

# PROCEDURE Corewell Health East - Rh Immune Globulin Evaluation - Blood Bank

# 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 Blood Bank policies relating to Rh Immune Globulin (RhIG) candidacy, dosage, and the preparation of RhIG. The Rh Immune Globulin eligibility testing is normally accomplished by antenatal performance of ABO/Rh to determine RhD antigen status, and an Antibody Screen to rule out previous sensitization to RhD antigen. Subsequent testing during the pregnancy is completed as care dictates, at admission for delivery, and postpartum testing is completed to include determination of Rh Immune Globulin dosage, as indicated.
- B. This procedure is applicable for the following patients:
  - 1. Postpartum and antenatal patients for whom an Rh Immune Globulin evaluation is ordered by a provider, e.g., a pregnant patient in the emergency room, or a postpartum patient.
  - 2. Patients identified by the Blood Bank as potential RhIG candidates, e.g., when the Obstetrical Delivery Log is reviewed.
- C. Rh Immune Globulin (RhIG) acts by suppressing the immune response of RhD-negative individuals to RhD positive red blood cells. RhIG is indicated whenever it is known or suspected that RhD-positive fetal red cells have entered circulation of an RhD-negative (or partial D) mother.
- D. RhD immunization in pregnancy most commonly results from the fact that, at delivery, a variable volume of fetal blood enters the maternal circulation when the placenta separates from the uterine wall. In most cases, RhD immunization can be prevented by the administration of Rh Immune Globulin (RhIG) within 72 hours from the time of delivery. One standard 300 µg dose of RhIG is generally sufficient to prevent immunization when up to 30 mL of fetal whole blood (approximately 15 mL of RBCs) have entered the maternal circulation.

## 2. Responsibility

- A. Personnel listed below who have completed the competency requirements will perform this testing and complete these tasks as specified in the procedure.
  - 1. Blood Bank
  - 2. Flow Cytometry
  - 3. Hematology



- 4. Registered Nurse
- 5. Provider
- 6. Outpatient provider

## 3. Contents

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#### 4. Definitions

- A. ACDEL: The EPIC Beaker test for Fetal Cells by Kleihauer Betke; LAB474
- B. BBIS: Blood Bank Information System; SafeTrace
- C. Caregiver: Licensed clinical staff member assigned to the care of the patient
- D. 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.
- E. Delivery: as used in this document this term refers to the cessation of all pregnancies greater than 23 weeks gestation including full-term births and pregnancies that are terminated or interrupted for any reason.
- F. Designee: a Blood Bank Technical Director or Blood Bank fellow.
- G. FCS: refers to the qualitative fetal cell screen test that is performed in the Blood Bank. This test is called the FMH Rapid Screen; see the package insert provided by Immucor/Gamma®. FETALBLDSC is the test code used for this test.
- H. FMH: Fetal Maternal Hemorrhage
- FMHA: The blood bank computer test code assigned to the final FMH report; completed after consideration of the FMH testing used for final determination of total number of RhIG vials indicated for the patient.
- J. FRBCG: The EPIC Beaker test for the Fetal Cells by Flow Cytometry; LAB292
- K. HIS: Hospital Information System; Epic
- L. HyperRHO®: Trade name for Grifols Rh Immune Globulin.
- M. LIS: Laboratory Information System
- N. RhIG: Rh Immune Globulin
- O. RHIGANT: The Blood Bank computer test code assigned to the Rh Immune Globulin Antenatal profile.

Entities will reference associated Documentation contained within this document as applicable Printouts of this document may be out of date and should be considered uncontrolled.

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- P. RHIGCAN: The Blood Bank computer test code assigned to the RhIG Candidacy report.
- Q. RHIGPOSTES: The Blood Bank computer test code assigned to the Rh Immune Globulin -Postpartum profile.
- R. RhoGAM®: Trade name for Kedrion Biopharma Inc. Rh Immune Globulin.
- S. Rhophylac®: Trade name for CSL Behring LLC Rh Immune Globulin.

## Specimen

- A. The sample required is an EDTA sample with affixed identifying label. Refer to Transfusion Medicine Policy, <u>Corewell Health East Triaging And Identifying Acceptable Samples For Testing- Blood Bank All Beaumont Hospitals.</u>
  - Note: If the specimen does not have a complete band number, all applicable RhIG Evaluation testing may be completed, however the specimen will be unable to be used for transfusion purposes. If applicable, a result comment is added to the antibody screen, "This sample cannot be used for transfusion purposes.". The specimen is also inactivated in the BBIS once the Rh Immune Globulin Evaluation testing is complete.
- B. Postpartum testing requires the specimen to be collected from the mother after delivery of all products of conception. It is best to wait about an hour after delivery to allow any fetal RBCs to mix thoroughly in the maternal circulation, but the sample collection occurs as soon as possible thereafter.

# 6. Reagent/Equipment Needed

- A. Rh Immune Globulin, 300 µg
  - 1. HyperRHO® S/D Full Dose, stored at 2°C to 8°C
  - 2. Rhophylac®, stored at 2°C to 8°C
  - 3. RhoGAM® Ultra-Filtered PLUS, stored at 2°C to 8°C
- B. X23480 Blood/Component Pick-Up Tag

# 7. Procedure

- A. Patient Caregiver Responsibility:
  - 1. At Corewell Health East (CHE) the patient caregivers will order one of two available tests:
    - a. Rh Immune Globulin Evaluation Antenatal (RHIGANT); a complex test code ordered in EPIC using order code LAB2111163, and comprised of:
      - 1) Maternal ABO/Rh (ABORhGEL)
      - 2) Maternal Antibody Screen (ABSG)
      - 3) History Check (HxCheck)
      - 4) RhIG Candidacy Report (RHIGCAN)
      - 5) FMH Comment (FMHA)
    - b. Rh Immune Globulin Evaluation Postpartum (RHIGPOSTES); a complex test code ordered in EPIC using order code LAB2111164, and comprised of:
      - 1) Fetal Cell Screen Lot (FBSLOT)
      - 2) Fetal Cell Screen (FETALBLDSC)
      - 3) RhIG Candidacy Report (RHIGCAN)
      - 4) FMH Comment (FMHA)
- B. Patients at Gestational Age Less than 12 Weeks
  - 1. For patients at less than 12 weeks of gestation, the American College of Obstetrics and Gynecology suggests forgoing routine Rh testing and RhIG prophylaxis.
  - 2. A patient that is less than 12 weeks gestation will still be considered a candidate for Rh Immune Globulin, however RhIG will not be routinely set up for the patient.
  - 3. After completion of applicable Type and Screen testing, continue with the following:
    - a. Result the RhIG Candidacy as "Yes" with the following free text comment "Rh Immune Globulin NOT recommended <12 weeks gestation (ACOG 2024)".
    - b. If the patient's provider requests RhIG to be dispensed, proceed to <u>L. Preparation of RhIG dose for Patients Determined to be Eligible for RhIG below.</u>
  - 4. Refer to attachment 33761-1 Antenatal Determination of RhIG Candidacy.



- C. Maternal RhD Sensitization/Requirement for Medical Director Review.
  - Mothers who are previously sensitized to RhD are not candidates for RhIG. However, in some cases it may be difficult to determine whether the mother is truly sensitized to RhD. For this reason:
    - a. All RhIG Candidacy that are interpreted as No and resulted with the canned comment code RNCSD (Not Rh Immune Globulin Candidate; Patient is sensitized to the Rh (D) Antigen) shall be reviewed by Medical Director or designee. This review will be documented with a note in the patient profile.
    - b. All RhIG evaluation cases for patients in which there is any question as to whether Anti-D specificity is due to recent RhIG administration or to alloimmunization (DNK antibody determination) shall be considered RhIG candidates. Final determination whether RhIG is to be given is to be made by the ordering provider.
    - c. Refer to Transfusion Medicine Policy, <u>Corewell Health East Policies Specific to Patients</u> with Passive Anti-D (<u>Due to Recent RH Immune Globulin Administration</u>) All Beaumont Hospitals.
- D. Rh Immunoglobulin Preparation Without a Completed Rh Immune Globulin Evaluation Order
  - 1. When assessing maternal RhIG candidacy, it is preferred to complete the indicated testing on a current sample prior to dispensing RhIG. However, the Blood Bank will not refuse to dispense RhIG if the patient's provider or caregiver chooses not to order and collect the tests that are normally required to prepare RhIG as outlined in this procedure.
  - 2. It is acceptable to issue one vial of RhIG if requested by the patient provider in the following scenarios:
    - a. Patients with a historic blood type available in LIS or Medical Record but no current specimen is available.
    - b. Specimen collected, but test results are still pending.
    - c. There is no historical blood type on file, but patient is known to be Rh Negative by outside hospital testing provided that verification of the previous test results has been obtained.
  - 3. Request for RhIG (Patient Caregiver Responsibility)
    - a. The Request for RhIG (33761-3) form may be documented and delivered to blood bank to confirm request for RhIG dispense in these scenarios.
  - 4. An order for an Rh Immune Globulin Evaluation will be placed regardless of specimen collection to document the patient's RhIG Candidacy and for preparation of the Rh Immune Globulin dose.
  - 5. RhIG Evaluation Orders without a Specimen
    - a. The RhIG Evaluation order is placed in Epic with a comment added to indicate the request for RhIG is to be completed without maternal testing completed. For example, "request for RhIG without testing per [provider's name]."
    - b. A collection is simulated in Epic
    - c. Lab responsibility:
      - 1) Receive simulated specimen in LIS and BBIS
      - 2) Invalidate test results that will not be completed (Type, Antibody Screen, Fetal Screen, FMHA, as applicable)
      - 3) Result Candidacy Report (RHIGCAN):
        - a) Interpretation: Y (Yes)
        - b) Comments:
          - 1. RHIG1 (One total vial Rh Immune Globulin Indicated)
          - 2. ROD (Product available upon receiving the Blood Component/Pick Up form in Blood Bank)
          - 3. Free text indication, (i.e. "Patient eligibility based on historical results")
      - 4) Proceed with <u>Preparation of RhIG Dose procedure</u> below.
      - 5) Contact RN to confirm product is available for pick up.
- E. Requests for Antenatal RhIG for patients with current Type and Screen



- 1. In the event that a patient has a current Type and Screen and is subsequently identified as a potential RhIG candidate, the caregiver shall communicate with blood bank to have the RhIG Antenatal Evaluation order added onto the Type and Screen specimen.
  - a. The Request for RhIG (33761-3) form may be used for this communication.
- 2. Blood Bank responsibility:
  - a. Add on the RhIG Evaluation
  - b. Invalidate the Type and Antibody Screen tests as duplicate
  - c. Proceed to Resulting RhIG Candidacy Report procedure below
- F. Determination of Antenatal RhIG Candidacy and Dosage
  - 1. It is the responsibility of the patient's provider to determine whether an antenatal RhIG evaluation is indicated. If the provider orders an Rh Immune Globulin Evaluation - Antenatal, the Blood Bank will set up the RhIG as described below.
  - 2. Possible reasons that the patient's provider may order an Antenatal RhIG Evaluation include:
    - a. 28-week prophylaxis
    - b. Threatened miscarriage or vaginal bleeding
    - c. Ectopic pregnancy, placenta previa, or abdominal trauma
    - d. Known or suspected fetal-maternal hemorrhage
    - e. Invasive obstetrical procedures (amniocentesis, chorionic villus sampling, percutaneous umbilical blood sampling [PUBS], and manipulative procedures such as an external cephalic version)
  - Determination of Maternal ABO/Rh
    - a. Maternal ABO/Rh testing is completed to determine Rh status as described in Transfusion Medicine procedure, Corewell Health East - ABO and Rh Typing - All Beaumont Hospitals.
    - b. Partial/Weak D analysis is completed when indicated as described in Transfusion Medicine procedure, Corewell Health East - Weak D Testing - All Beaumont Hospitals.
  - 4. Determination of Maternal Alloimmunization to D antigen
    - a. Antibody Screen testing is completed as described in Transfusion Medicine Policy, Corewell Health East - Antibody Screening - Blood Bank - All Beaumont Hospitals.
    - b. If applicable, antibody identification testing will be completed as described in Transfusion Medicine procedures, Corewell Health East - Antibody Identification - Blood Bank - All Beaumont Hospitals and Corewell Health East - Policies Specific to Patients with Passive Anti-D (Due to Recent RH Immune Globulin Administration) - All Beaumont Hospitals.
  - 5. Refer to attachment Antenatal Determination of RhIG Candidacy (33761-1) for resulting of RHIGCAN and indication for FMH testing.
  - 6. If FMH testing is not indicated, result the FMHA as NA (Not Applicable).
    - a. If FMH testing is indicated proceed to Quantitative Fetal Maternal Hemorrhage Testing procedure below.
- G. RhIG Requests for Rh(D) Positive Mothers
  - 1. Complete a history check on the patient, if not already completed.
  - 2. Confirm with the patient's RN:
    - a. Order placed in error
    - b. History of RhD negative, weak D, or partial D date and location
      - 1) Add the information obtained to a Note in the patient's profile in the BBIS.
  - 3. If patient is confirmed to be Rh(D) positive refer to attachment Postpartum Determination of RhIG Candidacy (33761-2) for result comment.
  - 4. If patient is found to have history of RhD negative, weak D, or partial D correct the patient blood type and complete the RhIG Evaluation. Refer to Transfusion Medicine procedure Corewell Health East - Weak D Testing - All Beaumont Hospitals.
- H. Determination of Postpartum RhIG Candidacy and Dosage
  - 1. Confirm that the maternal patient is RhD negative, weak D/partial D, or the RhD of the mother is undetermined.
  - Determination of Neonatal RhD



- a. Before assessing postpartum maternal RhIG candidacy, neonatal RhD testing shall be completed on a sample from the current admission.
- b. Access the maternal/neonate's record in EPIC and/or Maternal MRN indicated in neonatal testing order to verify that you are testing the correct baby.
- c. Perform ABO/Rh of baby. Refer to Transfusion Medicine procedures, <u>Corewell Health</u>
  <u>East Forward Typing Determination Of Neonatal ABO and Rh All Beaumont Hospitals</u>
  and <u>Corewell Health East Newborn Blood Bank Work Up and Cord Blood Evaluation Blood Bank All Beaumont Hospitals.</u>
  - If the neonate ABO/Rh is tested by tube method and the Rh is determined to be negative, include weak D testing as indicated in Transfusion Medicine procedure <u>Corewell Health East - Weak D Testing - All Beaumont Hospitals.</u>
- d. If determination of neonatal RhD is unable to be completed, the neonate will be assumed to be RhD Positive for the purposes of RhIG candidacy determination.
- 3. If the neonate is determined to be Rh Negative and the postpartum maternal sample has not been collected, the Rh Immune Globulin Evaluation Postpartum (RHIGPOSTES) may be added onto the maternal Type and Screen specimen.
  - a. Result the Fetal Screen component tests (FETALBLDSC and FBSLOT) as INV (Invalid)
  - b. Result the FMHA as NA (Not Applicable).
  - c. Refer to *Postpartum Determination of RhIG Candidacy* (33761-2) for applicable result comments for RHIGCAN.
- 4. Maternal Fetal Cell Screening
  - a. Determine whether FCS testing is indicated. Refer to the attachment *Postpartum Determination of RhIG Candidacy* (33761-2).
    - FCS testing is indicated only for an RhD negative mother after the delivery or the cessation of pregnancy of an RhD positive neonate with a gestation of greater than 23 weeks.
  - b. Perform Fetal Screen testing, if indicated, as described in Transfusion Medicine Policy, Corewell Health East - Fetal Cell Screening Using the FMH Rapid Screen Kit - Blood Bank.
  - c. Result the fetal screen in the BBIS, refer to Transfusion Medicine procedure <u>SafeTrace</u> (Blood Bank) Application East.
  - d. If the fetal screen is negative result the FMHA as NA (Not Applicable).
  - e. If the fetal screen is positive proceed to <u>Quantitative Fetal Maternal Hemorrhage Testing</u> procedure below.
  - f. If the RhIG evaluation is ordered postpartum and the fetal screen is not indicated result the Fetal Screen component tests (FETALBLDSC and FBSLOT) as INV (Invalid)
  - g. Note: The FCS is a qualitative test only and is used to determine whether one vial of RhIG is sufficient or if quantitative fetal maternal hemorrhage (FMH) testing is required to determine the total number of vials of RhIG that are indicated.
- 5. Note: For patients that have received recent administration of Rh Immune Globulin, the patient's provider and Blood Bank MDs can be consulted to determine the need for an additional dose postpartum taking into consideration the results of FMH testing.
- I. Quantitative Fetal Maternal Hemorrhage Testing
  - 1. Quantitative testing for fetal maternal hemorrhage is performed for gestational age of 23 weeks or greater in the following situations:
    - a. When the FCS test is positive.
    - b. When the Rh status of mother or baby is a weak D/partial D and considered to be Rh negative or D variant analysis has not been completed.
    - c. When the RhD of the mother or neonate/fetus cannot be determined.
    - d. If a sample cannot be obtained for any reason, e.g., intra-uterine fetal death (IUFD), medical interruption of pregnancy (MIP), etc.
    - e. When delivery has not yet occurred, e.g., in antenatal cases greater than 23 weeks gestation.



- f. Refer to attachments Antenatal Determination of RhIG Candidacy (33761-1) and Postpartum Determination of RhIG Candidacy (33761-2).
- g. Note: Quantitative fetal maternal hemorrhage testing is not indicated for Rh immune globulin dosage calculation for gestations less than 23 weeks since 1 vial of Rh Immune globulin is indicated for these patients.
- When quantitative testing is indicated, the FMHA test component will be left pending on the RhIG Evaluation order in the BBIS to be used for the final RhIG dosage result comments following completion of the FMH testing. FMH test results will be evaluated to determine whether additional vials are indicated.
- 3. If the FMH testing is indicated for any reason, one vial of RhIG will be prepared as soon as possible and may be issued for the patient, while the FMH testing is still pending.
- 4. FMH testing is generally completed by Flow Cytometry using the test Fetal Cells by Flow Cytometry (LAB292)
- 5. If the Fetal Maternal hemorrhage testing is required stat (i.e. associated with maternal trauma) and the flow cytometry test cannot be performed timely (e.g., the Flow Cytometry laboratory may be closed on certain holidays or weekend shifts), then the test Kleihauer-Betke (LAB474) is used as an alternative method.
- 6. The hematology laboratory at Royal Oak, will perform stat Kleihauer-Betke testing when requested for patients seen in the emergency room or for mothers being discharged at Farmington Hills, Grosse Pointe, and Royal Oak. Note: Stat Quantitative testing at Farmington Hills, Grosse Pointe will require blood bank medical director approval.
- 7. The blood bank at Dearborn will perform stat Kleihauer-Betke testing for patients seen in the emergency room or for mothers being discharged at Dearborn, Taylor, Trenton, or Wayne before the Flow Cytometry laboratory will reopen. Note: Stat Quantitative testing at Taylor, Trenton, and Wayne will require medical director approval.
- 8. The hematology laboratory at Troy will perform Kleihauer-Betke testing for all patients requiring quantitative Fetal Maternal Hemorrhage testing.
- 9. If indicated, order the Fetal Cells by Flow Cytometry Test if indicated (and not already ordered by the patient's provider).
  - a. Flow Cytometry Responsibility:
    - 1) Complete the testing as indicated in procedure <u>Corewell Health East Quantitation of Hemoglobin F Containing Red Blood Cells by Flow Cytometry Royal Oak.</u>
    - 2) Call Blood Bank if result is positive, as outlined in above procedure.
- 10. If stat testing is required but the flow cytometry test cannot be performed (e.g., flow cytometry is closed) order and submit a sample for a stat Kleihauer-Betke Testing.
- 11. Once FMH testing has been completed the FMH test code is resulted in the BBIS as described in N. Completion of FMH Test Result Documentation and Final Determination of RhIG Dosage section below.
- J. Timing of RhIG Administration
  - 1. Postpartum RhIG administration occurs within 72 hours or as soon as possible after delivery.
  - 2. Antenatal RhIG is administered within 72 hours, or as soon as possible, after known or potential exposure to RhD positive red blood cells.
  - 3. If the FMH test is indicated for any reason as described in attachments, one vial of RhIG is prepared and dispensed as soon as possible. Do not wait until the FMH testing is complete.
  - 4. Blood Bank will follow up on any RhIG doses that have not been dispensed within approximately 24 hours from the time that eligibility is determined. Each morning, a Blood Bank technologist will verify that all vials that were set up on previous dates have been dispensed. If any vials have not been dispensed, the patient's caregivers are notified. This verification and any required notifications will be documented on Communication Logs/Boards and/or site-specific logs.
  - 5. If a dose of RhIG is indicated but is not administered within 72 hours:
    - a. The dose is administered as soon as possible, thereafter; it may still be beneficial to administer the indicated RhIG dose for up to approximately 21 days. The half-life of RhIG is about 24 days.



- b. A variance report is submitted.
- K. Resulting RhIG Candidacy Report
  - 1. If RhIG evaluation is ordered antenatal, result the RHIGCAN (RhIG Candidacy Report) using the result comment codes indicated in the attachment *Antenatal Determination of RhIG Candidacy* (33761-1).
  - 2. If RhIG evaluation is ordered postpartum, result the RHIGCAN (RhIG Candidacy Report) using the result comment codes indicated in the attachment *Postpartum Determination of RhIG Candidacy* (33761-2).
  - 3. If FMH testing is required add the FMH result comment; "More than 1 vial of RhIG may be indicated, testing in progress" to the RhIG candidacy result.
  - 4. Add the FMHA test code to the RhIG orders in the BBIS. [This will be resulted after the receipt of FMH test results in Epic.]
  - 5. If RhIG is indicated include the following in the result comment: Comment ID: ROD (Product available upon receiving the Blood Component/Pick Up form in the Blood Bank)
  - 6. If applicable per site specific policy, notify the provider once RhIG is ready for issue. Document this communication in the Candidacy test result comment.
- L. Preparation of RhIG dose for Patients Determined to be Eligible for RhIG
  - 1. Obtain one vial of RhIG from the refrigerator.
  - 2. For Antenatal requests add-on a derivative order for the RhIG in the BBIS. Refer to Transfusion Medicine Policy SafeTrace (Blood Bank) Application East.
  - 3. If preparing the RhIG in advance for the patient, reprint Beaker specimen label and affix to plastic bag or box.
  - 4. Administration Control Record/Control Form/Injection Form
    - This form is documented by Blood Bank during a computer downtime with the following information:
      - 1) Patient identifiers are indicated in top section of form.
      - 2) Product lot number
      - 3) Verification of Blood Bank test results in Laboratory section of form, as applicable
      - 4) Initial where indicated
      - 5) See attachments for examples, *HyperRHO Injection Form* (33761-4), *RhoGAM Control Form* (33761-5), and *Rhophylac Administration Control Record* (33761-6)
    - b. Place form back in the RhIG bag/box.
    - Place the labeled RhIG in the designated area in a blood bank refrigerator.
- M. Dispense of Rh Immune Globulin
  - When the completed Blood/Component Pickup Slip (X23480) is received for the RhIG the technologist shall inspect the slip to ensure that it was documented completely, legibly, and accurately by the patient's caregiver.
    - The dispense form must be documented correctly and legibly with the following information:
      - 1) Recipient's name.
      - 2) Recipient's medical record number (MRN).
      - 3) The quantity indicated next to Rh Immune Globulin.
      - 4) The requester's or courier's employee identification number or name (the dispensing technologist may ask the runner/courier for this information, if present).

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- 5) Note: Wristband number is not a required patient identifier for dispense of Rh Immune Globulin
- b. Note: Rh Immune Globulin is NOT able to be dispensed through pneumatic tube. A runner must come to blood bank to pick it up.
- 2. Issue each vial of RhIG that has been allocated for the patient and print the D-Tag (Derivative Tag) in the BBIS. Refer to Transfusion Medicine Policy, <u>SafeTrace (Blood Bank) Application East.</u>
- 3. Affix one of the D-Tag labels to the plastic bag or box containing the product.



- 4. Include the remaining D-Tag label attached to the paper with the product for use during downtime documentation.
- 5. Final Verification of Information Prior to Dispense
  - a. A final check of dispense requirements as indicated in bold in the <u>Requirements for Dispensing Rh Immune Globulin chart</u> below is required before releasing the Rh Immune Globulin to the runner.
  - b. Dispensing with Verbal Clerical Checks (Read Back): The dispensing technologist and the courier/runner picking up the RhIG will read back the information working down the form matching the information between the P-Tag, the transfusion label attached to the unit, the face label of the blood product, and the Product Dispense form to verify all dispense requirements are met.
    - 1) Note: Read back is routinely performed at Dearborn, Farmington Hills, Grosse Pointe, Trenton, Taylor, and Wayne.
  - c. Dispensing With Written Clerical Checks: If read back is not performed at the time of issue, the dispensing technologist must document a check mark (or equivalent mark) next to each dispense requirement to indicate that the dispense requirement has been met. In addition, the dispensing technologist must write RhIG or circle the RhIG request line to acknowledge the type of product that was requested on the dispense form. This practice helps to ensure that the technologist dispenses the correct kind of product/derivative.
    - 1) Note: Documentation with clerical checks routinely occurs at Royal Oak and Troy.
- 6. Retain the dispense copy of the tag in the blood bank and staple to the dispense form.

7. Requirements for Dispensing Rh Immune Globulin

Dispense Requirement	Dispense Form	BBIS	D-Tag	RhIG Package	Derivative Label (adhered to RhIG packaging)
Product(s) dispensed match product(s) requested	✓	✓	<b>√</b>	✓	✓
Patient MRN	✓	✓	✓		✓
Patient Name	✓	✓	✓		✓
Patient blood type		✓	✓		✓
RhIG Lot Number		✓	✓	✓	✓
RhIG Expiration		✓	✓	✓	✓
RhIG Dosage		✓	✓	✓	✓
Initials of the person who prepared the RhIG dose				<b>√</b>	

- N. Completion of FMH Test Result Documentation and Final Determination of RhIG Dosage
  - 1. If FMH testing was indicated, upon completion of the Fetal Cells by Flow Cytometry (or Kleihauer Betke) test perform the following:
    - a. Obtain the % Fetal Bleed from the results in EPIC and compare to the RhIG dosage chart below to determine if more than one (1) vial of RhIG is required.
    - b. If additional RhIG vials are not required:
      - 1) Result the FMHA test code as SEE (See Comments)
      - 2) Enter Result Comment ID RHFIN (Additional Testing complete. \_\_\_\_\_ total number of vials Rh Immune Globulin indicated) and free text 1 for the total number.
    - c. If additional RhIG vials are required, then prepare and document the Control Form for each vial of RhIG as described above.
      - 1) Result the FMHA test code as SEE (See Comments)



- Enter Result Comment ID RHFIN (Additional Testing complete. \_\_\_\_\_ total number of vials of Rh Immune Globulin indicated) and free text the total amount that is indicated.
- 3) Notify the patient's caregivers that the additional RhIG vials are ready and document this notification in the result comment.
- O. Return of the RhIG Control Form to the Blood Bank
  - 1. In most instances the completed RhIG Control Form is scanned into Epic Chart and not returned to Blood Bank. However, a copy of the RhIG Control Form may be returned to the Blood Bank, indicating that a vial has been injected to the patient.
  - 2. If returned, the RhIG Control Form will be set aside for review on the following day by the technologist reviewing the Obstetrical Delivery Log. Refer to Transfusion Medicine Procedure, Corewell Health East Review of the Obstetrical Delivery Log Blood Bank All Beaumont Hospitals.
    - a. The Blood Bank technologist will confirm the RhIG vial is issued and service charge added in the BBIS then file the RhIG Control form in designated site-specific area.
- P. Return of Unused Rh Immune Globulin Vials to the Blood Bank
  - 1. There may be instances when an unused vial of Rh Immune Globulin is returned to the Blood Bank after it was issued for a patient. In these situations, the Rh Immune Globulin will be inspected to determine whether it will be discarded or returned to inventory.
  - 2. If the returned Rh Immune Globulin vial was not opened and the integrity is not in question (i.e. there is no visible damage to the Rh Immune Globulin, the plunger was not pushed into the vial, the needle cover was not removed, etc.), the Rh Immune Globulin may be set up and used again, as long as it is has been returned within 6 hours.
  - When the Rh Immune Globulin is set up for a new patient, a new RhIG Control Form must be documented.
  - 4. If the returned Rh Immune Globulin is clearly damaged or the vial has been opened, it will be discarded in a sharps biohazard container, and a variance is submitted.
  - 5. If the Rh Immune Globulin vial has been returned after 6 hours and/or the integrity of the Rh Immune Globulin is in question for any reason, it will be placed into quarantine until it is reviewed by the Medical Director. This is documented on department communication logs or whiteboards where applicable.
- Q. Refusal of Rh Immune Globulin
  - 1. If a patient or the patient's provider refuses to administer RhIG when indicated, as described in this document.
    - a. The refusal must be documented in the HIS or by completion of applicable form by the caregiver.
    - b. All RhIG refusal details must be documented in a patient profile note in the BBIS.
    - c. An internal variance report must be submitted if documentation to confirm refusal is unable to be obtained.
  - 2. The following forms may be used to document this refusal:
    - a. Provider RhIG refusal (33761-7)
    - b. Patient Refusal of Rh Immune Globulin (33761-8)
- R. Special Situations
  - At some sites, a patient will arrive at the hospital outpatient laboratory with a script for a Type & Screen and RhIG Evaluation. In these cases, the Type & Screen sample will be tested as soon as possible by the Blood Bank. The patient is directed to the L&D or Family Birth Center, where the RhIG will be administered, if applicable.
  - 2. It is not necessary to obtain informed consent for a blood transfusion in order to administer Rh Immune Globulin (RhIG is not considered a blood product).
  - 3. Grosse Pointe ONLY
    - a. Outpatients are given a Rhogam Study Information sheet that provides additional information to the blood bank. Any outpatient that has had a miscarriage or possible miscarriage is not to be sent to the obstetrics (OB) unit to receive RhIG. Staff must call OB and request that a nurse come to the outpatient laboratory to give the injection.



# 8. Results/Interpretation

- A. Determining RhIG Dosage
  - 1. RhIG dosage is determined based upon the % Fetal Cells determined by the results of the Fetal RBC Assay or Kleihauer Betke methods as indicated in the following table: For values greater than 4.4%, each row is calculated by adding 0.6 to the prior row's % range. For each additional "% fetal cell" row, one additional vial of RhIG is indicated.

Rh Immune Globulin Dosage			
% Fetal Cells	Vials of RhIG Indicated		
<0.3	1		
0.3 - 0.8	2		
0.9 - 1.4	3		
1.5 - 2.0	4		
2.1 - 2.6	5		
2.7 - 3.2	6		
3.3 - 3.8	7		
3.9 - 4.4	8		

- B. Once all tests have been resulted the following specimens are inactivated in the BBIS:
  - 1. Antenatal specimens that do not have a complete band number
  - 2. All postpartum specimens

#### 9. Revisions

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

# 10. References

- A. Rho(D) immune Globulin Human HyperRHO ® package insert, Rev 06/2018
- B. College of American Pathologists Transfusion Medicine Checklist, current edition.
- C. AABB Technical Manual, current edition.
- D. AABB Standards for Blood Banks and Transfusion Services, current edition.
- E. Transfusion Therapy: Clinical Principles and Practice, 2nd ed. Mintz PD, ed.Bethesda, MD: AABB Press, 2005.

# 11. Procedure Development and Approval

## **Document Owner:**

Laura Judd (Operations Specialist)

# Writer(s):

Melissa Bajcz (Medical Technologist Lead)

## Reviewer(s):

FAPC NURSING, Alyssa Malone (Medical Technologist Lead), Danae Regan (Medical Technologist Lead), Hilary Morey (Medical Technologist Lead), Jillian Traskos (Nursing Policy Manager), Karrie Torgerson (Medical Technologist Lead), Leila Baalbaki (Medical Technologist Lead), Susan Pelley (Medical Technologist Lead)

#### Approver:

Ann Marie Blenc (System Med Dir, Hematopath), Brittnie Berger (Dir Sr, Lab Operations), Christopher Ferguson (Dir, Laboratory Services), Elzbieta Wystepek (Dir, Laboratory Services), Fatima Bazzi (Supv, Laboratory), Hassan Kanaan (OUWB Clinical Faculty), Jeremy Powers (Chief, Pathology), John Pui (Chief, Pathology), Kelly Sartor (Mgr, Division Laboratory), Kristina Davis (Staff Physician), Masood Siddiqui (Staff Pathologist), Muhammad Arshad (Chief, Pathology), Ryan

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Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Teresa Lovins (Supv, Laboratory)

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