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Correlation of Results Between Instruments and Methods - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is provide policies and procedures needed to perform correlation studies between various instruments and methodologies. The correlation study is an additional tool, required by the College of American Pathologists (CAP), which is used to control quality and accuracy of patient test results when multiple instruments and methodologies are used in the laboratory. These studies are required at least bi-annually, between ORTHO VISION™ automated instruments, gel methodology, and tube methodology.

II. DEFINITIONS:

A. **Bi-annually**: As used in this document, the various tests performed as part of this correlation study shall be performed every 6 months ± 2 months from the date that the test / correlation study was most recently performed.

III. POLICIES:

A. The results of this correlation study shall be reviewed by the Medical Technologist Lead assigned to Quality Control (QC) and by the Blood Bank Manager / Supervisor.

B. Any discrepancies observed between the different instruments and methodologies must be explained and / or resolved.

C. Correlation studies as described in this document shall be performed bi-annually.

D. Patient samples tested as part of this correlation study should be current on the date of testing.

E. CAP competency and proficiency samples may be used for this correlation study, but only if the CAP's submission deadline date has passed.

IV. SPECIMEN COLLECTION AND HANDLING:

Refer to section XIV. *Applicable Policies*, below.

V. REAGENTS / EQUIPMENT / SUPPLIES:

Refer to section XIV. *Applicable Policies*, below.

VI. QUALITY CONTROL (QC):

The routine quality control testing shall be performed as indicated by each applicable Transfusion Medicine policy. Copies of this QC shall be attached to the *Correlation of Results Between Instruments and Methods* form.

VII. TESTS PERFORMED AS PART OF CORRELATION STUDY:

Test	Sample Source	Number of Tests	Instrument / Methodologies	Transfusion Medicine policy
ABO / Rh	Alba Q-Chek® samples (Vials 1 and 3) and 2 patient samples.	4	ORTHO VISION™ (including correlation between instruments)	Transfusion Medicine policy, ORTHO VISION Analyzer QC and Transfusion Medicine policy, Routine Testing on the ORTHO VISION Analyzer.
			Tube Method	Transfusion Medicine policy, Determining the ABO and RhD of Patients Who Are At Least Four Months Old.
			Manual Gel Method	Transfusion Medicine policy, Determining the ABO and RhD of Patients Who Are At Least Four Months Old and Transfusion Medicine policy, *Quality Control of Blood Bank Reagents.*
Antibody Screen	Alba Q-Chek® samples (Vials 1 and 3) and 2 patient samples.	4	ORTHO VISION™ (including correlation between instruments)	Transfusion Medicine policy, ORTHO VISION Analyzer QC and Transfusion Medicine policy, Routine Testing on the ORTHO VISION Analyzer.
			Tube Method	Transfusion Medicine policy, Antibody Screening - Blood Bank.
			Manual Gel Method	
Direct Antiglobulin Test (DAT)	Samples from the CAP DAT survey or patient samples.	3	Gel Method	Transfusion Medicine policy, Performing Neonatal Direct Antiglobulin Test (DAT) by the

				Gel Method.
			Tube Method	Transfusion Medicine policy, *Direct Antiglobulin Test (DAT) for Patients Greater than Four Months Old*.
Eluate	Samples from the CAP eluate survey or patient samples.	1	Gel Method	Transfusion Medicine policy, *Testing of Eluates by the Gel Method.*
			Tube Method	Transfusion Medicine policy, *Testing of Eluates by the Tube Method (Alternate Method)*.
Antibody Identification Panel	Samples from the CAP antibody identification survey or patient samples.	1	ORTHO VISION™	Transfusion Medicine policy, ORTHO VISION Analyzer QC and Transfusion Medicine policy, Routine Testing on the ORTHO VISION Analyzer.
			Tube Method	Transfusion Medicine policy, *Antibody Identification*.
			Gel Method	
Crossmatch	Two samples from patients with a single known antibody will be crossmatched against antigen positive and antigen negative donor RBCs, by the ORTHO VISION™ gel method, the manual gel method, and the manual AHG method.		ORTHO VISION™	Transfusion Medicine policy, Routine Testing on the ORTHO VISION Analyzer.
			Manual Gel Method	Transfusion Medicine policy, Serologic Crossmatching of Red Blood Cells.
			Manual AHG Method	

VIII. PROCEDURE:

A. Using the *Correlation of Results Between Instruments and Methods* form, document the sample identification column as follows:

1. Alba Q-Chek® samples: Indicate the manufacturer, lot number, vial number, and expiration date.
2. Patient samples: Document the medical record number (MRN), accession number, and collection date.
3. Donor samples: Document the donor number and the expiration date.
4. CAP samples: Indicate the CAP identification number from the sample.

B. Use the table above to determine which tests may have already been performed and which tests need to be performed.

C. Document the interpretation of those tests that have already been performed on the *Correlation of Results Between Instruments and Methods* form.

D. Perform any tests that still need to be performed as indicated by Transfusion Medicine policies, including any quality control indicated.

E. For the tests performed in step D, record the interpretations on the *Correlation of Results Between Instruments and Methods* form.

F. Gather copies of all patient and QC test results, by all instruments and methodologies. This documentation may be from the following sources:

   1. Instrument printouts
   2. Computer printouts
   3. Downtime worksheets

G. Submit the completed *Correlation of Results Between Instruments and Methods* form and the copies of all patient and QC test results to the Blood Bank Manager / Supervisor or Medical Technologist Lead assigned to QC.

H. The Manager / Supervisor or Medical Technologist Lead assigned to QC will perform the following:

   1. Review the submitted data.
   2. Determine whether the results of the correlation study are acceptable or unacceptable, and whether additional testing is indicated.
   3. Document the *Correlation of Results Between Instruments and Methods* form with the determination of whether the results are acceptable or unacceptable, any additional testing that may be indicated, signature, and the date.

IX. EXPECTED VALUES:

A. The interpretations of all tests between different instruments and methodologies should correlate.

B. Results must be within ± 1 graded reaction strength for correlation between instruments to be considered satisfactory.

C. Quality control must perform as expected.

X. LIMITATIONS:

Differences in the sensitivity of test methodologies may result in difference of graded reactions.

XI. APPLICABLE POLICIES:

A. Transfusion Medicine policy, Determining the ABO and RhD of Patients Who Are At Least Four Months Old.

B. Transfusion Medicine policy, Antibody Screening - Blood Bank.

C. Transfusion Medicine policy, *Serologic Crossmatching of Red Blood Cells*.

D. Transfusion Medicine policy, *Quality Control of Blood Bank Reagents.*

E. Transfusion Medicine policy, Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method.

F. Transfusion Medicine policy, *Antibody Identification.*

G. Transfusion Medicine policy, *Direct Antiglobulin Test (DAT) For Patients Greater than Four Months Old*.

H. Transfusion Medicine policy, *Eluate Preparation.*

I. Transfusion Medicine policy, *Testing Eluates by the Gel Method*.

J. Transfusion Medicine policy, *Testing Eluates by the Tube Method*.

K. Transfusion Medicine policy, ORTHO VISION Analyzer QC.

L. Transfusion Medicine policy, Routine Testing on the ORTHO VISION Analyzer.

XII. REFERENCES:

1. College of American Pathologist Accreditation Program, version 06/17/2010.

Attachments

Correlation of Results Between Instruments and Methods

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	3/16/2022
	Craig Fletcher: System Med Dir, Blood Bank	3/14/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	3/14/2022
Policy and Forms Steering Committe (if needed)	Brooke Klapatch: Medical Technologist Lead	3/14/2022
	Rebecca Thompson: Medical Technologist Lead	3/14/2022
	Brooke Klapatch: Medical Technologist Lead	3/11/2022

Applicability

Royal Oak