



BBQC 5.0-Reagent Quality Control

A. Principle

Reagents used in the Blood Bank must be tested prior to use to ensure they are reacting as expected.

B. General Policies

- a. Routine reagents must be tested daily.
- b. All routine reagent racks will contain the same lot number of reagents.
- c. One routine rack will be tested daily. Rack tested will be rotated daily.
- d. First shift will be responsible for routine reagent quality control.
- e. Each shift will be responsible for ensuring that additional quality control is performed, if needed.

C. Specimen Collection and Preparation

N/A

D. Equipment

- a. Calibrated blood bank centrifuge
- b. Agglutination lamp

E. Supplies

- a. Test tubes
- b. Dispipettes

F. Reagents

- a. Commercial Anti-A
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- b. Commercial Anti-B
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- c. Commercial Anti-A,B
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- d. Commercial Anti-D
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- e. Commercial Reverse Cells

- i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- f. Commercial Antibody Detection Cells
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- g. Anti-Human Globulin (green)
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- h. Anti-IgG
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- i. Anti-C3b,C3d
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- j. Dilute Anti-D
 - i. Preparation: Prepare a dilution to give a 1-2+ reaction when tested at AHG.
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until visual turbidity is noticed
- k. N-Hance
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- l. PEG
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- m. Coombs Control Cells
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer
- n. Bovine Albumin Solution 22%
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer



- o. Complement Control Cells
 - i. Preparation: Use as supplied
 - ii. Storage: 1-8C when not in use
 - iii. Expiration: Use until date listed by manufacturer

G. Quality Control

N/A

H. Safety

Refer to Chemical Hygiene and Blood Borne Pathogen Plan for Memorial Hospital Laboratory.

I. Procedure

- a. Obtain form *BBF 22.0-Daily Reagent Quality Control Form*
- b. Determine if any QC will need to be performed for as needed reagents:
 - i. A₂ cells
 - ii. N-Hance
 - iii. Polyspecific AHG
 - iv. Anti-C3,C3d
 - v. Albumin
- c. Label necessary test tubes with the following (Refer to form *BBF 22.0-Daily Reagent Quality Control Form*):
 - i. Test tube number
 - ii. Antisera being tested
 - iii. Cells being tested
- d. To tube #s 1-10:
 - i. Add 2 drops of the appropriate antisera
 - ii. Add 1 drop of the appropriate test cells.
 - iii. Centrifuge tubes according to the equipment in use.
 - iv. Immediately, read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.
- e. To tubes 11 & 12:
 - i. Add 2 drops of the appropriate antisera
 - ii. Add 1 drop of the appropriate test cells.
 - iii. Add 2 drops of PEG.
 - iv. Gently mix, then incubate for 15 minutes at 36-38C.
 - v. Wash a minimum of three (3) times with physiologic saline.
 - vi. Add two (2) drops Anti-IgG to each tube.
 - vii. Mix gently and centrifuge for the specific time designated on the equipment used.



- viii. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.
- ix. Add one (1) drop of Coombs Control Cells to all negative reactions.
- x. Mix gently and centrifuge for the specific time designated on the equipment used.
- xi. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.
- f. To tubes 13 & 14:
 - i. Add 2 drops of the appropriate antisera
 - ii. Add 1 drop of the appropriate test cells.
 - iii. Add 2 drops of N-Hance.
 - iv. Gently mix, then incubate for 10 minutes at 36-38C.
 - v. Mix gently and centrifuge for the specific time designated on the equipment used.
 - vi. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - vii. Wash a minimum of three (3) times with physiologic saline.
 - viii. Add two (2) drops Anti-IgG to each tube.
 - ix. Mix gently and centrifuge for the specific time designated on the equipment used.
 - x. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be macroscopic to be considered valid.
 - 2. Any test less than 1+ will be considered invalid and must be repeated.
 - xi. Add one (1) drop of Coombs Control Cells to all negative reactions.
 - xii. Mix gently and centrifuge for the specific time designated on the equipment used.
 - xiii. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.
- g. To tubes 15-17:
 - i. Add 2 drops of the appropriate antisera
 - ii. Add 1 drop of the appropriate test cells.

- iii. Centrifuge tubes according to the equipment in use.
- iv. Immediately, read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.
 - 3. *Note: If reaction with complement is weaker than 2+, test may be incubated up to 5 minutes at room temperature to enhance reaction after reading at immediate spin. Record extended reaction in same block as IS reaction with note of incubation time and temperature.*
- h. To tubes 18 & 19:
 - i. Add 2 drops of the appropriate antisera
 - ii. Add 1 drop of the appropriate test cells.
 - iii. Add 2 drops of Albumin.
 - iv. Gently mix, then incubate for 60 minutes at 36-38C.
 - v. Mix gently and centrifuge for the specific time designated on the equipment used.
 - vi. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - vii. Wash a minimum of three (3) times with physiologic saline.
 - viii. Add two (2) drops Anti-IgG to each tube.
 - ix. Mix gently and centrifuge for the specific time designated on the equipment used.
 - x. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be macroscopic to be considered valid.
 - 2. Any test less than 1+ will be considered invalid and must be repeated.
 - xi. Add one (1) drop of Coombs Control Cells to all negative reactions.
 - xii. Mix gently and centrifuge for the specific time designated on the equipment used.
 - xiii. Read, grade and record reactions according to SOP Reading and Interpretation of Agglutination Reactions.
 - 1. Reactions must be 2+ to be considered valid.
 - 2. Any test less than 2+ will be considered invalid and must be repeated.

J. Reporting Results

- a. Record routine reagent lot number and expiration date on the first day of the new worksheet.
- b. Check reagent daily to ensure that lot number and expiration are acceptable.



- c. All reactions using routine reagents must be within the acceptable range listed on the daily QC form.
 - i. If invalid, repeat testing.
 - ii. If problem remains, contact supervisor or designee for further instruction.
- d. Quality control records will be reviewed, at a minimum, weekly by the blood bank supervisor or designee.

K. Appedices

- a. Appendix A: Table of Reference Testing

L. References

- a. Standards for Blood Banks and Transfusion Services, AABB, Current Edition, Bethesda, MD.
- b. Technical Manual, AABB, 16th Edition, 2008, pp. 396-399, Bethesda, MD.
- c. Immucor manufacturer package inserts for antisera and commercial reagent testing cells.

Appendix A: Table of Reference Testing

Antisera/Cells		Expected Results			Reagent tested
Anti-A & A ₁ cells		2-4+			Anti-A & A ₁ cells
Anti-A & B cells		0			Anti-A
Anti-B & A ₁ cells		0			Anti-B
Anti-B & B cells		2-4+			Anti-B & B cells
Anti-A,B & A ₁ cells		2-4+			Anti-A,B
Anti-A,B & B cells		2-4+			Anti-A,B
Anti-A,B & Screen cell (Any)		0			Anti-A,B
Anti-A & A ₂ cells		2-4+			A ₂ cells
Anti-D & Screen cell 1 (I)		2-4+			Anti-D
Anti-D & Screen cell 3 (III)		0			Anti-D
Dil. Anti-D & Screen cell 3 (III)	Check cells	PEG-IgG			PEG & IgG
		0		2-4+	
Dil. Anti-D & Screen cell 1 (I)	Check cells	PEG-IgG			PEG
		2-4+			
Dil. Anti-D & Screen cell 3 (III)	Check cells	N-Hance			N-Hance & IgG
		10' 37C	IgG	2-4+	
		0	0		
Dil. Anti-D & Screen cell 1 (I)	Check cells	N-Hance			N-Hance
		10' 37C		IgG	
		0-2+		1-4+	
Poly AHG & Check cells		2-4+			Poly
Poly AHG & C3 cont cells		2-4+			Poly
Anti-C3 & C3 cont cells		2-4+			Anti-C3
Dil. Anti-D & Screen cell 3 (III)	Check cells	Albumin			Albumin
		60' 37C	IgG	2-4+	
		0	0		
Dil. Anti-D & Screen cell 1 (I)	Check cells	Albumin			Albumin
		60' 37C		IgG	
		0-2+		1-4+	



PROCEDURE AND FORM CHANGE CONTROL

Title: BBQC 5.0-Reagent Quality Control										
Written		Validated		Path Review		Review		Effective		Reason for Revision
Date	By	Date	By	Date	By	Date	By	Date	By	
2/22/10	PAB	3/6/10	GJM	3/10/10	ESB			4/1/10	PAB	
Revised										
3/6/12	PAB	3/7/12	MLH	4/3/12	ESB			4/5/12	PAB	Added MCare QC entry
9/4/12	PAB							9/4/12	PAB	Added verify QC directions
8/6/13	PAB			8/7/13	ESB			8/8/13	PAB	Changed diluted reagent exp date
						8/13/14	PAB			
2/6/15	JLH	2/9/15	KMS	2/9/15	ESB			2/10/15	JLH	Added document control. Removed unnecessary QC and added as needed QC to be performed.

Location of any copy(s) of the procedure:

Out of use:

Date: _____ By: _____ Reason: _____