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Procedure: Daily Reagent Quality Control

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I. PURPOSE

To provide daily proof of potency and specificity for all routine Blood Bank reagents being used for manual bench blood bank testing.

II. SCOPE

Quality control must be done on each current lot of reagents day of use. This SOP applies to all trained blood bank lab team members.

III. STATEMENTS/REQUIREMENTS

A. All current lot reagents will have quality control performed each day of use.

B. New lots of reagents opened after daily QC has been done must also have QC performed and documented on New Lot QC before being placed into use.

C. When opening a new vial of reagent, document the date opened and your initials on the bottle.

D. Reagents will not be routinely used past manufacturer's expiration date.

E. Any reagent not meeting QC standards will not be used and management will investigate the occurrence.

F. Place any questionable reagents in the quarantine refrigerator. Notify a supervisor for further investigation and finalize the process.

G. The Daily Reagent Quality Control testing is completed alongside the daily required maintenance tasks and cleaning.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

QC: Quality Control

SOP: Standard Operating Procedure

V. EQUIPMENT/RESOURCES

ORTHO ID-MTS:

ID-MTS 25/50 uL pipette/tips	ID-MTS IgG Gel Cards
ID-MTS Diluent 2	

Commercial Reagents:

A_1 RBCs	AHG
B RBCs	Potentiating media (LISS)
Antibody Screen Cells	Quality Control Test System, Antibody and Red Cells
IgG sens. Cells (IgG Coombs Control Cells)	Monoclonal Control
Anti-A, Anti-B, Anti-D	Complement Coated Cell (C3d)
Anti-C3b-C3d	
Saline	

Equipment:

Centrifuge	ORTHO ID-MTS
Heat block or water bath	ID-MTS Centrifuge
Cell washer	ID-MTS Incubator
Water Bath	*IMPACT*® or Biohit pipettor

VI. PROCEDURE

A. Reagent Quality Control testing:

1. Obtain and initiate the appropriate quality control record:
   a. Daily QC: Document the date on the site-specific form

Form Number	Location	Form Name
BBQC-F003	Riley Hospital	BBQC- F003 Daily Reagent QC: RHBB
BBQC-F004	University and Methodist Hospitals	BBQC-F004 Daily Reagent QC: University and Methodist

   b. New Lot QC: On Form New Lot QC, circle the site, and complete form as indicated.
2. For each reagent on the Daily Reagent QC Form:
   a. Document Date of Testing and Circle site location as it applies to form.
   b. Perform visual inspection of each reagent. Vials should not be turbid, discolored, hemolyzed, or expired.
      i. If any of these conditions are found, discard and replace with new vial.
   c. Check each vial to ensure that the open date and the initials of team member who opened the vial has been recorded.
      i. If the open date or initials has not been recorded, then document the current date with tech initials.

ii. Notify blood bank management when discovered for further investigation and corrective action.

d. On the Daily Reagent QC form:

i. Document the lot number

ii. Document expiration date

iii. Initial that the appearance check was acceptable,

iv. Ensure open dates were on vials and all lot numbers were visually verified on all reagent racks in use.

3. Quality Control of MTS cards and Ortho Screen Cells I, II and III (manual gel methods)

a. Label Four (4) columns on Gel card: I , II, & III and Neg

b. To column I add 50 µL of 0.8% screen cell I.

c. To column II add 50 µL of 0.8% screen cell II.

d. To column III add 50 µL of 0.8% screen cell III.

e. To column Neg add 50 ul of 0.8% screen cell I, II or III.

f. Add 25 µL antibody reagent from Quality Control Test System to cell I, II and IIIcolumns.

g. Add 25 µL Negative Control plasma to Neg column using cell (Refer to section B for Neg Control preparation).

h. Incubate Gel card at 37°C for 15 minutes.

i. Spin Gel card in MTS centrifuge for 10 minutes.

j. Examine card for reactions, grade and record results on appropriate Daily QC log form.

k. Compare the observed results to the expected results on the Daily QC form.

i. If the observed results match the expected results, then circle **Y** in the **OK?** column.

ii. If the observed results do not match the expected results, circle **N** in the **OK?** column and notify management.

4. Quality Control of Panoscreen, LISS, AHG, and check cells (tube methods):

a. Label Four (4) 10mm x 75mm or 12mm x75mm tubes I, II, and III and Neg:

b. Place One (1) drop of reagent screen cell I into tube labeled I.

c. Place One (1) drop of reagent screen cell II into tube labeled II.

d. Place One (1) drop of reagent screen cell III into tube labeled III.

e. Place One (1) drop of reagent screen cell I, II, or III into tube labeled Neg.

f. Place One (1) drop of Antibody Reagent from the Quality Control Test System into tubes I, II and III and mix.

g. Place two (2) drops of Negative Control plasma into tube labeled Neg.

h. Centrifuge, resuspend, grade, and record results.

i. Add Two (2) drops of LISS and incubate at 37°C for 10-30 minutes.

j. Centrifuge, resuspend, grade, and record results.

k. Wash contents of each tube 3-4 times with full tubes of saline (an automatic cell washer may be used).

l. Add Two (2) drops of AHG to each tube.

m. Centrifuge, resuspend, grade reactions, and record results.

   i. If positive, grade 1-4+.

   ii. If negative, add one drop of IgG Sensitized Cells (IgG Coombs Control Cells). Centrifuge, resuspend, grade reactions and record results.

      1. If negative with IgG Sensitized cells, then document. Test is invalid and should be repeated.

      2. If positive with IgG Sensitized cells, then document with checkmark/grade. This is a valid result

n. Compare the observed results to the expected results on the Daily QC form.

   i. If the observed results match the expected results, then circle **Y** in the **OK?** column.

   ii. If the observed results do not match the expected results, circle **N** in the **OK?** column and notify management.

5. Quality control of anti-A, anti-B and anti-D reagents (tube method)

   a. Label Four (4) 10mm x 75mm or 12mm x 75mm tubes: A, B, D+ and D neg.

   b. Tube A: Place One (1) drop of Anti-A and One (1) drop of A1 reverse cells.

   c. Tube B: Place One (1) drop of Anti-B and One (1) drop of B reverse cells.

   d. Tube D+: Place One (1) drop of Anti-D and One (1) drop of Quality Control Testy System red cell.

   e. Tube D Neg: Place One (1) drop of Anti-D and One (1) drop of one of reverse cells (A_1 or B).

   f. Centrifuge, resuspend, grade reactions, and record on appropriate Daily Reagent Quality Control form.

      i. If positive, grade 1-4+.

      ii. If negative, add one drop of Complement Control Cells. Centrifuge, resuspend, grade reactions and record results.

         1. If negative with Complement Control cells, then document. Test is invalid and should be repeated.

         2. If positive with Complement Control Cells, then document with checkmark/grade. This is a valid result.

   g. Compare the observed results to the expected results on the Daily QC form.

      i. If the observed results match the expected results, then circle **Y** in the **OK?** column.

      ii. If the observed results do not match the expected results, circle **N** in the **OK?** column and notify management.

6. Quality Control of Anti-C3b, -C3d (AHG):

   1. Positive control: Place 2 drops of Anti-C3b, -C3d and 1 drop of Complement coated cells (C3d) into a labeled 10x75 tube.

   2. Negative control: Place 2 drops of Anti-C3b, -C3d and 1 drop of antibody screening cell into a second labeled 10x75 tube.

3. Centrifuge, resuspend, grade and record results.
4. Compare the observed results to the expected results on the Daily QC form.
    1. If the observed results match the expected results, then circle **Y** in the **OK?** column.
    2. If the observed results do not match the expected results, circle **N** in the **OK?** column and notify management.

B. Preparation of Negative Control plasma aliquots:

1. Select an AB thawed plasma or thaw a plasma for the control.
    a. The plasma control may be AB Pos or AB Neg plasma product.
    b. The product may be in-date or expired.
2. Complete ABO serum typing per Procedure: ABO & Rh Determination, Manual Tube and Procedure: Antibody Screen documenting on a BB Miscellaneous Testing Form to verify the ABO type and IAT results.
    a. If the unit is antibody screen negative by both methods and the AB, then the unit is qualified for use.
    b. If the unit is antibody screen positive or not confirmed as AB, then the unit may not be used. Use another plasma.
3. Label sufficient plastic Screw-top tubes with: **NEG CTRL**/date (mm-dd-yyyy) = Lot number = date of preparation and tech initials.
4. Aliquot the plasma into the labeled tubes.
5. Store these labeled tubes in a freezer (minus 18 C or colder).
6. Store tube in the Daily QC rack, to be used as manual MTS and Bench NEGATIVE Control Plasma.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.

AABB Standards, current edition.

Current Manufacturers Package Inserts

IX. FORMS/ APPENDICES

BBQC- F003 Daily Reagent QC: RHBB

BBQC-F004 Daily Reagent QC: University and Methodist

Donor Red Cell - RETYPE Reagent QC

New Lot QC

X. APPROVAL BODY

None

PROCEDURE #:

BBQC – 002

Daily Reagent QC: RHBB

Test Date: _____

QC Reagent Rack	Lot #/Expiration
QC Antisera	
QC Cells	
Monoclonal Ctrl	
Antibody Detection Cells	
MTS Antibody Detection Cells	**Are all sets of MTS Screen Cells the Same Lot #** Yes ( ), No ( ) if No, QC both lot numbers in use
MTS Diluent 2	
MTS IgG Card	
Anti-C3b,d	
Complement Control Cells	
Negative Control	Date Prep: | Date Exp:
Appearance ✓& Open Date/init. on all reagents	Tech:

Current Lot Number	All Reagent Racks Lot #/Expiration
Anti-A	
Anti-B	
Anti-D	
A1 Cells	
B Cells	
LISS	
IgG-AHG	
Coombs Check Cells	
Saline (Bottle) *All bottles should be same lot number*	
All lot numbers were visually verified	Tech:
Appearance ✓and Open Date/initials on all reagents	Tech:

Peer Review _____ **Sup Review:** _____ **Date:** _____

Daily Reagent QC: RHBB

EXPECTED RESULTS	Anti-A	Anti-B	Anti-D
A_1	3-4+		0
B		3-4+	
QC Cells			3-4+

EX-PECTED	IS	37 LISS	AHG		Gel IgG
I	0	0-3+	1-3+		3-4+
II	0	0-3+	1-3+		3-4+
III	0	0-3+	1-3+		3-4+
Neg	0	0	0✓		0

EXPECTED RESULTS	
Anti-C3b,d Pos (C3 control cell)	1-3+
Anti-C3b,d Neg (Antibody Detection	0✓

If not a scheduled maintenance day, then leave Maintenance blank. If scheduled maintenance day, complete Maintenance below.

Weekly Maintenance	Tech
Weekly UltraCW and Ultra CW II System Flush and Clean, including port cleaning. (BBQC JA015)	
Auto & DD RBC Visual Inspection	
ID-MTS Dil2 Cleaning	
Eyewash Flush	**Document on the Applicable Form**

		Anti-A	Anti-B	Anti-D	OK?	Tech
Current Lot	A_1				Y	
	B				N	
	QC Cells					

Manual Tube					Ortho Gel		Anti-C3b,d Pos	Anti-C3b,d Neg	OK?	Tech
Cell #	IS	37 LISS	AHG	OK?	IgG	OK?				
I + QC Antisera				Y N		Y N			Y	
II + QC Antisera				Y N		Y N			N	
III + QC Antisera				Y N		Y N				
Neg + I, II or III				Y N		Y N				

DAILY Maintenance:	Result	OK?	Tech
Bench Incubator # 39 (36-38°C)		Y N	
Bench Incubator # 40 (36-38°C)		Y N	
Bench Incubator # 41 (36-38°C)		Y N	
MTS Workstation Tach (1022-1042)		Y N	
MTS Workstation Timers (10/15/15)		Y N	
MTS Workstation Temp: Green light?		Y N	
Ultra CW and Ultra CW II Daily DI Water Flush and Tubing Inspection			
Ultra CW and Ultra Cell Washer II Wipe and Empty Waste			

DAILY: Scale QC	Result Scale #1/ HT3000	Result Scale #2/ 11111-02	Both Scales OK?	Tech
20g			Y	
50g			N	
100g				

DAILY:	Tech
Daily Bench / Equipment Decontamination Performed	

Daily Waterbath Temp.	Result	Okay	Tech
Waterbath 6 (30-37°C)		Y N	
Waterbath 7 (30-37°C)		Y N	

Peer and Sup Review:

See page 1 of 2

Daily Reagent QC: University and Methodist

QC Reagent Rack	Lot #/Expiration	
QC Antisera		
QC Cells		
Monoclonal Control		
Antibody Detection Cells		
MTS Screen Cells	**Are all sets of MTS Screen Cells the Same Lot#** Yes ( ) No ( ) If No, QC all lot#	
MTS IgG Card		
MTS Diluent 2		
Negative Control	Date Prep:	Date Exp:
Appearance ✓& Open date/init on all reagents	Tech:	

Test Date: _____

Circle One: **University** or **Methodist**

Reagent	Reagent Rack Current Lot #/Expiration
Anti-A	
Anti-B	
Anti-D	
A1 cells	
B cells	
LISS	
IgG-AHG	
Coombs Check Cells	
Anti-C3b,d	
Complement Control Cells	
Saline (Bottle)	
All lot numbers were visually verified	Tech:
Appearance ✓and Open Date/initials on all reagents	Tech:

	Immucor Tube				Ortho Gel		Tech
Cell #	IS	37°C LISS	AHG	OK?	IgG	OK?	
I + QC antisera				Y N		Y N	
II + QC antisera							
III + QC antisera							
Neg + I, II or III							

EXPECTED RESULTS	IS	37°C LISS	AHG	Gel IgG
I/II/III	0	0-3+	1-3+	3-4+
Neg	0	0	0✓	0

Rack Reagent		Anti-A	Anti-B	Anti-D	OK?	Tech
	A_1				Y N	
	B					
	QC cells					

Required Maintenance Tasks	Result	OK?	Tech
Bench Incubator # _____ (36-38°C)		Y N	
MTS Workstation Tach (1022-1042)		Y N	
MTS Workstation Timers (10/15/15)		Y N	
MTS Workstation Temp: Green light?		Y N	
Daily Bench/Equipment Decontamination Performed			
Waterbath #_____ (30-37°C)		Y N	
Daily Ultra CW II DI Water Flush and Tube Inspection	Daily		
ID-MTS Diluent Dispenser Cleaning	Weekly	Y NA	
Weekly Ultra CW II Flush and Clean	Weekly	Y NA	

Anti-C3bd Pos C3 Control Cell	Anti-C3bd Neg Screen Cell	Ok?	Tech
		Y N	

EXPECTED RESULTS	Anti-A	Anti-B	Anti-D	Anti-C3b,d Pos	Anti-C3b,d Neg
A_1	3-4+		0	C3b,d + C3 Check cells	C3b,d + Screen cell I, II, III
B		3-4+			
QC Cells			3-4+	1-3+	0✓

Peer Review: _____ **Sup Review/Date:** _____

Maintenance Reminder: Document on the applicable Form Weekly Eye-wash Flush and Weekly Clean Waterbath