Beaumont Laboratory
Clinical Pathology
Royal Oak

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Related Documents: P104, P120, ~~P122~~, P328, P332, P516, P606, P716

ROUTINE QUALITY CONTROL OF BLOOD BANK REAGENTS

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Purpose

The purpose of this document is to provide policies and procedures relating to the routine quality control (QC) of reagents used in the Blood Bank.

Scope

The QC of the reagents used in the Blood Bank is organized by racks. The scope of this document includes the QC of reagents that are generally used in tube testing methods, and that are organized in the following racks:

Rack	Contains reagents to perform the following procedures:
RQ1 and RQ2	ABO/Rh testing by the tube method
RQ60M	60-minute no-LISS indirect antiglobulin tests
RQLIS	LISS indirect antiglobulin tests
RQDAT	Direct antiglobulin tests

Refer to the documents listed below for information related to QC of reagents for the ORTHO VISION™, the manual gel system, antigen typing, and fetal cell screening.

- P716, *ORTHO VISION™ Analyzer QC*
- P328, *Quality Control of the Manual Gel System Reagents*
- P606, *Antigen Typing Policies*
- P516, *Fetal Cell Screening Using the FMH Rapid Screen Kit*

Principle

QC testing is performed to ensure the proper functioning of materials, equipment, and methods during operation. QC specimens should be tested in the same manner as patient and donor samples, and by the same personnel who routinely perform testing of patient and donor samples. All technologists are not required to perform QC daily, but all should participate in the performance of QC on a regular basis. The expectations of QC testing must be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately.

Policies

The QC for a given test must be performed in advance of testing patient or donor samples. The QC of all reagents in a rack must pass before the reagents in the rack may be used to test patient or donor samples.

Check Cells

When testing the controls by the 60-minute no-LISS and LISS / AHG methods, check cells must be used if the reaction of the control at the AHG phase is negative. The check cells are expected to react positive at any strength ~~2+ or greater~~. If the check cells do not react as expected, the testing must be repeated.

Appearance of Reagents

The appearance of all reagents must be inspected before they are used to test patient or donor samples, and the appearance must be satisfactory. The appearance is documented in the Blood Bank computer as satisfactory (S) or unsatisfactory (U), as described in the Computer Documentation Manual (CDM).

Reagent	Appearance Unsatisfactory
Test cells	Marked hemolysis Leaking vials Beyond expiration date
Anti-sera, AHG reagents, LISS, Rh controls	Marked turbidity Leaking vials Beyond expiration date

Reagent Expiration Date

All reagents should be used within their indicated expiration date. Routine testing should be done with in-date reagents.

Rare antisera may be used beyond their expiration date with MD approval if appropriate positive and negative controls are run each day of use and react as expected.

Documentation of the MD approval as well as results should be documented as an internal unit comment or patient comment, depending on how the antisera is used.

Failing QC

As described in the *Interpretation* section, the routine QC of reagents is interpreted as passing or failing. If the QC fails for any reason, the following apply:

- A variance will be submitted.
- Test results of patient or donor samples may not be released unless / until QC passes.
- The QC will be repeated with the same lot number.
- If the QC fails upon repeat with the same lot number, then the QC will be tested with a different lot number, if possible.
- If the QC initially fails, and fails upon repeat testing with the same lot number, then all vials of that lot number will be placed in quarantine. Perform QC with a different lot number.
- Once placed in quarantine, reagents cannot be used to test patient or donor samples unless the Medical Director or manager indicates that the reagents may be used.

QC Documentation

A rack is selected in the Blood Bank computer and the QC results and interpretations are documented as described in the Computer Documentation Manual (CDM). During computer downtimes, QC is documented on downtime forms; see P120, *Manual Operations.*

QC Frequency

QC of each of the following racks is performed each day: RQ1, RQ2, RQ60M, and RQDAT. QC for the RQLIS rack is performed each day of use.

Definitions

- **Each day:** The QC is tested each day, regardless of whether the reagent is used to test patient or donor samples on that day. QC is defined each day for reagents that are expected to be used each day or most days.

- **Each day of use:** The QC is tested each day that the reagent is used to test patient or donor samples. QC is defined each day of use for reagents that are not expected to be used each day.

Reagents

Rack	Reagents included in Rack
RQ1 RQ2	• Ortho BioClone Anti-A and Anti-B • Ortho BioClone Anti-D and the ~~6 – 8%~~ 7% BSA ~~bovine albumin control (prepared as described in P122, *Preparing the 6-8% Bovine Serum Albumin Control*)~~ • Gamma Clone Anti-D and the Gamma Clone control • Ortho 3% Affirmagen reverse typing cells.
RQ60M	• Ortho Surgiscreen, 3-cell screen kit • AlbaQ 1(Positive Control) • AlbaQ 2 (Positive Control) • AlbaQ 4 (Negative Control) • Ortho Anti-Human Globulin Anti-IgG (Rabbit) • Ortho® Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells)
RQLIS	• Ortho 3% Surgiscreen, 3-cell screen kit • AlbaQ 1 (Positive Control) • AlbaQ 2 (Positive Control) • AlbaQ 4 (Negative Control) • Ortho Anti-Human Globulin Anti-IgG (Rabbit) • Ortho Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells) • Ortho Antibody Enhancement Solution (LISS)
RQDAT	• Ortho Anti-Human Globulin (Rabbit and murine Monoclonal) BioClone, Anti-IgG, -C3d polyspecific • Ortho Anti-Human Globulin Anti-IgG (Rabbit) • Immucor/Gamma Anti-Human Globulin, Anti-C3b, -C3d (Murine Monoclonal) Gamma-clone • Ortho Coombs Control IgG Coated Reagent Red Blood Cells (Pooled cells) • Immucor/Gamma Complement Control Cells

Equipment and Supplies

- Normal saline
- 10 X 75 mm or 12 x 75 mm test tubes
- Disposable pipettes

- Table top centrifuge
- Automated Cell Washer

Forms

- Refer to P120, *Manual Operations*, for a list of downtime forms used for QC.

Procedure

Directions for Performing the QC of the RQ1 and RQ2 Racks

1. Evaluate the appearance of each reagent in the rack; see the policy *Appearance of Reagents.*
2. Label 10 test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.
4. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
5. Read, grade, and record the reactions of each tube in the computer as described in the CDM (or on a downtime form, if applicable).
6. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
7. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the *Interpretation* section near the end of this document.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	1 drop Anti-A	1 drop A1 cells	3+ or greater
2	1 drop Anti-A	1 drop B cells	negative
3	1 drop Anti-B	1 drop B cells	3+ or greater
4	1 drop Anti-B	1 drop A1 cells	negative
5	1 drop Gamma Clone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
6	1 drop Gamma Clone Anti-D	1 drop Surgiscreen Cell # 3	negative
7	1 drop Gamma Clone control	1 drop Surgiscreen Cell # 2	negative
8	1 drop Ortho BioClone Anti-D	1 drop Surgiscreen Cell # 1	2+ or greater
9	1 drop Ortho BioClone Anti-D	1 drop Surgiscreen Cell # 3	negative
10	1 drop ~~6 – 8%~~ 7% BSA ~~bovine albumin control~~	1 drop Surgiscreen Cell # 2	negative

Directions for Performing the QC of the RQ60M Rack

1. Evaluate the appearance of each reagent in the rack; see the policy *Appearance of Reagents.*
2. Label 7 test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction at the 37°C Phase	Expected Reaction at the AHG Phase
1	1 drop Surgiscreen Cell # 1	3 drops of AlbaQ 1	0 to 2+	Weak+, 1+, or 2+
2	1 drop Surgiscreen Cell # 2	3 drops of AlbaQ 1	0 to 2+	Weak+, 1+, or 2+
3	1 drop Surgiscreen Cell # 3	3 drops of AlbaQ 2	0 to 2+	Weak+, 1+, or 2+
4	1 drop Surgiscreen Cell # 1	3 drops of AlbaQ 4	negative	negative
5	1 drop Surgiscreen Cell # 2	3 drops of AlbaQ 4	negative	negative
6	1 drop Surgiscreen Cell # 3	3 drops of AlbaQ 4	negative	negative
7	2 drops Anti-IgG AHG	1 drop IgG coated check cells	NA	Positive (any strength) ~~2+ or greater~~

4. Proceed as follows

Tubes # 1 - 6	DO NOT ADD LISS. Incubate the tubes at 37°C for 60 minutes, complete the 60-minute no-LISS antibody screen, and control with IgG coated check cells as described in P104, *Antibody Screening*. Note: Read and record results for 37°C, AG, and check cells.
Tube #7	Gently mix the contents of the tube, and centrifuge according to the time calibrated for the centrifuge.

5. Read and grade the reactions of each tube.
6. Record the graded reactions of each tube, at each phase, in the computer as described in the CDM (or on a downtime form, if applicable).
7. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
8. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the *Interpretation* section near the end of this document.

Directions for Performing the QC of the RQLIS Rack

1. Evaluate the appearance of each reagent in the rack; see the policy *Appearance of Reagents.*
2. Label 7 test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.

Tube #	# Drops of Reagent	# Drops of Reagent	# Drops of Reagent	Expected Reaction at the 37°C Phase	Expected Reaction at the AHG Phase
1	1 drop Surgiscreen Cell # 1	2 drops of AlbaQ 1	2 drops LISS	0 to 2+	Weak+, 1+, or 2+
2	1 drop Surgiscreen Cell # 2	2 drops of AlbaQ 1	2 drops LISS	0 to 2+	Weak+, 1+, or 2+
3	1 drop Surgiscreen Cell # 3	2 drops of AlbaQ 2	2 drops LISS	0 to 2+	Weak+, 1+, or 2+
4	1 drop Surgiscreen Cell # 1	2 drops of AlbaQ 4	2 drops LISS	negative	negative
5	1 drop Surgiscreen Cell # 2	2 drops of AlbaQ 4	2 drops LISS	negative	negative
6	1 drop Surgiscreen Cell # 3	2 drops of AlbaQ 4	2 drops LISS	negative	negative
7	2 drops Anti-IgG AHG	1 drop IgG coated check cells	NA	NA	Positive (any strength) ~~2+ or greater~~

4. Proceed as follows:

Tubes # 1 – 6	After adding 2 drops of LISS, incubate the tubes at 37°C for 15 minutes, complete the LISS antibody screen, and control with IgG coated check cells as described in described in P104, *Antibody Screening*. Note: Read and record results for 37°C, AG, and check cells.
Tube #7	Gently mix the contents of the tube, and centrifuge according to the time calibrated for the centrifuge.

5. Read and grade the reactions of each tube.
6. Record the graded reactions of each tube, at each phase, in the computer as described in the CDM (or on a downtime form, if applicable).
7. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.

8. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the *Interpretation* section near the end of this document.

Directions for Performing the QC of the RQDAT Rack

1. Evaluate the appearance of each reagent in the rack; see the policy *Appearance of Reagents.*
2. Label 7 test tubes consecutively.
3. Add the number of drops of the reagents specified in the table below to the correspondingly labeled tubes.
4. Gently mix the contents of each tube and centrifuge according to the time calibrated for the centrifuge.
5. Read, grade, and record the reactions of each tube, at each phase, in the computer as described in the CDM (or on a downtime form, if applicable).
6. Evaluate the performance of the reagents by comparing the observed reaction with the expected reaction.
7. Document the appearance / performance of the reagents as S or U (satisfactory or unsatisfactory) and interpret the QC; refer to the *Interpretation* section near the end of this document.

Tube #	# Drops of Reagent	# Drops of Reagent	Expected Reaction
1	2 drops polyspecific AHG	1 drop IgG coated check cells	Positive (any strength) ~~2+ or greater~~
2	2 drops polyspecific AHG	1 drop complement coated check cells	Positive (any strength)
3	2 drops polyspecific AHG	1 drop Surgiscreen Cell # 1	negative
4	2 drops Anti-IgG AHG	1 drop IgG coated check cells	Positive (any strength) ~~2+ or greater~~
5	2 drops Anti-IgG AHG	1 drop complement coated check cells	negative
6	2 drops complement AHG	1 drop complement coated check cells	Positive (any strength)
7	2 drops complement AHG	1 drop IgG coated check cells	negative

Interpretation

- Appearance of reagents: Refer to the policy *Appearance of Reagents* in evaluating whether the appearance is satisfactory or unsatisfactory.
- Performance of Reagents: The performance of the reagent is evaluated by comparing the observed reactions with the expected reactions. The expected reactions are listed in the *Procedure* for each rack.
  - The performance is considered satisfactory if the observed reactions match the expected reactions.
  - The performance is considered unsatisfactory if the observed reactions do not match the expected reactions.

Appearance of Reagents	Performance of	QC Interpretation

	Reagents	
Satisfactory	Satisfactory	Pass
Satisfactory	Unsatisfactory	Fail
Unsatisfactory	Satisfactory	Fail
Unsatisfactory	Unsatisfactory	Fail

Notes

- The RQ3 rack is used to perform QC of reagents in the rack as they are received from the manufacturer. For additional information, refer to P332, *Receipt of Critical Reagents, Materials and Review of Manufacturers' Printed Materials.*

References

- AABB, *Technical Manual*, current edition.
- AABB, *Standards for Blood Banks and Transfusion Services,* current edition.
- Ortho Anti-Human Globulin Bio-Clone, *Qualitative Procedure for the Detection of Cell-Bound Blood Group Antibody and/or Components of Complement*, revised January 2013.

Authorized Reviewers

Chief, Pathology and Laboratory Medicine
Medical Director and/or Designee, Blood Bank
Manager/Supervisor, Blood Bank

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Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/ Master printed document stored in the *Transfusion Medicine Standard Operating Procedure Manual*.

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Document History

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QA: Louisa Serafimovska	10/19/2011			
Supervisor: Judy Easter	10/19/2011			
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Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
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QA: Louisa Serafimovska	08/15/2012			
Supervisor: Judy Easter	08/15/2012			
Approved by: Peter Millward, MD	08/15/2012			
Revisions to r02.01.00 New SOP format. For the policy *QC Frequency*, deleted table and replaced with "QC of each of the following racks is performed each day: RQ1, RQ2, RQ3, RQ60M, RQLIS, and RQDAT." Added the policy *Check Cells*. For the RQ60M and RQLIS racks: added expected reactions for 37C, and added note "Read and record results for 37°C, AG, and check cells."				
Revised by: Jennifer Sarhan	03/30/2013	r02.01.01		
Additional Review by: Karrie Torgerson	04/08/2013			
Supervisor: Judy Easter	04/08/2013			
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Approved by: Peter Millward, MD	04/08/2013			
Revisions to r02.01.01 The RQ1 and RQ2 racks are documented daily; the RQ3 rack is no longer documented daily. Added the *Note* indicating that the RQ3 rack will be used to perform QC as reagents are received from the manufacturer. Added reference to P332, *Receipt of Critical Reagents and Supplies and Review of Manufacturers' Printed Material*s.				
Reviewed by: Peter Millward, MD	08/02/2013			
Revised by: Jennifer Sarhan	12/27/2013	r02.02.00	The polyspecific AHG reagent is now also tested against complement coated check cells. Revised the *Directions for Performing the QC of the RQDAT Rack* accordingly. Updated the *References.*	
Supervisor: Judy Easter	01/03/2014			
Approved by: Peter Millward, MD	01/03/2014			

Document Control, continued

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Reviewed by: Peter Millward, MD	03/09/2015			
Revised by: Ashley Wilson	08/16/2016	r02.03.00	Added 3 tubes of negative controls for RQ60M and RQLIS racks. Added 1 additional positive control for RQ60M and RQLIS racks. The RQLIS rack is no longer documented daily.	
QA: Anne Sepienza	08/17/2016			
Supervisor: Judy Easter	09/27/2016			
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Revised by: Karrie Torgerson Approved by: QA: Anne Sepienza Supervisor: Billie Ketelsen Peter Millward, MD	06/01/2017 06/27/2017 06/12/2017 06/15/2017	r02.04.00	Removed reference to Tube Antibody Screen Control - contains Anti-D, prepared as described in P318, Preparation of the Antibody Screen Control and replaced with AlbaQ 1. Changed variance form to electronic variance.	
Revised by: Steve Holden	07/18/2017	r.02.05.00	Added a policy on using reagents passed expiration date.	
Approved by: Peter Millward, MD	07/18/2017			
Revised by: Christopher Ferguson	01/18/2018	r02.05.01	Changed “provue” references to “vision” references. Clarified statement on use of expired antisera.	
Approved by: Peter Millward, MD	01/19/2018			
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Approved by: Craig Fletcher, MD	03/27/2019			
Revised by: Christopher Ferguson	05/21/2019	r02.06.00	Routine QC may not be run in parallel with patient/donor testing anymore. Must be completed ahead of time. Updated the *Authorized Reviewers* titles. Updated names of referenced SOPs.	
QA: Jennie Green	07/03/2019			
Manager: Billie Ketelsen	06/17/2019			
Approved by: Craig Fletcher, MD	07/24/2019			
Revised by: Christopher Ferguson	02/17/2020	r02.06.01	Changed LISS reagent from ImmuAdd to N-HANCE. Removed QA from authorized reviewer. Added automated cell washer to equipment. Updated names of referenced material.	
Approved by: Craig Fletcher, MD	02/25/2020			
Revised by: Christopher Ferguson	05/04/2020	r02.07.00	Check cells are only added to AHG results that are negative instead of negative or less that 2+. Changed LISS reagent from Immucor N-HANCE to Ortho Antibody Enhancement Solution.	
Manager: Billie Ketelsen	05/05/2020			
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Document Control, continued

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Revised by: Samantha Maynard	08/09/2021	r02.08.00	Changed 6-8% Bovine albumin control to 7% BSA. Removed reference to P122. Any strength check cells is okay, no longer 2+ or greater	
Manager:				
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