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Rh Immune Globulin Evaluation - Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To outline the steps required and tests that need to be performed to determine patient's Rh Immune Globulin eligibility and dosage. Routine testing includes prenatal ABO/Rh and antibody screen, subsequent testing during the pregnancy as care dictates and at admission for delivery.

II. CLINICAL SIGNIFICANCE:

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.

RhD immunization may result if the mother produces antibodies that are directed at antigens present on the fetal red blood cells (RBCs) but absent on the maternal RBCs. RhD negative mothers delivering RhD positive infants are most susceptible.

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.

Rh Immune Globulin eligibility testing is normally accomplished by performing an ABO/Rh to determine RhD antigen status, and an Antibody Screen to rule out previous sensitization to RhD antigen. 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 a RhD-negative (or partial D) mother.

III. SCOPE:

- A. This document will provide Blood Bank policies relating to Rh Immune Globulin (RhIG) candidacy and the preparation of RhIG.
- B. It is applicable for the following patients:
 - 1. Postpartum and antepartum patients for whom a Rh Immune Globulin evaluation is ordered by a physician; e.g., a pregnant patient in the emergency room, or a post-partum patient or
 - 2. Patients identified by the Blood Bank as potential RhIG candidates; e.g., when the OB Delivery List is provided.

- C. At Corewell Health East (CHE) the patient caregivers will order one of two available tests:
 - 1. Rh Immune Globulin Evaluation Antepartum (**RHIGANT**); a complex test code ordered in EPIC using order code LAB2111163, and comprised of:
 - a. Maternal ABO/Rh
 - b. Maternal Antibody Screen
 - c. RhIG Candidacy Report (RHIGCAN)
 - 2. Rh Immune Globulin Evaluation Postpartum (**RHIGPOSTES**); a complex test code ordered in EPIC using order code LAB2111164, and comprised of:
 - a. Fetal Cell Screen Lot (FBSLOT)
 - b. Fetal Cell Screen (FETALBLDSC)
 - c. RhIG Candidacy Report (RHIGCAN)

IV. DEFINITIONS/ACRONYMS:

- A. Current Sample: a sample that was collected no more than 3 days before the current date. For example, if a sample is drawn on Monday (day 0), then the sample remains "current" all day Mon., Tues., Wed., and Thur.
- B. Delivery: as used in this document this term refers to the cessation of all pregnancies greater than 18 weeks gestation including full-term births and pregnancies that are terminated or interrupted for any reason.
- C. CAP: College of American Pathologists
- D. Designee: a Blood Blood Technical Director or Blood Bank fellow.
- E. RHIGANT: The Blood Bank computer test code assigned to the Rh Immune Globulin Antenatal profile.
- F. RHIGPOSTES: The Blood Bank computer test code assigned to the Rh Immune Globulin Postpartum profile.
- G. RHIGCAN: The Blood Bank computer test code assigned to the RhIG Candidacy report.
- H. RhIG: Rh Immune Globulin
- I. Rhogam[®]: Trade name for Rh Immune Globulin.
- J. HyperRho®: Trade name for Rh Immune Globulin.
- K. Rhophylac[®]: Trade name for Rh Immune Globulin.
- L. 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.
- M. FMH: Fetal Maternal Hemorrage
- N. 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.
- O. FRBCG: The EPIC Beaker test for the Fetal Cells by Flow Cytometry; LAB292
- P. ACDEL: The EPIC Beaker test for Fetal Cells by Kleihauer Betke; LAB474

V. SPECIMEN COLLECTION AND HANDLING:

- A. The sample required is an EDTA sample with affixed identifying label. Refer to Transfusion Medicine Policy, <u>Triaging And Identifying Acceptable Samples For Testing</u>.
- B. Postpartum testing requires a blood specimen 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 should be collected as soon as possible thereafter.

VI. POLICIES:

A. Indications for Antepartum RhIG Administration

- 1. It is the responsibility of the patient's physician to determine whether antepartum RhIG is indicated. If the physician orders antepartum RhIG, the Blood Bank will set up the RhIG as described in; *Antepartum Determination of RhIG Candidacy*.
- 2. Possible reasons that the patient's physician may order antepartum RhIG 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 cord sampling [PUBS], and manipulative procedures such as an external cephalic version)

B. Rh Immunoglobulin Preparation Without a Current Sample

- 1. When assessing maternal RhIG candidacy it is preferred to complete a maternal ABO/Rh, antibody screen, and antibody identification studies, if indicated, on a current sample. However, the Blood Bank should not refuse to dispense RhIG if the patient's physician or caregiver chooses not to order and collect the tests that are normally required to prepare RhIG based on this document.
 - a. In this case a written request for RhIG without maternal testing shall be documented in the EPIC RhIG order by the caregivers. For example, the RhIG order should include a statement such as "request for RhIG without testing per [physician's name].
 - b. An order for **Rh Immune Globulin Antenatal** will be requested regardless for preparation of the Rh Immune Globulin dose.
- 2. It is acceptable to issue one vial of RhIG if requested for patients with a historic blood type available in LIS or Medical Record but no current specimen is available or results are still pending.
- 3. It is also acceptable to issue one vial of RhIG if 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.
- 4. A variance must be submitted for review and follow up.

C. Determination of Neonatal RhD

Before assessing postpartum maternal RhIG candidacy, neonatal RhD testing should be completed on a sample from the current admission. Neonatal RhD is determined as described in Transfusion Medicine Policies, Newborn Blood Bank Workup & Cord Blood Evaluation, and Forward Typing Determination Of

Neonatal ABO and Rh for Patients Less Than Four Months of Age By Tube Method.

D. 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:

- All RhIG evaluations that are interpreted as Ineligible 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.
- 2. 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 physician.

Refer to Transfusion Medicine Policy, <u>Policies Specific to Patients with Passive Anti-D (Due to Recent RH Immune Globulin Administration)</u>.

E. Maternal Fetal Cell Screening

- 1. Fetal cell screening is performed when indicated as described in Transfusion Medicine Policy, <u>Fetal</u> <u>Cell Screening Using the FMH Rapid Screen Kit</u>.
- 2. The FCS may be performed only on a sample from a RhD negative mother after the delivery of a RhD positive neonate. It is not performed on antepartum patients. The specimen used to perform the FCS test must be collected after delivery of all products of conception.
- 3. 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.

F. Quantitative Fetal Maternal Hemorrhage Testing

- 1. Quantitative testing for fetal maternal hemorrhage is performed in the following situations:
 - a. When the FCS test is positive.
 - b. When the mother or baby is weak D / partial D positive.
 - c. When the RhD of the mother or neonate / fetus cannot be determined or if a sample cannot be obtained for any reason; e.g., intra-uterine fetal death (IUFD), medical interruption of pregnancy (MIP), when an unresolved RhD discrepancy is present, etc.
 - d. When delivery has not yet occurred; e.g., in antepartum cases greater than 18 weeks gestation as described in Table Antepartum Determination of RhIG Candidacy.

Note: flow cytometry testing is not required for gestations less than 18 weeks since 1 vial of Rh Immune globulin is indicated for these patients.

- When quantitative testing is indicated an order for Fetal Cells by Flow Cytometry (LAB292) will be
 placed in Epic Beaker. The results of this test are used to determine the total number of vials of RhIG
 that are indicated. Note: Samples from Troy will be tested by Fetal Cells, Kleihauer-Betke
 Test (ACDEL).
 - a. The FMHA test component will be added to the Rhogam orders in BBIS for the final RhIG

candidacy report. The results from the FMH test will be evaluated to determine whether additional vials are indicated and documented with this test code.

3. If the FMH testing is indicated for any reason one vial of RhIG should be prepared as soon as possible; do not wait until the flow cytometry or Kleihauer-Betke testing is complete.

G. Kleihauer-Betke Test (ACDEL)

- 1. If the Fetal Maternal hemorrhage testing is required stat (i.e. associated with maternal trauma) <u>and</u> the flow cytometry test cannot be performed timely (e.g., the Flow Cytometry laboratory may be closed on certain holidays or weekends), then the Kleihauer Betke stain (LAB474) is used as an alternative method.
- 2. If a order is placed directly by a patient caregiver then both the Fetal Cell Flow Cytometry test and Kleihauer Betke test will reflex. Flow Cytometry and Hematology will decide which laboratory will perform the testing and will cancel the applicable unperformed test.
- 3. The hematology laboratory at Royal Oak, will perform stat Kleihaeur-Betke (ACDEL) 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.**
- 4. The blood bank at Dearborn will perform stat Kleihaeur-Betke (ACDE)L 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.**
- 5. The hematology laboratory at Troy will perform Kleihauer-Betke testing for all patients requiring quantitative Fetal Maternal Hemorrhage testing.

H. Determining RhIG Dosage

1. RhIG dosage is determined based upon the the % Fetal Cells determined by the results of the Fetal RBC Assay or Kleihauer Betke methods as indicated in the following table:

2.	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

For each additional "% fetal cell" row, one additional vial of RhIG is indicated. Each row is calculated by adding 0.6 to the prior row's % range.

I. Refusal of Rhogam

If a patient or the patient's physician refuses to administer RhIG when indicated, as described in this document, the refusal should be documented and a variance report should be submitted.

- 1. Dearborn, Grosse Pointe, Farmington Hills, Taylor, Trenton, Wayne:
 - a. Details regarding the refusal must be included in the comment canceling the RhIG in Soft

2. Royal Oak, Troy Only:

The following forms are used to document this refusal:

- a. Physician's Decision not to Administer Rh Immune Globulin
- b. Patient Refusal of Rh Immune Globulin and Release from Responsibility
- 3. Complete an internal variance for follow up.

J. Timing of RhIG Administration

- 1. Postpartum RhIG administration should occur within 72 hours or as soon as possible after delivery.
- 2. Antepartum RhIG should be 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 tables 1 & 2 below one vial of RhIG should be prepared and dispensed as soon as possible. Do not wait until the FMH is complete.
- 4. The Blood Bank will supply prophylactic RhIG at 28 weeks gestation when ordered by the patient's physician as described in Table 2: Antepartum Determination of RhIG Candidacy.
- 5. If a dose of RhIG is indicated but is not administered within 72 hours:
 - a. The dose should be administered as soon as possible; 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 should be submitted.
- 6. The Blood Bank should issue RhIG within approximately 24 hours from the time that eligibility is determined. Therefore, each morning, a technologist will verify that all vials that were set up on previous dates have been dispensed from the Blood Bank. If any vials have not been dispensed, the patient's caregivers should be notified. This verification and any required notifications will be documented on Communication Logs/Boards, Site Specific Delivery Logs or on the Daily Temperature and Quality Control Record (Royal Oak).

K. Disposition of the RhIG

1. A RhIG vial that is dispensed by the Blood Bank will be issued in the Blood Bank Computer.

L. Return of the RhIG Control Form to the Blood Bank

- 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.
 - Upon return, the Blood Bank will confirm the RhIG vial is issued in the Blood Bank computer then file the RhIG Control form with the daily product dispense forms.
- 2. Royal Oak Only:
 - a. A copy of the RhIG Control Form should be returned to the Blood Bank, indicating that the vial has been injected to the patient.
 - b. Upon return, the Blood Bank will proceed as follows:
 - i. If RhIG vial was dispensed by the Blood Bank, the issue of RhIG will appear in the Blood Bank computer. The Blood Bank will document that the RhIG was injected on the OB

Delivery List.

ii. If the RhIG vial was not dispensed by the Blood Bank, the issue of RhIG will not appear in the Blood Bank computer. The Blood Bank will document that the RhIG was injected by adding a patient comment. For example: "Patient received RhIG on [date] in the emergency center."

M. Return of Unused RhoGAM® Vials to the Blood Bank

There may be instances when an unused vial of RhoGAM[®] is returned to the Blood Bank after it was issued for a patient. In these situations, the RhoGAM[®] will be inspected to determine whether or not it should be discarded or can still be used.

- 1. If the returned RhoGAM[®] vial was not opened and the integrity is not in question (i.e. there is no visible damage to the RhoGAM[®], the plunger was not pushed into the vial, the needle cover was not removed, etc.), the RhoGAM[®] may be set up and used again, as long as it is has been returned within 6 hours.
 - a. When the RhoGAM[®] is set up for a new patient, a new RhIG Control Form must be documented.
- 2. If the returned RhoGAM[®] is clearly damaged or the vial has been opened, it should be discarded in a sharps biohazard container and a variance should be submitted.
- 3. If the RhoGam[®] vial has been returned after 6 hours and/or the integrity of the RhoGAM[®] is in question for any reason, it should be placed into quarantine until it is reviewed by the Medical Director. This should be documented on department communication logs or white boards where applicable.

VII. SUPPLIES:

- A. Rh Immune Globulin, 300 μg
- B. F-1564 Blood Product Dispense Form

VIII. PROCEDURE:

- A. Perform maternal compatibility testing. Complete the maternal ABO/Rh, antibody screen, and antibody identification (if applicable). Refer to Transfusion Medicine Policies, <u>Determining The ABO and RhD Of Patients Who Are At Least Four Months Old, Antibody Screening, Antibody Identification</u> and <u>Routine Testing on the Ortho Vision Analyzer</u>
- B. If RhIG is ordered post partum, initiate/complete neonatal RhD testing if the mother is RhD negative, weak D/partial D, or if the RhD of the mother is undetermined.
 - Access the maternal/neonate's record in EPIC to verify that you are testing the correct baby, to check for multiple births etc. (Refer to Epic Education Sharepoint Page for instructions on how to access delivery report in Epic.)
 - Perform ABO/Rh of baby and include weak D testing if the RhD reaction is negative with manual tube method. Refer to Transfusion Medicine Policy, <u>Weak D Testing</u> and <u>Forward Typing</u> Determination of Neonatal ABO and RH
- C. Fetal Cell Screening.
 - 1. Determine whether FCS testing is indicated.

- a. FCS testing is indicated only for a RhD negative mother after the delivery or the cessation of pregnancy of a RhD positive neonate with a gestation of greater than 18 weeks.
- b. 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)
- c. Refer to the attachments *Antepartum Determination of RhIG Candidacy & Postpartum Determination of RhIG Candidacy*
- 2. Perform Fetal Screen testing if indicated as described in Transfusion Medicine Policy, <u>Fetal Cell Screening Using the FMH Rapid Screen Kit.</u>
- D. Fetal Maternal Hemorrhage (FMH) Testing
 - 1. Order the Fetal Cells by Flow Cytometry Test if indicated (and not already ordered by the patient's physician)
 - a. Fetal Cell Quantitation is indicated if:
 - i. Gestational age > 18 weeks
 - ii. Fetal screen is positive or
 - iii. Mother or Infant is Weak D Positive or undetermined
 - 2. If the flow cytometry test is indicated but cannot be performed (e.g., flow cytometry is closed) order and submit a sample for Kleihauer-Betke Testing if stat testing is required
 - 3. One vial of RhIG should be prepared as soon as possible as described in step F; do not wait until the FMH is complete.
 - Refer to Transfusion Medicine Policy, Fetal Cell Screening Using the FMH Rapid Screen Kit.
- E. Resulting RhIG Candidacy Report
 - 1. If RhIG evaluation is ordered antepartum, result the RHIGCAN (RhIG Candidacy Report) using the result comment codes indicated in the attachment *Antepartum Determination of RhIG Candidacy*
 - 2. If RhIG evaluation is ordered postpartum, result the RHIGCAN (RhIG Candidacy Report) using the result comment codes indicated in the table *Postpartum Determination of RhIG Candidacy*.
 - 3. If FMH testing is required add the **FMH** result comment; "More than 1 vial of RhIG may be indicated, ..." to the RhIG candicacy result.
 - a. 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.]
- F. If the patient is a RhIG candidate
 - 1. Obtain one vial of RhIG from the refrigerator.
 - 2. Add-on a derivative order for the RhIG if not already on the order. Refer to Transfusion Medicine Policy, Safetrace (Blood Bank) Application.
 - 3. If preparing the RhIG in advance for the patient reprint Beaker specimen label and affix to plastic bag or box.
 - 4. a. DB,FH,GP, RO,TTW: Document the Control Form with the Patients Name, Hospital Medical Record Number and Room Number. A patient accession label may also be used for this purpose.
 - b. Verify completion of patient's Rh type, baby's Rh type and FMH screen result as applicable.

- c. Enter the lot number and expiration date of the Rhlg.
- d. Initial where indicated on the form.



- 5. Place the insert and control card back in the bag /box.
- 6. Place the RhIG vial in the designated area in the crossmatch refrigerator.
- G. When the completed dispense form (Blood/Component Pickup Slip x23480) is received for the RhIG, issue each vial of RhIG that has been allocated for the patient.
 - 1. Issue the RhIG and print the D-Tag (Derivative Tag) in the BBIS. Refer to <u>Transfusion Medicine Policy, Safetrace Application; Issuing Derivative (RhIG)</u>.
 - 2. Affix one of the D-Tag labels to the plastic bag or box containing the product.
 - 3. Include the remaining D-Tag label attached to the paper with the product.
 - 4. Retain the dispense copy of the tag in the blood bank and staple to the dispense form.
- H. If FMH testing was indicated, upon completion of the Fetal Cells by Flow Cytometry (or Kleihauer Betke) test perform the following:
 - 1. Obtain the % Fetal Bleed from the results in EPIC and compare to the RhIG dosage chart above to determine if more than one (1) vial of RhIG is required.
 - 2. If additional RhIG vials are not required:
 - a. Result the FMHA test code as SEE; See Comments
 - i. Free text in the result comment field "Additional Testing Complete" and " One total vial Rh Immune Globulin Indicated"
 - 3. If additional RhIG vials are required then prepare and document the Control Form for each vial of RhIG. Refer to step F of this Procedure.
 - a. Notify the patient's caregivers that the additional RhIG vials are ready. This notification is documented in step 2.b.iv below
 - b. Result the FMHA test code as SEE; See Comments
 - i. Free text in the comments "Additional Testing complete" and " _____ total number of vials of Rh Immune Globulin indicated" for the total amount that are indicated.

ii. Notify the patient's caregivers that the additional RhIG vials are ready, and document this notification in the result comment.

IX. SPECIAL NOTES:

- A. 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 should be tested as soon as possible by the Blood Bank. The patient should be directed to the L&D or Family Birth Center, where the RhIG will be administered, if applicable.
- B. 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).
- C. The Blood Bank typically dispenses RhIG for postpartum patients who delivered at Corewell Health, or for antepartum patients in Labor & Delivery/Family Birth Centers At some site RhIG may be dispensed for patients in other locations by the pharmacy. However, if RhIG is requested from the Blood Bank for any patient in any location at this facility, the Blood Bank will supply the RhIG.
- D. The dispense of RhIG should not be delayed while waiting for testing to be completed. For example, in situations where physician intends to discharge the patient prior to completion of testing.
- E. At Grosse Pointe, 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 are 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.

X. REFERENCES:

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

Attachments

Antepartum Determination of RhIG Candidacy (rev. 07/15/2024)
Postpartum Determination of RhIG Candidacy (rev 07/21/2024)

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	8/27/2024

Step Description	Approver	Date
	Hassan Kanaan: OUWB Clinical Faculty	8/14/2024
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	Masood Siddiqui: Staff Pathologist	8/13/2024
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Karrie Torgerson: Medical Technologist Lead	8/9/2024	
	Teresa Lovins: Supv, Laboratory	8/9/2024
	Kelly Sartor: Mgr, Division Laboratory	8/8/2024
Kelly Sartor: Mgr, Division Laboratory Kelly Sartor: Mgr, Division Laboratory	8/8/2024	

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne