TRAINING UPDATE

Lab Location:	All Sites	**Date Implemented:**	9/26/23
Department:	Blood Bank	**Due Date:**	10/15/23

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Control Failure Resolution

Description of change(s):

Lookback instructions were provided in more detail:

1. Select 5 patient specimens from BEFORE the last successful QC run. Be sure to pick samples with differing ABOs, Rhs, and AbS results.

2. Rerun the samples after QC is successful again.

3. Compare results.
    a. Interpretation must match EXACTLY
    b. Results of each reaction must match within one grade.
    For example:
    Anti-A = 3+ or 4+ is acceptable (1 grade)
    Anti-A of 2+ and 4+ is not acceptable (2 grades)

Non-Technical SOP

Title	**Quality Control Failure Resolution**	
Prepared by	Stephanie Codina	Date: 2/26/2011
Owner	Stephanie Codina	Date: 2/26/2011

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:	

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1. PURPOSE

Quality Control (QC) is a system of checks that assures the accuracy of all instruments, reagents, tech performance, and procedures in use.

2. SCOPE

This procedure provides the laboratory with constant appraisal of the precision and accuracy of each test performed to maintain high quality performance.

3. RESPONSIBILITY

All blood bank staff members must know the QC policies of the blood bank and be competent in performing blood bank QC. The lead technologist or supervisor will review the QC a minimum of monthly. Reagent QC will be reviewed weekly. A QC summary will be prepared by the supervisor and reviewed monthly by the Blood Bank Medical Director.

Employees are encouraged to communicate any concerns or complaints with respect to the quality of patient testing and safety. A PI variance form is utilized to document the concern/complaint, investigation, corrective action, and preventive action as appropriate.

4. DEFINITIONS

N/A

5. PROCEDURE

Quality Control Failure

Step	Action
1	QC is performed each day of use for every reagent.
2	Inappropriate QC results warrant immediate action. A. Patient testing for the test involved must be suspended until the problem has been corrected. B. The scope of the problem must be assessed to determine if previous test results were affected. C. Blood product preparation must be assessed for conformance whenever equipment fails or is out of calibration. D. All corrective action must be documented on a Quality Control or Equipment Failure Review Form. Staple the completed form to the appropriate QC form. a. Problem identified b. Date and time patient testing was suspended or equipment was removed from service c. Action taken and results of that action d. Patient and/or blood product impact e. Date and time patient testing was resumed or equipment was returned to service f. Supervisor's review
3	When a QC failure occurs repeat the test involved using the same reagent. Ascertain that the proper test methods are being used. This includes verifying any equipment involved for proper operation. A. Appropriate results on repeat testing indicate improper use of reagents, methodology, or clerical error on initial testing. B. Proceed to the next step if the results continue to be out of range.
4	Repeat the test involved using a different bottle of antisera. A. A correction of results indicates that the original bottle of reagent used must be discarded. B. Proceed to the next step if the results continue to be out of range.
5	Repeat the test involved using a different bottle of reagent red cells (use the original bottle of antisera first and then with the new bottle of antisera). A. A correction of results indicates a defective bottle of reagent red cells or that both the reagent red cells and antisera are defective. B. Proceed to the next step if the results continue to be out of range.

Step	Action
6	Repeat the test with a new lot number of reagent red cells and a new lot number of antisera if available. Notify a supervisor or results.

Equipment Failure

Step	Action
1	QC of equipment is performed on a regular basis as outlined in the Quality Plan.
2	When equipment QC fails, determine if a test or component preparation is involved. If not, troubleshoot the specific piece of equipment following manufacturer's instructions or by contacting Biomedical Engineering.
3	If testing is involved, repeat the QC using alternative equipment when available.
4	Remove the defective equipment from service. Refer to procedure, "Equipment Records and Repair" procedure or the procedure for the specific piece of equipment.
5	If blood products are involved, assess each blood product for conformance with FDA regulations and AABB standards with regard to temperature, sterility, purity, safety, etc. Seek guidance from the Blood Bank Supervisor and Medical Director as appropriate.
6	All corrective action must be documented on a Quality Control or Equipment Failure Review Form. Staple the completed form to the appropriate maintenance form. A. Problem identified B. Date and time patient testing was suspended or equipment was removed from service C. Action taken and results of that action D. Patient and/or blood product impact E. Date and time patient testing was resumed or equipment was returned to service F. Supervisor's review

QC Lookback

Step	Action
1	A QC lookback must be performed whenever there is a QC or equipment failure that could have affected patient results. In this case, select 5 specimens that were tested using the same methodology before the last successful QC/maintenance was run. Select specimens that have varying results such as different ABO and Rh results, antibody screen positive and negative, etc.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>2</td><td>Repeat testing on the instrument/method that had the QC or maintenance failure.</td></tr>
<tr><td>3</td><td>Print or document both sets of results. Document which are "PRE" and which are "POST" on the result forms.</td></tr>
<tr><td>4</td><td>Compare results for each reaction. Pre and post results must agree within 1 grade for semi-quantitative results while the interpretation of qualitative results must match exactly.

For example, the following results are not acceptable, because the B cell results are more than one grade different.

<table>
<tr><th></th><th>Anti-A</th><th>Anti-B</th><th>Anti-D</th><th>A1 Cell</th><th>B Cell</th><th>Interpretation</th></tr>
<tr><td>PRE</td><td>3+</td><td>0</td><td>4+</td><td>0</td><td>2+</td><td>A-pos</td></tr>
<tr><td>POST</td><td>4+</td><td>0</td><td>4+</td><td>0</td><td>4+</td><td>A-pos</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>Notify a supervisor immediately if the QC lookback is not acceptable.</td></tr>
<tr><td>6</td><td>Attach copies of the QC lookback to the Quality Control and Equipment Review form for supervisor review.</td></tr>
</table>

6. RELATED DOCUMENTS

SOP: Equipment Records and Repair Instructions
Form: Quality Control or Equipment Failure Review Form (AG.F406)

7. REFERENCES

1. Standards for Blood Banks and Transfusion Services, AABB, current ed. AABB Publishing, Bethesda, Maryland

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH-SGAH B501.001		
000	1.29.14	Section 3: Added statement that reagent QC will be reviewed weekly to align with corporate reagents and controls policy.	SCodina	NCacciabeve
		Footer: version # leading zeros dropped due to new EDCS in use as of 10/7/13.	LBarrett	
1	12.21.17	Header: Added WAH	LBarrett	NCacciabeve
2	4.11.2018	Section 5: Added requirement to complete new form. Section 6: Added new form	SCodina	NCacciabeve
3	8.25.21	Header: Changed WAH to WOMC, added FWMC Footer: Updated prefix to AHC	LBarrett	NCacciabeve
4	9.19.23	Added QC lookback section. Updated references.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

N/A