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Cell Washer and Serofuge Maintenance: Daily, Monthly, Quarterly, Annually and After Major Repairs

Purpose

This procedure will describe how to perform maintenance and inspection of the serological cell washers and serofuges.

Policy

- Cellwashers and Serofuges maintenance is scheduled and performed at a minimum that is in accordance with the manufacture's written instructions.
  - Transfusion Service managers/designees must confirm that all required maintenance indicated by device manufacture is performed confirming to the required specifications.
- Routine maintenance is documented on the Daily Maintenance and Inspection form provided by Laboratory Technology Services (LTS)
  - Each form provided is unique for the cell washer or serofuge in use.
- Cellwashers and Serofuges when calibrated by a Clinical Laboratory Scientist use the current test media and procedures.
  - Document calibration and acceptability on the *Cellwasher Serofuge Calibration Worksheet* form.
  - After a major repair, an assessment of prior testing must be conducted and documented by the transfusion service manager or designee to verify if testing results were adversely affected and if other equipment is similarly affected by the malfunction.
    - The review shall assess the time period from which the equipment was last known to be functioning appropriately.

We must calibrate after a major repair

Cell Washer and Serofuge Maintenance: Daily, Monthly, Quarterly, Annually and After Major Repairs, Continued

Equipment and Reagents

- Saline
- Red cell suspensions
- 22% Albumin or 6-8% albumin
- Volumetric container to measure between approximately 30-60 mL.12x75 mm test tubes
- Tachometer

Definition

Major Repair:
- Replacement of critical part, i.e. motor, brushes, timer
- Sent to manufacturer for repair

Minor Repair:
- Replace latch on lid
- Replace tubing

Procedural Notes

Major Repairs involves replacement of the motor, or other major electrical device. It does not include replacement of tubing.

Record the following in the daily column if necessary
- N = if the instrument is not in use for that day or series of days
- R= if the instrument has been sent for repairs and thus is not in use for that day or series of days
- S= if the instrument is in storage and thus is not in use for that day or series of days.

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Maintenance Intervals

The Interval, what maintenance is performed and who performs the maintenance is described below:

Interval	Maintenance Performed	Responsible Party
Daily-**Cellwashers and Serofuges**	• As indicated on form-usually inspection and cleaning	Clinical Laboratory Scientist (CLS)
Weekly-**Cellwashers**	• As indicated on form-usually verification of fill volume	CLS
Quarterly/Semi-annual **Cellwashers and Serofuges**	• Refer to Preventative Maintenance Checklist and Operator's manual	Laboratory Technology Systems (LTS)
After major repairs or when new **Cellwashers and Serofuges**	• Check calibration-spin times (IS, and AHG) • Packing cells-washing phase	CLS

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Procedure Daily/Weekly

Follow the steps below for daily and weekly maintenance	
Step	**Action**
1.	Perform the following daily and/or weekly tasks as indicated on the *Daily Maintenance and Inspection* form provided by Laboratory Technology Services.
2.	Refer to manufactures instructions for complicated tasks, such as verifying fill volume for cellwashers.
3.	Initial completion and documentation required for task where indicated on the *Daily Maintenance and Inspection* form.

Procedure Quarterly

Follow the steps below for quarterly maintenance for cell washers and serofuge	
Step	**Action: (Cell Washer and Serofuge)**
1.	LTS generally performs quarterly maintenance or staff on site may perform some of all of the maintenance.
2.	Review the LTS report to be assured that: • RPM checks were performed and are acceptable • Timer checks were performed and are acceptable • Extended cleaning (diaphragm, etc.) was performed, if required • Tubing was replaced, if required, on cell washer. • Other additional maintenance as indicated by the manufacture's written instructions was completed.
3.	Report any problems or failures to meet the LTS parameters, by contacting LTS for follow-up. • Remove the instrument from service until problems are fixed or resolved.
4.	The report from LTS is reviewed for items outlined in Step 2 and/or as indicated by the manufacture's written instructions. If acceptable it is initialed and dated by the Manager or designee.
5.	Initial completion and documentation required for task where indicated on the *Daily Maintenance and Inspection* form.

Cell Washer and Serofuge Maintenance: Daily, Monthly, Quarterly, Annually and After Major Repairs, Continued

Calibration Procedure

AFTER MAJOR REPAIRS OR WHEN NEW	
Follow the steps below for checking spin times for immediate spin testing	
Step	**Action**
1.	Prepare the following samples, diluted in 6-8% albumin, for testing (use commercially prepared or prepare fresh from 22% albumin). • Anti-D to result in an IS reaction with D+ red cells of 2+ (approximately 1:8 dilution). • Anti-B to result in a reaction of 1-2+ with B+ red cells. (Approximately 1:1 dilution) • Red Cells at a 3-5% saline suspension.
2.	Label tubes as page 1 of the Cellwasher/Serofuge Calibration Worksheet.
3.	Add the diluted serum and red cells as on page 1 of the Cellwasher/Serofuge Calibration Worksheet
4.	Working in pairs, spin the 10 pos and 10 neg tubes for 10 seconds. • Evaluate each tube and complete the Cellwasher/Serofuge Calibration Worksheet page 2 for the appropriate tests.
5.	Repeat 3 above for each of the sets, spinning the tubes for 15 sec, 20 sec, and 25 sec respectively.
6.	Select the shortest spin time that gives • Clear, delineated cell button • Cell button resuspends easily after gentle rotation, and • Does not give falsely positive or rough readings. • Record in Optimum time at the bottom of the sheet. Note: the time selected should not have changed significantly from the last time (if being performed after repair).

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Calibration Procedure

AFTER MAJOR REPAIRS OR WHEN NEW	
Follow the steps below for checking spin times for antiglobulin test.	
Step	**Action**
1.	Prepare the following samples for testing, dilutions made in 6-8% albumin. Label 4 sets of 2 tubes as follows (page 2 of the Cellwasher/Serofuge Calibration Worksheet):
2.	Prepare a diluted anti-D reagent to react in the antiglobulin test with strength of at least 2+ with D+ cells. (Approximately 1:8 dilution (in saline) may vary depending on reagent.) • Label tubes and add reagent and cells as described in page 2 of the Cellwasher/Serofuge Calibration Worksheet .
3	Incubate the tubes for 10 min. at 37°C.
4.	Remove one set of tubes at a time and wash at least 3 times in a cell washer.
5.	To the dry cell button, add 2 drops of anti-IgG.
6.	Spin the first set (10) of tubes for 10 seconds.
7.	Examine the tubes and record in the appropriate place on the Maintenance Checklist.
8.	Repeat steps 5-7 for the next 3 sets, spinning for 15, 20 and 25 seconds respectively. Record in the appropriate column on the form. Note: X through any additional columns on the form if they should appear unnecessary because previous results were acceptable- i.e. 25 sec. test may not be needed.
9.	Expected Results: Select the shortest spin time that gives: • Clear, delineated cell button • Cell button resuspends easily after gentle rotation. • Does not give falsely positive or rough readings.

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Calibration Procedure

AFTER MAJOR REPAIRS OR WHEN NEW	
Follow the steps below for checking spin times for packing cells after wash step (washing)	
Step	**Action**
1.	Prepare one set of 12 tubes for the wash cycle of the cell washer. • This is one drop of a 3-5% cell suspension • Fill the tube approximately 2/3 full of saline.
2.	Place the tubes in the cell washer.
3.	Turn on the cell washer/serofuge for the fixed spin time (usually 60 secs.)
4.	Inspect the spun tubes and complete the Cell Washing portion of the page 2 of the Cellwasher/Serofuge Calibration Worksheet

Completion of Worksheet

Follow the steps below to complete the worksheet and review.	
Step	**Action**
1.	CLS to document on the cell washer or serofuge, (or clearly mark on an existing tag) the optimal time for IS and AHG spin, and washing, with the date and initials of the person performing the calibration
2.	CLS to complete the Cellwasher/Serofuge worksheet under the washing cells calibration section and sign performed by/Date

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Completion of Worksheet

After completing worksheet, manager reviews before placing instrument back into use

Follow the steps below to complete the worksheet and review.	
Step	**Action**

3.	The Serofuge Calibration Worksheet is reviewed by a Manager or designee.
	• Verify make/model of equipment is recorded with IR#, Date, and CLS who performed calibration
	• Verify that either new equipment or repair calibration is checked.
	• Verify all calibration testing (IS, AHG, Wash) has been completed and an optimal time is recorded.
	• Verify all reagent cell and antisera have been documented
	• Verify all calibrated spin times have been posted on equipment with CLS initials and date.
	• Verify boxes checked for optional spin times and acceptance of calibration testing
	• For post repair calibration only:
	  ○ Verify that assessment of prior testing was completed and documented
	  ○ Verify that assessment if other equipment was similarly affected was completed and documented.
	• Verify Performed by/Date completed.
	
	Manager or designee to complete Reviewed by/Date signifying items above are completed.

4.	The completed form (and repair record if applicable) will be filed with the annual Preventative Maintenance (PM) reports or with the monthly PM forms for the cell washer or serofuge.
5.	If any of the above calibration test are found unacceptable: • Repeat tests • If the equipment continues to give unacceptable results or does not perform as expected, report to LTS and do not release the instrument for use.

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Non-Controlled Documents

The following non-controlled documents support this policy.

- AABB Standards, current ed.
- CAP Requirements, checklist, current ed.
- Fung, Mark K. Ed. Technical Manual, 19th Ed. AABB, 2017
- Cellwasher 2 plus-operator's manual
- CW3 Model-operator's manual
- Cellwasher 2-operator's manual

Controlled Documents

The following controlled documents support this policy.

- Cellwasher Serofuge Calibration Worksheet form (Page1&2)
- Critical Equipment Validation-New Installation And After Repairs
- Equipment Out of Calibration: Actions to Take
- Daily Maintenance and Inspection forms

See these policies/ forms when calibrating.

Author

All SCPMG Transfusion Service Managers
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Distribution

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