TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	3.31.2014
Department:	Blood Bank	**Due Date:**	4.30.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Serologic Centrifuge Maintenance and Function Checks

Description of change(s):

The form was updated. The procedure was updated to reflect changes in the form.

1. When Biomed comes to perform RPM/timer checks, they must obtain the form from us. Our form is pre-populated and contains the most up to date information. DO NOT let them use a form they brought with them.

2. Biomed is responsible for filling in the top portion of the form. This includes:
    a. Date
    b. Speeds obtained
    c. Times obtained
    d. Interpretation (S or U)
    e. Tech performing the QC (this is the BIOMED tech)

3. BEFORE BIOMED LEAVES, they will give the form to a BB staff member for review.
    a. Verify that work has been completed and ALL BLANKS OF THE FORM ARE COMPLETE.
    b. Verify RPM and timer checks for each piece of equipment are in range (ranges are printed on the form for each piece of equipment).
    c. Remove from service any equipment with unacceptable QC.
    d. Sign the form in section 2.
    e. Place the form in the supervisor's box for final review and approval. Note: Biomed usually takes the original and leaves a copy. This is OK.

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√ Shady Grove Adventist Hospital
□ Washington Adventist Hospital

Centrifuge/Cell Washer Functional Quality Control

Section 1: To Be Completed by BioMedical Engineering

Date	Equipment Description	Serial Number	Speed Setting	Speed Obtained	Acceptable Range (RPM)	Timer Setting	Timer Obtained	Acceptable Range	Timer Setting	Timer Obtained	Acceptable Range	Interp (S or U)	Tech
	Sorvall RC4	40319638	2000RPM		1800-2200	10 min		9'30"-10'30"	N/A	N/A	N/A		
	Serofuge 2002 S1	4640018	N/A		3100-3550	15 sec		13-17 sec	60 sec		58-62 sec		
	Serofuge 2002 S2	4650031	N/A		3100-3550	15 sec		13-17 sec	60 sec		58-62 sec		
	Serofuge 2002 S3	4650071	N/A		3100-3550	15 sec		13-17 sec	60 sec		58-62 sec		
	UltraCW S1	0002233	3500 RPM		3375-3625	15 sec		13-17 sec	60 sec		58-62 sec		
	UltraCW S2	0002234	3500 RPM		3375-3625	15 sec		13-17 sec	60 sec		58-62 sec		
	StatSpin Express 3	1023M50203872	3 Min Spin		6840-7560	3 min		2'51"-3'09"	N/A	N/A	N/A		
	Horizon MiniE	520809-175	N/A		3280-3480	7 min		5-10 min	N/A	N/A	N/A		
	Horizon MiniE	521212-267	N/A		3280-3480	7 min		5-10 min	N/A	N/A	N/A		
	Immuspin	0001780-03-00	450 RCF		2188-2674	2 min		1'54"-2'06"	N/A	N/A	N/A		
	Immuspin	0001780-03-00	530 RCF		2374-2902	5 min		4'45"-5'15"	N/A	N/A	N/A		
	Immuspin	0001780-03-00	850 RCF		3007-3675	N/A	N/A	N/A	N/A	N/A	N/A		
	Immucor Incubator P2	30205913	N/A	N/A	N/A	20 min		19-21 min	N/A	N/A	N/A		

Interpretation: S=Satisfactory U=Unsatisfactory, corrective action required, DO NOT USE equipment with unsatisfactory performance!

Stopwatch Identification_____

Stopwatch checked against telephone time through 30 seconds, OK _____ (Acceptable Range = 27-33 seconds)

Tachometer Identification_____ Tachometer field calibrated to 60Hz, OK_____

Section 2: To Be Completed By Blood Bank Staff

1 Verify that work has been performed and all blanks on the form are filled in.
2 Verify that all RPM and timer checks are within acceptable range.
3 Sign the form to indicate BB tech review has been performed.

Reviewed by:_____ Date: _____

Section 3: Supervisor Review and Approval

Reviewed by: _____

Date: _____

Electronic Document Control System

Quest Diagnostics

Document No.: WAH.BB46[2]
Title: SEROLOGIC CENTRIFUGE MAINTENANCE AND FUNCTION CHECKS
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 27-Apr-2014 **Next Review Date:**

Non-Technical SOP

Title	**Serologic Centrifuge Maintenance and Function Checks**	
Prepared by	Stephanie Codina	Date: 6/11/2010
Owner	Stephanie Codina	Date: 6/11/2010

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

1. PURPOSE

The optimum centrifugation time for hemagglutination procedures is dependent on RPM and timer accuracy. These values are checked periodically to assure each centrifuge is functioning within acceptable limits.

Serologic calibration evaluates the behavior of red blood cells in solutions of differing viscosities (not the reactivity of different antibodies). The procedure is used to determine the optimum time needed for proper serofugation for immediate spin and antihuman globulin reagent (AHG) phases of testing.

2. SCOPE

Serologic centrifuge maintenance will be performed quarterly, before being placed into service, and after repairs.

3. RESPONSIBILITY

All blood bank staff members must understand the quality control and maintenance requirements of serologic centrifuges.

4. DEFINITIONS

A. **Tachometer** - an instrument used to measure rotational speed in revolutions per minute (RPM).
B. **Relative centrifugal Force (RCF)** - the force exerted on a spun object, which is dependent on that object's speed of rotation and distance from the center of rotation.
C. **Revolutions Per Minute (RPM)** - the number of complete rotations that a centrifuge rotor completes in one minute at a defined operating setting.

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Site: Washington Adventist Hospital
Title: Serologic Centrifuge Maintenance and Function Checks

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5. PROCEDURE

5.1 Daily Maintenance

Step	Action
1	Visually inspect each centrifuge and clean as necessary. Document on the "Centrifuge Maintenance Log" form. A. Clean the centrifuge interior and exterior immediately upon detection of spillage or contamination using a cleaning solution or dispatch. B. Adhere to appropriate safety precautions when removing broken glass from the centrifuge chamber. Refer to the Laboratory Safety Manual. C. Appropriate safety precautions must be maintained when cleaning up any biohazardous materials. Refer to the Laboratory Safety Manual.
2	Spin times are <u>not</u> verified daily. Testing personnel is expected to program the appropriate time into the serofuge during each use per procedure.

5.2 Monthly Maintenance

Step	Action
1	Clean the centrifuge/serofuge chamber using a cleaning solution recommended by the manufacturer. Document on the "Centrifuge Maintenance Log" form. A. Clean tube shields, cups, or carriers. B. Soak serofuge heads in warm water with a gently cleaner and rinse well.

5.3 Quarterly Maintenance

Step	Action
1	Quarterly speed and timer checks are routinely performed by the Biomedical Engineering department.
2	The Biomedical Engineering staff member will obtain the most current copy of the "Centrifuge/Cell Washer Functional Quality Control" form from a blood bank staff member. A. The form is prepopulated with equipment descriptions, serial numbers, speed/timer settings, and acceptable ranges. B. Biomedical engineering will be responsible for completing the date, speeds obtained, timer readings obtained, and interpretation of results for each piece of equipment that is quality controlled. He/she will interpret the results for each piece of equipment and initial.

Step	Action
3	Once completed, the form will be presented to a blood bank staff member for review. The blood bank staff member is responsible for the following: A. Verifying that work has been performed and all fields on the form are completed. B. Verifying that all speed and timer checks are within acceptable range for each piece of equipment. C. Removing from service any equipment that does not yield acceptable speed or timer checks. D. Signing the form to indicate the review has been successfully performed.
4	The supervisor or designee will perform final review of the form and sign to indicate approval.

5.4 Annual Maintenance--Serological Calibration of Blood Bank Centrifuges

Annual maintenance is performed prior to placing a serologic centrifuge into use, after repairs, and annually.

Prepare 6% albumin

Step	Action
1	Label a clean urine cup or other container "6% albumin" and the date prepared.
2	Place approximately 37 mL of saline in the urine cup. Estimate the measurement using the measurements on the side of the urine cup.
3	Add 10 mL (1 full bottle) of 22% albumin.
4	Place the cap on the container and mix well.

Determining saline phase of serofugation

Step	Action
1	For this test, the following will be used: A. Test Serum = Plasma from a group A patient (anti-B) diluted with 6% albumin B. Positive Control = Group B reverse cells (2-5% cell suspension) C. Negative Control = Group A reverse cells (2-5% cell suspension)
2	Dilute the plasma of a group A patient with 6% albumin to demonstrate 1+ agglutination.
3	Label 5 test tubes "B+."
4	Label 5 test tube "B=."
5	Add test cells to the tubes. A. Add 1 drop of B cells to each tube labeled "B+." B. Add 1 drop of A cells to each tube labeled "B=."

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Site: Washington Adventist Hospital
Title: Serologic Centrifuge Maintenance and Function Checks

Step	Action
6	Test one set of tubes at 10 seconds. A. Immediately before serofugation, add 1 drop of the diluted plasma to 1 tube labeled "B+" and 1 tube labeled "B=." B. **Do not allow sera and cells to incubate.** C. Serofuge the tubes for 10 seconds. D. Observe for agglutination and the following criteria: a. Is the supernatant fluid clear? b. Is the cell button clearly delineated and the periphery sharply defined, not fuzzy? c. Is the cell button easily resuspended? d. Is agglutination present in the positive (B+) tubes? e. Is there no agglutination or ambiguity in the negative (B=) tubes? E. Document results on the "Serofuge / Cell Washer Serologic Calibration Record."
7	Repeat step 6, but serofuge for 15 seconds.
8	Repeat step 6, but serofuge for 20 seconds.
9	Repeat step 6, but serofuge for 30 seconds.
10	Repeat step 6, but serofuge for 45 seconds.
11	Select the optimal time for the saline phase of serofugation, which is the shortest time to fulfill the following criteria. Notify a supervisor if none of the times tested meet the criteria. A. The supernatant fluid is clear. B. The cell button is clearly delineated and the periphery is sharply defined, not fuzzy. C. The cell button is easily resuspended. D. Agglutination in the positive tubes is as strong as determined in preparing the dilution. E. There is no agglutination or ambiguity in the negative tubes.

Determining wash phase of serofugation

Step	Action
1	This procedure should only be used to determine the wash phase on centrifuges. Refer to procedure, "Helmer UltraCW Automatic Cell Washer Quality Control" for calibration of automated cell washers.

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Step	Action
2	For this test, the following will be used: A. Test Serum = Anti-D diluted with 6% albumin B. Positive Control = Screen cell II (Rh-positive red cells in a 2-5% cell suspension) C. Negative Control = Screen cell III (Rh-negative red cells in a 2-5% cell suspension)
3	Dilute anti-D with 6% albumin to demonstrate 1+ agglutination.
4	Label 5 test tubes "D+.
5	Label 5 test tubes "D=."
6	Add test cells to the tubes. A. Add 1 drop of screen cell II to each tube labeled "D+." B. Add 1 drop of screen cell III each tube labeled "D=."
7	Add 2 drops of diluted anti-D to each of the 10 tubes.
8	Incubate the tubes at 37°C for 15 minutes.
9	Fill 1 set of tubes with saline and serofuge for 30 seconds. Determine whether the red cells form a clearly delineated button, with minimal cells trailing up the side of the tube.
10	Decant the saline from the tube. Determine whether the cell button is easily resuspended in the residual fluid. **Do not discard tubes. They will be used to determine the AHG phase of centrifugation.**
11	Repeat steps 9 and 10 using the following serofugation times: A. 45 seconds B. 60 seconds C. 90 seconds D. 120 seconds
12	Select the optimal time for the wash phase of serofugation, which is the shortest time to fulfill the following criteria. Notify a supervisor if none of the times tested meet the following criteria. A. The red cells form a clearly delineated button, with minimal cells trailing up the side of the tube. B. The cell button is easily resuspended in the residual fluid.

Determining the AHG phase of serofugation

Step	Action
1	Wash the above tubes used to determine the wash phase of serofugation a minimum of 3 times in an automated cell washer.
2	Test 1 set of tubes at 10 seconds. A. Add 2 drops of anti-IgG to 1 "D+" tube. B. Add 2 drops of anti-IgG to 1 "D=" tube. C. **Do not allow cells to incubate with IgG.** D. Serofuge the tubes for 10 seconds. E. Observe for agglutination and the following criteria: a. Is the supernatant fluid clear? b. Is the cell button clearly delineated and the periphery sharply defined, not fuzzy? c. Is the cell button easily resuspended? d. Is agglutination in the positive (D+) tubes? e. Is there no agglutination or ambiguity in the negative (D=) tubes? f. Document results on the "Serofuge / Cell Washer Serologic Calibration Record."
3	Repeat step 2, but serofuge for 15 seconds.
4	Repeat step 2, but serofuge for 20 seconds.
5	Repeat step 2, but serofuge for 30 seconds.
6	Repeat step 3, but serofuge for 45 seconds.
7	Select the optimal time for the AHG phase of serofugation, which is the shortest time to fulfill the following criteria. Notify a supervisor if none of the times tested meet the following criteria. A. The supernatant fluid is clear. B. The cell button is clearly delineated and the periphery is sharply defined, not fuzzy. C. The cell button is easily resuspended. D. Agglutination in the positive tubes is as strong as determined in preparing the dilution. E. There is no agglutination or ambiguity in the negative tubes.

6. RELATED DOCUMENTS

SOP: Timer Accuracy Check
Form: Serologic Centrifuge Maintenance Log (AG.F147)
Form: Centrifuge/Cell Washer Functional Quality Control (AG.F55)
Form: Serofuge / Cell Washer Serologic Calibration Record (AG.F57)

7. REFERENCES

1. Roback, J.D., Combs, M.R., Grossman, B.J., Hillyer, C.D. 2008. Technical Manual of the AABB, 16th ed. AABB Publishing, Bethesda, Maryland.
2. 2009. Standards for Blood Banks and Transfusion Services, 26th ed. AABB Publishing, Bethesda, Maryland.
3. Instruction Manual IM-3131, Centra-B Plus Centrifuge, IEC, Needham Heights, MA. 1/95.
4. User's Guide, MTS Centrifuge, Ortho-Clinical Diagnostics, 6/04.
5. User's Guide, Hettich Zentifugen, EBA21, Andreas Hettich GmbH & Co. KG, Rev. 00/12.09.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP B511.00, B514.002		
000	11.18.11	Section 5: Deleted references to MTS centrifuges (discontinued). Removed requirement to check spin/speed times daily; this is required for each phase of testing. Removed timer check section and referred reader to timer accuracy procedure. Removed instructions for determining the dilution of antibody and preparing a solution of diluted antibody. Section 6: Updated documents	SCodina	NCacciabeve
001	3.28.14	Section 5: Updated the quarterly maintenance section to delineate who is responsible for maintenance tasks and how the form is completed. Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

N/A

Electronic Document Control System

Quest Diagnostics

Document No.: AG.F55[3]
Title: CENTRIFUGE / CELL WASHER FUNCTIONAL QUALITY CONTROL
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 27-Apr-2014 **Next Review Date:**

Quest Diagnostics

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☐ Washington Adventist Hospital

Centrifuge/Cell Washer Functional Quality Control

Section 1: To Be Completed by BioMedical Engineering

Date	Equipment Description	Serial Number	Speed Setting	Speed Obtained	Acceptable Range (RPM)	Timer Setting	Timer Obtained	Acceptable Range	Timer Setting	Timer Obtained	Acceptable Range	Interp (S or U)	Tech

Interpretation: S=Satisfactory U=Unsatisfactory, corrective action required, DO NOT USE equipment with unsatisfactory performance!

Stopwatch Identification_____

Stopwatch checked against telephone time through 30 seconds, OK_____ (Acceptable Range = 27-33 seconds)

Tachometer Identification_____ Tachometer field calibrated to 60Hz, OK_____

Section 2: To Be Completed By Blood Bank Staff

1 Verify that work has been performed and all blanks on the form are filled in.
2 Verify that all RPM and timer checks are within acceptable range.
3 Remove from service any equipment with unsatisfactory performance.
4 Sign the form to indicate BB tech review has been performed.

Reviewed by:_____ Date: _____

Section 3: Supervisor Review and Approval

Reviewed by:_____

Date:_____