PROCEDURE
Corewell Health East - Newborn Blood Bank Work Up and Cord Blood Evaluation - Blood Bank - All Beaumont Hospitals

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

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

A. This procedure outlines the process to be used by Blood Bank staff to determine if there is serologic evidence for Hemolytic Disease of the Newborn (HDN) that any antibodies of maternal origin may cause or to determine possible Rh Immune globulin candidacy for the mother. This testing includes a blood type, direct antiglobulin test (DAT), and any other indicated testing as outlined in the procedure below on cord blood or neonatal heel stick specimens.

B. With HDN, red blood cells (RBCs) of the fetus become coated with IgG alloantibody of maternal origin. This alloantibody is directed against an antigen of paternal origin that is present on the fetal RBCs. The sensitized RBCs undergo accelerated destruction before and after birth.

C. Clinical severity of the disease is extremely variable, ranging from intrauterine death to a condition that can be detected only by serologic tests. The most severe cases of HDN are usually caused by antibodies in the Rh system (primarily Anti-D), while those cases that are only detectable serologically are most often due to ABO incompatibility. Sometimes the offending maternal antibody is directed at a paternal antigen of low frequency in the general population and is, therefore, difficult to detect and identify. The Cord Blood Evaluation and Newborn Blood Bank Workup test profiles are designed to determine whether serologic evidence of HDN exists.

2. Responsibility

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

3. Definitions

A. **HDN**: also referred to as HDFN, HDNB; Hemolytic Disease of the Fetus/Newborn. The destruction of fetal or newborn red blood cells by maternal alloantibodies specific for inherited paternal red cell antigens.

B. **CORDE**: Cord Blood Evaluation test code

C. **NEWBRNBBES**: Newborn Blood Bank Workup test code

D. **Unexpected antibodies**: any antibody (other than naturally occurring Anti-A or Anti-B that is regularly found in normal serum or plasma) that is currently or was historically present in a patient's sample.
E. **Passively acquired antibodies**: antibodies that are transferred from the donor(s) to a recipient through the transfusion or administration of plasma-containing components (i.e., RhIG administration).
F. **Alloimmunization**: the process whereby a recipient forms antibody in an immune response to foreign antigens on donor RBCs.
G. **Neonates**: from birth to 4 months of age.
H. **Clinically significant antibody**: an antibody that:
    1. is known to cause Hemolytic Disease of the Newborn (HDN) or shortened survival of antigen positive RBCs, and
    2. requires transfusion of antigen negative red cells, and
    3. is usually IgG and best detectable with antihuman globulin (AHG).
I. **Clinically insignificant antibody**: an antibody that:
    1. does not cause shortened red cell survival of antigen positive RBCs, and
    2. does not require transfusion of antigen negative red cells, and
    3. is usually IgM and reacts best below 37C.
J. **HIS**: Hospital Information System; the hospital-wide computer system, patient electronic health record.
K. **LIS**: Laboratory Information System
L. **BBIS**: Blood Bank Information System
M. **Standard panel**: a commercially prepared panel that usually consists of 11 vials of human RBCs. It is usually performed on patients who do not have a historical antibody record.
N. **Selected cell panel**: a panel that is pre-selected based on the antigenic profile of the test RBCs.

4. Specimen

A. It is the policy of the Labor and Delivery department that a cord blood specimen is collected on all deliveries.
    1. Blood is collected from the infant's umbilical cord at the time of delivery and is placed in a labelled pink EDTA tube.
    2. If the cord blood sample volume is insufficient for testing, mislabeled or no cord blood sample is available, a Newborn Blood Bank Workup order may be requested and a heel stick specimen collected in EDTA.
    3. Neonatal Microtainer Samples (heel stick) specimens are frequently used to perform Type and Screens on newborns.
        a. If the requested test is Type and Screen (not Newborn Blood Bank Workup), refer to Transfusion Medicine Policy Corewell Health East - Newborn Compatibility Testing Guidelines - Blood Bank - Dearborn, Farmington Hills, Royal Oak, Troy.
        b. Do not perform a DAT and do not perform testing to verify HDN.
B. Cord Blood Labeling Policies/Not Acceptable for Transfusion Purposes
    1. Cord blood samples are labeled according to Transfusion Medicine policy Corewell Health East - Triaging And Identifying Acceptable Samples For Testing- Blood Bank - All Beaumont Hospitals.
    2. Cord blood samples are not acceptable for transfusion purposes. If a neonatal transfusion is required, a direct sample from the infant is required. Refer to Transfusion Medicine Policy Corewell Health East - Newborn Compatibility Testing Guidelines - Blood Bank - Dearborn, Farmington Hills, Royal Oak, Troy.
C. Neonatal Microtainer® Labeling Policies
    1. A properly labeled neonatal microtainer® sample is acceptable for transfusion purposes. These specimens should be collected for testing when a cord sample was not collected, and neonatal testing is indicated or when a neonatal transfusion is needed. Neonatal microtainer® samples are labeled according to Transfusion Medicine policy Corewell Health

East - Triaging And Identifying Acceptable Samples For Testing- Blood Bank - All Beaumont Hospitals.

5. Reagent/Equipment Needed

A. Ortho BioClone Anti-A
B. Ortho BioClone Anti-B
C. Ortho BioClone Anti-D
D. Ortho 7% BSA
E. Immucor Gamma Clone Anti-D
F. Immucor Gamma Clone Control
G. MTS™A/B/D Monoclonal and Reverse Grouping Cards
H. MTS™ Diluent 2 Plus
I. Ortho MTS™ Anti-Human Globulin Anti-IgG (Rabbit) Anti-IgG Card
J. Ortho MTS Diluent 2™ (a hypotonic buffered saline solution)
K. Transfer pipettes
L. Pipette Tips
M. Gauze
N. Test Tubes, 10x75mm and/or 12x75mm, plastic or glass
O. Blood Bank Isotonic Saline
P. Automated Method
    1. ORTHO VISION™ Analyzer
Q. Manual Gel Method
    1. MTS Centrifuge or Ortho Workstation
    2. Calibrated pipette (electronic or manual)
R. Tabletop centrifuge
S. Lighted agglutination viewing mirror

6. Quality Control

A. Ortho Vision™ and Manual Gel Testing
    1. Daily quality control for the Ortho Vision™ instruments are performed as described in Transfusion Medicine policy Corewell Health East - ORTHO VISION Analyzer QC - All Beaumont Hospitals.
    2. Daily quality control for the Manual Gel reagents are performed as described in Transfusion Medicine policy Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals.
B. Manual Tube ABO/Rh(D) and Weak D Testing
    1. Daily quality control of ABO and Rh testing is performed as described in Transfusion Medicine Policy, Corewell Health East - Quality Control of Blood Bank Reagents - All Beaumont Hospitals.
    2. Weak D testing should not be performed on samples with a positive direct antiglobulin test (DAT); false-positive weak D results may be obtained.
    3. IgG-coated RBCs are used as a control if the graded reaction of the weak D test is negative. The graded reaction after the addition of the IgG-coated RBCs must be positive. If the requirements are not met, then the weak D test is not valid and must be repeated.

7. Procedure

A. Ordering of the Cord Blood Evaluation (CORDE) or Newborn Blood Bank Workup (NEWBRNBBES) is ultimately the responsibility of the patient's physician. The testing shall generally be performed in the following situations:
    1. Whenever it is ordered by the caregivers (for example: due to possible ABO incompatibility between the mother and infant)
    2. Babies born to Rh negative mothers to determine respective RhIG candidacy
        a. If testing has not been ordered by the caregiver, Blood Bank will reach out to request order to be placed.

3. When clinically significant maternal unexpected antibodies are present:
   a. In the current maternal sample
   b. In the neonatal antibody screen (Note: a neonatal antibody screen is generally not indicated but is indicated if a transfusion is required and a maternal sample is unavailable.)
   c. Note the following exceptions: The following maternal antibodies are not routinely considered clinically significant: Anti-M, Anti-Le^a, Anti-Le^b, Anti-Lu^a, Anti-I, Anti-H, Anti-P1, Anti-A_1, a cold reacting antibody of unknown specificity or cold autoantibody (CLD), or reactions due to reagent preservatives (NSG). These antibody specificities are generally not associated with causing HDN. This may be because the corresponding neonatal antigens are not well formed at birth, and/or because the antibodies are usually IgM and therefore do not cross the placenta.

   Note: If testing is not ordered by the caregiver, the testing should be added on as an automatic reflex test per Corewell Health East procedure Corewell Health East - Laboratory Reflex Testing - All Beaumont Hospitals.

B. Neonatal ABO/Rh Testing Policies
   1. The preferred method of ABO/Rh testing for cord blood samples is in gel on the Ortho Vision.
   2. The alternate method of ABO/Rh testing for cord blood samples and primary method for neonatal microtainer samples is manual tube.
   3. Refer to Transfusion Medicine policy Corewell Health East - Forward Typing Determination Of Neonatal ABO and Rh - All Beaumont Hospitals.
C. Neonatal Direct Antiglobulin Test (DAT) Policies
   1. The preferred method for DAT testing of cord blood samples is in gel on the Ortho Vision.
   2. The alternate method of DAT testing of cord blood samples and primary method for neonatal microtainer samples is manually in gel (not tube method).
   3. Refer to Transfusion Medicine policy Corewell Health East - Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method - All Beaumont Hospitals.
D. Specimen Receipt
   1. Receive the specimen in BBIS in accordance with the Transfusion Procedure, Corewell Health East - Triaging And Identifying Acceptable Samples For Testing- Blood Bank - All Beaumont Hospitals.
   2. It is necessary to select the testing to be performed on the specimen:
      a. Go to Tests Tab
      b. Check box for Pending **CORD E S** or **NEWBRNBBES** Test Battery
         1) Click Results Button
         2) Click Add → Test
         3) Mark the checkboxes for ABORhFWDES and DATIGGGEL test codes.
            a) Note: For cord blood specimens tested on the Ortho VISION it is very important to add the tests in that order (ABORh first and DAT second) to help prevent duplicate testing on the automation.
            b) Do not select ABORhFWDG as this test code does not include the control well.
         4) Click Select.
         5) Click Cancel to exit screen.
E. Cord Blood Testing using the Gel Method on the Ortho Vision Analyzer
   1. Cord Blood Samples drawn in EDTA tubes are required when performing neonate testing on Ortho Vision. If a heel stick is drawn in a microtainer or if the cord specimen is received in a red top (no anticoagulant) tube, then testing must be performed using alternative manual methods.
   2. Rim out the patient sample using wood applicator sticks to remove any clots that may be present.
   3. Centrifuge the patient sample for 10 minutes at the centrifuge's calibrated speed to obtain packed red blood cells.
   4. Load the patient samples onto the Ortho Vision. Testing should begin automatically once the samples are scanned by the instrument.

a. Specimen caps should be removed prior to loading on the Ortho Vision
b. Refer to Transfusion Medicine procedure, Corewell Health East - Routine Testing on the ORTHO VISION Analyzer - All Beaumont Hospitals for additional information.

Note: If the Ortho Vision is unable to perform the testing, the ABO/Rh testing is performed by Manual Tube Method and the DAT is performed using Manual Gel Method, see procedure below.

5. Upon completion, the test results will interface to the BBIS or require manual review.
   a. If the test results interface automatically, they should be verified in the BBIS as described in Transfusion Medicine policy, Corewell Health East - Blood Bank Autoverification Policy - All Beaumont Hospitals.
   b. If the test results require manual review, proceed as described in Transfusion Medicine procedure, Corewell Health East - ORTHO VISION Analyzer Manual Card Review - All Beaumont Hospitals.

F. Cord Blood Evaluation and/or Newborn Blood Bank Workup Using the Alternative Manual Methods
   1. Perform the ABO/Rh (Forward Type Only) in accordance with Transfusion Medicine procedure Corewell Health East - Forward Typing Determination Of Neonatal ABO and Rh - All Beaumont Hospitals.
      a. Note: To prevent erroneous results due to Wharton's jelly, all cord blood samples are to be washed 4 times with saline prior to testing by tube methods. Neonatal specimens that appear Rh negative require further confirmation before results should be reported. See procedure step 3.
      b. Perform Manual Gel DAT in accordance with Transfusion Medicine policy Corewell Health East - Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method - All Beaumont Hospitals. Record results in BBIS using the Transfusion Medicine procedure, SafeTrace (Blood Bank) Application - East.
   2. Cord blood or neonatal microtainer specimens that appear to be Rh negative using only manual tube method must be repeated for Rh(D) type using the Immucor Gammaclone Anti-D reagent and Gamma clone Rh Control. Document these test results in the BBIS using the ABO/Rh Repeat (ABOR) test code. If the results with the 2 different Anti-D reagents are different, refer to Transfusion Medicine policy Corewell Health East - Resolution of ABO and Rh Discrepancies - Blood Bank - All Beaumont Hospitals.
   3. Weak D: If the neonatal blood type has only been tested in tube method and appears to be Rh negative Weak D testing must be completed if the mother is Rh negative. An Rh control must be included in the Weak D test.
      a. The weak D results are not valid if the specimen has a positive DAT and/or positive Rh control. Interpret the Rh as negative with free text result comment "Unable to determine infant's Rh. Infant will be considered Rh Negative for Transfusion Purposes. Infant's mother should receive a post-partum dose of RhIG." Refer to Transfusion Medicine Policy Corewell Health East - Weak D Testing - All Beaumont Hospitals.

G. Additional Testing - Additional required testing is described in the attachment *Newborn Blood Bank Workup and Cord Blood Evaluation – Testing and Result Comments* (33741-1)
   1. Antigen Testing
      a. Indications for antigen testing include:
         1) Maternal clinically significant antibody in current specimen
            a) Note: Antigen typing will not be completed for antibodies to low incidence antigens without reagent antisera available. Refer to attachment 33741-1.
      b. As described in Transfusion Medicine policy, Corewell Health East - Antigen Typing - Blood Bank - All Beaumont Hospitals, the following factors must be considered:
         1) Neonatal transfusion history (if applicable).
         2) Neonatal DAT results. RBCs with a positive DAT result cannot be accurately tested with typing reagents that require an Indirect Antiglobulin Test (IAT).
         3) Note: A1 antigen typing should not be performed on neonates. ABO antigens are not well developed on a neonate.

2. Eluate Testing
    a. Indications for eluate testing include a positive DAT result and one or more of the following:
        1) No ABO incompatibility, DIG/recent RhIG administration, and no maternal clinically significant antibodies
        2) Maternal Warm Autoantibody (WRM), Unidentified Antibody (WkU), Anti-D of Unknown Origin (DNK)
        3) Maternal history of only D Passive antibody, no ABO incompatibility, and baby is Rh Negative
        4) Maternal clinically significant antibody
        5) For the following scenarios the technologist should consult with the Blood Bank MD to determine eligibility for eluate testing:
            a) ABO Incompatibility with DAT 3+ or greater
            b) Passive Anti-D with DAT 3+ or greater
    b. If an unexpected antibody has been identified in the maternal sample or history, then the eluate should be tested against a selected cell panel. The test cells should include the following:
        1) 3 cells that are positive for the antigen corresponding to the maternal antibody
        2) Appropriate cells to perform antibody exclusions (rule-outs).
    c. If unexpected antibody(ies) have been detected in the maternal sample or history but have not been identified (i.e. weak unidentified) then the eluate should be tested against a standard cell panel.
    d. If the Blood Bank is already performing an eluate due to unexpected maternal antibodies, and the neonatal DAT is positive with an ABO incompatibility, then the eluate should also be tested against 2 examples each of A1 and B cells (use a set of reverse cells, an A-negative donor cell, and a B-negative donor cell).
    e. If an unexpected antibody is identified in the eluate (one that was not previously identified in the maternal sample or maternal history) then the Medical Director should be consulted.

H. Special Situations
1. ABO Incompatibility
    a. The mother and neonate are considered ABO incompatible when the maternal plasma contains ABO antibodies that correspond to ABO antigens present on the neonatal RBCs. For example, when the mother is group O (Anti-A and Anti-B are present in her plasma) and the baby is group A or B. Many positive neonatal DATs can be explained by an ABO incompatibility. The Blood Bank will not perform a neonatal eluate due to ABO incompatibility, unless:
        1) The neonatologist specifically requests an eluate.
        2) The DAT was 3+ or greater.
        3) The Blood Bank is already preparing an eluate due to unexpected maternal antibodies.
2. Recent RhIG administration with a maternal negative antibody screen and no other antibody history or ABO incompatibility
    a. If there is a maternal history of receiving RhIG in the previous 4 months for an Rh-positive infant with no ABO Incompatibility and a positive DAT (≤2+) the positive DAT can be assumed to be due to the recently administered RhIG, without need for an eluate.
3. Suspected Maternal Antibody to a Low Prevalence (paternal) Antigen
    a. This could happen when the father passes a low prevalence antigen to the fetus, and the mother develops the corresponding antibody to this fetal antigen. The neonate's DAT may be strongly positive, but the maternal antibody screen may be negative (because the screen cells do not include test cells with the low prevalence antigen). If a maternal antibody to a low prevalence antigen is suspected, consult the supervisor or Medical Director. Testing with the paternal sample may be required to confirm the presence of a maternal antibody to a low prevalence antigen.

4. Blocking: Possible False Negative Antigen Typing
    a. Anti-D and Anti-K have the potential to cause blocking. Blocking may occur when the mother has Anti-D or Anti-K, and the neonatal RBCs become heavily coated with maternal antibody. Testing of the neonatal RBCs may yield a false negative result. Therefore, if the maternal antibody is allo Anti-D or Anti-K, and the neonatal DAT is positive, an eluate will be performed regardless of the neonatal antigen typing (as described in the Procedure section of this document).

8. Results/Interpretation

A. Interpretation:
    1. ABO and Rh test: Refer to Transfusion Medicine Procedure Corewell Health East - Forward Typing Determination Of Neonatal ABO and Rh - All Beaumont Hospitals for interpretation guidelines.
    2. Gel DAT: Refer to Transfusion Medicine procedure Corewell Health East - Performing Neonatal Direct Antiglobulin Test (DAT) by the Gel Method - All Beaumont Hospitals for interpretation guidelines.
    3. Antigen typing: Refer to Transfusion Medicine procedure Corewell Health East - Antigen Typing - Blood Bank - All Beaumont Hospitals for interpretation guidelines.
    4. Eluate testing: Refer to Transfusion Medicine procedure Corewell Health East - Eluates - Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Troy for interpretation guidelines.

B. Results:
    1. Record all test results in BBIS using the Transfusion Medicine procedure, SafeTrace (Blood Bank) Application - East.
    2. Eluate resulting
        a. Eluate result including last wash testing will be documented on an antigram copy.
        b. Eluate should be ordered and resulted in the BBIS.
    3. The HDN test code will be resulted when indicated (see attachment *Newborn Blood Bank Workup and Cord Blood Evaluation Testing and Result Comments* (33741-1) for HDN result indications and appropriate result comments). Indications for resulting the HDN test code include:
        a. A positive DAT result
        b. Maternal clinically significant antibody

C. Final Verification of Test Results in LIS
    1. When test resulting is complete the results need to be final verified in the LIS. Refer to LIS workflow Resulting Clinical Pathology Specimens.

9. Limitations

A. In order to minimize the risk of missing an Rh Immune Globulin candidate or maternal history of clinically significant antibody(ies), blood bank will review the previous day's deliveries as described in Transfusion Medicine Policy, Corewell Health East - Review of the Obstetrical Delivery Log - Blood Bank - All Beaumont Hospitals.

B. Cord blood specimens may be contaminated with Wharton's jelly and other cord contaminants. In the event of discrepant results, the red cells from cord blood specimens must be washed thoroughly before they are tested.

C. Newborns do not make their own ABO antibodies; therefore, ABO reverse type is not performed.

D. Eluates may be more sensitive in detecting the presence of an antibody coating the red cells than the DAT.

E. If the neonate has a positive DAT with no recent maternal testing completed, a Type & Screen may be ordered on the mother, if available for testing.
    1. Consult with Medical Director for further clarification.
    2. If a maternal sample/history is unavailable, then an antibody screen will be performed on the neonatal sample. Because alloimmunization is rare during the neonatal period, unexpected antibodies detected in the neonatal sample are generally assumed to be of maternal origin.

10. Revisions

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

11. Procedure Development and Approval

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12. Keywords

Not Set