Status Draft PolicyStat ID 1207	73521			
Beaumont	Origination Last	N/A N/A	Document Contact	Kelly Sartor
	Approved		Area	Laboratory-Blood
	Effective	N/A	Applicability	Bank
	Last Revised	N/A		Dearborn
	Next Review	N/A		

Helmer UltraCW™II Automatic Cell Washing System Operation - Dearborn Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and instructions for the Blood Bank staff to operate the Helmer UltraCW™II Automatic Cell Washing System.

II. INTRODUCTION:

A. The red blood cells (RBCs) used in compatibility testing, to which antihuman globulin (AHG) will be added, must be washed free of all proteins because AHG is inactivated readily by unbound protein. The Helmer UltraCW™ II Automatic Cell Washing System automatically fills test tubes with large volumes of saline, spins the tubes at a high speed, decants the saline, and agitates the tubes. When the operator selects the desired program, the cell washer automatically proceeds through the number of wash cycles in the program, unless interrupted by the operator or by an error.

III. SCOPE:

- A. This document includes directions for the operation of the Helmer UltraCW[™]II Automatic Cell Washing System only.
- B. The Helmer UltraCW™ II Automatic Cell Washing System will only be used with 12 x 75 mm test tubes.

IV. POLICIES:

A. The test tubes in the cell washer must always be balanced before operation.

- B. Preventative maintenance of this cell washer is performed as described in Transfusion Medicine policy, Quality Control and Preventative Maintenance of the Helmer UltraCW™II Automatic Cell Washing System.
- C. The Helmer UltraCW™II Automatic Cell Washing System will only be used with 12 x 75 mm test tubes.
- D. IgG-coated check cells must be used for every test that requires the addition of antihuman globulin in which the graded reaction of the test is negative at the indirect antiglobulin phase. Refer to the applicable standard operating procedures for additional information.

V. EQUIPMENT:

A. Helmer UltraCW™ II Automatic Cell Washing System

VI. SUPPLIES:

- A. 3 mL, 12 x 75 mm test tubes
- B. Blood Bank Saline

VII. QUALITY CONTROL (QC):

The saline fill volume and daily maintenance checks must be performed each day prior to use and documented on *Cell Washer Daily Maintenance Log*.

VIII. PROCEDURE

A. Before You Get Started

- 1. Determine whether the saline fill volume and daily maintenance checks have been documented for the current date on *Cell Washer Daily Maintenance Log*.
- If the saline fill volume and daily maintenance checks have not been documented for the current date, refer to Transfusion Medicine policy, <u>Quality Control and Preventative</u> <u>Maintenance of the Helmer UltraCW™II Automatic Cell Washing System: Saline Volume</u> <u>Checks</u> to complete all required QC and Maintenance.

B. Washing Test Tubes using Pre-set programs:

- 1. Touch the display screen to wake the display if not already illuminated.
- 2. Select the Open Lid button

to release the lid lock and open the cell washer.

- 3. Balance the 12 x 75 mm test tubes that are to be washed in the rotor.
- 4. Place the rotor in the cell washer and close the lid latch.
- Make sure the cell washer is set to Program 1. If it is not set to Program 1, select the Menu button is and touch the back or forward arrow buttons to navigate through the program menu to select the correct program.

- a. If desired use green and yellow directional arrows to scroll through and review the program process setting to verify their accuracy.
- 6. Select the green checkmark **v** to load the program. The Start screen appears with the loaded program name at the top of the screen.
- 7. Press START Program button to begin the run.
- 8. After the completion of the wash steps the cell washer will automatically pause and release the lid to allow for the addition of the AHG reagents. The display will indicate *Program paused*
 - a. Select the green checkmark to open the lid
 - b. Add two drops of Anti-Human Globulin Reagent and close the lid to continue the programming.
- 9. At the end of the run, the cell washer will display the *Program Successful* dialog box and give an audible alert.
- 10. Press the green checkmark 🖌 to return to the main screen.
- 11. Select the lid release button **11** to unlock the lid.
- 12. Remove the tubes and proceed with testing.
- 13. Wipe down the inside of the lid using a dry cloth to prevent condensation.
- 14. Close the lid.

C. Centrifuging using the Pre-Set Spin Program

- 1. Touch the display screen to wake the display if not already illuminated.
- 2. Select the Open Lid button to release the lid lock and open the cell washer.
- 3. Balance the 12 x 75 mm test tubes that are to be centrifuged in the rotor.
- 4. Place the rotor in the cell washer and close the lid latch.
- 5. Make sure the cell washer is set to 15-second spin program. If it is not set to 15-second spin, select the Menu button is and touch the back or forward arrow buttons to navigate through the program menu to select the correct program.
 - a. If desired use green and yellow directional arrows to scroll through and review the program process setting to verify their accuracy.
- 6. Select the green checkmark to load the program. The Start screen appears with the loaded program name at the top of the screen.
- 7. Press START Program button to begin the run.
- 8. At the end of the run, the cell washer will display *Program Successful* dialog box and give an audible alert.
- 9. Press the green checkmark 🖌 to return to the main screen.

10. Select the lid release button

to unlock the lid.

- 11. Remove the tubes and proceed with testing.
- 12. Close the lid.

D. Troubleshooting

- A. During a program, errors can occur that will prevent the completion of the programmed cycle. If this occurs, the cell washer will be put into error mode, and will not be operational again until the error has been addressed and cleared. Refer to the Helmer UltraCW™II Automatic Cell Washing System Service Manual for specific guidance on each error code.
 - 1. If a LIQUID CONTAINER EMPTY or BUBBLES DETECTED error message occurs, proceed as follows:
 - a. Attempt to determine and correct the reason that the saline supply was interrupted. For example:
 - i. If the tubing is obstructed or kinked, attempt to correct the obstruction.
 - ii. If the saline cube is empty or near empty, replace the saline cube. After the cube is replaced, verify that the tubing is not kinked.
 - iii. If the tubing is damaged or broken, replace the tubing as described in Transfusion Medicine procedure, Quality Control & Preventative Maintenance of the Helmer UltraCW™II Automatic Cell Washing System. Submit a variance and Place Equipment out of Service on the cell washer until the tubing is replaced.
 - iv. If the cause of the error cannot be determined and resolved, refer to the Helmer UltraCW™ II Automatic Cell Washing System Service Manual.
 - b. Perform a flush program to remove any air bubbles in the saline tubing and to verify the correct amount of saline is being dispensed.
 - 2. After the cause of the saline supply interruption has been resolved, the washing cycle that was in progress at the time of the error **cannot** be continued where it left off. Clearing the errors will reset the program that was running and If there are partially-filled test tubes on the cell washer and the START button is hit again, the test tubes will overflow and the RBCs will be lost.
- B. For any error code that causes the cell washer to be taken out of service, submit a variance and place *Equipment Out of Service* on the cell washer.

IX. EXPECTED RESULTS:

A. Saline Fill Volume Check

Determine whether the volume dispensed into the tubes is acceptable. The approximate volume per $12 \times 75 \text{ mm}$ test tube is 3.2 mL, which fills the tube up to the middle of the opening in the test tube holder. The volume dispensed into the tubes is acceptable if the volume is within $\pm 0.5 \text{ cm}$ of this point.



X. REFERENCES:

- Helmer UltraCW[™] II Automatic Cell Washing System Operation Manual, rev D. August 20, 2018.
- 2. Helmer UltraCW[™] II Automatic Cell Washing System Service Manual, rev B. August 20, 2018.
- 3. AABB, Standards for Blood Banks and Transfusion Services, current edition.
- 4. College of American Pathologists, Transfusion Medicine Checklist, current edition.

Approval Signatures

 Step Description
 Approver
 Date

 Applicability

Dearborn