Customer Resource Manual For Laboratory Testing Services
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SECTION I: GENERAL IBC INFORMATION and REQUIREMENTS

A. Laboratory Services Overview

The Indiana Blood Center (IBC) is comprised of many departments committed to serving the needs of surrounding hospitals, blood centers, collection sites for tissues, organs, and hematopoietic cells, physician’s offices, and the general public by performing specialized testing. The Laboratory Services Department specifically includes Donor Testing, NAT, HLA, and the Immunohematology Reference Laboratory.

- The Testing Laboratory performs routine testing on all donor samples collected by the Indiana Blood Center and various other blood centers, collection sites for tissues and hematopoietic cells, hospital blood banks and plasma centers throughout the United States. In addition to routine donor testing, the laboratory offers a variety of patient tests to hospitals, organ procurement agencies and local laboratories. It includes the NAT Laboratory which tests donor samples for viral RNA using trans-mediated amplification methods for blood centers, collection sites for tissues, organs, and hematopoietic cells, hospital collections centers, and cord banks across the eastern half of the United States.

- The Reference Laboratory specializes in providing essential testing services for patients with specific serologic complexities. Hospitals throughout Indiana utilize the services of the Reference Laboratory routinely for simple to complex serologic investigations and the provision of specially typed red cell units for patients with a transfusion need.

- The HLA Laboratory performs specialized Histocompatibility testing and DNA relationship testing.

It is with a sense of pride and commitment that the Indiana Blood Center offers the services included within this manual.

B. Laboratory Services Mission Statement

The Laboratory Services Department provides timely, cost-effective and quality services to local and regional customers through the provision of laboratory testing and blood products, with an emphasis on meeting the specific individualized needs of each. This is accomplished through utilizing the latest technology, our expertise in blood banking, educational leadership, and management of product inventory and mix.

C. Blood Center Personnel Directory

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Phone # (317)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>Byron B. Buhner</td>
<td>916-5001</td>
</tr>
<tr>
<td>President/CEO</td>
<td>Dan A. Waxman, M.D.</td>
<td>916-5008</td>
</tr>
<tr>
<td>Executive VP/Chief Operating Officer</td>
<td>Mike Parejko</td>
<td>916-5007</td>
</tr>
<tr>
<td>VP/Quality Systems</td>
<td>Lora Poore</td>
<td>916-5141</td>
</tr>
</tbody>
</table>
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Donor/ NAT Testing

For operational issues

Director of Testing        Tara Williams  916-5197
Manager of Testing        Blake Batthauer  916-5156
Customer Service Administrator  Bill Fullerton  916-5199

If you have an urgent request and cannot reach one of these individuals, please call the main laboratory at 317-916-5193.

For confirmatory results

Customer Service Administrator  Bill Fullerton  916-5199

For testing status and general results

Testing Laboratory (24 hours)  General Number  916-5193

Reference

Manager/ Reference Laboratory  Jayanna Slayten  916-5186
Reference Lab  General Number  916-5188

HLA

Manager/ HLA-DNA Laboratory  Vicki Yarnell  916-5236
HLA-DNA Laboratory  General Number  916-5237

Distribution

Director of Operations  Terry Joseph  916-5275
Distribution Department  General Number  927-1719

NOTE: Personnel listed above are routinely available Monday-Friday from 8:00 a.m. - 4:30 p.m. During evenings, overnights or weekends, contact the Distribution Department to page the necessary staff for resolution of issues or questions.

D. Regulatory License / Registration Numbers

The following information may be helpful to your hospital or donor center during an inspection. IBC utilizes only Food and Drug Administration (FDA)-licensed test kits and FDA-cleared medical devices for Donor Testing. Tests are performed and interpreted, and IBC procedures are written in accordance with manufacturer’s directions. IBC may utilize other laboratories for special testing and has ensured that they also are FDA-licensed and use only approved methodologies. Current copies of licenses, certificates, may be obtained from IBC upon request or from the IBC website, www.indianablood.org.
E. General Information

1. **Testing Contracts / Requests for Proposal** - Requests for contracts that include pricing and test packages should be forwarded to the Executive VP/Chief Operating Officer. All requesting facilities will receive a draft contract for review that addresses their specific needs. At IBC, contracts are reviewed by the VP/Chief Financial Officer, VP/Quality Systems, and CEO. Contracts are reviewed annually.

2. **Handling of Complaints** - It is IBC’s desire to provide its customers with a quality service in every way. In the event your facility is not satisfied with the service provided, we request that you notify us so we can evaluate the situation to determine where systems can be improved. Please contact us verbally or in writing of any problems, concerns, or issues that your facility may have regarding any area of our service. Anyone from the list of departmental contacts is available to assist you with concerns.
SECTION II: TESTING LABORATORY SERVICES

A. Description of Available Tests

The Indiana Blood Center is licensed by the FDA to perform routine donor screening or patient testing using FDA-cleared reagent kits and medical devices where applicable. All test results are generated and interpreted in accordance with manufacturer’s instructions or alternate procedures that have been approved by the FDA and outlined in CFR 640.120. Cadaveric samples are tested with assays licensed for those samples. The following tests may be requested for either donor or patient samples.

1. **Viral Marker** testing is performed using Abbott Diagnostics Prism chemiluminescence technology. The current battery of viral marker testing includes:
   
a. Hepatitis Core Antibody (HBC) (Prism technology)
b. Hepatitis C Antibody (HCV) (Prism technology)
c. HTLV I/II Antibody (HTLV) (Prism Technology)
d. HIV 1 / 2 Antibody (HIV) (Prism Technology)
e. Hepatitis B Surface Antigen (HBS) (Prism technology)

2. **Syphilis (STS)** screening is performed using the Beckman Coulter PK7300 system.

3. **Cholesterol** testing is performed using the Roche C501 Chemistry Analyzer for donor incentive purposes.

4. **Atypical red cell antibodies (ABY)** are currently detected using the Bio-Rad Tango Optimo System.

5. **ABO/Rh** blood grouping is performed using the automated Beckman Coulter PK7300 analyzer, or manually by tube testing. The Beckman Coulter PK7300 is an FDA-cleared medical device that utilizes a microplate agglutination technique. All results are interpreted in accordance with manufacturer’s instructions. Samples that cannot be tested by that technology may be tested with either Bio-Rad Tango Optimo, or by manual tube.

6. **CMV- Cytomegalovirus** testing is performed on the Beckman Coulter PK7300 as requested.

7. **Chagas-** Chagas testing for antibodies to the causative agent, T. cruzi, is performed using the licensed Abbott Diagnostics Prism chemiluminescence.

8. **Nucleic Acid Testing (NAT)** is performed using Roche Cobas Taq Screen MPX HIV-1/HCV/HBV Assay and WNV Assay. This testing may only be ordered on donor samples since it may not be used diagnostically for patient samples. WNV testing is performed using licensed systems. Since NAT results become test of record with the initial results, these assays are not generally repeated except for counseling purposes. Repeat tests may also be performed on WNV for purposes of donor counseling.

9. **Repeat Testing** is performed in duplicate on all initially reactive viral marker assays (except NAT and CMV) and individually for STS tests in accordance with manufacturer’s requirements.

10. **Confirmatory Testing Resolution** of repeat reactive viral markers is performed by IBC or outside agencies subcontracted by IBC. Refer to Section H for the list of confirmatory
procedures performed on specific, repeatedly reactive viral marker assays or STS samples. Samples are sent out on a daily basis and tested based on the reference laboratory’s schedule. Results are available within two weeks for all tests. In the event special handling or an expeditious turn-around is necessary (e.g. autologous surgery), please notify the Customer Service Administrator.

B. Testing Request Process

1. Donor Testing

NOTE: Barcode labels and the specific number series, except for ISBT 128 labels which are facility unique, will be controlled by IBC to prevent duplicate customer number series. Currently IBC is able to accommodate ISBT 128 labels, Code 128 labels, and codabar type labels with all numeric characters.

a. > 50 Donors: Large collection facilities will forward a sample-accessioning list with the sample shipment. These facilities will receive a full panel of testing and do not need to indicate the individual tests on the packing list acceptable to IBC. Additional paperwork identifying what samples are in the shipment is normally not necessary. A large site will normally receive results electronically or via an electronic facsimile. Refer to Section G for result reporting.

b. < 50 Donors: Small collection facilities may supply one of the following:

1.) Only an accessioning list is needed if the full testing panel is ordered.
2.) If only an infectious disease panel is ordered, the Test Request Form (see Attachment A) may be used. The Test Request Form is completed with the sample ID numbers of the tubes in the shipment. This form is used to verify presence of all samples within the shipment and to confirm that all samples in this shipment receive HBS, HIV, HTLV, HBC, HCV by Prism, HIV1/ HCV / HBV NAT, WNV NAT and STS. Please request this form from the Customer Service Manager when needed.
3.) The current full testing panel includes ABO/RH, ABY, HBS, HIV, HBC, STS, HTLV, HCV, and HIV-1/ HCV / HBV and WNV NAT. If all of these tests are not needed, please use the Test Request Form to order tests individually.

2. Patient Testing

a. Individual Samples: An outpatient Test Request Form may be used for individual samples that are forwarded to the laboratory for testing by local hospitals, Physician Fertility Clinic offices, blood centers, and organ procurement agencies. This form is a multi-part form. Each page is labeled so it is clear which pages stay with the tube and which stay with the customer.

The Test Request Form has pre-attached barcode labels that match the imprinted number appearing on all copies of the form. The barcode labels should be used to label the test tubes sent to IBC for testing. The pink copy is the facility’s record of the sample number and the tests requested. Do not record patient name or any confidential information on the tubes, or on the forms. For patients, we do request the patient’s age to comply with CLIA regulations. If none is filled in, 99 will be entered. Refer to Section G for information on result reporting using the Test Request Form.
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The Test Request Form can be used to indicate the donation type on the Special Instructions line for NAT testing. Donations of whole blood and hematopoietic cells can be tested in pools up to 16. Samples from donors of other tissues and organs must be tested individually. The lab must be called so that special arrangements can be made if cadaveric sample is sent for testing. Please note that only the venous samples from hematopoietic progenitor cell donors can be tested; the products themselves are not suitable samples.

b. **Multiple Samples**:
   If a collection site collects many patient samples, it may be easier and less cumbersome to use the Patient/Donor Test Request Form. This form is completed by recording the sample ID of each tube being sent and requires the site to pre-label their samples with IBC approved barcodes. It is incumbent upon the customer to be able to correlate their ID numbers back to the individual patients. This system is used by blood banks that collect both donors and patients. Please request this form from the Director of Testing or the Customer Service Manager if this represents a suitable method for patient sample request notification.

C. **Sample Integrity Criteria**

The quality of the sample sent for testing impacts the laboratory’s ability to generate quality test results. Upon receipt, samples at IBC are evaluated using the following standards:

1. **Labeling** - Place the barcode label directly under the tubes stopper or cap, straight up and down as illustrated below. It is not critical which way the numeric numbers start, as the scanners in the laboratory interpret the barcodes. The barcode label must be accurately positioned to ensure accurate interpretation by the automated instrumentation utilized during the testing process. The IBC barcode label must be prominently displayed on the tube. No other barcodes are to be placed over the IBC labels. Doing so decreases the ability of the instruments to accurately scan the barcode labels.

   ![Correctly vs Incorrectly Labeled Samples]

   Samples that are not properly labeled often require manual entry of the number, thereby circumventing the most precise method of barcode identification and interpretation. Sites that incorrectly position barcode labels will be contacted for additional training.

   **NOTE**: Contact IBC regarding which number series can be used on the sample tubes for either donor or patient testing. Currently, IBC utilizes the Codabar, ISBT 128 or Code 128 symbology for its label sets. Number assignments are done only via a Client Information Worksheet (CIW) (see Attachment E). Contact the Customer Service Administrator or the Director of Testing for more information.
2. **Volume** - Since much of the testing is performed utilizing automation, a certain sample volume is required by each instrument to account for dead space and to ensure accurate results. A minimum of 3 mL of plasma or serum must be present in each sample submitted to guarantee complete initial testing and potential repeat testing is performed. When multiple samples are submitted, as in the case of requesting routine donor screening, each sample should have the minimum required volume. Full 6-7 mL tubes are the ideal sample in all cases. The testing equipment is designed to manage 6-7 mL tubes only. If you have questions about acceptance of other tubes, please call the Testing Customer Service Administrator to discuss options.

3. **Shipping Conditions** - Sample tubes that are shipped long distances, or that arrive at IBC more than four hours after leaving the collection facility must be shipped on a cold pack. Cold packs are used in a proportion that maintains 2 – 25 degrees C of the samples in the box. Frozen packs will hemolyze red blood cells and should not be used with whole blood. Sample management personnel will measure the temperature upon arrival in the laboratory. If sample integrity is compromised, laboratory personnel will contact the collection facility immediately. Wet ice should only be used if well-protected from any leakage onto samples or paperwork. Shipment of samples must comply with 42CFR 72 regulations.

The 42CFR 72 and DOT regulations require that blood for donor testing be considered a diagnostic sample and must travel in a triple layer package. This means that the specimen must be in a closed container, that there must be a leakproof secondary container with sufficient absorbent material to capture any spills, and there must be an outer container that can withstand a drop of nine (9) meters. For NAT, the samples must be maintained at temperatures less than 25 degrees C. For a small blood box, generally one cool pack will be sufficient to maintain temperature for the duration of the shipping.

Note: Shippers frequently refuse to deliver leaking boxes due to melting wet ice. This makes the triple packaging mentioned above critical to ensuring samples arrive at IBC for testing.

4. **Age** - Each manufacturer defines the acceptable age limits for samples tested when using their reagents. Please review the Testing Laboratory Sample Requirements Table to ensure that your samples arrive at IBC within the specified time guidelines. IBC laboratory personnel will contact the collection facility if samples arrive for testing after the manufacturer’s time limits.

5. **Hemolysis** - Lysed red cells may interfere with the accuracy and reliability of test results. IBC uses a maximum standard of 200 mg/dL for hemolysis for viral testing. Samples that exceed 200 mg/dL will not be tested. The collection facility will be contacted and new samples requested if this situation occurs. If your needs differ from this, please contact the Customer Service Administrator to make arrangements.

6. **Lipemia** - Fatty acids and protein levels often interfere with the accuracy and reliability of test results. IBC currently uses a maximum standard of 2000 mg/dL for lipemia in the Donor Testing Laboratory. IBC screens samples on the Roche c501 Chemistry analyzer to determine the triglyceride value for sample suitability. The collection facility will be contacted and new samples requested if the sample is higher than the suitability limits. As with hemolysis, IBC recognizes that, in general, laboratories will not want NAT completed on a sample that cannot be tested for the rest of the profile. If your needs differ
from this, please contact the Customer Service Manager to make appropriate arrangements.

7. **Bilirubin** - Icteric samples may not generate accurate or reliable test results. IBC uses a maximum standard of 20 mg/dL for bilirubin in both the Donor Testing and NAT Laboratories. Samples that exceed 20 mg/dL will not be tested. The collection facility will be contacted and new samples requested if this situation occurs.

8. **Sample source** – Venous samples are preferred. In some instances, plasma from a whole blood product may be substituted. Please contact the lab to verify sample acceptability. Only samples from whole blood and hematopoietic progenitor cells may be tested for NAT in pools. Samples from HPC products themselves are not acceptable. Call ahead to make arrangements for cadaveric sample testing to ensure that the assay requested is approved for cadaveric specimens and to allow planning for the special processing required for cadaveric samples.

D. **Sample Type / Number of Tubes**

Refer to Section H for a complete listing of tests available by name and the corresponding specimen requirements relating to type of sample and number of tubes for each test or package available.

**Donor Testing** - The routine donor screening profile requires a minimum of three 6 or 7 mL samples. If NAT is ordered, then a fourth 6 or 7 mL EDTA tube is required. MPX (HIV 1/ HCV / HBV) and WNV NAT can be performed from a single test tube. If a testing contract is for a package other than full donor screening, fewer tubes may be acceptable but the exact specifications must be outlined and approved by IBC and the collection facility.

If a special circumstance mandates smaller tubes, for example a pediatric stem cell collection, please call the Customer Service Manager to make special arrangements. Any routine deviations from the stated sample type or number must be determined as part of the contract negotiations.

**Patient Testing** - The routine patient profile requires a minimum of two 6-7 mL red top samples and two 6-7 mL EDTA tube to ensure initial, repeat and confirmatory testing can be performed as required.

E. **Sample Racking / Packaging / Transport**

**Donor Testing**

**Racking** - Place each of the four tube types into separate designated racks or tube boxes. For example, each tube type, EDTA, Red Top #1, Red Top #2 and the NAT EDTA tubes are placed in different racks. Racks may be supplied, if requested. Load all tubes in each rack or tube box, in sequential order, starting in the left front of the rack and loading left to right in each row. Racks and tube boxes will be returned to the collection facility in their original shipping containers. IBC will return shipping containers to the collection facility via UPS ground unless other arrangements are made.

**Packaging** - Samples must be packaged and transported according to the Department of Transportation (DOT) Regulations for clinical specimens and 42CFR 72. We recommend the following protocol:
1. Use a blood box that has a plastic bag placed between the inner walls of the outer box and Styrofoam support inserts that can be tied up prior to closing the box. This practice will ensure that contents do not spill out if the lid gets opened. It will also contain large spills better and prevent the outer blood box from becoming contaminated. If the outer box becomes contaminated during shipment, the airlines and ground courier services will not guarantee delivery. It is important even for local shipments that the box is appropriate in size for the samples. Acceptable containers include clear, plastic bags, Styrofoam sample holders, and small blood boxes.

Use of thin cardboard boxes from other applications is not acceptable as they may leak or tear and may not hold the temperature. If a single sample is placed in a large box, it is at risk for rolling around and breaking. It also is at risk for being covered by the packing materials and mislaid. Please see Attachment D for examples of the correct and incorrect ways to package individual samples.

2. Wrap each rack in enough absorbent material to ensure broken tubes will not contaminate the other contents within the box. We suggest placing each wrapped rack in a plastic bag that gets tied or taped to minimize the handling risk in case of broken tubes. Bubble wrap may also be used for this purpose.

3. Number the wrapped test tube racks in sequential order on the outside for ease of unpacking and arranging tubes.

4. Enclose a packing list listing the sample ID numbers contained within the shipment. Refer to Section B for specific testing request forms and information. Place the packing list in a plastic bag and include it in the first box of the shipment. Enclosing the list in a plastic bag prevents it from becoming contaminated in the event of a large blood spill.

5. Enclose sufficient gel packs to maintain temperatures between 2 to 25 degrees C. Do not use frozen gel packs as they can hemolyze samples. If a frozen sample is being shipped, then a frozen gel pack may be used. Do not use dry ice.

6. Number the outside of the shipping container boxes in sequential order, 1 of x, 2 of x, etc., when more than one box is present in the shipment. The letter (x) represents the total number of boxes contained within the shipment.

Transport - The method of shipment by air, ground or both, is best determined by the customer’s proximity to IBC and also by the customer’s expectation for turn-around of test results. Regardless of shipment method, each customer is expected to notify IBC via the Notification of Sample Shipment Form on the day that samples are shipped. Please fax the form at least one hour prior to shipment arrival. The Laboratory fax number is (317) 916-5195. This form notifies IBC of the method of transport, transport carrier, approximate arrival time and the total number of samples contained within the shipment. The total number of samples sent should reflect the number of donors or patients represented in the shipment, not the total number of tubes sent.

It is the customer’s responsibility to deal directly with the local courier services and to finalize shipping arrangements. Contact the Administrator of Customer Service and Support for information regarding ground transportation courier services from the Indianapolis Airport to IBC. If the shipment has not arrived an hour after the arrival time noted on the Notification of Sample Shipment Form, Testing Laboratory personnel will contact the sending facility. It is the responsibility of the sending facility to track the location of the package.
Patient Testing

Racking - If patient samples are racked as part of a larger donor testing shipment, then they can be placed in the same rack / container as long as the tubes are marked clearly “Patient Samples” and will not get incorrectly identified as donors. Refer to Section B for instructions regarding patient testing request forms.

Packaging / Transport - Indianapolis facilities transport their samples to the IBC Distribution Department. Samples will be received and logged into the building. The Testing Laboratory will be notified that samples have arrived.

Do not send samples in a plastic bag with wet ice. Any coolant, especially wet ice, should be kept protected and away from samples and paperwork. Ensure all samples that are being sent via air or ground transportation are packaged and transported according to Department of Transportation Regulations. See the “Packaging” section above in the Donor Section for more specifics about acceptable shipping conditions.

F. Turn-Around Time: Donor Testing

The IBC Donor Testing Laboratory is open for testing Monday through Saturday. Both donor and patient testing results are routinely available within twenty-four (24) hours from receipt of samples according to this schedule unless a specific testing schedule is agreed to with the customer.

STAT testing must be arranged by contract and is subject to additional fees. Small shipments of samples that are received by 11:30 a.m. Monday through Friday may be tested on the same day of receipt. Repeat testing of initially reactive EIA samples will be performed on the next business day. The Director of Testing or Customer Service Manager will contact you with information regarding which days the laboratory will perform testing around any calendar holiday. A letter will be sent to customers in advance of any holiday describing the holiday schedule.

G. Reporting of Results

Donor Testing

Donor Testing results can be reported back to the customer in a variety of ways. IBC currently offers three primary methods: electronic transmission, e-mail, and facsimiles of a laboratory test report.

1. Electronic Transmission - The most efficient and accurate means of reporting test results is through the electronic transmission of data files from IBC to the LIS in the customer’s facility. IBC Information Systems Specialists will work to outline the most practical means of receiving data electronically based on the hardware and software capabilities of each customer. To ensure the integrity of the data, all electronic transmission systems are validated prior to use in a live environment by a transmission sent from IBC that will be verified by the customer within their environment.

2. E-mail Transmission - Results can be e-mailed to a designated e-mail address at the customer’s facility via FTP file. As with the electronic result transmission, to ensure integrity of the data, e-mail transmission of results will be validated prior to use in a live environment.
3. **Test Report Facsimile** - Results reports are faxed from the Testing Laboratory IBC’s lab system to the customer’s fax number. This will be validated with sample reports.

4. **Verbal Results** - IBC is aware that emergency situations arise that may require a facility to request a verbal test result. Verbal test result requests are available through Testing Laboratory Management (or designee) only. Any such verbal request will always be followed up with a printed test result report sent through usual and customary channels.

**Small Volume Testing**

**Test Request Form (outpatient)** - The Statement of Laboratory Testing Results Status Report is attached to the Test Request Form to report results on tests ordered on the Test Request Form. Qualified laboratory personnel review the form for accuracy prior to releasing results. The forms are always mailed to Client, and will be faxed or E-mailed as PDF attachments if so indicated on the test requisition. See the attached example for a legend of testing results.

**H. Confirmatory Tests**

IBC works with customers to understand their individual needs for confirmatory testing. These are the confirmatory tests available for the viral assays routinely performed:

IBC routes confirmatory testing to those laboratories indicated in the following list.

**Human Immunodeficiency Virus Antibody (HIV):**
South Bend Medical Foundation by anti-HIV-1 (Western Blot) using Genetic System’s licensed test; HIV 2 (EIA) Antibody using Genetic System’s licensed test. If the HIV 2 antibody is positive, then the HIV 2 Western Blot is performed at Specialty Labs using an unlicensed assay.

**Hepatitis C Virus Antibody (HCV):**
South Bend Medical Foundation by anti-HCV (RIBA) using Recombinant Immunoblot Assay by Chiron RIBA HCV 3.0t or Anti HCV by ORTHO Elisa Version 3.0

**Human T-Lymphotropic Virus Antibody (HTLV-I/II):**
If EIA positive, confirmatory testing may be performed by Life Source using the Innogenetics unlicensed line immunoassay at customer’s request.

**Hepatitis B Surface Antigen (HBsAg):**
IBC by HBsAg Enzyme Immunoassay Neutralization using Abbott’s licensed Prism test

**Serological Test for Syphilis:**
Tested at Indiana Blood Center performing RPR (w Titer if Positive) and Trepsure Anti-Treponema EIA Screen

**Chagas Disease (T. cruzi)**
Quest, using an unlicensed RIPA assay for T. cruzi

Note: Confirmatory testing for HIV and HCV will be performed by the FDA-licensed tests noted above according to customer needs. Please note that the HCV or HIV confirmatory testing is not required when the corresponding HCV or HIV NAT is positive but only if the customer has filed a variance stating this practice with the FDA. Confirmatory testing may also be discontinued for
positive HBsAg if the HBV NAT is positive per guidance provided by FDA. This is an individual laboratory preference and the desire to use this guidance should be relayed to the Customer Service Administrator at the Testing Laboratory. It is the Client's responsibility to notify the Testing laboratory customer Service Administrator of their confirmatory testing needs for all testing performed.

CT/NG NAT

South Bend Medical Foundation using the Gen Probe Aptima Combo 2 assay or Aptima individual probe assays for NG and CT. Method listed on FDA web site as cleared for tissues.
I. SAMPLE SUITABILITY CHART

Note: test tubes may be glass or plastic.

<table>
<thead>
<tr>
<th>TEST CODE</th>
<th>Assay</th>
<th>SPECIMEN REQUIREMENTS</th>
<th>SAMPLE SUITABILITY @ 2-8°C</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAT</td>
<td>HIV 1/HCV / HBV NAT</td>
<td>(1) 6 or 7 mL EDTA tube</td>
<td>8 days (samples must be centrifuged prior to 72 hours)</td>
<td>Roche Cobas TaqScreen HIV 1/HCV / HBV Assay</td>
</tr>
<tr>
<td>WNV</td>
<td>West Nile Virus NAT</td>
<td>(1) 6 or 7 mL EDTA tube</td>
<td>8 days (samples must be centrifuged prior to 72 hours)</td>
<td>Roche Cobas TaqScreen WNV Assay</td>
</tr>
<tr>
<td>HBS</td>
<td>Hepatitis B Surface Antigen</td>
<td>6 or mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum)</td>
<td>14 days at 2-8°C; long-term storage at -20°C</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Confirmatory: Neutralization</td>
</tr>
<tr>
<td>HBC</td>
<td>Hepatitis B Core Antibody</td>
<td>6 or 7 mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum).</td>
<td>14 days at 2-8°C; long-term storage at -20°C</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total Antibody</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>No Confirmatory Test Available</td>
</tr>
<tr>
<td>HIV</td>
<td>HIV 1/HIV 2 Antibody</td>
<td>6 or 7 mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum).</td>
<td>14 days; long term storage frozen</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Confirmatory: Anti-HIV-1 WB, HIV-2 AB</td>
</tr>
<tr>
<td>HTLV</td>
<td>HTLV I/II Antibody</td>
<td>6 or 7 mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum).</td>
<td>14 day; storage greater than 14 days at -20°C.</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Supplemental: Anti-HTLV I by (Western Blot)</td>
</tr>
<tr>
<td>HCV</td>
<td>HCV Antibody</td>
<td>6 or 7 mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum).</td>
<td>14 days; long-term storage frozen</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total Antibody</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Supplemental: Anti-HCV (RIBA II)</td>
</tr>
<tr>
<td>CHA</td>
<td>Chagas Disease</td>
<td>6 or 7 mL purple top tube (EDTA) OR 6 or 7 mL red top tube (serum).</td>
<td>2 - 8º C for 10 days; frozen (&lt;-20º C) if longer; up to 5 freeze-thaw cycles</td>
<td>Prism Chemiluminescence Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Supplemental: Chagas RIPA</td>
</tr>
<tr>
<td>STS</td>
<td>Syphilis</td>
<td>6 or 7 mL red top tube (serum).</td>
<td>5 days @ 2 – 8 deg. then seperated and frozen at -20ºC indefinitely</td>
<td>Beckman Coulter PK TP system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Confirmatory: Trepsure EIA &amp; RPR,</td>
</tr>
<tr>
<td>ABY</td>
<td>Antibody Screen</td>
<td>6 or 7 mL red top tube (serum)</td>
<td>24 hours a room temperature, followed by 6 days at 2-8 º C for 7 days total</td>
<td>Tango or Manual Tube Method</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Normal Reference: Negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Confirmatory: Antibody Identification upon request</td>
</tr>
<tr>
<td>Test</td>
<td>Description</td>
<td>Specimen Type</td>
<td>Storage Conditions</td>
<td>Normal Reference</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------</td>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>CHOL</td>
<td>Total Cholesterol</td>
<td>6 or 7 mL red top tube (serum)</td>
<td>5 days; -20°C for 3 months</td>
<td>Normal Reference: &lt; 200 mg/dL</td>
</tr>
<tr>
<td>CMV</td>
<td>Cytomegalovirus Antibody</td>
<td>6 or 7 mL red top tube (serum)</td>
<td>14 days for serum 3 days for plasma no limit specified at -20°C</td>
<td>Olympus CMV Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td>HBCONF</td>
<td>Hepatitis B Surface Antigen Neutralization</td>
<td>4 mL serum or plasma</td>
<td>7 days; -15°C if longer</td>
<td>Prism Chemiluminescence Method Normal Reference: Negative (Non-neutralizable)</td>
</tr>
<tr>
<td>HBSAB</td>
<td>Antibody to Hepatitis B Surface Antigen</td>
<td>4 mL serum or plasma</td>
<td>7 days; -20°C if longer</td>
<td>Centour Chemiluminescence Method Normal Reference: Reactive (immune)</td>
</tr>
<tr>
<td>FTA</td>
<td>Antibody</td>
<td>4 mL serum</td>
<td>5 days; -20°C if longer</td>
<td>Fluorescent antigen or micro-hemagglutination Normal Reference: Non-Reactive</td>
</tr>
<tr>
<td>TP EIA</td>
<td>TP EIA</td>
<td>4 mL serum or plasma</td>
<td>5 days, 2 - 8°C. Freeze if longer</td>
<td>Trepsure EIA screen</td>
</tr>
<tr>
<td>WB</td>
<td>Anti-HIV-1 by Western Blot</td>
<td>4 mL serum or plasma</td>
<td>7 days; -20°C if longer</td>
<td>Genetic Systems AutoBlot Method Normal Reference: Negative</td>
</tr>
<tr>
<td>HTLV WB</td>
<td>Anti-HTLV-I/II by Western Blot</td>
<td>4 mL serum or plasma</td>
<td>5 days; -20°C for 3 months</td>
<td>Genelabs Western Blot Normal Reference: Negative by WB/Negative by RIPA</td>
</tr>
<tr>
<td>HCV</td>
<td>HCV EIA</td>
<td>Serum or plasma 2.0ml preferred</td>
<td>10 days @ 2-8 deg 30 days @ -20°C</td>
<td>Anti-HCV assay by ORTHO Elisa Version 3.0</td>
</tr>
<tr>
<td>RIBA</td>
<td>HCV Recombinant Immuno-Blot Assay</td>
<td>4 mL serum or plasma</td>
<td>7 days; -20°C if longer</td>
<td>Chiron Immunoblot Method Normal Reference: Negative</td>
</tr>
<tr>
<td>HIV2</td>
<td>Antibody to HIV 2</td>
<td>4 mL serum or plasma</td>
<td>7 days; -20°C for 3 months</td>
<td>Genetic Systems EIA Method Normal Reference: Negative</td>
</tr>
<tr>
<td>HIV2 WB</td>
<td>HIV 2 Western Blot</td>
<td>4 mL serum or plasma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHL/GC</td>
<td>Chlamydia plus GC</td>
<td>Urine or vaginal swab</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Swab specimens must be transported to the laboratory in the swab specimen transport medium and tube. Swab specimens must be transported to the laboratory at 2°C to 30°C and tested within 60 days of collection.

Urine specimens can be transported to the laboratory at 2°C to 30°C in either the primary collection device (urine cup) or in the urine specimen transport tube. Urine specimens must be transferred into the APTIMA specimen transport tube within 24 hours of collection and before being assayed. After transfer, urine specimens can be stored at 2°C to 30°C for up to 30 days after collection.

Target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the TIGRIS DTS Automated Analyzer or semi-automated instrumentation as specified.
SECTION III: IMMUNOHEMATOLOGY REFERENCE LABORATORY SERVICES

A. Description of Available Tests

The IBC Immunohematology Reference Laboratory (IBC-IRL or Reference Laboratory) is a highly specialized area that focuses attention on the identification and resolution of red cell transfusion-related problems. It is accredited by the AABB and maintains satisfactory standing with all inspection agencies. Outlined below is the list of available tests and services that can be requested through the IBC-IRL.

1. Red Cell Antibody Investigations
   a) Single to Complex Multiple Antibodies
   b) Auto-Antibodies
   c) Drug-Dependent Antibodies
   d) Antibodies to High and Low-incidence Antigens
   e) Reagent-Dependent Reactivity

2. Hemolytic Disease of the Newborn Investigations
3. Transfusion Reaction Investigations
4. Aberrant or Discrepant Result Investigations
   a) ABO Discrepancies
   b) Discrepant Red Cell Antigen Typing
   c) Weak Antigen Expression Investigations

5. Polyagglutination Investigation
6. Donor/Patient Red Cell Phenotype Requests
   a) Routine red cell antisera phenotyping
   b) RBC Genotyping if serologic methods are inconclusive or unavailable

7. Prenatal Evaluations (ABO/Rh, ABID, titer)
8. Procurement of Antigen-Negative Donor Units (including hemoglobin S negative units)

IBC has staff available twenty-four (24) hours daily to assist you with your transfusion needs. For more information about the services provided by the IBC Reference Laboratory contact Jayanna Slayten, Manager/Reference Laboratory (jslayten@indianablood.org).

The IBC-IRL is mandated by AABB IRL Standards to provide continuous (on-site or on-call) availability of qualified individuals for:

- Serologic Investigation
- Serologic Consultation
- Procurement of Antigen-Negative Donor Units
- Response to Requests for Rare Donor Units from the American Rare Donor Program (ARDP)
B. Testing Request Process / Forms: According to AABB IRL Standards; all samples received in IRL must have an accompanying request

All testing request and/or rare donor unit requests must be placed by phone.

1. For patient investigations:
   - Complete the Reference Laboratory Consultation Request Form as thoroughly as possible to ensure that patient information is clear. This form may be obtained by contacting the Reference Laboratory (317-916-5188). The IBC-IRL or ordering facility may coordinate shipping.
   - Flowchart of Submitting Samples to IBC-IRL is attached as a summary of the process.

2. For rare donor unit requests:
   - Phone order alone is adequate. The order will be annotated by the IBC-IRL, completed and the units shipped to the requesting facility.
   - Flowchart of Requesting Rare Units from IBC-IRL is attached as a summary of this process.

C. Sample Requirements

The following sample criteria are also outlined on the Reference Lab Consultation Request Form. Testing may be started as long as adequate sample volume has been submitted and tubes are appropriately labeled.

1. Volume and Number of Sample Tubes:
   a) If the DAT is negative:
      - Minimum for an antibody work-up should be two (2) red top tubes and two (2) EDTA tubes.
   b) If the DAT is positive:
      - Minimum for an antibody work-up should be two (2) red top tubes and four (4) EDTA tubes. Additional EDTA sample is important for adsorption, elution and/or cell separation techniques that may be necessary.
   c) For suspected transfusion reactions:
      - Submit pre- and post-transfusion specimens and segments from the transfused units.
   d) For HDN evaluations:
      - Send samples from the mother and the baby (cord sample).
      - Please submit a consult form for both the mother and the baby.
   e) For RBC Molecular Typing
      - The sample for performing the testing is either a buccal swab or a 7 mL EDTA test tube.
      - A buccal swab is mandatory for any transplanted patient.
      - The sample is stable at room temperature for at least 7 days.
      - Older samples may be acceptable but have greater risk of DNA degradation.
      - A guide for collecting buccal swab samples is posted on the IBC website, www.indianablood.org.
      - Contact the Reference Laboratory if you have any questions regarding the appropriateness of a sample.
f) For miscellaneous testing requests or when the sample volume is a problem, the facility is encouraged to call the Reference Laboratory for guidance on the amount of sample to be submitted.

2. **Labeling Requirements and Sample Suitability**

The Reference Laboratory has defined minimum labeling expectations in accordance with the Standards of the American Association of Blood Banks. The stated criteria must be adhered to for the safety of the patient. All phases of testing and reporting of results must be documented. This is to ensure trackability of each case in the event of an adverse reaction.

Each patient sample tube must be labeled with following minimum information:

a. Patient first and last name
b. Patient identification number
c. Date specimen collected
d. Phlebotomist’s identification; the identification may be either initials or numeric code.

If the tube label is illegible, or if the patient data on the tube is not identical to the patient data on the Reference Laboratory Consultation Request Form, the specimen will be rejected. The lab will be notified by phone and fax to document the rejection.

A patient sample that is hemolyzed may be an indication of a recent transfusion reaction, traumatic draw, or improper storage during transportation to the Reference Laboratory. True hemolysis will be distinguished from hemolysis due to external factors upon receipt at the laboratory. If all tubes received are hemolyzed, the facility will be contacted to inquire as to the phlebotomy technique and transfusion history, if not provided. If some of the tubes are unacceptable, testing will be completed on the tubes that are acceptable.

3. **Specimen Age / Retention.**

a) The Reference laboratory routinely performs all case evaluations on specimens that were collected within the previous three (3) days. If a sample is received for testing on the day in which it expires (day 3), the facility will be contacted and asked if they still want the investigation completed.

b) If transfusion is not required (e.g. prenatal workups, RBC genotyping), exceptions may be made to the 3-day sample age policy.

c) All samples submitted for evaluation will be retained for two (2) weeks in the event additional testing is deemed necessary, e.g. transfusion reaction investigation.

D. **Sample Packaging / Transport**

It is the responsibility of the requesting facility to establish transport for the samples forwarded to the IBC Reference Laboratory. Notify the Reference Laboratory in advance of sample arrival. Ensure samples are sent in protective packaging or canister to ensure sample stability during transport.

Samples sent by ground are subject to DOT requirements and must be packed in a three-part assembly. This means that the specimen must be in a closed container, there is a secondary
container with sufficient absorbent material to capture any spills, and there is an outer container that can withstand a drop of 9 meters. Contact the Reference Laboratory for the packing materials provided by IBC to meet this requirement.

E. Turn-around Time

1. STAT samples will be processed and prioritized before ASAP or ROUTINE samples. STAT samples are investigated until the completion of antibody identification with a TAT expectation of within 1 working day.

2. ASAP samples will be completed within 12-24 hours of when the sample is received at the IBC.

3. ROUTINE samples will be completed between 1 and 5 days from when the sample is received at IBC.

4. Samples referred to another Reference Lab for high complexity resolution, drug studies and/or molecular sequencing may take up to three (3) months for resolution.

5. RBC molecular typing requests will be completed within 7 working days.

6. Antigen screening typing orders will be filled at the rate of 1 hour / antigen/ 10 units tested providing units are available. TAT for antigen orders follow the STAT, ASAP and ROUTINE TAT guidelines above.

F. Reporting of Results: Phone, Fax, Final Report

Depending on the antibody(ies) present in a sample or complexity of the work-up, complete resolution may not be possible.

Upon completion of testing, the Reference Laboratory personnel will call the ordering facility and give a verbal preliminary report. If applicable, units that are available for transfusion will be delivered to the IBC Distribution Department who will make arrangements for units to be delivered to the ordering facility.

A summary of the results will also be documented and forwarded to the ordering facility. This report will outline the patient’s results for the following tests:

1. ABO/Rh
2. DAT
3. Eluate Reactivity
4. Serum Reactivity
5. Preliminary Interpretation

A final Reference Laboratory Consultation Report will then be prepared after supervisory review of each Reference Laboratory investigation. The Reference Specialist, Reference Laboratory Manager or designee and Medical Director, will review the final report. The final report will be provided to the ordering facility within two (2) weeks from the time the sample was received.
SECTION IV: HISTOCOMPATIBILITY (HLA) LABORATORY SERVICES

A. Description of Available Tests

The HLA Laboratory services area hospitals and other blood centers with histocompatibility testing related to platelet support, disease associations, and transplantation. In addition, the laboratory offers testing for platelet antibody screening, platelet antigen typing and relationship testing services.

HLA - Typing
- HLA-A,B,C Low Resolution typing by SSP-PCR or Lab Scan SSO
- HLA-DR,DQ Low Resolution typing by SSP-PCR or Lab Scan SSO

Antibody Screen
- Platelet Antibody screen by ELISA
- HLA Class I Antibody screen (Percent Reactive Antibody-PRA) by CDC, Flow, or Lab Scan
- HLA Class II Antibody screen (PRA) by Flow or LabScan

Crossmatching
- T cell Direct crossmatch by CDC or Flow
- B cell Direct crossmatch by Flow
- Platelet crossmatch by Solid Phase Red Cell Adherence (SPRCA)

Disease Association
- Class I (ABC) or Class II (DR,DQ)

Parathyroid Tissue Cryopreservation

Neonatal Alloimmune Thrombocytopenia Panel (NATP)

Platelet Antigen Typing (PLA1 and Full antigen profile)

Relationship Testing

B. Testing Request Process / Form

The HLA Laboratory only performs tests upon the written or electronic request of the client. A test order form (i.e. HLA-DNA Test Order Form - see Attachment C) should accompany each specimen. Oral requests for laboratory tests are permitted only if the laboratory obtains subsequent written authorization for testing within thirty (30) days of request. Relationship testing samples are drawn by appointment only.
• Specimens should be sent directly to the IBC Distribution Department.
• As a general guideline, routine testing is performed on specimens received by 11:00 a.m. Monday through Friday.
• Specimens received after 11:00 a.m. or on Sunday will be tested the following day.
• Routine testing is not performed on weekends or holidays – STAT testing is available.
• Cardiac and Renal transplant work-ups will be performed on demand. Notify Distribution to contact the “on-call” technologist.
• The hospital should call the HLA laboratory when sending a specimen.

C. Sample Requirements / Packaging / Transport

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Specimen</th>
<th>Anticoagulant/Storage Medium</th>
<th>Vol.</th>
<th>Sample Age (Optimal)</th>
<th>Storage Temp</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLA class I/II ABO Autocrossmatch</td>
<td>Whole blood</td>
<td>ACD (EDTA acceptable for ABO or typing only)</td>
<td>20-40 mL (min. 1ml for typing only)</td>
<td>&lt;48 hrs.</td>
<td>RT</td>
</tr>
<tr>
<td>HLA class I/II</td>
<td>Lymph node</td>
<td>Culture medium (RPMI)</td>
<td>N/A</td>
<td>&lt;24 hrs.</td>
<td>4ºC</td>
</tr>
<tr>
<td>Crossmatch and PRA by CDC/Flow</td>
<td>Serum</td>
<td>None</td>
<td>5-10 mL</td>
<td>&lt;24 hrs.</td>
<td>4ºC</td>
</tr>
<tr>
<td>DNA-STR (Relatedness testing)</td>
<td>Whole Blood</td>
<td>EDTA</td>
<td>0.5-3 mL</td>
<td>24-48 hrs.</td>
<td>RT</td>
</tr>
<tr>
<td>DNA-STR (Relatedness testing)</td>
<td>Buccal Swab</td>
<td>None</td>
<td>2 swabs</td>
<td>&lt;72 hrs</td>
<td>RT</td>
</tr>
<tr>
<td>Platelet Ab Screen</td>
<td>Serum or Plasma</td>
<td>EDTA/ None</td>
<td>1-5 mL</td>
<td>&lt;24 hrs.</td>
<td>4ºC</td>
</tr>
<tr>
<td>Platelet crossmatch (SPRCA)</td>
<td>Serum or Plasma</td>
<td>EDTA or ACD plasma</td>
<td>5-10 mL.</td>
<td>Serum for XM expires in 7 days</td>
<td>4ºC</td>
</tr>
<tr>
<td>Platelet antigen typing by PCR</td>
<td>Whole Blood</td>
<td>EDTA, ACD</td>
<td>1-3 mL</td>
<td>NA</td>
<td>RT</td>
</tr>
<tr>
<td>Cryopreservation</td>
<td>Parathyroid</td>
<td>Sodium heparin</td>
<td>10-20 mL</td>
<td>&lt;48 hrs.</td>
<td>4ºC</td>
</tr>
</tbody>
</table>

Histocompatibility testing

Specimens must be labeled with the name or unique identification for the donor/patient and the date of collection. Additionally, specimens should be labeled with the following as applicable: hospital name and/or number, collection time, phlebotomist ID.

In the event specimen collection and storage requirements are not met (i.e. volume, storage time, storage temperature, method of shipment), testing may be performed and followed to completion if it can be determined that the sample is still suitable (i.e. sufficient viable cells, sufficient DNA). This will be done at the discretion of the technologist performing the testing.
The 42CFR 72 and DOT regulations require that diagnostic samples must travel in a triple-layer package. This means that the specimen must be in a closed container, there must be a secondary container with sufficient absorbent material to capture any spills, and there must be an outer container that can withstand a drop of nine (9) meters. Contact the HLA/DNA for IBC-provided packaging materials.

Samples for platelet crossmatch are good for seven (7) days (day of collection is day one).

D. Turn-around Time

- Preliminary HLA test results are available two (2) to three (3) business days after specimen is received. Final results for HLA are available in approximately ten (10) business days. Relationship testing results are available in five (5) business days.

- STAT orders will be performed on demand. STAT and after hours charges will apply to these requests.

NOTE: The HLA laboratory will call a courier for the hospital if requested. The customer will be billed for the courier run.

E. Reporting Results

**Histocompatibility testing**

HLA testing reports are sent by facsimiles, but may be sent by mail or email upon client request.

**Relationship testing**

Relationship testing reports are sent by mail, but may be faxed or emailed upon client request. Results are not given over the phone.
## ATTACHMENT A

**TEST REQUEST FORM**

(Use "CONSULTATION REQUEST FORM" for Reference Lab Orders)

Indiana Blood Center • Laboratory Services
3480 N. Meridian St. • Indianapolis, IN 46298 • (317) 916-5190

Patient ID: (Numbers Only) Only): ______________________________ Age: ______________________________

Form Completed By: ____________________________________________

Special Instructions: ____________________________________________

Dept. To Be Billed: ____________________________________________

Facility Name & Address (Please include full address if result is to be mailed via US Mail):

_________________________________________________________________

☐ Perform Confirmatory If Reactive ☐ Perform Confirmatory REGARDLESS Of Initial Result

<table>
<thead>
<tr>
<th>BILL</th>
<th>CODE</th>
<th>DESCRIPTION</th>
<th>RESULTS SEE ATTACHED REPORT FOR RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>5151</td>
<td>BMR</td>
<td>Bone Marrow Panel</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV, ABORH</td>
</tr>
<tr>
<td>5502</td>
<td>FULL</td>
<td>Complete Donor Profile &amp; NAT</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV, ABORH</td>
</tr>
<tr>
<td>5503</td>
<td>FULL</td>
<td>Complete Donor Profile</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV, ABORH</td>
</tr>
<tr>
<td>5091</td>
<td>TBANK</td>
<td>Tissue Bank Profile</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5120</td>
<td>EIA</td>
<td>Infectious Disease Profile Only</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5552</td>
<td>FERT</td>
<td>Fertility Donor Profile</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis</td>
</tr>
<tr>
<td>5030</td>
<td>ABORH</td>
<td>ABO Group and Rh Type (donor)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5031</td>
<td>ABORH</td>
<td>ABO Group and Rh Type (cord)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5010</td>
<td>HBSAG</td>
<td>Hepatitis B Surface Antigen (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5110</td>
<td>HIV 1/2</td>
<td>Antibody to HIV-1/2 (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5040</td>
<td>HBC</td>
<td>Antibody to HB Core (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5065</td>
<td>STS</td>
<td>Syphilis</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5062</td>
<td>HTLV-III</td>
<td>Antibody to HTLV-1/2 (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5105</td>
<td>HCV</td>
<td>Antibody to HCV (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5011</td>
<td>NAT</td>
<td>HIV-1/2/HCV (NAT) (IDT)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5012</td>
<td>WNV</td>
<td>West Nile Virus (NAT) (IDT)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5060</td>
<td>CMV</td>
<td>Total (IgG and IgM Ab to CMV)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5200</td>
<td>ABS</td>
<td>Antibody Screen</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5021</td>
<td>CHA</td>
<td>Chagas</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5005</td>
<td>HBCNF</td>
<td>HBSAG Confirmatory Neutralization</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5125</td>
<td>HICNF</td>
<td>HIV 1 (WB) / HIV 2 ABY (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5096</td>
<td>HTCONF</td>
<td>HTLV ABY (WB)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5005</td>
<td>HCCNF</td>
<td>HCV IMMUNO BLOT ASSAY</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5007</td>
<td>FTA</td>
<td>FTA (Syphilis)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5020</td>
<td>HBSAB</td>
<td>Antibody to HBS (EIA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5126</td>
<td>HICNF2</td>
<td>HIV 1 Whole Viral lysate</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5128</td>
<td>GC/C</td>
<td>GC/Chlamydia</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
<tr>
<td>5121</td>
<td>CHCONF</td>
<td>Chagas Confirmation (RIPA)</td>
<td>HBSAG, HCV, HIV 1/2, HBC, HTLV-III, (STS) Syphilis, CMV</td>
</tr>
</tbody>
</table>

**TEST RESULT LEGEND**

- **N** = Non-Reactive
- **R** = Initial-Reactive
- **P** = Repeatedly Reactive
- **CLR** = All Results completed for requested tests
- **I** = Pending initial testing
- **TOF** = Pending final result resolution
- **UNA** = Unable to obtain a valid result

**SEE SEPARATE REPORT**

Date Sent: ______________________________

Date Sent: ______________________________

Date Sent: ______________________________

Date Sent: ______________________________

Date Sent: ______________________________

Date Sent: ______________________________

Mail: ______________________________

Fax: ______________________________

Reviewed By: ______________________________

Date: ______________________________

Comments: ______________________________
**IBC-IRL CONSULTATION REQUEST: ATTACHMENT B**

Call 317-916-5188

The Reference Lab or the IBC-IRL technologist on-call is available at this number 24 hours a day. The IBC-IRL can arrange for a sample pick-up.

The name of the physician to contact for clinical or serologic consultation, if necessary:

<table>
<thead>
<tr>
<th>◆ Name of Contact Physician:</th>
<th>◆ Physician Phone Number</th>
</tr>
</thead>
</table>

**SERVICE REQUESTED**

<table>
<thead>
<tr>
<th>STAT</th>
<th>Investigation / Blood request with an order to IMMEDIATELY TRANSFUSE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Mark for any urgent order for provision of blood.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AS SOON AS POSSIBLE</th>
<th>Investigation / Blood request available within 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Mark for any provision of blood considered a scheduled provision of blood.</td>
</tr>
<tr>
<td></td>
<td>◆ Please indicate when blood is needed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ROUTINE</th>
<th>Investigation / No blood requested. Completion within 1-5 days.</th>
</tr>
</thead>
</table>

**PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>◆ Facility Name</th>
<th>Facility Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Patient Name</td>
<td>Patient Date of Birth</td>
</tr>
<tr>
<td>◆ Patient Id #</td>
<td>Current Hgb/Hct</td>
</tr>
<tr>
<td>◆ Race</td>
<td></td>
</tr>
<tr>
<td>◆ Date of Last Transfusion</td>
<td>Antibody History? Yes ( ), No ( )</td>
</tr>
<tr>
<td>◆ Sample Date:</td>
<td>Ab. identified? _____________</td>
</tr>
<tr>
<td></td>
<td>History at IBC? Yes ( ), No ( )</td>
</tr>
</tbody>
</table>

**REASON FOR SUBMISSION**

<table>
<thead>
<tr>
<th>Antibody Identification</th>
<th>Transfusion Reaction Suspected</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAT Positive</td>
<td>Difficulty in Crossmatch</td>
<td></td>
</tr>
<tr>
<td>ABO or RH Discrepancy</td>
<td>Hemolytic Disease of the Newborn</td>
<td>Prenatal Testing: ABO/RH, Ab Id. &amp; Titer Rh Ig Given? Yes ( ), No ( ) date _____</td>
</tr>
</tbody>
</table>

**PROVISION OF BLOOD FOR TRANSFUSION**

<table>
<thead>
<tr>
<th>Antigen Negative Units?</th>
<th>Yes ( ), No ( )</th>
<th>Compatibility Screened Units?</th>
<th>Yes ( ), No ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td>How Many?</td>
<td></td>
<td>How Many?</td>
<td></td>
</tr>
</tbody>
</table>

SAMPLE REQUIREMENTS: SEE BACK OF FORM
BASIC SAMPLE REQUIREMENTS

Full listing of sample requirements below

Improperly labeled samples will not be tested / Samples should not be separated prior to submission.

All tubes must have Patient Name, Patient Id #, Draw Date and identification of phlebotomist.

DAT Negative Samples  2-Red Top Tubes, 2-EDTA Tubes
DAT Positive Samples  2-Red Top Tubes, 4-EDTA Tubes

Please indicate any additional information on the lines provided below

As the sample is completed, the Reference Specialist will call the results to your facility and submit a Preliminary Fax Report with a summary of preliminary findings. Final Report will follow.

PROVISION of UNITS for TRANSFUSION

When requesting units from the Reference Lab, you may request antigen negative or compatibility screened or both. Segments from units at your facility may also be submitted.

Antigen Negative units are units that are negative for the appropriate antigens for the patient. Compatibility Screened units are units that are screened as reactive or non-reactive with the patient’s current sample.

LABELING REQUIREMENTS

IMPROPERLY LABELED SAMPLES WILL NOT BE TESTED

All specimens MUST be labeled with the following information

1) Patient’s First and Last Name
2) Patient’s ID Number
3) Date Collected
4) Initials of Phlebotomist

IF samples to be submitted are separated, each tube must have correct sample labeling requirements as well as indicate the sample type (serum or plasma).

SAMPLE REQUIREMENTS

1. For Antibody Investigation: Minimal Sample
   a. If DAT negative:  2 – 7 mL red top tubes, 2 – 5 mL EDTA tubes,
   b. If the DAT positive:  2 – 7 mL red top tubes, 4 – 5 mL EDTA tubes.
   c. Additional EDTA sample is important for adsorption, elution or cell separation techniques that may be necessary.
2. For suspected transfusion reactions, pre and post-transfusion specimens and segments from the transfused unit(s).
3. For HDN investigations, send samples from mother and baby (cord sample) with a request for mother and baby.
4. For miscellaneous sample requests or when sample volume is a problem, call the Reference Lab for adequate sample volume to be submitted.

BILLING

A billing invoice will be forwarded to your facility at the end of testing. The submitting facility is responsibility for all charges and/or fees related to the resolution of the patient’s serologic investigation.

ATTACHMENT C
## HLA-DNA TEST ORDER FORM

**Indiana Blood Center • Indianapolis, IN 46208**

**CLI# 15D0664389 | Medicare # 15-HL-01 | UNOS # 15 (NCI) | ASH # 05-4-JN-06-1 | NYSDOH PFI: 7968**

Lab Phone: (317)916-5237  FAX: (317)916-5230

---

**PLEASE COMPLETE ALL INFORMATION REQUESTED BELOW.**

### PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Sample Date</th>
<th>Hospital:</th>
<th>Ph #:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Address:</th>
<th>STAT</th>
<th>Diagnosis:</th>
<th>Person Completing Requisition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOB</th>
<th>HOSP. ID #:</th>
<th>Race</th>
<th>SS#:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M</td>
<td>F</td>
</tr>
</tbody>
</table>

Testing performed the following day if received Sunday or after 11:00 am Monday-Thursday. Please call for special scheduling needs or STAT orders. All specimens must be labeled according to CLIA regulations.

### TEST

<table>
<thead>
<tr>
<th>TEST/PROFILE</th>
<th>SPEC REQ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PLATELET SUPPORT SERVICES

- **Hematology Workup for Platelet Support**
  - Includes: HLA Typing (AB), ABO, Autocrossmatch A+H C+D+ (T-Cell), Platelet Antibody Screen*, Matched Donor List

- **Platelet Antibody Screen* (Performed Automatically on Patients Receiving Platelet Support)**

- **HLA Class I PRA and/or Identification (Flow)* (PerformAutomatically on Patients Receiving Platelet Support)**

- **SPRCA Crossmatch for HLA matched Platelets** (Call Donor Patient Services @ 317-916-5236 with order information)

- **SPRCA Crossmatch for Single Donor Platelets** (Call Donor Patient Services @ 317-916-5236 with order information)

### CARDIAC TRANSPLANT SERVICES

**Patient received Thymoglobulin? Y/N**

- **Pre Transplant Candidate Profile**
  - Includes: HLA Typing(ABDRDQ), ABO, Autocrossmatch Blood(T&B cell) A+H C+D+ Mixed (T/B), Flow Antibody Screen Class I & II*, PRA, CDC, PRA

- **Flow Antibody Screen Class I & II* (PRA) only**

- **Donor Specific Antibody Screen (DSA) Class I and Class II**

- **Day of Transplant Working Up**
  - Includes: Crossmatch A+H C+D (Donor T-Cell), Flow (Donor T-Cell/B-Cell), Flow Antibody Screen Class I & II, PRA

### RENAL TRANSPLANT SERVICES

**Patient received Thymoglobulin? Y/N**

- **Pre Transplant Candidate Profile**
  - Includes: HLA Typing(ABDRDQ), ABO, Autocrossmatch Blood(T&B cell) A+H C+D+ Mixed (T/B), Flow Antibody Screen Class I & II*, PRA, CDC, PRA

- **Flow Antibody Screen Class I & II (PRA) only**

- **Donor Specific Antibody Screen (DSA) Class I and Class II**

- **Day of Transplant Working Up**
  - Includes: Crossmatch A+H C+D (Donor T-Cell), Flow (Donor T-Cell/B-Cell), Flow Antibody Screen Class I & II, PRA

### DISEASE ASSOCIATION SERVICES

- **Specify HLA antigen(s) and/or Disease Association**
  - i.e., Antilyosing Spondylitis/Reumatoloid Arthritis (B27), Narcolepsy (DR2/DQ1)

### BONE MARROW SERVICES

- **Bone Marrow Transplant Profile**
  - Includes: HLA Typing(ABDRDQ), ABO, Autocrossmatch A+H C+D+ (T/B), Flow Antibody Screen Class I & II*, PRA

### OTHER SERVICES

- **Platelet Antigen Typing**
  - circle one: PLA 1 / Full typing

- **Parathyroid Tissue Cryopreservation**

- **TRALI Investigation**
  - Please include information on suspected unit(s).

### SPECIMEN REQUIREMENTS

- **A**: 5 ml Cit Tube
- **A**: Good for 7 Days
- **B**: 20 ml ACD Sol A
- **C**: 40ml ACD Sol A
- **D**: 10 ml Na Heparin or ACD Sol A
- **E**: Lymph Node
- **F**: Parathyroid Tissue
- **G**: 4ml EDTA

*Antibody Identification is performed on all samples with a positive HLA Antibody Screen result.*

See page 2 for donor test orders.
ATTACHMENT C CONTINUED

HLA-DNA TEST ORDER FORM

Indiana Blood Center • Indianapolis, IN 46208
CLIA #15D064296 • Medicare #15-HE-01 • UNOS #10181 • ASHI #06-4-86-1 • NYSDOH PFI: 7968
Lab Phone: (317)916-5237  FAX: (317)916-5230

PLEASE COMPLETE ALL INFORMATION REQUESTED BELOW

<table>
<thead>
<tr>
<th>DONOR INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>Donor Name</td>
</tr>
<tr>
<td>DCB</td>
</tr>
<tr>
<td>Race</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RECIPIENT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>Recipient Name</td>
</tr>
<tr>
<td>DCB</td>
</tr>
<tr>
<td>Race</td>
</tr>
</tbody>
</table>

Testing performed the following day if received Sunday or after 11:00 am Monday-Thursday. Please call for special scheduling needs or STAT orders. All specimens must be labeled according to CLIA regulations.

<table>
<thead>
<tr>
<th>TEST</th>
<th>TEST/PROFILE</th>
<th>SPEC REQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARDIAC DONOR TRANSPLANT SERVICES</td>
<td>Cadaveric Transplant Donor Includes: ABO – Final Crossmatch</td>
<td>C,E,G</td>
</tr>
<tr>
<td>RENAL DONOR TRANSPLANT SERVICES</td>
<td>Cadaveric Transplant Donor Includes: ABO – Final Crossmatch</td>
<td>C,E,G</td>
</tr>
<tr>
<td>Living (Renal) Transplant Donor Includes: HLA Typing (DRDQ), ABO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living (Renal) Transplant Donor Final Crossmatch only includes: Crossmatch AHG CDC (T-Cell), Flow (Donor T-Cell/VB-Cell)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BONE MARROW SERVICES</td>
<td>HLA Typing (ABRDQ) - Donor</td>
<td>C</td>
</tr>
</tbody>
</table>

See page 1 for patient test orders.

SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>A</th>
<th>5 ml Clot Tube</th>
<th>F</th>
<th>Parathyroid Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>20 ml ACD Sol A</td>
<td>G</td>
<td>4ml EDTA</td>
</tr>
<tr>
<td>C</td>
<td>40ml ACD Sol A</td>
<td>D</td>
<td>10 ml Na Heparin or ACD Sol A</td>
</tr>
<tr>
<td>E</td>
<td>Lymph Node</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Form #110.1 (Rev. 03/16/2009)
ATTACHMENT E

Indiana Blood Center
Indianapolis, IN 46208

Testing Laboratory
Surround Client Information Worksheet

<table>
<thead>
<tr>
<th>1</th>
<th>Implementation Date: _____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>(Check one) □ New □ Change □ Deactivate</td>
</tr>
<tr>
<td>3</td>
<td>Client Name:</td>
</tr>
<tr>
<td>4</td>
<td>Contact Name(s):</td>
</tr>
<tr>
<td>5</td>
<td>Address:</td>
</tr>
<tr>
<td>6</td>
<td>Phone Number(s):</td>
</tr>
<tr>
<td>7</td>
<td>Do you wish to be contacted following a transfer? □ YES □ NO</td>
</tr>
<tr>
<td>8</td>
<td>Prefixes</td>
</tr>
<tr>
<td>9</td>
<td>Transfer results? (Check one)</td>
</tr>
<tr>
<td>10</td>
<td>Routine Test Panel (Check each applicable test)</td>
</tr>
<tr>
<td>11</td>
<td>□ HBsAg □ HCV □ HIV □ Hbc □ HTLV □ AbScr</td>
</tr>
<tr>
<td>12</td>
<td>□ STS (Syph) □ CMV □ ABORh □ CHOL □ MPX (only)</td>
</tr>
<tr>
<td>13</td>
<td>□ MPX (w/HIN &amp; HCN) □ WNV □ CHA □ PHENO (C, C, E, e)</td>
</tr>
<tr>
<td>14</td>
<td>Transfer default tests only? (Check one)</td>
</tr>
<tr>
<td>15</td>
<td>Primary transfer method (Check one)</td>
</tr>
<tr>
<td>16</td>
<td>Secondary transfer method (Check one)</td>
</tr>
<tr>
<td>17</td>
<td>E-mail address (if applicable)</td>
</tr>
<tr>
<td>18</td>
<td>Fax number(s) (if applicable)</td>
</tr>
<tr>
<td>19</td>
<td>Do you need results faxed to multiple numbers? □ YES □ NO</td>
</tr>
<tr>
<td>20</td>
<td>Network transfer information (if applicable)</td>
</tr>
<tr>
<td>21</td>
<td>Network address:</td>
</tr>
<tr>
<td>22</td>
<td>User ID:</td>
</tr>
<tr>
<td>23</td>
<td>Password:</td>
</tr>
<tr>
<td>24</td>
<td>File name:</td>
</tr>
<tr>
<td>25</td>
<td>Create unique file name? (Check one) □ YES □ NO</td>
</tr>
</tbody>
</table>

Worksheet completed by: ____________________________ (Name) ____________ (Date)

Worksheet/Client info reviewed by: __________ (initials) __________ (Date)

CIO (or designee): ____________________________ (initials) __________ (Date)

QA: __________ (initials) __________ (Date) CCF#: __________

Client created/modified in Surround: __________ (Initials) __________ (Date)

*The CIW will need to be approved by the appropriate IBC personnel prior to any results being transmitted.

3173.1 (rev. 5/14/09)
ATTACHMENT E - CONTINUED

Indiana Blood Center
Indianapolis, IN 46208

Testing Laboratory
Instructions for completing the Surround Client Information Worksheet (CIW)

1. Implementation date—the date the client expects the action (new transfer, change, or deactivation) to occur

2. Mark the appropriate box:
   • New—a test panel is being established for a new client
   • Change—an existing test panel is being revised. Only the client name, the implementation date, and the desired change need to be documented on the worksheet.
   • Deactivate—testing will no longer be performed for the client. Only the client name and the implementation date need to be completed.

3. Client name—institution name as the client would like it to appear on the Surround reports

4. Contact information—record the name of the person(s) who will serve as the main contact. Record the site address and the contact numbers for contact person(s) or the lab.

5. Prefixes—record the appropriate sample ID prefixes that will be used by your site. The Customer Service Administrator should be contacted before prefixes are selected to ensure the prefixes have not been assigned to any other clients.

6. Transfer initial results?—does the client want to receive non-final test results (i.e. initial reactive/R)?

7. Routine Test Panel—check all tests that will be part of your routine test panel.

8. Optional test only—the client only wants to receive results for tests marked on the test panel.

9. Primary transfer method—select the main mode of result transmission

10. Secondary transfer method—select a secondary mode of result transmission should the primary mode be unavailable. The site will be contacted prior to results being sent via the secondary method.

11. E-mail address—record the applicable e-mail address if "EMAIL" was selected as a mode of transmission

12. Fax number—record the applicable fax number if "FAX" was selected as a mode of transmission

13. Network transfer—document the information as requested for a network transfer

14. Worksheet completed by—record the name of the person completing the form and the date the form was completed

IMPORTANT—It is the responsibility of the client to validate that all configurations are compatible with their respective system. The Customer Service Administrator should be contacted to have test transmission files created.

The client is also responsible for sending the CIW back to IBC, affording us ample time to enter the necessary information and make any necessary changes prior to the requested implementation date.

3173.1 (rev. 5/14/09)
Rare Units are Needed from the Reference Lab

Call the Reference Lab at 317-916-5188
24/7/365

Give the Phone Request to the Reference Specialist

Indiana Blood Center Indianapolis, IN 46208
Flowchart of Requesting Rare Units from the IBC-IRL

JA7000.4 (11/30/10) JKS

All confirmed antigen negative units will be tagged with REF1 tag, see below

<table>
<thead>
<tr>
<th>REFERENCE Lab Tag</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unit Number</td>
</tr>
<tr>
<td>2. Ewing/DAH Positive</td>
</tr>
<tr>
<td>3. Antibody Status</td>
</tr>
<tr>
<td>4. Name</td>
</tr>
<tr>
<td>5. Technician</td>
</tr>
</tbody>
</table>

REMINDER
Any unit received as historically antigen negative, will NOT have a tag. The typing information will be at the packing site.

The IRL Tech will clarify when the blood is needed. Is the blood needed immediately?

YES

Is this a Super STAT situation or after-IRL hours?

NO

Routine Request. The units will be completed within 12-24 hours after the order is received; unless the shipment date is specified by the requestor.

No

The IRL will send pre-confirmed units

Yes

If pre-confirmed units are not available to complete the order, historically negative units will be released

The IRL will complete STAT/ASAP. An on-call tech will complete if necessary. Additional fees will apply.

Units will be shipped by IBC Indianapolis Distribution

STAT Pre-confirmed units or Historically Negative Rare Units will be shipped by IBC.

If the units are historically negative, the facility will confirm that the units are negative for the antigen(s) requested.

If the facility cannot receive historically negative units, the IBC-IRL on-call tech will complete the order if necessary. Additional fees will apply.
Flowchart of Submitting Samples to the IBC-IRL

A Sample Needs to be Sent to the Reference Lab

Obtain the Pink IBC-IRL Consultation Request

Indicate the name and contact phone number of the contact physician.

Complete the Service Requested Section

Complete the Patient Information Section

Complete the Reason for Submission Section

Complete the Provision of Blood For Transfusion Section

Have Sample Drawn for Send out. Pack the sample as outlined in IBC Customer Resource Manual

Call the Reference Lab to Submit the Sample at 317-916-5188

Yes - Mark as STAT
The IRL will complete immediately. An on-call tech will complete if necessary. Additional fees will apply.

Does the patient have an urgent order to transfuse?

Does the patient have an order to transfuse within 24 hours?

No

Yes

Either the facility or the Reference Lab will arrange for a courier to deliver/pick-up the sample

The IRL will call and fax preliminary reports. The IRL will send units, if necessary.

Final Report to follow in 12-14 days after submission of the sample.

No - Mark as Routine
This sample will be completed within 1-3 days of being received in the Reference Lab.

Yes - Mark "AS SOON AS POSSIBLE"
The IRL will complete within 24 hours of receiving the sample in the Reference Lab. If this is for a surgery or an inpatient, please inform the appropriate persons of the delay to the procurement of blood. If necessary, a physician consultation will be completed to confirm any observational care necessary within 24 hours. The physician will verify the urgency for provision of service.

Is the IRL staff currently on call?

Yes

No Contact the Technologist On Call As Instructed on the Voicemail at 317-916-5188

The sample will be investigated by the IBC-IRL

The IRL will call and fax preliminary reports. The IRL will send units, if necessary.

Final Report to follow in 12-14 days after submission of the sample.