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Area	Laboratory-Blood Bank
Applicability	Dearborn, FH, Troy

Correlation Of Results Between Instruments and Methodologies - Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and procedures needed to perform correlation studies between various instruments and methodologies for the Blood Bank. 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 the Ortho Vision™ automated instrument, manual gel methodology, and tube methodology.

II. POLICIES:

A. The results of this correlation study shall be reviewed by the Blood Bank supervisor or Lead Medical Technologist.

B. Any discrepancies observed between the different instruments and methodologies must be explained and / or resolved. The supervisor or lead shall bring any unsatisfactory correlation studies to the Medical Director's attention for a determination of appropriate actions. These actions will be documented on attachment Correlation of Results between Instruments and Methods. Investigation of Results that do not Correlate, which will be signed by the supervisor and Medical Director.

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. Alba Q-Chek® samples tested must be within their expiration date on the date of testing.

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

G. CAP Quality Crosscheck samples intended for method correlation, if used, may be used from date of receipt.

III. DEFINITIONS:

A. Current sample: a sample that was collected no more than 3 days before the current date. For example, if a sample is drawn on Monday (day 0), then the sample remains "current" all day Mon., Tues., Wed., and Thur.

B. 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.

IV. SPECIMEN COLLECTION AND HANDLING:

Refer to applicable Procedures, below.

V. REAGENTS/EQUIPMENT/SUPPLIES:

Refer to applicable Procedures

VI. QUALITY CONTROL (QC):

A. The routine quality control testing shall be performed as indicated by each applicable procedure.

B. Copies of QC results shall be included with the Correlation of Results between Instruments and Methods Form.

VII. TESTS PERFORMED AS PART OF CORRELATION STUDY:

Tests/ Samples/ Methods/ Instruments for Correlation Study

Test	Sample Source	Number of Tests	Instrument/ Methodologies	Procedure
ABO/ Rh	Alba Q-Chek® samples (Vials 1 and 3) and 2 patient or previously submitted CAP samples	4	Ortho Visions™	Routine Testing on the ORTHO VISION Analyzer
			Tube method	Determining The ABO and RhD Of Patients Who Are At Least Four
			Manual gel	

			method	Months Old
Antibody screen	Alba Q-Chek® samples (Vials 1 and 3) and 2 patient or previously submitted CAP* samples	4	Ortho Visions™	Routine Testing on the ORTHO VISION Analyzer
			Manual Gel method	Antibody Screening-Blood Bank
			LISS Tube method	
			60MNL Tube Method	
Direct antiglobulin test (DAT)	Samples from previously submitted CAP* DAT survey or patient samples	2	Gel method	Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method
			Tube Method	*Direct Antiglobulin Test (DAT) by the Tube Method*
Special Antigen	Two samples from patients or previously submitted CAP* samples	2	Gel Method	Antigen *Typing*
			Tube Method	
Antibody identification panel	Samples from the previously submitted CAP* antibody identification survey or patient samples, or Alba Q-Chek® Vial 1 and 2	1	Ortho Visions™	Routine Testing on the ORTHO VISION Analyzer
			Gel Method	*Antibody Identification by the Gel Method* Eluate Preparation
			LISS Tube Method	*Antibody Identification by the Tube Method*
			60MNL Tube Method	
Eluate	Samples from the CAP ELUATE survey or patient samples	1	Gel Method	Eluate Preparation Testing Eluates by the Gel Method
			Tube Method	Eluate Preparation Testing Eluates by the Tube Method
Crossmatch	Two samples from patients or previously submitted CAP* samples with a single known antibody will be crossmatched		Ortho Vision™	Routine Testing on the ORTHO VISION Analyzer

	against antigen positive and antigen negative donor RBCs, by both the Ortho Vision™ and manual gel methods.	Manual Gel	Serologic Crossmatching of Red Blood Cells
		Liss Tube method	
		60MNL Tube method	

*CAP Quality Crosscheck samples may be used prior to date of submission

VIII. PROCEDURE:

A. Using attachment, Correlation of Results between Instruments and Methods, 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 Table Tests / Samples / Methods / Instruments for Correlation Study to determine which tests may have already been performed and which tests need to be performed.

C. Document the interpretations of those tests that have already been performed on the attachment Correlation of Results between Instruments and Methods.

D. Perform any tests that still need to be performed as indicated by the appropriate procedure, including any indicated quality control.

E. For the tests performed in step D, record the interpretations on the attachment Correlation of Results between Instruments and Methods.

F. Document whether the results of the correlation study are acceptable or unacceptable and sign and date the form.

G. 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

H. Submit the completed attachment and the copies of all patient and QC test results to the Supervisor or Lead for review.

I. The supervisor and/or lead will perform the following:
    1. Review the submitted data.
    2. Confirm whether the results of the correlation study are acceptable or unacceptable, and whether additional testing is indicated.

3. Document the attachment 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. Quality control must perform as expected.

X. LIMITATIONS:

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

XI. NOTES:

A. Not all tests are performed at all sites.

XII. REFERENCES:

1. College of American Pathologist Accreditation Program, current edition

Attachments

Correlation of Results between Instruments and Methods

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	5/23/2022
	Vaishali Pansare: Chief, Pathology	5/19/2022
	John Pui: Chief, Pathology	5/18/2022
	Craig Fletcher: System Med Dir, Blood Bank	5/18/2022
	Ryan Johnson: OUWB Clinical Faculty	5/17/2022

Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	5/9/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	5/6/2022
	Karrie Torgerson: Supv, Laboratory	5/6/2022
	Teresa Lovins: Supv, Laboratory	5/6/2022
	Kelly Sartor: Supv, Laboratory	5/6/2022
	Kelly Sartor: Supv, Laboratory	5/6/2022