to as Test), identified by a unique assigned number.
5. A minimum of two weight balanced tubes. If temperature is to be verified, one tube containing glycerin and closed with a stopper containing a hole in which the probe from the NIST traceable thermometer can be inserted.

**Equipment Calibration/Maintenance**

**(Complete any or all of the steps below as applicable)**

1. **Verification of rotation speed**

Some of the centrifugation protocols provide instructions in RPM, not in RCF.

**NOTE:**  RCF stands for relative centrifugal force, which is used to measure the force of a rotor. RCF is better known as g force. It indicates the force from a spinning action in the centrifuge. It can be calculated using RPM.

**RCF (Relative Centrifugal Force or gForce) = 1.118x10-5 x r x (RPM)2 ;where r = rotational radius (cm)**

RPM describes the revolution per minute, and it is the measurement of the fastness of a centrifugal rotation. It stands for the speed of the rotor. RPM doesn’t provide any force-related data on a rotor. It is only related to the speed at which the rotor spins around in the centrifuge.

**RPM (Revolutions per Minute) = √[RCF/(1.118x10-5 x r )]; where r = rotational radius (cm)**

Online calculations tools are available to perform the above calculations if conversion is needed.

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| **Step** | **Action** |
| **1** | * Centrifuges used in the laboratory are to be considered as contaminated and should only be handled with gloves and other personal protective equipment and/or thoroughly disinfected before calibration verification.
 |
| **2** | * Place a small section of black and white reflective tape that comes with the tachometer on the center spindle of the Test centrifuge.
 |
| **3** | * 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.
 |
| **4** | * 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.
 |
| **5** | * Start the centrifuge and allow it come to equilibrium at a normal operating speed.
* Use the tachometer through the viewing port above the reflective tape to take a rotation rate reading.
 |
| **6** | * 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 (see **Related Document** for example).
 |
| **7** | * Record the reading from the certified tachometer on the Record Sheet.
 |
| **8** | * Calculate the difference between the two rotation readings and record.
* Indicate whether the Test centrifuge difference is negative with a minus sign or positive with a plus sign.
 |
| **9** | * Assess the acceptability of the difference using the criteria specified later in this procedure under **Interpretation of Results** section.

|  |  |
| --- | --- |
| **If** | **Then** |
| * Different is acceptable
 | * Label the centrifuge with the date, the tech and the signed difference and proceed to step (10).
 |
| * Difference is NOT acceptable
 | * Repeat the process.
 |
| * Setting on the centrifuge can be adjusted to achieve the correct rotation rate
 | * Mark the corrected setting with the verified rotation rate.
 |
| * Not able to obtain the correct rotation
 | * 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.
 |

 |
| **10** | * Ensure all fields of the Centrifuge Calibration Verification Record Sheet are complete and filed with centrifuge calibration records. (See **Related Document** for an example Record Sheet).
 |
| **11** | * Repeat the process for Part A for all speeds called for in the testing procedures.
 |

1. **Verification of timer**

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| **Step** | **Action** |
| **1** | * Centrifuges used in the laboratory are to be considered as contaminated and should only be handled with gloves and other personal protective equipment and/or thoroughly disinfected before calibration verification.
 |
| **2** | * Set the centrifuge timer at a setting frequently used in procedures, and start the NIST stopwatch simultaneously.
 |
| **3** | * Stop the NIST stopwatch at the same time as the centrifuge timer ends.
 |
| **4** | * Record both times of the stopwatch and the timer setting, as accurately as possible, on the Centrifuge Calibration Verification Record Sheet.
 |
| **5** | * Calculate the difference between the two times and record.
 |
| **6** |

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| **If** | **Then** |
| * 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.
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| **7** | * Assess the acceptability of the difference using the criteria specified later in this procedure under **Interpretation of Results** section.

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| **If** | **Then** |
| * Difference is acceptable
 | * Label the timer with the date, the tech and the signed difference and proceed to step 8.
 |
| * Difference is NOT acceptable
 | * Repeat the process
 |
| * Setting on the centrifuge can be adjusted to achieve the correct timing
 | * Mark the corrected setting with the verified time.
 |
| * Not able to obtain the correct timing
 | * 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 or use an external timer until repairs can be made.
 |
| * External timer is used
 | * The centrifuge timer must be clearly labeled to use external timer.
 |

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| **8** | * Ensure all fields of the Centrifuge Calibration Verification Record Sheet are complete and filed in the Centrifuge Log Notebook.
 |
| **9** | * Note all actions taken on the Record Sheet.
 |
| **10** | * Repeat the process for Part B for all times called for in the testing procedures.
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1. **Verification of centrifuge temperature**

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| **Step** | **Action** |
| **1** | * Centrifuges used in the laboratory are to be considered as contaminated and should only be handled with gloves and other personal protective equipment and/or thoroughly disinfected before refrigeration verification.
 |
| **2** | * Place the balanced tubes, one of which contains glycerin into the specimen carriages of the centrifuge.
 |
| **3** | * Set the centrifuge refrigeration setting to the temperature called for in the procedure.
 |
| **4** | * Insert the NIST traceable thermometer probe into the glycerin tube,

|  |  |
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| **IF** | **Then** |
| * Temperature is not within a few degrees of the desired refrigerated temperature
 | * Allow the glycerin to equilibrate in a closed centrifuge until the temperature is close to the desired refrigerated temperature.
 |

 |
| **5** | * When the temperature is equilibrated, remove the thermometer probe and close the carriage covers.
 |
| **6** | * Close and start the centrifuge to spin for five minutes at the speed called for in the procedure or at the highest speed normally used.
 |
| **7** | * When the centrifuge stops, remove the carriage cover and immediately place the probe of the NIST traceable thermometer into the glycerin tube.
 |
| **8** | * Record the temperature of the centrifuge refrigeration setting and the certified thermometer, as accurately as possible, on the Centrifuge Calibration Verification Record Sheet.
 |
| **9** | * 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.
 |
| **10** | Assess the acceptability of the difference using the criteria specified later in this procedure under **Interpretation of Results** section.

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| **IF** | **Then** |
| * Different is acceptable
 | * Label the timer with the date, the tech and the signed difference and proceed to step 11.
 |
| * The difference is NOT acceptable
 | * Repeat the process.
 |
| * The setting on the centrifuge can be adjusted to achieve the correct temperature
 | * Label the centrifuge with the date, the tech and the signed difference and proceed to step 11.
 |
| * Not able to obtain the correct temperature
 | * 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 **Related Document** for an example sheet)
 |
| **12** | * Repeat the process for Part C for all temperatures called for in the testing procedures.
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**Interpretation of Results**

**NOTE: Each laboratory is responsible for establishing acceptability criteria. The values below are examples/recommendations.**

1. Verification of rotation speed

If the difference between the Test centrifuge and the certified tachometer is ±5% of the procedure speed, then the Test centrifuge rotation calibration is verified as acceptable.

1. Verification of timer

Acceptable difference between the Test timer and the certified timer should be ±2% of the total Test timer setting.

1. Verification of refrigeration temperature

If the difference between the Test thermometer and the certified thermometer is ±1° C then the Test thermometer calibration is verified as acceptable.

**Post-analytic Procedure**

Record and document all results

1. A notebook for holding record sheets and centrifuge calibration logs is recommended
2. Centrifuge calibration verification record sheets should include the following information:
	1. Sheet identified with the same unique number as the Test centrifuge at initial calibration
	2. Sheet contains the following information (See **Related Document)**
* Centrifuge location
* Procedures for using centrifuge
* Calibration date
* Technologist signature/initials
* Test centrifuge reading (rotation)
* Certified centrifuge reading (rotation)
* Difference between Test and Certified
* Acceptance or rejection
* Any actions taken (clean, adjust, etc.)

Archiving Results and Report Documents

1. Calibration records should indicate dates of removal, return to service or if centrifuge is discarded
2. All centrifuge calibration verification record sheets should remain on file as a record, even after the centrifuge has been removed permanently from service

**References**

1. College of American Pathologists (CAP) 2021. Commission on Laboratory Accreditation, Laboratory Accreditation Program; All Common Checklist, 2021.
2. Clinical and Laboratory Standards Institute (CLSI). General Laboratory Equipment Performance Qualification, Use, and Maintenance. 2nd ed. CLSI guideline QMS23. Clinical and Laboratory Standards Institute, Wayne, PA, 2019.
3. DAIDS Good Clinical Laboratory Practice Guidelines. Rev 08/16/2021

**Related Document**

Example of Centrifuge Calibration Verification Record Sheet