1. **Sample Collection and Labeling:**

   a. Collect whole blood samples into standard blood collection tubes in accordance with manufacturer's instructions. Refer to the appropriate testing requisition for sample requirements on tube type and volume required.

      - Grossly hemolyzed or lipemic specimens will not be accepted. However, mildly hemolyzed or lipemic specimens may be accepted upon evaluation by testing personnel.

      - Lithium Heparin and/or Sodium Heparin samples (green top tubes) should not be submitted.

      - Serum separator tubes should be avoided, if possible.

   b. Label tubes with at least **2 different identifiers**, such as patient name, unique hospital number, and/or date of birth. Include the **collection date and time** on each tube and on the laboratory requisition.

   c. Proper sample identification is necessary for accurate and efficient testing. A delay in testing will occur if any aspect of sample identification is incorrect or illegible, or if submitted samples do not meet sample requirements listed on the requisition.

2. **Storage:**

   a. Allow serum sample to clot at room temperature.

   b. Store all samples at 2°-8°C.

3. **Test Requisition:**

   a. Review appropriate laboratory testing requisition for sample instructions and patient information required.

   b. Sample label and requisition documentation must match in order for testing to be performed. Any documentation or sample type discrepancies detected during specimen/request reconciliation by testing personnel will result in the rejection of the questionable sample.

4. **Shipping:**

   a. Pack samples according to your hospital's protocol for shipping biological specimens.

   b. Notify CBC Hospital Services when samples are ready to be shipped. CBC Hospital Services will arrange for a courier to pick up specimens as needed.

END

Tel (937) 461-3295 Fax (937) 461-2738

PATIENT/DONOR INFORMATION				
Name(Last, First):	ID:	DOB:	Sex:	Race:

Donor for:/ NA	Relationship to Pt:/ NA	Physician:	Institution:
Diagnosis: If Abnormal: % Lymphocyte WBC Count		☐ Diagnostic ☐ HLA Selected Platelets ☐ Other	
Sample Collection	Date:	Time:	Collected by:

MINIMUM SAMPLE REQUIREMENTS	
HLA- B27	**10 ml Sodium Heparin *DO NOT REFRIGERATE***
DNA Typing	**7ml EDTA**
Antibody ID	**10 ml Plain Red Top (Serum Separator Tubes are NOT acceptable) or 5 ml EDTA**

Contact Hospital Services (937) 461-7557 for specimen pickups

Samples will *NOT* be accepted after *12:00 Noon* on Fridays without prior approval

Samples should be received within 24 hours of collection

TEST REQUESTED	
☐ HLA-B27 serologic (701, 729)	☐ DNA-A,B,C (Class I)(753)
☐ DNA-B27 (754)	☐ DNA-DR,DR345 (Class II)(751)
☐ TRALI Workup (728)	☐ DNA-DQ (Class II)(723)
☐ Other	☐ DNA-Single Locus- A B C(754)
Comments:	

HLA Laboratory Use ONLY

Received: Date: Time: By:	Volume:	Log #:

Policy

Background:

Sickle cell anemia patients are subject to chronic transfusion of red cells for treatment of their anemia. Historically, chronic transfusion of sickle cell patients has often resulted in the formation of multiple red cell alloantibodies, and occasionally, HLA antibodies. As a result, most sickle cell transfusion programs have instituted guidelines to reduce the probability of alloimmunization in these patients, and to provide the best possible products for transfusion.

The purpose of this policy is to list a set of suggested guidelines for the transfusion of sickle cell anemia patients in the CBC/CTS service area. The policy was developed with input from several area hospitals, the Reference Laboratory, and the Medical Director of CBC/CTS.

Guidelines:

The following guidelines are suggested for the transfusion of red cells to sickle cell anemia patients:

A. Phenotype matching

- Patients who are negative for the C, E, and/or K antigens should receive red cells that are negative for these antigens.
- CBC/CTS will attempt to supply Rh(D) positive patients who are C-E- with red cells that are of the R_0 phenotype. Since most donors of the R_0 phenotype are African-American, these donor red cells further serve to potentially match the patient for other antigens. O negative red cells will be supplied if there are no R_0 red cells in the current inventory.

B. Leukoreduction

- Sickle cell anemia patients should receive red cells that are leukocyte reduced.

C. Hemoglobin S status

- Sickle cell anemia patients should receive red cells that have been tested and found to be hemoglobin S (Hgb S) negative.
- Red cell units that have a historic Hgb S negative property are acceptable for issue without further testing.
- If previously untested, hospitals have the choice to test for Hgb S or to have CBC/CTS do the testing for an additional fee.

D. Additional Information

- If additional information is required regarding the transfusion history of a sickle cell patient, the Reference Laboratory of CBC/CTS may be called to inquire about any records that may be available regarding phenotyping, previously identified antibodies, etc.

END

Background

Standards for Immunohematology Reference Laboratories, as written and approved by the American Association of Blood Banks (AABB), mandate that the Reference Laboratory shall have a process to recognize and investigate drug-dependent antibodies. This policy serves to give information on the recognition of suspected drug-induced immune hemolysis and the referral of samples for laboratory investigation. Our Reference Laboratory does not perform laboratory investigation of suspected drug-induced immune hemolysis; proper controls are not available and these investigations are seldom performed. Therefore, proficiency and competency testing are not easily accomplished. Any investigations will be referred to another laboratory that routinely performs serologic drug investigations.

Policy

A. Recognition

Drugs rarely cause immune hemolytic anemia; the estimated incidence is 1 in 1 million of the population. Many drugs have been implicated over the years and a list may be found in the current edition of the AABB Technical Manual.

The drug-related problems most commonly encountered in the blood bank are those associated with a positive DAT and a nonreactive eluate. When other more common causes of immune-mediated hemolysis have been excluded AND a temporal relationship exists between the administration of a drug and the hemolytic anemia, a drug antibody investigation should be pursued.

If a drug(s) is suspected as the cause of an immune hemolytic anemia, the physician should be advised to immediately discontinue the use of the drug(s) in the patient.

B. Laboratory Investigation of Suspected Drug-Induced Immune Hemolysis

1. May be requested/initiated by a physician from a hospital in the CBC service area in consultation with a CBC Medical Director.
2. May be suggested by the CBC Reference Laboratory based on initial laboratory findings and after consultation with a CBC Medical Director. Hospital would be notified of the need for a laboratory investigation of a suspected drug-induced hemolytic anemia and would be advised of sample requirements and associated charges; the hospital would be responsible for obtaining the order for the testing from the attending physician.

C. Referral of Specimens

Specimens will be referred to an AABB accredited IRL (Immunohematology Reference Laboratory) that regularly performs drug related serologic investigations. These laboratories will be approved in accordance with QRA-620-POL, Testing Laboratory Qualification. Sample requirements, completion of patient/sample request forms, shipping of the sample, turnaround time, and testing charges will be discussed with the referring laboratory prior to shipment of the sample.

D. Hospital Notifications

The hospital requesting the investigation will be notified of:

1. All charges associated with the external investigation, including shipping charges, as they become available.
2. Approximate turnaround time.
3. Results as they become available.

A CBC Medical Director is available for additional consultation as necessary.

END

Telephone: (937) 461-3264	**After Hours:** (937) 461-7557 Ask for Reference Laboratory On-Call Technologist	**Fax:** (937) 461-2738

***INSTRUCTIONS*:**

1. **Please call the Reference Laboratory before sending samples, regardless if the request is urgent or routine (not time sensitive). This allows for the tracking and prioritizing of samples received in the Reference Laboratory.**
2. Complete the first page of this form as completely as possible concerning the hospital and patient information. A medication history is not critical unless anemia is unexplained and may be due to drug administration. Race and diagnosis are very important pieces of information that often give the Reference Laboratory direction for the resolution of the problem. A date of birth or social security number MUST be provided in order to process any sample.
3. Complete the second page of this form to indicate the problems that have been observed by your facility and what tests are being requested. Also record the date that the sample was collected and all relevant hospital laboratory findings.
4. Our Reference Laboratory does not perform red cell crossmatching as part of the case resolution. However, a space exists at the bottom of page 2 to record the number of red cell products needed for the patient if clinically significant antibodies are identified. It also has a section to mark any special requests for the product such as leukoreduction, irradiation, or "other".
5. See page 3 of this form for **specimen and shipping requirements** for various kinds of cases that are referred for testing.

Hospital		***Telephone Number for Report***		
Patient Name		***Age***	***Race***	***Sex***
Diagnosis	***Physician***	***D.O.B. or Social Security Number***		
Medications: (please provide if requested by Reference Lab Staff)		***Medical Record Number (optional)***		

Number of Pregnancies:_____ ***Pregnant now? _____*** ***Date Due:_____***

Does the patient have a history of red cell or platelet transfusion: (REQUIRED INFORMATION)

Within Last 4 Months: ☐ ***Yes*** ☐ ***No*** ***If So, Dates:_____***

Prior to Last 4 Months ☐ ***Yes*** ☐ ***No*** ***If So, Dates:_____***

Previous Transfusion Reaction: ☐ ***Febrile*** ☐ ***Allergic*** ☐ ***Hemolytic*** ☐ ***Other (describe)***

Hemoglobin/Hematocrit: ***Retic***: ***Bilirubin***: ***Platelet Count:***

Has patient previously been referred to this lab or to any other consultation lab?	☐ **Yes**	☐ **No**
If yes, where?	***When?***	

Results:

(Also complete information on the reverse side of this form – page 2)

Nature of Difficulty (Please mark all that apply):

- ☐ ABO Typing Problem
- ☐ Rh(D) Typing Problem
- ☐ Incompatible Crossmatch
- ☐ Suspected Transfusion Reaction
- ☐ Other_____
- ☐ Hemolytic Disease of Fetus and Newborn (HDFN)
- ☐ Unidentified Antibodies
- ☐ Positive Direct Antiglobin Test (DAT)
- ☐ Platelet Refractoriness

Requested Tests

- ☐ Reference Case (includes antibody identification and all tests deemed necessary by the reference laboratory for complete resolution of the problem, i.e., adsorptions, elutions, associated ABO and Rh(D) typing problems, etc.)
- ☐ Resolution of ABO Type and/or Rh(D) Type
- ☐ Platelet Crossmatch (Please check with CBC before ordering.)
- ☐ Molecular RBC genotyping
- ☐ Other (please specify):

Hospital Laboratory Findings: (Please submit copies of panel sheets and/or screening results)

Date Sample Collected:_____

ABO Group_____ Rh(D) Type_____ Other Phenotyping:_____

DAT Testing: Polyspecific_____ anti-IgG_____ anti-complement:_____

Antibodies identified (including those previously identified):_____

Antibodies suspected:_____

Enhancement Used (mark all that apply):

☐ LISS | ☐ PEG | ☐ Gel | ☐ Saline | ☐ Enzyme | ☐ Solid Phase | ☐ Other_____

Transfusion Requirements:

Number of Red Cell Products Needed (**will not** be crossmatched by Ref Lab):_____

Special Requests (mark all that apply):

☐ Leuko-reduced ☐ Irradiated ☐ Other_____

Comments:

Sample Requirements:

1. Routine antibody identification (suspected single or multiple alloantibodies):
   Minimum of 5 ml of EDTA anticoagulated blood and 7 ml of clotted blood (plain red top tube – NO serum separator tubes)
2. Suspected warm autoantibody:
   Minimum of 10 ml (2 tubes) of EDTA anticoagulated blood and 7 ml of clotted blood (plain red top tube – NO serum separator tubes)
3. Investigation of suspected hemolytic transfusion reaction:
   a. P**re**-transfusion sample (including EDTA tube if possible)
   b. P**ost**-transfusion samples (minimum of 1 EDTA tube and 1 blood bank clot tube)
   c. Unit number(s) of suspected unit(s) and segments from units if possible
4. Investigation of suspected HDFN (Hemolytic Disease of the Fetus/Newborn):
   a. Mother: 1 EDTA tube and 1 clot tube
   b. Baby: minimum of 2 cc of anticoagulated whole blood
   c. Biologic Father (only if antibody to a low incidence antigen is suspected): 1 EDTA tube
5. Platelet Antibody Investigations (includes platelet crossmatching and additional testing as needed):
   Minimum of 5 ml of EDTA anticoagulated blood and 7 ml of clotted blood (plain red top tube – NO serum separator tubes).
   NOTE: if the patients WBC count is 1,000 or below, a minimum of 10 ml of EDTA anticoagulated blood will be required.
6. Molecular RBC genotyping:
   Minimum of 5 ml of EDTA anticoagulated blood. **NOTE:** If the patients WBC count is 1,000 or below, a minimum of 10 ml of EDTA anticoagulated blood will be required. Also see Indications for Molecular RBC genotyping below.
7. Thermal Amplitude testing or Donath-Landsteiner test:
   Call the Reference Laboratory for specific directions for sample collection and shipping.

Shipping Requirements:

Any samples shipped to the Reference Laboratory must be sufficiently packaged to prevent leakage and breakage during transport. Regulations for the shipment of biologic materials must be followed. Samples may be shipped at room temperature or on wet ice. A request form must accompany all samples.

Tube Labeling Requirements:

1. Patient's blood samples must be sent in stoppered tubes with firmly attached labels containing the patient's first and last names, social security number and/or birth date, and the date the tubes were drawn. The patient's first and last names must match what is recorded on this form. The Reference Laboratory reserves the right to reject specimens that are not properly labeled or collected according to the above sample requirements.
2. If sending samples after hours, please separate the serum/plasma from the red cells into clearly labeled tubes before sending.

Indications for Molecular RBC genotyping:

Molecular RBC genotyping is recommended for any patient for whom a serologic phenotype is difficult to obtain; it is also recommended for selected patients with complex serologic problems. This would include patients who have positive DATs (with or without an underlying warm autoantibody), patients who have been recently transfused, selected patients with multiple alloantibodies, and patients with an antibody to a high prevalence antigen. Molecular RBC genotyping is also recommended for sickle cell anemia and thalassemia patients. The Reference Laboratory reserves the right to obtain additional information for orders for molecular RBC genotyping that are not consistent with these recommendations.

SECTION A:

Hospital: _____ Date/Time of Order: _____

Patient Name: _____ DOB: _____

Ordering Physician: _____

SECTION B:

- All products supplied will be leukocyte-reduced, HgbS negative, irradiated, and ≤ 5 days old unless otherwise specified.
- Group O red cells will be reconstituted with Group AB plasma, unless otherwise specified or discussed.
- Red cells must be confirmed as negative for the following antigens: _____

List any other additional requirements for the product in this box.

SECTION C:

Total Volume of Reconstituted red cells ordered (include any prime volume): _____

Requested hematocrit of final product: _____

NOTE: A hematocrit > 50% must be approved by a CBC physician after consultation with the ordering physician.

SECTION D:

Form Completed By: _____ Date: _____

Date and Time Faxed to Reference Laboratory (937-461-2738): _____

Date and Time Order verbally given to Reference Laboratory: _____

Reference Laboratory Technologist receiving verbal order: _____

Instructions for completion of REF-220-F-01:

A. All sections are to be completed by the requesting facility.

B. List any antigens for which the red cells must be confirmed as negative for. Also record any additional requirements for the product in the box required.

C. The total volume of requested reconstituted red cells must be recorded in Section C; any PRIMING volume required must be included in this total.

D. Section D must be completed as follows:

1. The hospital technologist completing REF-220-F-01 must sign or initial on the line next to “Form Completed By:” and date on the line next to “Date:”

2. The technologist completing the form must record the date and time the form was faxed to the Reference Laboratory.

3. The technologist must also record the date and time the order was verbally called to the Reference Laboratory and the name of the Reference Laboratory technologist who they gave the verbal order to.

Policy

1.0 Definitions

1.1 Immunologically selected platelet product – A platelet product that is immunologically tested and selected for a specific patient transfusion; immunologic testing may include crossmatch compatibility status, patient HLA Class I antigen typing, patient HLA Class I antibody screening and identification, ABO of the product, or a combination of two or more of these criteria as determined by the Community Blood Center Reference Laboratory staff member.

1.2 PRA – The acronym PRA stands for "percent reactive antibody" or "panel reactive antibody". The PRA is expressed as a percentage of cells that react in the HLA Class I antibody screen (panel) and it is analogous to a red cell antibody identification panel. Since the HLA system is so polymorphic and so many HLA cells (types) are represented on the panel, the result is reported as the percentage of cells that react on the screen/panel. This percentage is calculated by a UNOS (United Network for Organ Sharing) computer program which takes into account all HLA types and all ethnicities. Therefore, the PRA isn't always accurate for a donor population that is not ethnically diverse or is fairly homogeneous. As a result, finding a donor for a particular patient based solely on a PRA value is not always reflective of the ease or difficulty in actually finding a donor in a given population.

1.3 Platelet crossmatch – Platelet crossmatching, as performed by the Reference Laboratory of CBC, is a solid phase red cell adherence assay. A commercial test kit, Immucor Capture-P, is utilized for this testing. This test detects antibodies to ABO antigens, platelet specific antigens, and HLA Class I antigens, but is usually unable to differentiate between them.

1.4 ELISA-based platelet antibody detection – ELISA-based platelet antibody detection is utilized to differentiate between platelet specific and HLA Class I antibodies. This testing is not performed by our laboratory and would be sent to an outside accredited laboratory if deemed necessary by the CBC medical director.

1.5 Platelet coordination fee – This fee is assessed whenever a Reference Laboratory or HLA staff member must search to find a preferred immunologically-selected platelet product from the available platelet inventory. This applies even when donors are actively being recruited for a patient but a product from a recruited donor isn't available at the time of the request (for example, recruited product isn't yet released, order for platelets exceeds the number recruited, etc.). This fee is meant to offset the labor expenses associated with the time needed to locate the best possible platelet product for the recipient.

1.6 HLAM fee – The HLAM fee (or HLA matched fee) is applied to a product that is HLA-selected for a patient. This fee is applied to platelet products from donors who are recruited, as well as to products that are selected by the Reference Laboratory staff. This fee is meant to offset the cost of maintaining an HLA-typed donor base.

2.0 All requests for "immunologically selected" platelet products (crossmatched or HLA-selected) must be directed to the Reference Laboratory at 937-461-3264. If there is no answer at the Reference Laboratory phone number, Hospital Services should be contacted at 937-461-7557 to

page a member of the Reference Laboratory staff (both during regularly scheduled hours and on-call hours).

2.1 A member of the Reference Laboratory staff will check to see if previous requests for immunologically selected platelet products for a particular patient have been made. The patient's chart will be reviewed as necessary. The hospital will be advised if additional testing is required. For example, if a patient has a history of HLA Class I antibodies but an HLA Class I antibody identification has not been recently performed (within the past 3-4 months), the Reference Laboratory technologist may suggest repeating the screen or transfusing crossmatch compatible products. These recommendations are situation dependent and many factors must be considered, such as previous PRA, after hours requests, inventory levels, and the platelet count of the patient, including any recent one-hour post platelet infusion counts.

2.2 If the request is for a first time patient, the Reference Laboratory will request the necessary samples to be drawn. A Reference Laboratory Request Form (REF-200-F-01) must accompany all samples.

3.0 For all first time requests, platelet crossmatching will be performed according to REF-400-WI-02, Platelet Crossmatch: Capture-P.

3.1 The number of platelet products to crossmatch will be at the discretion of the Reference Laboratory technologist and is often determined by the available inventory. Efforts will be made to crossmatch ABO type specific platelet products, but is dependent on inventory levels.

3.1.1 If all platelet products are crossmatch compatible, the cause of the platelet refractoriness is unlikely to be due to immunologic causes.

3.1.2 Products will be tagged as "crossmatch compatible" for the recipient. All products will be irradiated.

3.1.3 ABO type-specific platelet products will be supplied if available.

3.1.4 Careful monitoring of 1 hour post-infusion platelet counts is required. Post infusion counts must be called to Reference Laboratory staff for charting purposes and future transfusion decisions.

3.1.5 At the discretion of the CBC medical director, an HLA Class I antibody screen may be performed; this additional testing is more likely to be performed if one-hour post infusion platelet counts are not obtained.

3.2 If one or more platelet products is found to be crossmatch incompatible, samples of the patient's blood will be forwarded to the HLA department of CBC for an HLA Class I antibody screen and an HLA Class I antigen typing (if the Class I typing is not already on file or cannot be provided from another laboratory).

3.2.1 A crossmatch compatible platelet product will be supplied for the patient until HLA testing is completed. In the event that all crossmatches are incompatible, the hospital will be asked to contact the ordering physician to see if product delivery can wait until HLA testing is complete.

3.2.2 After HLA testing is completed, a Reference Laboratory staff member will attempt to locate a product based on the HLA Class I type of the patient, while avoiding HLA antigens to which the patient has formed identified antibodies. All products will be irradiated. A platelet coordination fee will be applied to any products shipped, and is in addition to the HLA-matched fee.

3.2.3 In the event the HLA department does not identify any Class I antibodies, the CBC Medical Director will be consulted for further instructions. The CBC Medical Director may elect to send a sample of the patient's blood to an outside laboratory for the investigation of the presence/absence of platelet specific antibodies. If a platelet specific antibody is identified, the Reference Laboratory, in conjunction with the CBC Medical Director, will make specific recommendations to the hospital for platelet transfusion.

3.2.4 The hospital will be billed for all testing performed by the Reference and HLA laboratories which are deemed necessary to supply a platelet product for the intended recipient, including those incurred by sending to an outside laboratory.

3.2.5 If immunologic testing is negative and the patient is refractory, the cause of the refractoriness is unlikely to be due to immunologic causes; specialty products are unlikely to benefit the patient.

4.0 Recruitment of donors for specific patients must be initiated by calling the Reference Laboratory at 937-461-3264.

4.1 The Reference Laboratory must be called to initiate all requests to recruit donors that are "immunologically-selected" for a particular patient.

4.1.1 The Reference Laboratory technologist will complete REF-400-F-02, Immunologically Selected Platelet Order Form.

4.1.2 The following information needs to be supplied by the hospital: patient name, patient date of birth, diagnosis, physician contact information (name and phone number of ordering physician), most recent platelet count, **number of products to be recruited on a WEEKLY basis**, and any special requirements of the product (all platelet products will automatically be leukoreduced and irradiated).

4.1.3 **A new order MUST be received from the transfusion service every 14 days in order for recruitment efforts to continue. It is the responsibility of the hospital transfusion service to contact the ordering physician for continuing orders for recruitment.**

4.1.4 The platelet coordination fee will not apply to donors that are recruited for a specific patient; the HLAM fee will be applied.

5.0 It is the responsibility of the transfusing facility to obtain a one hour post infusion platelet count for all immunologically-selected platelet products. Failure to do so may result in intervention by a CBC medical director. Additional testing may be necessary before additional products are supplied.

6.0 This policy is intended as a general guideline for the provision of immunologically-selected platelet products.

6.1 This policy is not intended to cover all testing scenarios.

6.2 Many cases will need to be evaluated on an individual basis, with input from many sources.

6.3 Medical decisions concerning platelet transfusion therapy will be made by a CBC physician in consultation with the ordering physician.

END