

Name of Policy: Equipment Calibration/Validation/
Preventative Maintenance

Policy Number: 3364-108-103

Approving Officer: Senior Hospital Administrator
Director, Blood Transfusion
Service

Responsible Agent: Blood Transfusion Service
Supervisor
Administrative Director, Lab

Scope: Pathology/Laboratory – Blood Bank



Effective date: 03/01/2025

Original effective date: 06/1996

Key words: Equipment, Maintenance, Calibration, Validation, Verification

<input type="checkbox"/>	<u>New policy proposal</u>	<input type="checkbox"/>	<u>Minor/technical revision of existing policy</u>
<input checked="" type="checkbox"/>	<u>Major revision of existing policy</u>	<input type="checkbox"/>	<u>Reaffirmation of existing policy</u>

(A) Policy Statement

The Blood Transfusion Service has a defined program to identify, assess the function and condition and to maintain equipment used in the department.

(B) Purpose of Policy

To assure safe and expected function of equipment.

(C) Procedure

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
All centrifuges	Daily	<ul style="list-style-type: none"> Clean with detergent disinfectant 	NA	NA
Serological Centrifuge <u>0036337</u> <u>0036338</u> <u>0036339</u>	<u>Every six months</u> <u>Annually</u> or after repairs	Timer accuracy: optimum time of centrifugation <ul style="list-style-type: none"> <u>See 500.010 Check RPMs.</u> 	2800 RPM (± 50); timer corresponds with stopwatch; optimum time of centrifugation determined by calibration.	Refer to Biomed. Dept.
	<u>Before first put into service or after repairs</u>	<ul style="list-style-type: none"> <u>Serological centrifuge calibration to determine optimum time of centrifugation. See 500.010.</u> 	<u>Optimum time of centrifugation determined by calibration.</u>	<u>Refer to Biomed Dept.</u>
MTS centrifuges <u>0033835</u> <u>0033837</u> <u>0044204</u>	Every six months <u>or after repairs</u>	<ul style="list-style-type: none"> Check RPMs, timer accuracy 	895 \pm 25 RPM 10:00 min \pm 10 sec	Factory pre-set: calibration performed by Biomed.

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
Electronic- pipettors <u>38680098</u> <u>42184575</u>	Annually	<ul style="list-style-type: none"> Check amount dispensed at <u>5025</u>µ and <u>30050</u>µ settings 	See 500.085 <u>50µ setting: 50µ ± 1.5µ</u> <u>300µ setting: 300µ ± 3µ</u>	Refer to Outside vendor
Automatic cell washer Helmer Ultra CW s/n0002451 <u>0043293</u>	Daily	<ul style="list-style-type: none"> Rinse and clean bowl and cabinet Check bowl for cracks and corrosion Check saline levels Check drain tubing; clear obstructions, if necessary Visual inspection of tubing and connections. Clean interior with dampened gauze after normal usage. Wipe dry. 	NA	NA
	Weekly For Helmer	<ul style="list-style-type: none"> Flush the system with 10% bleach solution followed by distilled water according to Operating Manual (6.2.3) Clean the fill ports according to Operating Manual (6.2.4) 	NA	NA
Automatic cell washers	Monthly	<ul style="list-style-type: none"> UltraCW - Inspect the rotor for wear, corrosion<u>corrosion</u>, or damage. Replace as needed. Inspect the tube holders for wear and damage. Replace if needed. Check saline dispensing volume. 		Change saline as needed Repair, or <u>Repair or</u> refer to Biomed Dept as necessary.
	<u>Annually</u>	<ul style="list-style-type: none"> <u>Replace supply and drain tubing.</u> 		

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
	Every six months, Annually; Before first put into service use and after repair.	—Measure dispensed saline volume. Cellwasher Function Verification. See 500.020 and Cellwasher Function Verification and Maintenance Log for performance testing. • Replace supply and drain tubing.		Adjust to correct dispensing volume; if not corrected, notify Biomed Dept.
	Annually	UltraCW Replace supply and drain tubing.		
Water baths 0035309 0008305	Daily	• <u>Record Temperature</u>	30-37°C	Adjust setting
	At least weekly or as needed	• <u>Drain, disinfect with hospital-supplied detergent, refill with DI water</u>	<u>Temperature 30-37°C</u>	<u>Adjust Setting</u>
Heating blocks 0008604 0008650 MTS Incubators 0033836 0033834	Daily	• <u>Record Temperature</u>	37° C ± 1° C	Adjust and calibrate using separate procedure.
	Daily	• <u>Record Temperature, rotating thermometer to appropriate position daily</u>		MTS Incubators are factory preset. Refer to Ortho.
MTS Incubators	Quarterly, Before use and after repair	• <u>Check temperature of all wells (500.060)</u>	37° C ± 1° C	Cover unacceptable wells; adjust heat block temp and repeat; if not corrected, refer to Biomed. Dept.
Sealer 0008975	Biannual	• <u>Electrical check;</u> • <u>Decontamination/ Cleaning as needed</u>	<u>Pass</u>	Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Centrifuge 0039752 0035672	Biannual	• <u>Electrical check;</u> • <u>Decontamination/ Cleaning as needed</u>	3600 rpm	Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Platelet Agitator 0037187	Biannual	• <u>Electrical check;</u> • <u>Decontamination/ Cleaning as needed</u>	<u>Pass</u>	Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
Storage Units Zone 1 Zone 2 Freezer Zone 3 Zone 5 Zone 6 Plt Incubator	Daily, Before use and after repair	<ul style="list-style-type: none"> Record temperature, assure proper chart recorder function. Ensure operating conditions are appropriate to manufacturers instructions 	See policy 3364-108-201	See policy 3364-108-201
Storage Units	Quarterly, Before use and after repair	<ul style="list-style-type: none"> Alarm and temperature display check 	See policy 3364-108-201	See policy 3364-108-201
Coolers	Before use	<ul style="list-style-type: none"> Monitor internal temperature maintained with cool-paks or ice. Check temperature indicators of units returned after storage in cooler. 	<10 °C after 12 hrs	Do not use for storage
Hemo-Temp indicators	Before implementation	<ul style="list-style-type: none"> Comparison of indicator with RBC units wrapped around NBS thermometer 	Temp indicated matches NBS thermometer within 2 °C	
<u>Microscope 0002406</u>	<u>Annually</u>	<ul style="list-style-type: none"> <u>Optically aligned</u> <u>Decontamination / Cleaning</u> 	<u>Refer to Biomed</u>	<u>Alignment Performed by Biomed, Decontamination/ Cleaning performed by Blood Bank</u>

Validation of expected function is performed on all new and repaired equipment. Equipment and Storage units must be monitored and meet acceptable criteria for 24 hours before placing in service.

Designated staff in the Blood Transfusion Service performs validation, calibration and maintenance procedures. Procedures for maintenance and calibration are written and performed according to manufacturer's instructions and accreditation standard requirements. The BTS supervisor reviews records of validations, calibrations and maintenance. The BTS supervisor initiates corrective actions. Equipment that fails to function or meet acceptable criteria shall be prominently identified as "Out of Service". Records of equipment maintenance, repair and operation are available in the BioMed Department and the BTS supervisor office.

(D) References

(1) AABB Standards for Blood Banks and Transfusion Services, current edition.

Approved by:

Lauren Stanoszek, M.D.
Assistant Professor
Director, Blood Transfusion Service

Policies Superseded by This Policy:

• None

Initial effective date:

<div style="border-bottom: 1px solid black; margin-bottom: 10px;"> <u>Date</u> </div> <div style="border-bottom: 1px solid black; margin-bottom: 10px;"> <u>Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator</u> </div> <div style="border-bottom: 1px solid black; margin-bottom: 10px;"> <u>Date</u> </div> <div style="border-bottom: 1px solid black; margin-bottom: 10px;"> <u>Review/Revision Completed by:</u> <u>Danielle Weinau MLS(ASCP)^{CM}</u> </div>	<p><u>All Review/Revision Dates:</u></p> <table style="width: 100%; border: none;"> <tr> <td style="text-align: left;"><u>6/96</u></td> <td style="text-align: right;"><u>11/01/2010</u></td> </tr> <tr> <td style="text-align: left;"><u>1/98</u></td> <td style="text-align: right;"><u>3/01/2013</u></td> </tr> <tr> <td style="text-align: left;"><u>3/99</u></td> <td style="text-align: right;"><u>3/2/2015</u></td> </tr> <tr> <td style="text-align: left;"><u>7/00</u></td> <td style="text-align: right;"><u>3/1/2017</u></td> </tr> <tr> <td style="text-align: left;"><u>5/02</u></td> <td style="text-align: right;"><u>3/1/2019</u></td> </tr> <tr> <td style="text-align: left;"><u>1/05</u></td> <td style="text-align: right;"><u>3/1/2021</u></td> </tr> <tr> <td style="text-align: left;"><u>1/2008</u></td> <td style="text-align: right;"><u>3/20/2023</u></td> </tr> <tr> <td style="text-align: left;"><u>6/9/2008</u></td> <td style="text-align: right;"><u>3/1/2025</u></td> </tr> </table> <p style="margin-top: 20px;"><u>Next review date: 03/01/2027</u></p>	<u>6/96</u>	<u>11/01/2010</u>	<u>1/98</u>	<u>3/01/2013</u>	<u>3/99</u>	<u>3/2/2015</u>	<u>7/00</u>	<u>3/1/2017</u>	<u>5/02</u>	<u>3/1/2019</u>	<u>1/05</u>	<u>3/1/2021</u>	<u>1/2008</u>	<u>3/20/2023</u>	<u>6/9/2008</u>	<u>3/1/2025</u>
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