PROCEDURE
Corewell Health East - Correlation of Results Between Instruments and Methods

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

Reference #: 33901

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Effective Date: 07/07/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

This document provides policies and procedures needed to perform correlation studies between various blood bank instrument and methodologies

A. 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(s), manual gel methodology, and tube methodology.
B. The results of the correlation study are reviewed by a Blood Bank Medical Technologist Lead or designee.
C. Any discrepancies observed between the blood bank instrument(s) and methodologies must be explained and/or resolved.
D. Patient samples tested as part of this correlation study should be current on the date of testing.
E. ORTHO Daily QC samples must be within their expiration date on the date of testing.
F. CAP competency and proficiency samples may be used for this correlation, ONLY if the CAP's submission deadline date has passed.
G. If needed for the neonatal DAT and/or Eluate test, a sample can be manufactured as described in the Procedure section of this document.
H. Correlation studies as described in this document are performed bi-annually.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. 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 Monday, Tuesday, Wednesday, and Thursday.

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.
C. IAT: Indirect Antiglobulin Test
D. 60MNL: 60 Minute No LISS

4. Specimen

A. The specimen of choice is a 6 mL EDTA sample with affixed identifying label.
B. Samples drawn in serum separator tubes are generally not acceptable.
C. Pre-transfusion samples are collected according to the Transfusion Medicine policy Corewell Health East - Transfusion Services Criteria for Specimen Acceptability - All Beaumont Hospitals .

5. Reagent/Equipment Needed

Refer to applicable procedures.

6. Quality Control

A. Quality control testing shall be performed as indicated in each applicable Transfusion Medicine procedure, Corewell Health East - ORTHO VISION Analyzer QC - All Beaumont Hospitals, Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals, and site specific Quality Control of Manual Gel System Reagents procedures.

7. Procedure

A. Tests performed as part of the correlation study are summarized in the table below:

Test	Sample Requirements	# of samples	Instrument/ Methodologies	Procedure
ABO/Rh	4 samples representing 4 different blood types including at least 1 Rh-positive and 1 Rh-negative.	4	Ortho Vision	Corewell Health East - Routine Testing on the ORTHO VISION Analyzer - All Beaumont Hospitals
			Manual Gel Method	Corewell Health East - ABO and Rh Typing - All Beaumont Hospitals
			Tube Method	
Antibody Screen	4 samples with at least 1 positive screen and 1 negative screen.	4	Ortho Vision	Corewell Health East - Routine Testing on the ORTHO VISION Analyzer - All Beaumont Hospitals
			Manual Gel Method	Corewell Health East - Antibody Screening - Blood Bank - All Beaumont Hospitals
			Tube Method	
Neonatal DAT	1 positive and 1 negative sample	2	Ortho Vision	Corewell Health East - Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method - All Beaumont Hospitals
			Manual Gel Method	
Antigen Typing (Rh Typing and Antigen typing by IAT)	1 antigen positive and 1 antigen negative sample	2	Ortho Vision	Corewell Health East - Antigen Typing - Blood Bank - All Beaumont Hospitals
			Manual Gel Method	
			Tube Method	
Antibody Identification panel	1 sample containing 1-2 identified antibodies	1	Ortho Vision	Corewell Health East - Antibody Identification - Blood Bank - All Beaumont Hospitals
			Manual Gel Method	
			Tube Method	
Eluate	1 sample with a positive DAT due to a known antibody	1	Manual Gel Method	Corewell Health East - Eluates -Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Troy
			Tube Method	
AHG Crossmatch	Two samples from patients with a single known antibody will be crossmatched against antigen positive & antigen negative donor RBCs, by both the Ortho Vision and manual gel/tube method.		Ortho Vision	Corewell Health East - Serologic Crossmatching of Red Blood Cells - All Beaumont Hospitals
			Manual Gel Method	
			Tube Method	

Note:

1. Tube Method for the following tests will be completed using 60 Minute No LISS methodology:
    a. Antibody Screen
    b. Antibody Identification Panel
    c. AHG Crossmatch
2. Neonatal DAT test is not applicable at Corewell Health Taylor.
3. Eluate testing is not applicable at Corewell Health Taylor, Trenton, and Wayne.
4. Rh Antigen Typing on Ortho Vision is only applicable at Corewell Health Dearborn and Royal Oak.
5. IAT Antigen Typing correlation should be completed for any site that uses manual gel as the primary method.

B. The *Correlation of Results between Instrument & Methods* form (33909-1) attachment is used to record sample information and test results. N/A should be written for any testing that is not applicable at the performing site.

C. The following sample types may be used for this procedure and should be documented on the *Correlation of Results Between Instruments and Methods* form (33909-1) as follows:
    1. ORTHO Daily QC samples: indicate the manufacturer, lot number, vial number and expiration date.
    2. Patient samples: document the medical record number, specimen ID, and the collection date/time.
    3. Donor samples: document the donor number and the expiration date.
    4. CAP samples: indicate the CAP identification number from the sample.
    5. Manufactured positive DAT sample (following procedure described below): document the donor number and expiration date, as well as the Anti-D manufacturer, lot number, and expiration date.

D. Optional: To manufacture a sample to be used for the Eluate and/or positive DAT sample:
    1. Obtain approximately 2 mL of Rh-positive packed RBCs (approximately 8-10 3-inch segments).
        a. Use scissors to cut off both ends of the segments and empty the contents into a 13 x 100 glass test tube. Do not use a segment splitter as the RBCs may be inadvertently hemolyzed.
    2. Add an equal volume of Anti-D into the glass test tube containing the packed RBCs. For example, for 2 mL of packed RBCs, add 2 mL of Anti-D.
    3. Cap the tube and incubate for one hour at 37°C, mixing the contents well after 30 minutes by gently inverting the tube several times.
    4. After an hour incubation, a tube DAT may be tested. DAT results should yield a reaction strength ≥ 3+.

E. Antigen Typing
    1. Rh Antigen Typing – select one Rh antigen for correlation study
    2. IAT Antigen Typing – select one antigen tested by IAT-method for correlation study

F. Instrument testing:
    1. Sites with more than one analyzer should test each analyzer separately.
    2. For sites with only one or two analyzers enter “N/A” on form for additional Vision columns.

G. Vision Reaction Grading Correlation chart:
    1. This chart is only completed for sites with more than one analyzer.
    2. The same sample runs as documented in the ABO/Rh and Antibody Screen charts may be used for the Reaction Grading Correlation charts.

H. Obtain copies of all required QC and test results, for all instrument(s) and methodologies showing reaction grades and interpretations. This documentation may be from the following sources:
    1. Instrument printouts
    2. Computer printouts from BBIS
    3. Downtime worksheets

B. Submit the completed *Correlation of Results Between Instruments and Methods* form (33909-1) and the copies of all sample and QC testing results to the Blood Bank Medical Technologist Lead or designee.
C. The Medical Technologist Lead or designee will perform the following:
   1. Review the submitted data.
   2. Determine and document whether the results of the correlation study are acceptable or unacceptable, and whether additional testing is indicated. Sign and date.

9. Results/Interpretation

A. The interpretation of tests between the instrument(s), manual gel method, and tube method should correlate. Graded reactions must agree where no true positive is negative & no true negative is positive.
B. Quality Control must be performed and pass as expected.

10. Limitations

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

11. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [33940 Corewell Health East - Correlation of Results Between Instrument and Methodologies - Taylor, Trenton, Wayne, 33818 Corewell Health East - Correlation of Results Between Instruments and Methodologies - Blood Bank - Dearborn, Farmington Hills, Grosse Pointe, Troy]

12. References

A. College of American Pathologists, All Common Checklist, COM.04250, 06.04.2020

13. Procedure Development and Approval

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14. Keywords

Not Set