Name of Policy:	**Equipment Calibration/ Validation/Preventative Maintenance**
Policy Number:	3364-108-103
Department:	Pathology/Laboratory – Blood Bank
Approving Officer:	Chief Operating Officer - UTMC Director, Blood Transfusion Service
Responsible Agent:	Blood Transfusion Service Supervisor Administrative Director, Lab
Scope:	Pathology/Laboratory – Blood Bank

THE UNIVERSITY OF TOLEDO 1872

Effective Date: **03/20/2023**
Initial Effective Date: 6/1996

_____ New policy proposal
_____ Major revision of existing policy
__X__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(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	Clean with detergent disinfectant	NA	NA
Serological Centrifuge 36337 36338 36339	Annually or after repairs	Timer accuracy: optimum time of centrifugation See 500.010	2800 RPM (±50); timer corresponds with stopwatch; optimum time of centrifugation determined by calibration.	Refer to Biomed. Dept.
MTS centrifuges	Every six months	Check RPMs, timer accuracy	895±25 RPM 10:00 min ±10 sec	Factory pre-set: calibration performed by Biomed.
Electronic-pipettors	Annually	Check amount dispensed at 25µ and 50µ settings	See 500.085	Refer to Outside vendor
Automatic cell washer Helmer Ultra CW s/n0002451	Daily	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

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
	Weekly For Helmer	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	UltraCW - Inspect the rotor for wear, corrosion 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 refer to Biomed Dept as necessary.
	Every six months, before use and after repair	Measure dispensed saline volume. See 500.020 and Cellwasher Function Verification and Maintenance Log for performance testing.		Adjust to correct dispensing volume; if not corrected, notify Biomed Dept.
	Annually	UltraCW-Replace supply and drain tubing.		
Water baths 35309 8305	Daily	Record Temperature	30-37°C	Adjust setting
	At least weekly or as needed	Drain, disinfect with hospital-supplied detergent, refill with DI water		
Heating blocks 8604 8650 MTS Incubators 33836 33834	Daily Daily	Record Temperature Record Temperature	37° C ± 1° C	Adjust and calibrate using separate procedure MTS Incubators are factory preset. Refer to Ortho.
MTS Incubators	Quarterly, Before use and after repair	Check temperature of all wells (500.060)	37° C ± 1° C	Cover unacceptable wells; adjust heat block temp and repeat; if not corrected, refer to Biomed. Dept.
Sealer	Biannual	Electrical check; Decontamination/ Cleaning as needed		Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank

Category/Tag Number	Frequency	Calibration/ Validation Technique	Acceptable Criteria	Corrective Procedure
Centrifuge	Biannual	Electrical check; Decontamination/ Cleaning as needed	3600 rpm	Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Platelet Agitator	Biannual	Electrical check; Decontamination/ Cleaning as needed		Performed by Biomed. Dept, decontamination/ cleaning by Blood Bank
Storage Units Zone 1 Zone 2 Freezer Zone 3 Zone 5 Zone 6 Plt Incubator	Daily, Before use and after repair	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	Alarm and temperature display check	See policy 3364-108-201	See policy 3364-108-201
Coolers	Before use	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	Comparison of indicator with RBC units wrapped around NBS thermometer	Temp indicated matches NBS thermometer within 2 °C	

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.

Approved by:		**Review/Revision Date:**
		6/96 03/01/2021 1/98 03/20/2023 3/99 7/00 5/02 1/05 1/2008 6/9/2008 11/01/2010 3/01/2013 3/2/2015 03/01/2017 03/01/2019
/s/ Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	03/21/2023 Date	
/s/ Christine Stesney-Ridenour Chief Operating Officer - UTMC	03/21/2023 Date	
Review/Revision Completed By: Danielle Weilnau, MLS(ASCP)^{CM}		**Next Review Date:** 3/01/2025
Policies Superseded by This Policy:		

References:

Reference: AABB Standards for Blood Banks and Transfusion Services, current edition.
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