* 8/3/24 Still being updated / gm

To be updated for Go Live

Sops to update = 9 and 2 new SOPs

#	Title	Last Reviewed	How Impacted?	Updated
1	CE QC/PM List and Schedule	02/11/2022	Remove Immucor Instruments and Add Ortho	Add new Analyzers *
NA	Critical Equipment	05/17/2022	No SOP Change and Update to add new equipment	No SOP update but add Vision to Critical Equipment List
2	Direct Antiglobulin Test (DAT)	06/27/2022	Small wording change about weak D on Max and Swift	Added a seciton for DAT Vision Testing with Weak D on NNP and CORD resolution. ✓
3	NeoNatal Transfusion Program (NNP) Eligibility	02/18/2020	Add may be tested on the Analyzer	Added NNP can be added and small wording changes ✓
4	Ortho Vision Daily QC	03/28/2022	Add new QC for Weak D and Buffered Card	Added total of 8 profiles for QC ✓
5	Ortho VISION Maintenance Record	02/21/2022	Add new QC to form	Updated with new profiles *
6	Vision - Changing Reagent Lots on the VISION	03/18/2022	Add all 8 profiles to this SOP	Ready 6/29/22 ✓

7	Vision - Daily Maintenance	02/18/2020	Add second saline container for Max	Small wording changes to expand for use on Max
8	Vision - Running CORD profile	04/21/2022	Add reflex for weak D	Added weak D and policy statement that it may
9	Weekly MTS Diluent Dispenser Cleaning	03/15/2022	Change to broaden when completed.	
New	Vision: Weak D	NEW	New for new reagents process	
New	Vision: Newborn ABO/Rh, ABORH2, IAT and DAT	NEW	New because not validated the first time	Added new SOP for neborn ABO/Rh

Sunset SOPs when Echo analyzers complete 67 SOPS

#	Title	Last Reviewed	How Impacted?	Updated
1	Antigen Testing on NEO	03/01/2022	Sunset	
2	Capture-P Maintenance Form	02/21/2022	Sunset	
3	Capture-P Method for Platelet Crossmatching	05/23/2022	Sunset	
4	Capture-P Ready Screen Result Interpretation Worksheet	05/23/2022	Sunset	
5	Cell Washer - CW-2 Glass Removal after Test Tube Breakage	02/18/2020	Sunset	
6	Cell Washer CW2 Maintenance / Quality Control	02/18/2020	Sunset	
7	Competency Assessment - ECHO: ABO/Rh/IAT/ABID/Crossmatch	02/16/2022	Sunset	
8	Competency Assessment - NEO: ABO/Rh/IAT/ABID/Crossmatch	02/16/2022	Sunset	
9	Competency Assessment - TEG	03/07/2022	Sunset	
10	Competency Assessment - Titer	02/16/2022	Sunset	

Indiana University Health	Original Creation Date: 03/27/2001	Publication Date: 06/27/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	Next Review: 06/27/2024
	Category: Labs AHC	
	Education: Level 1	
Approval Signatures: Muhammad Idrees (Physician) (06/27/2022)		

Direct Antiglobulin Test (DAT)

I. PURPOSE

To outline the procedure for detecting *in vivo* sensitization of red cells using Antihuman IgG and Antihuman C3b,-C3d.

II. SCOPE

This SOP addresses the procedures for performing the Direct Antiglobulin Test (DAT). Indications for the DAT may include the following:

a. Investigation of suspected hemolytic transfusion reaction
b. Detection of autoantibodies
c. Control for a positive weak D test
d. Investigation of Hemolytic Disease of the Newborn (See BBT-020 for additional information)
e. Investigation of Hemolytic Anemia

All MT-I/II, Supervisors and Manager are impacted by this procedure.

III. EXCEPTIONS

1. Hemolytic Disease of the Newborn investigations do not require anti-C3b, -C3d testing.
2. Antibody identifications require Anti-C3b,-C3d testing when DAT Anti-IgG is positive.
3. Other exceptions must be approved by the Transfusion Medicine (TM) Physician.

IV. DEFINITIONS

None

V. POLICY STATEMENTS

1. All patient physician orders for DAT only REQUIRE **both** Anti-IgG and Anti-C3b, -C3d testing.
2. Eluate testing is not required for positive DAT results for DAT only results.

3. DAT testing as part of Antibody Identification:
    1. Test IgG DAT and MTS DAT where indicated, see Flowchart: Autoantibody Investigation.
    2. If the IgG DAT or MTS DAT is positive, then Anti-C3b,d DAT is required.
4. The tube method is the primary method for performing DATs.
5. The MTS Gel method may be used for IgG DAT.
6. Grade all reactions according to SOP Uniform Grading Scale for Blood Bank Testing.
7. A positive DAT is considered a critical value and PRV should be completed per Critical Values.

VI. PRINCIPLE/BACKGROUND

None

VII. MATERIALS

Reagents:

Anti-Human Globulin IgG (AHG)
Anti-Human Anti-C3b, -C3d
Coombs control cells (IgG & C3d) coated red cells
MTS IgG cards
Physiologic saline

Monoclonal control

Supplies:

Test tubes (10 x 75, 12 x 75)
Test tube rack
Marker
MTS pipettor and disposable tips
MTS Diluent-2
Disposable pipettes
Parafilm
Centrifuge(s) – MTS and Serologic
Cell Washers
Optical Aid (viewbox/agglutination viewer)
Scissor-type hemostats

VIII. SPECIMEN REQUIREMENTS

Preferably less than 3 days old sample collected in one of the following anticoagulants:

> **Note:** Freshly drawn **clotted** sample may be used, however, positive results need to have an EDTA tube requested for further testing.

EDTA
ACD
CPD
CPDA-1

See Sop Requisition & Specimen Processing for additional specimen and requisition requirements.

IX. PROCEDURE

1. Anti-IgG Tube Method:
    1. Place 1 drop of a 3-5% red cell suspension of the sample to be tested in a test tube.
    2. Wash the red cells at least 3 times with large volumes of physiologic saline. Note: an automated cell washer may be used for this purpose. Additionally, if the red cell suspension has been previously washed at least 3 times, this step may be omitted.
    3. Decant as much supernatant saline as possible after each washing step to facilitate removal of unbound globulin when manually washing the red cells.
    4. Add 2 drops of anti-IgG (AHG) to the washed red cells and mix contents well.
    5. Centrifuge according to the calibrated time and speed for AHG test and examine macroscopically for agglutination. An optical aid may be used to facilitate detection of weak reactions.
    6. Immediately grade and record reactions in/on the appropriate computer / worksheet.
    7. Interpretation:
        1. Agglutination = Positive reaction. See section 3 below to add a DAT control when appropriate.
        2. No agglutination = Negative reaction
    8. Add one (1) drop of Coombs Control Cells to all negative reactions, centrifuge and examine for macro agglutination and record on the appropriate computer / worksheet. Failure of the Coombs Control cell to agglutinate renders the test invalid and the procedure must be repeated.
2. Anti-C3b, -C3d Tube Method:
    1. Place 1 drop of a 3-5% red cell suspension of the sample to be tested in a labeled test tube.
    2. Wash the red cells at least 3 times with large volumes of physiologic saline. Note: an automated cell washer may be used for this purpose. Additionally, if the red cell suspension has been previously washed at least 3 times, this step may be omitted.
    3. Decant as much supernatant saline as possible after each washing step to facilitate removal of unbound globulin when manually washing the red cells.
    4. Add 2 drops of Anti-C3b, -C3d (AHG) to the washed red cells and mix contents well.
    5. Centrifuge according to the calibrated time and speed for AHG test and examine for agglutination. An optical aid may be used to facilitate detection of weak reactions.
    6. For all negative reactions, incubate five (5) minutes at room temperature and re-spin.
    7. Immediately grade and record reactions in/on the appropriate computer / worksheet.
    8. Interpretation:
        1. Agglutination = Positive reaction. See section 3 below to add a DAT control when appropriate.
        2. No agglutination = Negative reaction
    9. Add one (1) drop of Complement Control Cells to all negative reactions, centrifuge and examine for macro agglutination and record on the appropriate computer / worksheet. Failure of the Complement Control cell to agglutinate renders the test invalid and the procedure must be repeated.
3. Testing DAT control: If both the **IgG and C3bd DAT are positive**, add a DAT control to ensure the positive result is not a false positive. DAT Control can only be tested with DAT tube method. There is not

a DAT control for the MTS DAT.

1. Place 1 drop of a 3-5% red cell suspension of the sample to be tested in a test tube.
2. Wash the red cells at least 3 times with large volumes of physiologic saline. Note: an automated cell washer may be used for this purpose. Additionally, if the red cell suspension has been previously washed at least 3 times, this step may be omitted.
3. Decant as much supernatant saline as possible after each washing step to facilitate removal of unbound globulin when manually washing the red cells.
4. Add 2 drops of Saline or Monoclonal Control to the washed red cells and mix contents well.
5. Centrifuge according to the calibrated time and speed for AHG test and examine macroscopically for agglutination. An optical aid may be used to facilitate detection of weak reactions.
6. Immediately grade and record reactions on appropriate worksheet.
7. Interpretation:
    1. Agglutination = Positive reaction, indicating false positive DAT result
    2. No agglutination = Negative reaction, indicating a valid DAT result
8. If DAT control is positive, then contact BB Management for troubleshooting steps.

4. Anti-IgG - Manual MTS DAT Method:
    1. Prepare 0.8% suspension of patient's cells.
    2. Label a MTS Anti-IgG card microtube with patient ID and test information.
    3. Remove foil seal from the microtube to be used.
    4. Pipette 50 uL of this 0.8% patient cell suspension into the appropriate microtube.
    5. Centrifuge the card for 10 minutes.
    6. Tests should be read immediately following centrifugation because results are affected by drying of the gel.
    7. Interpretation:
        a. Agglutination= Positive reaction
        b. No agglutination= Negative reaction
    8. Record results for the DAT in/on appropriate computer / worksheet.
5. Quality Control of Tube Anti-C3b, -C3d (AHG) = performed **once Daily**:
    1. Positive control: Place 2 drops of Anti-C3b, -C3d and 1 drop of Complement coated cells (C3d) into a labeled test tube.
    2. Negative control: Place 2 drops of Anti-C3b, -C3d and 1 drop of antibody screening cells into a second labeled test tube.
    3. Centrifuge according to the calibrated time and speed for AHG test and examine for agglutination. An optical aid may be used to facilitate detection of weak reactions.
    4. Record antisera and positive/negative control graded reactions with interpretations on appropriate form. (See BBQC-F003)

Positive DAT IgG and Reflex Eluate testing

1. Perform elution studies, if patient has been transfused within last 28 days or at the request of management or TM Physician (See SOP BBT-037).

2. Elution is not routinely required, if patient has never been transfused or if >28 days.
3. Complete elution if requested by BB Management or TM Physician.
4. Follow DAT and Eluate Flowchart (BBT JA109) for decision model for DAT testing and when to complete eluate testing.

7. Cerner
    1. Department Order Entry-to generate accession number
    2. Medical Record Number (MRN)>Enter
    3. Orderable-Select:
        1. Direct Coombs (DAT MTS + DAT Anti-C3)
           (May need to cancel DAT MTS and order DAT IgG)
        2. DAT Anti-C3 (Complement testing)
        3. DAT Anti-IgG (Tube testing)
        4. DAT MTS (Gel or automated testing)
    4. Enter
    5. Accession number generated
        1. Result Entry
        2. Enter Accession number
        3. Enter test results
        4. Verify

X. APPENDICES/ATTACHMENTS/FORMS/ LABELS

Flowchart: Autoantibody Investigation

XI. REFERENCES/CITATIONS

Quality System, IU Health.
AABB Technical Manual, current edition. AABB
Standards, current edition.

Policy #:

BBT – 005

Indiana University Health	**Original Creation Date:** 07/22/2002	**Publication Date:** 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 07/28/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

NeoNatal Transfusion Program (NNP) Eligibility

I. PURPOSE

To describe the process for managing neonatal patients who require red blood cell transfusions during their first four months of life.

II. SCOPE

This procedure applies to **eligible neonates**, during **one admission**. This SOP applies to MT-I and MT- II team members. Lab Assistant II team members may only load samples on Vision analyzers.

III. STATEMENTS/REQUIREMENTS

A. To determine eligibility of neonates for NNP, the followings tests must be performed:

1. Newborn ABO and Rh
2. Screen for Immune ABO antibodies for non group O neonates
3. Antibody Screen
4. Direct Antiglobulin Test

B. A second ABO/Rh verification is required to issue blood products. This is done by:

1. Retype of the same sample when collected by PPID.
2. Performing a Newborn ABO/Rh on a new sample drawn at a separate time.

C. The newborn profile testing may be completed manually or using the Vision analyzer (Max and Swift).

1. When using the analyzer, weak D is a reflex test on all newborn ABO/Rh which D Negative.

D. **Neonates** are defined as newborns **≤ 4 months of age**.

E. **Specimen Requirements**

1. (2) EDTA (lavender) microtainer tubes or 3 mL lavender tube
2. All samples must meet identification criteria as outlined in SOPBBT 011 Requisition & Specimen Processing.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

NNP: NeoNatal Transfusion Program

PPI: Patient Product Inquiry

PPID: Positive Patient Identification

V. EQUIPMENT/RESOURCES

Equipment

Ortho Vision/Vision MAX

Centrifuge(s) – MTS and Serologic Cell Washers

Reagents:

Potentiating Media – LISS

Anti-Human Globulin (IgG - AHG)

Coombs Control Cells (CC) (IgG sensitized cells)

Anti-A, -B, -D and Monoclonal Control

A_1 and B Reverse Group cells

Antibody Screen cells

IgG cards

A/B/D monoclonal grouping cards

Weak D reagent

0.1 N NaOH

Supplies:

10 x 75 mm test tubes

Test tube rack

Marker

MTS pipettor and disposable tips

Disposable pipettes

Physiologic saline

Heating block/MTS incubator

Optical Aid (viewbox / agglutination viewer / microscope)

VI. PROCEDURE

A. Newborn ABO, Rh Testing:

1. Perform ABO/D typing, including test for weak D if neonate is D negative. See SOP BBT-003 ABO & Rh Determination, Manual Tube .
   a. Reverse typing is not performed on neonates.
   b. If Weak D is positive, then correlate results with the anti- IgG or MTS DAT results. Refer to SOP BBT 005 Direct Antiglobulin Test (DAT) .
   c. Perform ABO/D serologic confirmation if sample is PPID collected. See BBT Procedure: ABO & Rh Determination, Manual Tube 003 ABO & Rh Determination, Manual Tube

B. Perform Antibody Screen or Indirect Antiglobulin Test (IAT).

1. See SOP BBT-004 Procedure: Antibody Screen .

2. Plasma/serum of either the Neonate or the Mother may be used when screening for unexpected antibodies.
3. NOTE: If the mother's plasma/serum is used, add Cerner comment stating "Mother's plasma/serum used" in PPI comment box.

C. Perform Direct Antiglobulin test (DAT). See SOP BBT-005 Direct Antiglobulin Test (DAT) .

If...	Then...
DAT Negative	Go to section E.
DAT Positive, infant is group O	Suspect non-ABO antibodies. Prepare and test eluate per BBT-037 Elution- Rapid Acid (Gamma Elu-Kit ™ II) .
DAT Positive, infant is non group O	Suspect ABO antibodies. See BBT-020 Hemolytic Disease of the Newborn Screen (HDN) • If ABO antibody negative, suspect non-ABO antibodies. Prepare and test eluate per BBT-037.

D. If the neonate is not group O, screen for maternal ABO antibodies (Immune ABO Screen).

1. **Note:** A patient with a negative Immune ABO Screen may receive uncrossmatched group-specific RBCs. The presence of anti-A, anti-B, or anti-A,B necessitates the transfusion of only Group O RBCs.

If Newborn Front Type is...	Then test newborn's plasma against...
Type A	A1 reverse grouping cells
Type B	B reverse grouping cells
Type AB	A1 and B reverse grouping cells

2. Label for each test required (see above table) a 10 x 75 mm test tube with the neonate's identifier and cell type required.
3. Place 2 drops of neonate plasma in each of the labeled 10 x 75 mm tubes.
4. Add one drop of appropriate 2-4% reverse group cells in the corresponding tube.
5. Centrifuge according to the calibrated time and speed. Examine for hemolysis.
6. Gently resuspend cell button and examine for agglutination.
7. Add 2 drops of LISS enhancement media to each tube, mix well. Another enhancement media may be used as directed by supervisor (follow manufacturer's instructions).
8. Incubate at 37°C for 10-30 min.
9. Centrifuge according to the calibrated time and speed. Examine for hemolysis.
10. Gently resuspend cell button and examine for agglutination.
11. Wash the red cells at least three (3) times with large amounts of physiologic saline. An automated cell washer may be used for this purpose.
12. Add two (2) drops of IgG-AHG to the washed red cells, mix contents well.
13. Centrifuge according to the calibrated time and speed.
14. Gently resuspend cell button and examine for agglutination. An optical aid may be used to facilitate detection of weak reactions.
15. Immediately grade reaction, documenting results directly in Cerner using Result Entry.
16. Add One (1) drop of Coombs Control Cells to all negative reactions, centrifuge and examine for macroscopic agglutination. Document results in Cerner using Result Entry.

17. **NOTE:** Failure of the Coombs Control cell to agglutinate renders the test invalid and the procedure must be repeated.

E. Determine NNP Eligibility

If...	Then...	Next Steps...
• IAT Negative • Group O neonate ***or*** Immune ABO Screen negative • DAT Negative	NNP Eligible, crossmatch not required Patient receives RBCs compatible with front type.	• Add **NNP** Transfusion Requirement • Add PPI comment: **NNP Eligible until mm/dd/yyyy**

If...	Then...	Next Steps...
• IAT Negative • Immune ABO Screen Pos • DAT Negative ***or*** Positive DAT but HDN Screen reveals ABO HDN	NNP Eligible, crossmatch not required. Patient receives Group O RBCs for transfusion.	• Add **NNP** Transfusion Requirement • Add PPI comment: **NNP Eligible until mm/dd/yyyy** • Add **Group O RBCs** transfusion requirement.
• Positive maternal IAT • Negative neonate DAT • Antibody identified via IAT and is NOT clinically significant.	NNP Eligible, crossmatch not required Patient receives RBCs compatible with front type.	• Add **NNP** Transfusion Requirement • Add PPI comment: **NNP Eligible until mm/dd/yyyy**
• Positive IAT • Positive DAT • IAT = Anti-D (RhIg) • Anti-D eluted from neonatal RBCs.	NNP Eligible, crossmatch not required Patient receives group compatible Rh negative RBCs.	• Add **NNP** Transfusion Requirement • Add PPI comment: **NNP Eligible until mm/dd/yyyy** • Add Transfusion Requirement consistent with the type of RBCs to be given (i.e. A Negative).
• Positive IAT • Positive DAT • Maternal IAT = Anti-D (RhIg) • Anti-D eluted from neonatal RBCs. • ABO HDN identified	NNP Eligible, crossmatch not required Patient receives O negative RBCs.	• Add **NNP** Transfusion Requirement • Add PPI comment: **NNP Eligible until mm/dd/yyyy** • Add Transfusion Requirement **O Negative RBCs**
• Positive IAT • Neonate DAT positive or negative. • Antibody identified via IAT. • Elution of neonate's RBCs identifies same antibody.	NNP Eligible, crossmatch required. Patient receives RBCs compatible with front type, antigen negative for antibody identified. First transfusion from a dedicated unit is crossmatched. Remaining aliquots of the same unit are not crossmatched. Unit may be aliquoted for 24 hours from the time of irradiation.	• Add NNP Transfusion Requirement. • Add PPI comment: **NNP Eligible until mm/dd/yyyy** • Add Transfusion Requirement for corresponding antigen negative RBCs.

If...	Then...	Next Steps...
• Positive IAT • Neonate DAT positive or negative. • Antibody not able to be identified by either IAT or elution.	NNP Ineligible. Serologic crossmatch required for each transfusion.	• Add PPI Comment: **NNP INELIGIBLE**

F. NNP Expiration

1. NNP Expiration: A report is generated daily listing patients who are discharged or have reached 4 months of age. Use the NNP Expiration report to remove NNP Transfusion Requirements and comments in PPI.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition. AABB Standards, current edition.

Quality System, AABB/IU Health.

IX. FORMS/APPENDICES

None

X. APPROVAL BODY

None

PROCEDURE #:

BBT- 008

Indiana University Health	**Original Creation Date:** 07/12/2017	**Publication Date:** 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 07/28/2024
	Category: Labs AHC	
	Education: Level 3	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

Ortho Vision Daily QC

I. PURPOSE

To provide daily proof of potency and specificity for all Ortho Vision reagents and analyzer performance.

II. SCOPE

Quality control must be done on all routine testing reagents on day of use. This SOP applies to all MT-I, MT-II and Lab Assistant II team members. Lab Assistant II team members may load samples and resources and start QC tasks only.

III. STATEMENTS/REQUIREMENTS

A. All Ortho Vision reagents will have quality control performed each day of use.

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

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

D. Any reagent not meeting QC standards will not be used and management will investigate the occurrence. Place unacceptable reagent lot in quarantine refrigerator.

E. All cards and specimens should be at room temperature.

F. The Alba-Q Chek QC reagents will be centrifuged 10 minutes before first use. QC reagents should be stored upright in the refrigerator to avoid mixing of reagents, requiring additional centrifugation.

G. **Specimen Requirements:**

1. Alba-Q Chek QC reagent (Vials 1 – 3)

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CAP: College of American Pathologists

QC: Quality Control

V. EQUIPMENT/RESOURCES

Ortho Vison/Vision MAX

A/B/D Monoclonal Grouping Cards

Anti-IgG Cards

Anti-D (Weak D) Ortho Reagent

0.1 N NaOH

0.8% Affirmagen

0.8% Surgiscreen (I, II, III)

MTS Diluent 2

MTS Diluent 2 Plus

Buffer Cards

A/B/D Reverse Cards

VI. PROCEDURE

A. Description of Daily QC for the VISION

1. Only Vials 1, 2 and 3 are used for QC Testing. Vial 4 is not used for daily QC on the VISION.

	Profile	**Assigned Alba-Q Chek QC**	**Expected Results**
1.1	ABORH	Vial 3	B, D Pos
1.2	ABO3CELL	Vial 1	A, D Neg, ABS Pos (SCI and SC II)
1.3	DONOR	Vial 3 Vial 1	B, D Pos and A, D Neg
1.4	ABORH2	Vial 2	O, D Pos
1.5	3CELL	Vial 2 Vial 3	ABS Pos (SCII and SCIII) ABS Neg
1.6	Weak D	Vial 3	Weak D Neg
1.7	Weak D2	Vial 1 or Vial 2	Weak D Pos
1.8	Buffer Card	Vial 1	Group A

B. Description of As-needed QC for the VISION

1. Panel testing requires QC on the first day of testing. Complete the Ortho Resolve QC Worksheet .

2. When these methods are tested, document completion of QC testing on Ortho VISION Maintenance Record.

3. Not all profiles have specific QC, because the reagents have been quality controlled as part of another test. Examples of these test profiles include, but are not limited to:

	Method	ID-MTS Card
4.1	CORD	A/B/D monoclonal grouping and reverse card
4.2	Titer	IgG card
4.3	Crossmatch	IgG card
4.4	Newborn Profile	IgG card, A/B/D monoclonal grouping card
4.5	DAT	IgG card

4. If no testing performed on the VISION, initial the applicable box on Ortho VISION Maintenance Record. Daily Quality Control Peer Review is not applicable (NA) when no testing is performed and the corresponding box on Ortho VISION Maintenance Record should indicate "NA."

C. QC Procedure

1. Confirm that all cards and MTS Anti-IgG cards are loaded. If necessary, load new cards.
    a. If a new lot of cards needs to be added, go to Vision - Changing Reagent Lots on the VISION.

2. Load Alba-Q Chek QC vials.
    a. If loading a new lot of Alba-Q Check QC vials or any VISION reagent, go to Vision - Changing Reagent Lots on the VISION.

3. Place vials into a sample rack.
    a. In Diagram View, select Samples.
    b. Choose and highlight a position (1 – 6) and select Load / Unload.
    c. Open the Load Station door and place the sample rack in the lower rotor position.
    d. Close Load Station door.
4. Select QC menu. (Touch > to expand the menu).
5. Daily QC: All QC profiles must be selected separately. QC testing will not begin until the Alba-Q Check QC Vials are loaded onto the analyzer.
6. Select 8 main profiles to be **tested daily. NOTE:** Allow first 5 daily QC profiles to pipette before ordering the Weak D/Weak D2 profiles for smoothest performance.
    a. 3CELL
    b. ABO3CELL
    c. ABO RH
    d. ABORH2
    e. DONOR
    f. Weak D
    g. Weak D2
    h. Buffer Card

7. Select Other As Needed QC profiles when appropriate.
8. After choosing the profile, select Run QC job for each test.
9. Confirm correct reagent and card lot numbers to QC for each test.
10. Touch "Save" for each test.
    a. As long as the QC sample is loaded, with the corresponding Ortho card, then the QC will start after save is touched.
11. When testing is complete, review results.
    a. If QC is valid, it will be accepted.
        i. One may need to manually review results (Procedure: Vision - Manually Reviewing or Printing Results) before the results are accepted and QC valid.
    b. If results are not acceptable, determine the cause, correct problems, and rerun QC (go to step C.5).
12. Initial on the Ortho VISION Maintenance Record when QC and maintenance testing is complete.

D. Complete the Daily Quality Control Peer Review

1. Ask a peer tech to review the completeness of the Ortho VISION Maintenance Record form.
    a. If the document is complete, the tech should initial in the applicable box on Ortho VISION Maintenance Record.
    b. If the document is incomplete, the tech should not initial but hand the form back to the testing tech for correction. After correction, then repeat steps in D.1 until acceptable.
    c. If a peer tech is not available to review form for completeness, then notify the next appropriate tech (next shift) to review the document.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition

AABB Standards, current edition

CAP Standards, current edition

IX. FORMS/APPENDICES

Ortho VISION Maintenance Record

X. APPROVAL BODY

None

PROCEDURE #:

BBV 105

Indiana University Health	**Original Creation Date:** 07/12/2017	**Publication Date:** 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 07/28/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

Vision - Changing Reagent Lots on the VISION

I. PURPOSE

To provide instruction for changing reagent lots on the Vision analyzers.

II. SCOPE

This SOP addresses the steps for changing the reagent lots used on the Vision analyzers. This SOP applies to MT-I, MT-II, and Lab Assistant II team members trained to operate the Visions.

III. STATEMENT/REQUIREMENTS

None

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

QC: Quality Control

V. EQUIPMENT/RESOURCES

Equipment:

Ortho Vision/Vision MAX

Reagents:

Applicable Vision Reagents and/or QC

VI. PROCEDURE

A. Changing Alba-Q QC Lots

1. Touch the QC Menu Button.
2. Select the profile to be processed then touch the "RUN QC JOB" action button at the bottom of the screen.
3. To configure the QC:
   a. Touch "Change" Ortho QC Sample ID (left hand column on the screen)
   b. Enter the lot number of the QC reagent into the Sample ID box by scanning the barcode on the tube, using the handheld barcode scanner or manually entering.
   c. The QC reagent manually entered or scanned must match the same QC reagent vial number as previously entered.

Profile	QC Vial Number
ABORH	3
ABORH2	2
ABO/3CELL	1
3CELL	2 and 3
DONOR	3 and 1
WEAK D	Surgiscreen Cell 3
WEAK D2	Surgiscreen Cell 1
Buffered Card	1

d. If manually entering the lot number of the QC reagent into the Verify Sample ID box, one must enter it a second time

e. If using the barcode scanner, a second entry is not necessary.

4. Repeat steps A.1-3 for all QC profiles.

B. Changing Lot Numbers of ID-MTS Gel Cards and Reagent Red Cells

1. Load lots requiring QC.
2. Touch QC. Touch the applicable QC Profile (see BBV-105 Ortho Vision Daily QC).
3. Touch Run QC Job.
4. To configure the ID-MTS Gel Cards and Reagent Red Cells
   a. Touch a **card lot** for each of the required card type or **reagent lot** for each required reagent kit (left hand column of screen).
   b. If there is more than one required lot loaded on the instrument, the default selection is the lot that was most recently registered.
   c. Touch the **card lot or reagent lot** twice to view all the lots that are loaded on the analyzer.
   d. For Weak D Testing, a vial of AlbQ QC method is not used.
      i. Surgiscreen 3 and 1 are used for this testing.
      ii. Update of the weak D reagent, and the NaOH for this change is scanned by the analyzer.
         1. Surgiscreen must be manually changed in this screen.
5. Select Manual Rev. Required, and touch Yes.
6. Touch Save. The system processes the QC job that was requested.
7. Repeat steps B.1-6 to QC other lots that are loaded.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERTIONS

None

VIII. REFERENCES

Ortho Clinical Diagnostics, current edition Vision Operator Manual

IX. FORMS/ APPENDICES

None

X. APPROVAL BODY

None

PROCEDURE #:

BBV 009

Indiana University Health	Original Creation Date: 07/12/2017	Publication Date: 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	Next Review: 07/28/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

Procedure: Vision - Daily Maintenance

I. PURPOSE

To provide instructions for mandatory daily maintenance (24 hour period) tasks for operation of the Vision. This SOP addresses the procedural steps to complete mandatory daily maintenance tasks for operation of the Vision.

II. SCOPE

This SOP is intended for all MT-I, MT-II, and Lab Assistant II team members that have been trained to operate the Vision.

III. STATEMENTS/REQUIREMENTS

A. QC and Maintenance are rotated to all team members.

B. Analyzer QC and Maintenance is rotated to all shifts to ensure expertise by all team members on the automated platform.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CAP: College of American Pathologists

SOP: Standard Operating Procedure

V. EQUIPMENT/RESOURCES

Equipment:

Ortho Vision/Vision MAX

Vision Diluent Rack

Vision Agitated Reagent Rack

Vision Liquid Waste Bottle

Vision Liquid Container

Reagents:

0.1 Normal NaOH

70% isopropyl alcohol

7% BSA (Bovin Serum Albumin)

0.9% Saline

Deionized Water

Ortho MTS Diluents, 2 and 2 Plus

Ortho Affirmagen Reagent Cells Ortho Surgiscreen Reagent Cells

Ortho AlbaQ-Chek QC reagents

Supplies

Lint-free wipes

10 ml glass vial with barcode

Transfer pipet

Evaporation caps

VI. PROCEDURE

A. Perform probe maintenance.

1. In the Home screen, select the Maintenance tab from the Menu bar.
2. Select Stop Processing and confirm by pressing the new Stop Processing prompt. The Vision may take a few seconds to finish processing.
3. Select Daily > Select Enter Maintenance Mode.
4. Select Daily Probe Maintenance > Press Execute button.
5. When prompted, open the Load Station Door.
   a. For Visions: With a transfer pipette, add 5 mL of 0.1 N NaOH to a 10 mL vial with a supported barcode.
   b. For Vision Max: With a transfer pipette, add 7 mL of 0.1 N NaOH to a 10 mL vial with a supported barcode.
      i. 0.1 N NaOH is obtained from the vendor.
      ii. Log the 0.1N NaOH into the blood bank reagent inventory SOP BBQC 052 Reagent/Supplies Inspection & Receiving .
   c. Place the vial into position 3 of a Diluent Rack.
   d. Place a new 5 ml or required 12 mL (dependent on the Vision) vial of ORTHO 7% BSA into position 2.
      i. Load the Diluent Rack in the Sample Rotor position.
      ii. Use a new vial of BSA each time.
      iii. Do not combine open vials for 5 mL vials, but 5 mL vials may be combined for use when 12 mL vials are not available. Follow instructions on the analyzer for combination of vials for the larger volume of BSA.
   e. Close the Load Station Door.
6. When prompted open the Maintenance Door.
   a. Clean the Probe(s) with a lint free cloth moistened with 70% isopropyl alcohol.
      i. **WARNING:** Be careful when cleaning to not cause harm to the probe. Be gentle and avoid bending probes.
   b. Close the Maintenance Door. (Door is locked in place until the blue release button on lower left hand side of door is pressed.) The system will automatically complete the decontamination.
7. When prompted, open the Load Station Door.
   a. Remove the Diluent Rack

b. Whenever possible, replace with alternate Diluent Rack.
    i. The 2 Diluent Racks will be alternated every day.
    ii. There should be one bottle of each, MTS Diluent 2 and MTS Diluent 2 Plus on the rack. Remove Diluent lids before loading on the Vision.
    iii. If an alternate rack is not available, then one may be use the same rack and rotate the bottles of diluent.

B. Perform Liquid System Monitoring
1. For proper system operation, the Liquid Container Bottles must be filled to capacity and the Liquid Waste Bottle must be completely emptied.
2. From the Dashboard touch Resources > Liquids > Refill.
    a. A message will display on the screen indicating that the Liquids Door can be accessed.
    b. If the door is not opened within 20 seconds the system will lock it.
3. Open the Liquids Door and pull the Bottle Release for the Liquid Container.
    a. A dialogue screen will be displayed when the Liquids Door is opened.
    b. CAUTION: After opening the door, the system allows 2 minutes to execute the following steps.
    c. Failure to close the door within the allotted time may increase the possibility of serological time-out errors, including the potential non-agitation of red cell reagents.
4. Remove the Liquid Container from the system.
    a. Remove the 2 bottle caps.
    b. Inspect the inside of the Liquid System Bottle for any particles. Inspect the outside of the bottle for any liquid residue or contamination. Clean as necessary.
    c. Fill the saline. The containers may be marked to designated volume.
        i. For single bottle analyzer, add labeled 1000 mL deionized H2O and 4200 mL saline.
        ii. For double bottle analyzer, add labeled 1000 mL deionized H20 and 4700 mL saline along with 4700 mL in the second saline bottle.
    d. Install the bottle caps.
    e. Push the container(s) back into the system either manually or with the Bottle Insertion Tool until it snaps into place.
5. Pull the Liquid Waste Bottle Release and remove the Liquid Waste Bottle from the system.
    a. Discard the Waste.
        i. For waste bottles on the analyzer:
            a. Remove the waste bottle.
            b. Remove the Liquid Waste Bottle cap.
            c. Dispose of the waste according to laboratory guidelines.
        ii. For waste containers outside of the analyzer:
            a. Remove the tubing from the waste container.
            b. Remove the Liquid Waste Bottle cap
            c. Dispose of the waste according to laboratory guidelines.
    b. Inspect the inside of the Liquid Waste Bottle for any particles. Inspect the outside of the bottle for any liquid residue or contamination. Clean as necessary.
    c. Re-install the waste.
        i. Install the bottle cap and place the Liquid Waste Bottle back into the system either manually or with the Bottle Insertion Tool until it snaps into place.

ii. Alternately, for the waste container re-connect the tubing to the waste container to place/re-install the waste for the analyzer.

d. Close the Liquids Door.

e. Select "Yes" onscreen to confirm that the Saline Bottle is filled to 4700 ml, the Deionized H2O is filled to 1000 ml, and the Waste bottle is empty.

C. Select Show Health Check Report from bottom of screen.

1. Verify that all conditions are OK and save results.

D. Diluent/RBCS/Reagent Rotations

1. Rotate the following daily:
   a. Diluents (Diluent 2 and Diluent 2 plus)
   b. RBCs (Surgiscreen I,II, III and Affirmagen A1, BC)
   c. Reagents (anti-D and NaOH 10 mL labeled bottle)
2. Per the manufacturer's suggestion, the reagents should not be on-board the instrument for longer than 5 days. That is why IUH had decided to rotate the reagents daily to allow for longer stability.
3. If the volume or availability of reagents (diluent or RBC reagents) does not allow for rotation of the reagents, as long as the reagents are in date then one may use the reagents. One should take the reagents off the instrument (Vision - Load/Unload Reagents) at the end of testing to conserve stability.
4. Select Resources.
5. Select Reagent or Diluent.
6. Select Load/Unload either the Diluent Rack or the Reagent Rack.
7. Obtain the second set of diluent bottles or RBCs from Vision Reagent storage.
8. Follow directions on screen to remove previous day's diluent and RBC rack and replace with the second set of the same reagent lot
   a. There should be one set of Affirmagen reagent cells and one set of Surgiscreen reagent cells on the rack.
   b. There are Evaporation Caps on all RBC reagent cell vials and anti-D reagent. Replace any evaporation caps, as needed.
   c. No evaporation caps are needed on the diluent trays.

E. Run Daily QC. See Ortho Vision Daily QC .

F. Document completion of maintenance tasks on Ortho VISION Maintenance Record BBV F101.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.

AABB Standards, current edition.

CAP Standards, current edition

Ortho VISION User's Guide, current version.

Quality System, AABB/IU Health.

IX. FORMS/ APPENDICES

Ortho VISION Maintenance Record

X. APPROVAL BODY

None

PROCEDURE #:

BBV 101

Indiana University Health	**Original Creation Date:** 07/12/2017	**Publication Date:** 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 07/28/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

Vision - Running CORD profile

I. PURPOSE

To provide instruction for running a CORD profile when testing is not interfaced.

II. SCOPE

This SOP addresses the steps of loading and ordering a CORD profile on the Vision. This SOP is intended for any MT-1, MT-2 team members. Lab Assistant II team members may load samples only.

III. STATEMENTS/REQUIREMENTS

A. Specimen Requirements

1. See SOP BBT 011 Requisition & Specimen Processing for specimen requirements in addition to the following:
    a. Check specimen for clots before spinning.
    b. If clots are found, remove clots and spin down or sample may be tested as whole blood.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

V. EQUIPMENT/RESOURCES

Equipment

Ortho Vision/Vision MAX

Supplies

Vision sample racks

Vision reagent racks

Evaporation caps

Reagents

Ortho A1/B Cells

Ortho Diluent 2

Ortho Diluent 2+

IgG cards

ABD monoclonal cards

Anti-D reagent

0.1 N NaOH

VI. PROCEDURE

A. Load Reagents

1. Load reagents on to Vision according to SOP BBV 006 Vision - Load/Unload Reagents.

B. Load Patient Samples

1. Load sample on to Vision according to SOP BBV 005 Vision - Load/Unload Patient Samples.

C. Create Profile Order

1. Select specimen on sample screen
2. Press the **Create Order** action button
3. Press the **Assigned Profiles** tab on the left side of the screen
4. Select **CORD** profile
    a. CORD profile is made up of newborn ABO/Rh and MTS-DAT.
    b. If the CORD profile Rh is negative, it reflexes to a Weak D test.
    c. If the Weak D is positive, then evaluate the MTS DAT results.
        i. If the Weak D and MTS DAT are positive, the results may be invalid and testing should be repeated.
            1. Refer to the supervisor for next steps, if repeat testing remains the same.
        ii. If the Weak D is positive and the MTS DAT is negative, accept results and report.
5. After the profile is selected press the **Save and Start** button in the lower right-hand corner.

D. Review Results

1. If results were auto-accepted and sent to LIS, remove specimen form Vision SOP BBV 005 Vision - Load/Unload Patient Samples and verify the results in Cerner according to SOP BBCE 005 Result Entry.
2. If grades/results were edited and manually accepted BBV 010 Procedure: Vision - Manually Reviewing or Printing Results), send results to LIS by touching the **Send to LIS** button before removing specimen (BBV 005) and resulting in Cerner (BBCE 005).

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.

AABB Standards, current edition.

Quality System, AABB/IU Health.

Ortho Clinical Diagnostics, Vision Operator Manual, current edition

IX. FORMS/APPENDICE

None

X. APPROVAL BODY

None

PROCEDURE #:

BBV 207

Indiana University Health	**Original Creation Date:** Not Set	**Publication Date:** 08/04/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	**Next Review:** 08/04/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (08/04/2022)		

Vision: Weak D Testing

I. PURPOSE

To detail the procedure for weak D testing using the Ortho Visions.

II. SCOPE

This SOP applies to MT-I and MT-II team members. Lab Assistant II team members may load samples only.

III. STATEMENTS/REQUIREMENTS

A. All Ortho vision instruments will have quality control performed each day of use according to SOP Ortho Vision Daily QC.

B. **Specimen Requirements**

Neonates – 3 years	2	Lavender or pink microtainers
3 years - Adult	1	3 mL or 6 mL lavender or pink top tubes
NOTE: Microtainer tubes are accepted if quantity is sufficient for testing		
NOTE: NO SERUM SEPARTOR TUBES ACCEPTED.		
Specimen suitability- refer to Department of Pathology and Laboratory Medicine Directory of Services for precautions and acceptability of specimens.		

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CAP: College of American Pathologists

LIS: Laboratory Information System

V. EQUIPMENT/RESOURCES

Ortho Vision/Vision MAX

Vision Sample Racks

Vision Reagent Racks

MTS IgG cards

VI. PROCEDURE

A. Vision Loading.

1. These reagents require a switch to "Ortho Sera" view when looking at the rotor/reagent screen.
    a. Load Anti-D (IAT) and 0.1N OH reagent on to Vision according to Procedure BBV 006 Vision - Load/Unload Reagents
    b. Use rack #N5B.
2. Load patient samples on to Vision according to Procedure BBV 005 Vision - Load/Unload Patient Samples .
3. Load MTS IgG cards onto Vision according to Procedure BBV 008 Vision-Load MTS Cards.

B. Create Profile Order for Non-CORD or Non-nABORH samples.

1. Select "Specimen" on sample screen
2. Press "Create Order" action button.
3. Press "Assigned Profiles" tab on the left side of the screen.
4. Select applicable "Weak D/Weak D2 Profile Testing".
5. After profile is selected press the "Save and Start" button in the lower right-hand corner.

C. Reflexed Order from CORD or nABORH/nABORH2 Profile Testing

1. Verify completed CORD profiles that yield an Rh negative result have reflexed to run weak D profile
2. Verify completed nABORH/nABORH2 that yield an Rh negative result have reflexed to run a corresponding weak D/ weak D2 profile.

D. Review Results

1. If results were auto-accepted and sent to LIS, remove specimen from Vision (BBV 005 Vision - Load/Unload Patient Samples) and verify results in Cerner (Result Entry).
2. If grades/results were edited and manually accepted (Procedure BBV 010 Procedure: Vision - Manually Reviewing or Printing Results), send results to LIS by touching "Send to LIS" button.
3. Do not report positive weak D results if MTS DAT is also positive.
    a. If the DAT is positive, the weak D results are invalid.
        a. Result ABO/Rh as "undetermined" and file for Medical Director review.
        b. The patient will require Rh negative RBCs until accurate weak D testing can be completed.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition

AABB Standards, current edition

CAP Standards, current edition

IX. FORMS/APPENDICES

None

X. APPROVAL BODY

None

PROCEDURE#:

BBV 221

Indiana University Health	Original Creation Date: 07/07/2022	Publication Date: 07/28/2022
	Owner: Elaine Skipworth (Director-Lab Transfusion Medicine)	Next Review: 07/28/2024
	Category: Labs AHC	
	Education: Level 4	
Approval Signatures: Muhammad Idrees (Physician) (07/28/2022)		

Vision - Running Newborn ABO/Rh (nABO/Rh) and Newborn Retype (nABO/Rh2) Profile

I. PURPOSE

To provide instruction for running a nABO/Rh and nABO/Rh2 profile when testing isn't interfaced.

II. SCOPE

This SOP addresses the steps of loading and ordering a nABO/Rh and nABO/Rh2 profile on the Vision. This SOP applies to MT-I and MT-II team members. Lab Assistant II team members may load samples only.

III. STATEMENTS/REQUIREMENTS

A. Specimen Requirements

1. Refer to SOP BBT 011 Requisition & Specimen Processing.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

V. EQUIPMENT/RESOURCES

Equipment:

Ortho Vision/Vision MAX

Supplies:

Vision sample racks

Vision reagent racks

Evaporation caps

Reagents:

Ortho A1/B cells

Ortho diluent 2

Ortho diluent 2+

ABD monoclonal cards

VI. PROCEDURE

A. Load Reagents

1. Load reagents on Vision according to SOP BBV 006 Vision – Vision - Load/Unload Reagents.

B. Load Patient Samples

1. Load sample on Vision according to SOP BBV 005 Vision – Vision - Load/Unload Patient Samples.

C. Create Profile Order

1. Select specimen on sample screen
2. Press the **Create Order** action button
3. Press the **Assigned Profiles** tab on the left side of the screen
4. Select **nABO/Rh, nABO/Rh2 or both** profile(s).
5. After the profile is selected, press the **Save and Start** button in the lower right-hand corner.

D. Review Results

1. If results were auto-accepted and sent to LIS, remove specimen form Vision (BBV-005) and verify the results in Cerner (BBCE-005 Result Entry).
2. If grades/results were edited and manually accepted (BBV-010 Vision - Procedure: Vision - Manually Reviewing or Printing Results), send results to LIS by touching the **Send to LIS** button before removing specimen (BBV-005) and resulting in Cerner (BBCE-005 Result Entry).

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Standards, current edition

AABB Technical Manual, current edition

Ortho Clinical Diagnostics, Vision Operator Manual, current edition

Quality System, AABB/IU Health

IX. FORMS/APPENDICES

None

X. APPROVAL BODY

None

PROCEDURE #:

BBV 220