HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Multidisciplinary Policy and Procedure		
Title:	Cleaning, Maintenance and Calibration of Refrigerated Centrifuges for Platelet Separation		
Applies To:	All Blood Bank Staff and Biomedical Engineers		
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1. PURPOSE:

1.1 Establishing system and setting responsibilities for measures taken to ensure the integrity, accuracy and reliability of refrigerated centrifuges of blood bank.

2. DEFINITONS:

N/A

3. POLICY:

3.1 Refrigerated centrifuge should be designed for the intended use .
3.2 The maintenance-free induction motor ensures quiet and low-vibration operation even at high speeds and guarantees a very long lifetime.
3.3 The user control panel friendly makes it easy to pre-set the speed, RCF value, running time, temperature and running profile (acceleration and braking curves) .
3.4 It can be chosen between the display of speed and RCF or the entry mode .
3.5 The centrifuge is equipped with various safety features:
  3.5.1 Housing, rotor chamber, base frame, and guard ring are made of high-strength, high quality steel.
  3.5.2 The lid is equipped with a lock.
  3.5.3 The lid of the centrifuge can only be opened while the centrifuge is switched on and the rotor has come to a complete stop
  3.5.4 The centrifuge cannot be started until the lid has been closed properly .
  3.5.5 Electronic imbalance detection .
  3.5.6 Lid emergency release: For emergencies only. e.g. during power failures.
3.6 The integrity, accuracy, and reliability of measurement data for refrigerated centrifuges used in the blood bank should be ensured .
3.7 Suitable schedules for maintenance; calibration frequency of refrigerated centrifuges have to be drawn up defining forward dates for the completion of maintenance and calibration .
3.8 Unscheduled maintenance can be achieved when needed .
3.9 Individual files of service reports of each centrifuge should be maintained including the details of all routine as well as trouble-shooting service calls by the manufacturer's engineer in the equipment maintenance register .
3.10 A file of all manufacturers 'instructions and where required display should be maintained close to the equipment .
3.11 Appropriate calibration of centrifuges gives adequate yield of platelets
3.12 In compliance with AABB standard, preparation of platelet should yield $\geq 5.5 \times 10^{10}$ platelets in 90 % of tested units.

4. PROCEDURE:

4.1 Cleaning:

4.1.1 Every week or every time after a spillage has occurred.

4.1.1.1 Wipe out under the rotor with a soft cloth to remove any condensation.

4.1.1.2 Once a week, or as required; if a spill occurs, buckets must be removed and soaked in a warm water (<50 °C) and mild soap for at least 10 minutes and cleaned thoroughly .

4.1.1.3 Rinse the rotor thoroughly with water .

4.1.1.4 Dry the rotor and buckets .

4.1.1.5 Document on weekly cleaning record Form

4.1.1.6 Notify supervisor of any abnormalities or malfunction and corrective action taken. Document in an incident report of Malfunction and Corrective Action Form

4.2 Maintenance:

4.2.1 Every 6 months or unscheduled when needed:

4.2.1.1 Record the set time, temperature, speed for each program to ensure it is as defined on the sheet posted on the lid of the centrifuge .

4.2.1.2 Observe and record actual temperature and speed for each program to ensure they are in accord with the program settings.

4.2.1.3 Document on Biannual maintenance form of refrigerated centrifuges for platelet separation. Notify in-charge biomedical engineer of any abnormalities .

4.3 Calibrating centrifuges for platelet separation:

4.3.1 Centrifuges used for platelet preparation should be calibrated when :

4.3.1.1 Receipt of new centrifuge .

4.3.1.2 Major repair of centrifuge was done .

4.3.1.3 Unacceptable platelet Q.C. (Preparation of platelet should Yield > 5.5×10^{10} platelet in 75% of tested units).

4.3.2 Preparation Of Platelet-Rich Plasma (PRP):

4.3.2.1 Four whole blood units and four EDTA tubes from donors.

4.3.2.2 Enter unit numbers in the two forms (PRP and PC).

4.3.2.3 Weigh each unit, calculate volume [weight/blood specific gravity 1.06] and enter in the two forms.

4.3.2.3.1 Deduct the weight of the empty bag from the total weight.

4.3.2.4 Perform a platelet count on the anticoagulated specimen. If the platelet count is below 133×10^3 /ul, this donor's blood should not be used for calibration .

4.3.2.4.1 You can withdraw 1 ml from well mixed EDTA tube, dispense in 3 ml red top tube properly labeled, and perform a platelet count.

4.3.2.5 Calculate and record the number of platelets in the unit of Whole Blood (WB):

4.3.2.5.1 Platelet/ul X 1000 X ml of WB = number of platelets in WB

4.3.2.6 Prepare platelet-rich plasma (PRP) at a selected speed and time (Sot spin).

4.3.2.6.1 Times include acceleration but no deceleration times. Times given are approximations only.

4.3.2.6.2 Each individual centrifuge must be evaluated for the preparation of the various components.

4.3.2.6.3 Soft spin = 2650 RPM for 5 minutes with a temperature setting of 20-24 °C.

4.3.2.6.4 Heavy spin = 3500 RPM for 7 minutes with a temperature setting 20-24 °C.

4.3.2.7 Whatever the bag type used, there must be two satellite bags (one for PRP and the other is empty). Place a temporary clamp on the tubing so that one satellite bag is closed off.

4.3.2.8 Express the PRP into the other satellite bag. Follow the procedure for PRBCs preparation. Seal the tubing close to the primary bag, leaving a long section of tubing,

or the "tail = a part attached to the Y-connection between the two satellite bags). Disconnect the two satellite bags from the primary bag. Do not remove the temporary clamp between the satellite bags until the platelets are prepared

4.3.2.9 Strip the tubing and "tail" several times so that they contain a representative sample of PRP.

4.3.2.10 Seal off a segment of the "tail" and disconnect it so that the bag of PRP remains sterile.

4.3.2.11 Weigh each PRP unit and calculate its volume (weight / plasma sp. Gr. 1.03) and enter on PRP form.

4.3.2.11.1 Deduct the weight of the empty bag from the total weight.

4.3.2.12 Perform a platelet count on the sample of PRP in the sealed segment. Calculate the number of platelets in the bag of PRP :

4.3.2.12.1 Platelets/ul X 1000 X ml of PRP = number of platelets in PRP

4.3.2.13 Calculate and record the percentage of yield: (number of platelets in PRP × 100) divided by (number of platelets in whole blood) = % yield. (Accepted value >75%).

4.3.2.14 Repeat the above process three or four times with different donors, using different speeds and times of centrifugation, and compare the yields achieved under each set of test conditions.

4.3.2.15 Select the shortest time and lowest speed combination that results in the highest percentage of platelet yield without unacceptable levels of red cell content in the PRP.

4.3.2.16 Record the centrifuge identification, the calibration settings selected, the date, and the identity of the person performing the calibration.

4.3.3 Preparation Of Platelet Concentrates (PC):

4.3.3.1 Centrifuge the PRP (as prepared above) at a selected time and speed to prepare platelets concentrate (PC).

4.3.3.2 Remove the temporary clamp between the two satellite bags, and express the supernatant plasma into the second attached satellite bag, leaving approximately 55 to 60 mL volume in the platelet bag. Seal the tubing, leaving a long section of tubing attached to the platelet bag.

4.3.3.3 Allow the platelets to rest for approximately 1 hour.

4.3.3.4 Placing the platelets on an agitator for at least 1 hour to ensure that they are evenly resuspended. Platelet counts performed immediately after centrifugation will not be accurate.

4.3.3.5 Strip the tubing several times, mixing tubing contents well with the contents of the platelet bag. Let the content flow back into the tubing. Seal off a segment of the tubing and disconnect it, so that the platelet bag remains sterile.

4.3.3.6 Perform a platelet count on the contents of the segment.

4.3.3.7 Calculate and record the number of platelets in the concentrate: platelets/µL × 1000 × mL of platelets = number of platelets in platelet concentrate.

4.3.3.8 Calculate and record the percentage of yield. (number of platelets in PC × 100) divided by (number of platelets in PRP) = % yield. (Accepted value >90%).

4.3.3.9 Repeat the above process with PRP from different donors, using different speeds and times of centrifugation; compare the yields achieved under each set of test conditions.

4.3.3.10 Select the shortest time and lowest speed combination that results in the highest percentage of platelet yield in the platelet concentrate.

4.3.3.11 Record the centrifuge identification, the calibration settings selected, the date performed, and the identity of the person performing the calibration.

4.3.4 Once a centrifuge has been calibrated, it is not necessary to recalibrate unless the instrument has undergone adjustment or repairs, or levels of platelet recovery fall below acceptable levels.

4.3.5 Each centrifuge used for preparing platelets must be calibrated individually. Conditions determined to be optimal for each instrument should be employed for that instrument.

4.3.6 Accepted Values:

4.3.6.1 % yield of platelet in PRP: > 75%

4.3.6.2 % yield of platelet in PC: > 90%

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

- 5.1.1 Separation centrifuge maintenance log sheet
- 5.1.2 Malfunction and Corrective Action Form
- 5.1.3 Biannual maintenance form of refrigerated centrifuges for platelet separation
- 5.1.4 Percent Platelet Yield-Platelet Rich Plasma form
- 5.1.5 Percent Platelet Yield-Platelet Concentrate form

5.2 **Materials:**

- 5.2.1 Refrigerated Centrifuge
- 5.2.2 EDTA tubes and 4 WB units
- 5.2.3 Dielectric heat sealer
- 5.2.4 Electronic Scale
- 5.2.5 Plastic tubing clips
- 5.2.6 Electronic Calculator
- 5.2.7 % Platelet yield - PRP worksheet
- 5.2.8 % Platelet yield - PC. Worksheet
- 5.2.9 Red Top blood collecting tube
- 5.2.10 200 ul pipette and Tips
- 5.2.11 Wassermann tubes

6. RESPONSIBILITIES:

6.1 Cleaning is performed by blood bank staff weekly and according to the equipment need.

6.2 Scheduled maintenance is performed by blood bank supervisor every 6 months according maintenance and calibration plane. Biomedical engineering help may be needed.

6.3 Unscheduled maintenance is performed by biomedical engineering when needed.

6.4 Calibration is the responsibility blood bank supervisor under supervision of lab director

6.5 It is the responsibility of the lab director (or his deputy) to review the results of cleaning, maintenance, calibration and any action taken and documentation of all corrective actions.

6.6 It is the responsibility of blood bank supervisor to maintain records of malfunction and repair during the working lifetime of the equipment.

6.7 It is the responsibility of blood bank supervisor to inform biomedical engineering when unscheduled maintenance is needed and maintaining the resets indicating the date of information.

7. APPENDICES:

N/A

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.

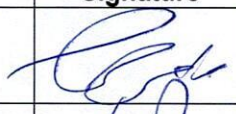
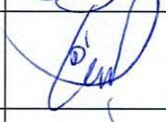
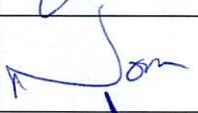
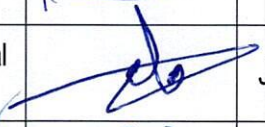
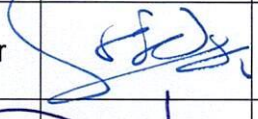
8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

8.6 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Mohammed Amer	Blood Bank Physician		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Wafi Abdo	Head of Biomedical Engineers		January 09, 2022
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
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Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025