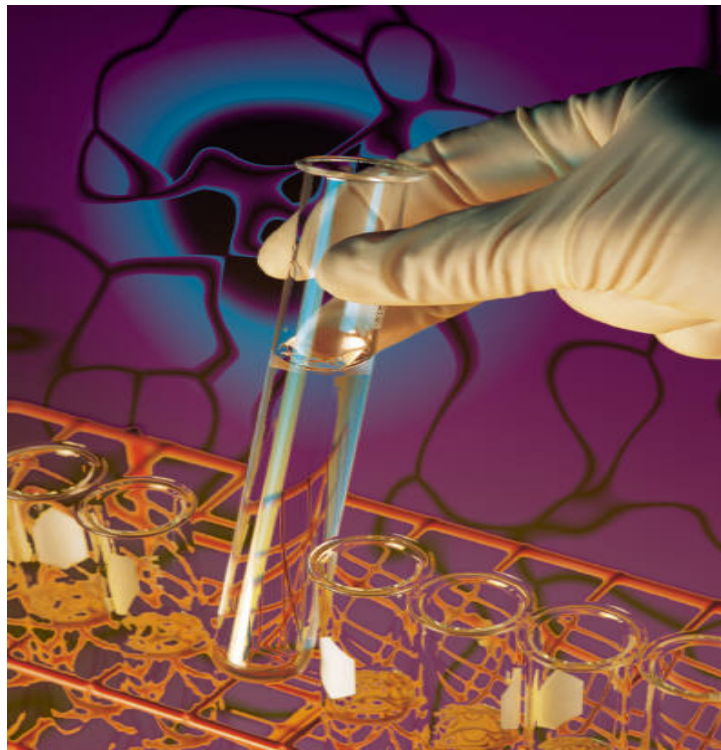




***Customer Resource
Manual For
Laboratory Testing
Services***



Indiana Blood Center
Indianapolis, IN 46208
Version 14, December 2011

**Indiana Blood Center
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

Title	Name	Phone # (317)
<u>Administration</u>		
President/CEO	Byron B. Buhner	916-5001
Executive VP/Chief Medical Officer	Dan A. Waxman, M.D.	916-5008
Executive VP/Chief Operating Officer	Mike Parejko	916-5007
VP/Quality Systems	Lora Poore	916-5141

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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
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For testing status and general results

Testing Laboratory (24 hours)	General Number	916-5193
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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. 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.

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AGENCY	LICENSE / REGISTRATION #
FDA	1759
FDA Registration	1873403
CLIA	15D0664398
Indiana Department of Health	(DOH) BC00005931
AABB	Institutional # 5486
ASHI	08-4-IN-06-1
UNOS	101NCI
NYS DH	PFI: 7968
California	COS 800236

Confirmatory Labs

South Bend Medical Foundation	15D0357169
Specialty Labs	05D0550302
Mayo Clinic	24D0404292
Focus Technologies Inc	05D0644251
Quest	3005010397 (FDA License)
Creative Testing Solutions (CTS)	0183-029 (FDA)
	03D0911463 (CLIA)
LifeSource	1025 (FDA)
)	

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.

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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

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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.

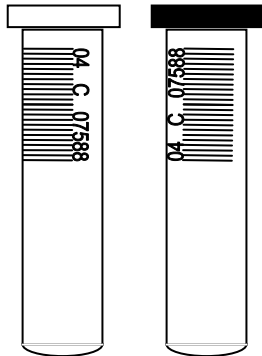
- b. **Multiple Samples:** If a collection site collects many patient samples, it may be easier and less cumbersome to use the Patient/Donor Test Request Form. This form is completed by recording the sample ID of each tube being sent and requires the site to pre-label their samples with IBC approved 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

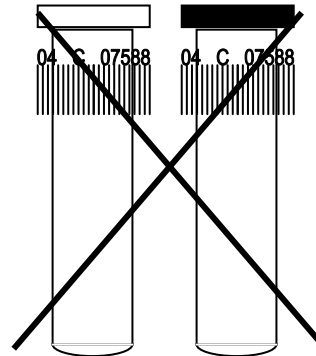
The quality of the sample sent for testing impacts the laboratory's ability to generate quality test results. Upon receipt, samples at IBC are evaluated using the following standards:

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 LABELED



INCORRECTLY LABELED



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.

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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 1000 mg/dL for lipemia in the Donor Testing Laboratory. IBC screens samples on the Abbott Aeroset 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.

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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

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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.

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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.

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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

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 Treponema 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 RIBA is not required when the NAT is positive if the customer has filed a variance stating this practice with the FDA.

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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.

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I. SAMPLE SUITABILITY CHART

Note: test tubes may be glass or plastic.

TEST CODE	Assay	SPECIMEN REQUIREMENTS	SAMPLE SUITABILITY @ 2-8°C	Methodology
NAT	HIV 1/HCV / HBV NAT	(1) 6 or 7 mL EDTA tube	8 days (samples must be centrifuged prior to 72 hours)	Roche Cobas TaqScreen HIV 1/ HCV / HBV Assay
WNV	West Nile Virus NAT	(1) 6 or 7 mL EDTA tube	8 days (samples must be centrifuged prior to 72 hours)	Roche Cobas TaqScreen WNV Assay
HBS	Hepatitis B Surface Antigen	6 or mL purple top tube (EDTA) <u>OR</u> 6 or 7mL red top tube (serum)	14 days at 2-8°C; long-term storage at -20°C	Prism Chemiluminescence Method Normal Reference: Non-Reactive Confirmatory: Neutralization
HBC	Hepatitis B Core Antibody	6 or 7 mL purple top tube (EDTA) <u>OR</u> 6 or 7 mL red top tube (serum).	14 days at 2-8°C; long-term storage at -20°C	Prism Chemiluminescence Method Total Antibody Normal Reference: Non-Reactive No Confirmatory Test Available
HIV	HIV 1/HIV 2 Antibody	6 or 7 mL purple top tube (EDTA) <u>OR</u> 6 or 7 mL red top tube (serum).	14 days; long term storage frozen	Prism Chemiluminescence Method Normal Reference: Non-Reactive Confirmatory: Anti-HIV-1 WB, HIV-2 AB
HTLV	HTLV I/II Antibody	6 or 7 mL purple top tube (EDTA) <u>OR</u> 6 or 7 mL red top tube (serum).	14 day; storage greater than 14 days at -20°C.	Prism Chemiluminescence Method Normal Reference: Non-Reactive Supplemental: Anti-HTLV I by (Western Blot)
HCV	HCV Antibody	6 or 7 mL purple top tube (EDTA) <u>OR</u> 6 or 7 mL red top tube (serum).	14 days; long-term storage frozen	Prism Chemiluminescence Method Total Antibody Normal Reference: Non-Reactive Supplemental: Anti-HCV (RIBA II)
CHA	Chagas Disease	6 or 7 mL purple top tube (EDTA) <u>OR</u> 6 or 7 mL red top tube (serum).	2 - 8° C for 10 days; frozen (<-20° C) if longer; up to 5 freeze-thaw cycles	Prism Chemiluminescence Method Normal Reference: Non-Reactive Supplemental: Chagas RIPA
STS	Syphilis	6 or 7 mL red top tube (serum).	7 days; no limit specified at -20°C	Olympus TP, ASI Reagents or Latex Agglutination Normal Reference: Non-Reactive Confirmatory: IGG EIA & RPR, VDRL
ABY	Antibody Screen	6 or 7 mL red top tube (serum)	24 hours a room temperature, followed by 6 days at 2-8 ° C for 7 days total	Tango or Manual Tube Method Normal Reference: Negative Confirmatory: Antibody Identification upon request

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CHOL	Total Cholesterol	6 or 7 mL red top tube (serum)	5 days; -20°C for 3 months	Normal Reference: < 200 mg/dL
CMV	Cytomegalovirus Antibody	6 or 7 mL red top tube (serum)	14 days for serum 3 days for plasma no limit specified at -20°C	Olympus CMV Normal Reference: Non-Reactive
HBCONF	Hepatitis B Surface Antigen Neutralization	4 mL serum or plasma	7 days; -15° if longer	Prism Chemiluminescence Method Normal Reference: Negative (Non-neutralizable)
HBSAB	Antibody to Hepatitis B Surface Antigen	4 mL serum or plasma	7 days; -20°C if longer	Centour Chemiluminescence Method Normal Reference: Reactive (immune)
FTA	Antibody	4 mL serum	5 days; -20°C if longer	Fluorescent antigen or micro-hemagglutination Normal Reference: Non-Reactive
TP EIA	TP EIA	4 mL serum or plasma	5 days, 2 - 8°. Freeze if longer	Trepsure EIA screen
WB	Anti-HIV-1 by Western Blot	4 mL serum or plasma	7 days; -20°C if longer	Genetic Systems AutoBlot Method Normal Reference: Negative
HTLV WB	Anti-HTLV-I/II by Western Blot	4 mL serum or plasma	5 days; -20°C for 3 months	Genelabs Western Blot Normal Reference: Negative by WB/Negative by RIPA
RIBA	HCV Recombinant Immuno-Blot Assay	4 mL serum or plasma	7 days; -20°C if longer	Chiron Immunoblot Method Normal Reference: Negative
HIV2	Antibody to HIV 2	4 mL serum or plasma	7 days; -20°C for 3 months.	Genetic Systems EIA Method Normal Reference: Negative
HIV2 WB	HIV 2 Western Blot	4 mL serum or plasma		
CHL/GC	Chlamydia plus GC	Urine or vaginal swab	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 <i>in vitro</i> qualitative detection and differentiation of ribosomal RNA (rRNA) from <i>Chlamydia trachomatis</i> (CT) and/or <i>Neisseria gonorrhoeae</i> (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)

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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.

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- 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

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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 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.

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- 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

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

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.

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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

(Please Use "CONSULTATION REQUEST FORM" For Reference Lab Orders)

Indiana Blood Center • Laboratory Services
3450 N. Meridian St. • Indianapolis, IN 46208 • (317) 916-5190

Patient ID (Numbers(s) Only): _____	Age: _____	Physician: _____
Form Completed By: _____		Sample Date: _____
Special Instructions: _____		<input type="checkbox"/> ASAP <input type="checkbox"/> Routine
Dept. To Be Billed: _____		<input type="checkbox"/> Need Result ASAP, Please Fax To:
Facility Name & Address (Please include full address if result is to be mailed via US Mail)		Fax #: _____ (Include Area Code)
		<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Imprint Area P 0023041 </div>
<input type="checkbox"/> Perform Confirmatory if Reactive <input type="checkbox"/> Perform Confirmatory REGARDLESS Of Initial Result		

Indicate Tests	BILL	CODE	DESCRIPTION	RESULTS SEE ATTACHED REPORT FOR RESULTS	
	5151	BMR	Bone Marrow Panel	HBSAG, HCV, HIV 1/2, HBC, HTLV-I/II, (STS) Syphilis, CMV, ABORH	
	5502	FULL	Complete Donor Profile & NAT	HBSAG, HCV, HIV 1/2, HBC, HTLV-I/II, (ABS) Antibody Screen, (STS) Syphilis, ABORH, HIV 1/HCV NAT	
	5503	FULL	Complete Donor Profile	HBSAG, HCV, HIV 1/2, HBC, HTLV-I/II, (ABS) Antibody Screen, (STS) Syphilis, ABORH	
	5091	TBANK	Tissue Bank Profile	HBSAG, HCV, HIV 1/2, HBC, HTLV-I/II, Syphilis (STS), CMV	
	5120	EIA	Infectious Disease Profile Only	HBSAG, HCV, HIV 1/2, HBC, HTLV-I/II, Syphilis (STS), HIV 1/HCV NAT	
	5552	FERT	Fertility Donor Profile	HBSAG, HCV, HIV 1/2, HBC, Syphilis (STS)	
	5030	ABORH	ABO Group and Rh Type (donor)	TEST RESULT LEGEND N = Non-Reactive R = Initial-Reactive P = Repeatedly Reactive CLR = All Results completed for requested tests *** = Incomplete Test or Abnormal Result I = Pending initial testing TOF = Pending final result resolution UNA = Unable to obtain a valid result	
	5031	ABORH	ABO Group and RH Type (cord)		
	5010	HBSAG	Hepatitis B Surface Antigen (EIA)		
	5110	HIV 1/2	Antibody to HIV- 1/2 (EIA)		
	5040	HBC	Antibody to HB Core (EIA)		
	5086	STS	Syphilis		
	5082	HTLV-I/II	Antibody to HTLV- 1/2 (EIA)		
	5105	HCV	Antibody to HCV (EIA)		
	5011	NAT	HIV- 1/HCV (NAT) (IDT)		
	5012	WNV	West Nile Virus (NAT) (IDT)		
	5060	CMV	Total (IgG and IgM Ab to CMV)		
	5200	ABS	Antibody Screen		
	5021	CHA	Chagas		
	5005	HBCONF	HBSAG Confirmatory Neutralization		Date Sent: _____
	5125	HICONF	HIV 1 (WB) /HIV 2 ABY (EIA)		Date Sent: _____
	5096	HTCONF	HTLV ABY (WB)	Date Sent: _____	
	5095	HCCONF	HCV IMMUNO BLOT ASSAY	Date Sent: _____	
	5097	FTA	FTA (Syphilis)	Date Sent: _____	
	5020	HBSAB	Antibody to HBS (EIA)	Date Sent: _____	
	5126	HICONF2	HIV 1 Whole Viral Lysate	Date Sent: _____	
	5128	GC/C	GC/Chlamydia	Date Sent: _____	
	5121	CHCONF	Chagas Confirmation (RIPA)	Date Sent: _____	
			Other	Date Sent: _____	

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Mailed: _____ Faxed: _____ 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:

◆ Name of Contact Physician:	◆ Physician Phone Number
-------------------------------------	---------------------------------

SERVICE REQUESTED (◆ Mandatory Field)

Mark with an X

STAT	Investigation / Blood request with an order to IMMEDIATELY TRANSFUSE <ul style="list-style-type: none"> • Mark for any urgent order for provision of blood. 	
AS SOON AS POSSIBLE	Investigation / Blood request available within 24 hours <ul style="list-style-type: none"> • Mark for any provision of blood considered a scheduled provision of blood. ◆ Please indicate when blood is needed _____ 	
ROUTINE	Investigation / No blood requested. Completion within 1-5 days.	

PATIENT INFORMATION (◆ Mandatory Field)

◆ Facility Name	Facility Phone Number	
◆ Patient Name	Patient Date of Birth	
◆ Patient Id #	Current Hgb/Hct	Race
◆ Date of Last Transfusion	Antibody History? Yes (), No ()	
◆ Sample Date:	Ab. identified? _____	
Patient's Clinical Diagnosis	History at IBC? Yes (), No ()	

REASON FOR SUBMISSION

Mark with an X all that apply

Antibody Identification	<input type="checkbox"/>	Transfusion Reaction Suspected	<input type="checkbox"/>	Other	<input type="checkbox"/>
DAT Positive	<input type="checkbox"/>	Difficulty in Crossmatch	<input type="checkbox"/>	Prenatal Testing: ABO/RH, Ab Id. & Titer Rhlg Given? Yes (), No () date _____	<input type="checkbox"/>
ABO or RH Discrepancy	<input type="checkbox"/>	Hemolytic Disease of the Newborn	<input type="checkbox"/>		

PROVISION OF BLOOD FOR TRANSFUSION

Antigen Negative Units?	Yes (), No ()	Compatibility Screened Units?	Yes (), No ()
How Many?	_____	How Many?	_____

SAMPLE REQUIREMENTS : SEE BACK OF FORM _____

IBC-IRL CONSULTATION REQUEST: ATTACHMENT B (CONTINUED)

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 REQUIRMENTS

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

CLIA# 15D0664398 • Medicare # 15-HL-01 • UNOS # 10INCI • ASHI # 08-4-IN-06-1 • NYSDOH PFI: 7968
Lab Phone: (317)916-5237 FAX: (317)916-5230

PLEASE COMPLETE ALL INFORMATION REQUESTED BELOW.

PATIENT INFORMATION			
Date	Sample Date	Hospital:	Ph #:
Name		Address:	STAT <input type="checkbox"/>
DOB	HOSP. ID #:	Diagnosis:	Person Completing Requisition _____
Race <input type="checkbox"/> M <input type="checkbox"/> F	SS#	Doctor:	
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	TEST/PROFILE		SPEC REQ
PLATELET SUPPORT SERVICES			
	Hematology Workup for Platelet Support Includes: HLA Typing (AB), ABO, Autocrossmatch AHG CDC (T cell), Platelet Antibody Screen*, Matched Donor List		A,B
	Platelet Antibody Screen* (Performed Automatically on Patients Receiving Platelet Support)		A
	HLA Class I PRA and/ or Identification (Flow)* (Performed Automatically on Patients Receiving Platelet Support)		A
	SPRCA Crossmatch for HLA matched Platelets (Call Donor Patient Services @ 317-916-5296 with order information)		A*
	SPRCA Crossmatch for Single Donor Platelets (Call Donor Patient Services @ 317-916-5296 with order information)		A*
CARDIAC TRANSPLANT SERVICES Patient received Thymoglobulin? Y/N			
	Pre Transplant Candidate Profile Includes: HLA Typing(ABDRDQ), ABO, Autocrossmatch Flow(T&B cell) AHG CDC (Mixed T/B), Flow Antibody Screen Class I & II* PRA, CDC PRA		A,C,G
	Flow Antibody Screen Class I & II* (PRA) <i>only</i>		A
	Donor Specific Antibody Screen (DSA) Class I and Class II		A
	Day of Transplant Work Up : Includes: - Crossmatch AHG CDC (Donor T-Cell), Flow(Donor T-Cell/B-Cell), Flow Antibody Screen Class I & II PRA		A
RENAL TRANSPLANT SERVICES Patient received Thymoglobulin? Y/N			
	Pre Transplant Candidate Profile Includes: HLA Typing(ABDRDQ), ABO, Autocrossmatch Flow(T&B cell) AHG CDC (Mixed T/B), Flow Antibody Screen Class I & II* PRA, CDC PRA		A,C,G
	Flow Antibody Screen* Class I & II (PRA) <i>only</i>		A
	Donor Specific Antibody Screen (DSA) Class I and Class II		A
	Day of Transplant Work Up : Includes: - Crossmatch AHG CDC (Donor T-Cell), Flow(Donor T-Cell/B-Cell), Flow Antibody Screen Class I & II PRA		A
DISEASE ASSOCIATION SERVICES			
	Specify HLA antigen(s) and/or Disease Association- _____ i.e. Ankylosing Spondylitis/Rheumatoid Arthritis (B27), Narcolepsy (DR2/DQ1)		B
BONE MARROW SERVICES			
	Bone Marrow Transplant Profile Includes: HLA Typing (ABDRDQ) ABO, Autocrossmatch AHG CDC (Mixed T/B), Flow Antibody Screen Class I & II* PRA		A,B,G
OTHER SERVICES			
	Platelet Antigen Typing - circle one: PLA 1 / Full typing		G
	Parathyroid Tissue Cryopreservation		D,F
	TRALI Investigation- Please <i>include information on suspected unit(s)</i> .		B
	Neonatal Alloimmune Thrombocytopenia (NATP) Panel – Draw Mother and Father – Notify Lab OR IBC Physician ASAP		A&G

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

See page 2 for donor test orders.

SPECIMEN REQUIREMENTS

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

ATTACHMENT C CONTINUED



HLA-DNA TEST ORDER FORM

Indiana Blood Center • Indianapolis, IN 46208
 CLIA# 15D0664398 • Medicare # 15-HL-01 • UNOS # 10INCI • ASHI # 08-4-IN-06-1 • NYSDOH PFI: 7968
 Lab Phone: (317)916-5237 FAX: (317)916-5230

PLEASE COMPLETE ALL INFORMATION REQUESTED BELOW.

DONOR INFORMATION			
Date	Sample Date	Facility:	Ph #:
Donor Name:		Address:	
DOB	SS#	Relationship: Cadaveric, non related, sibling, child, parent other	
Race	Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	ID#:	
RECIPIENT INFORMATION			
Date		Facility:	Ph #.
Recipient Name:		Address:	
DOB	SS#	Diagnosis:	Person Completing Requisition_____
Race	Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Doctor	

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	TEST/PROFILE	SPEC REQ
	CARDIAC DONOR TRANSPLANT SERVICES	
	Cadaveric Transplant Donor Includes: ABO – Final Crossmatch	C,E,G
	RENAL DONOR TRANSPLANT SERVICES	
	Cadaveric Transplant Donor Includes: ABO– Final Crossmatch	C,E,G
	Living (Renal) Transplant Donor Includes: HLA Typing (AB), HLA Typing (DRDQ), ABO	C,G
	Living (Renal) Transplant Donor Final Crossmatch only Includes: Crossmatch AHG CDC(T-Cell), Flow(Donor T-Cell/B-Cell)	C
	BONE MARROW SERVICES	
	HLA TYPING (ABDRDQ) - Donor	B

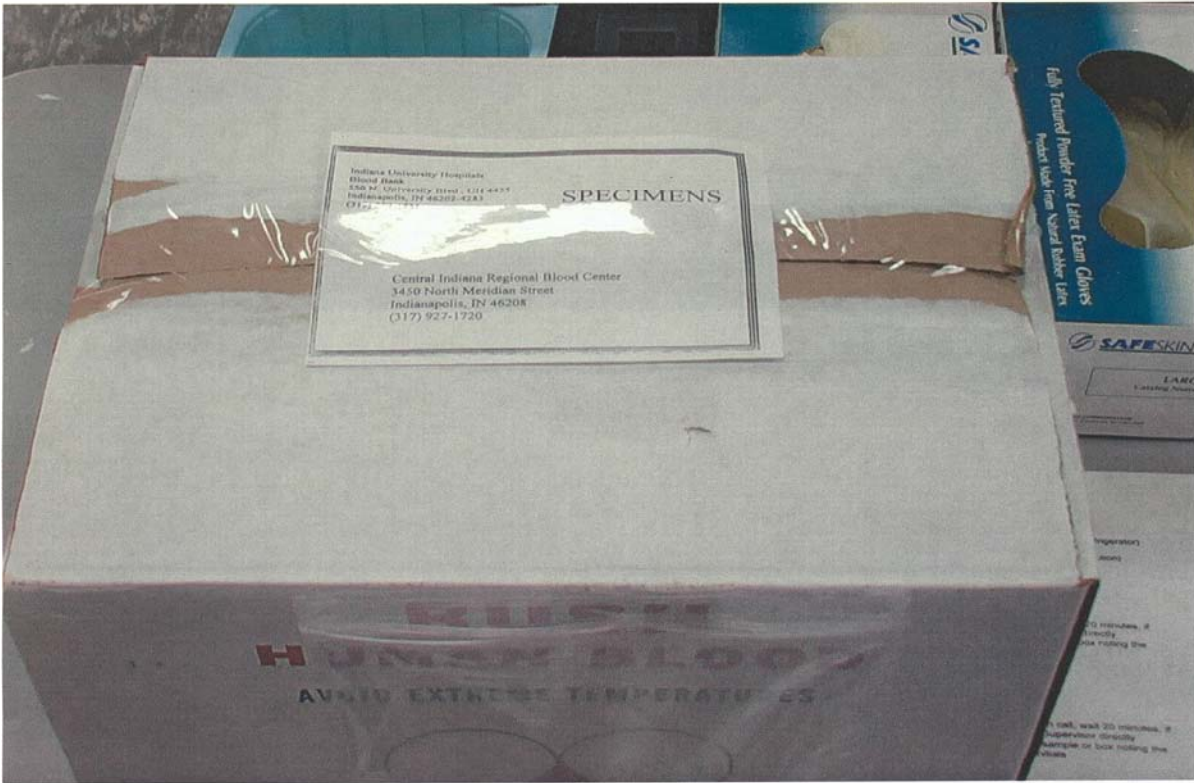
See page 1 for patient test orders.

SPECIMEN REQUIREMENTS

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

ATTACHMENT D

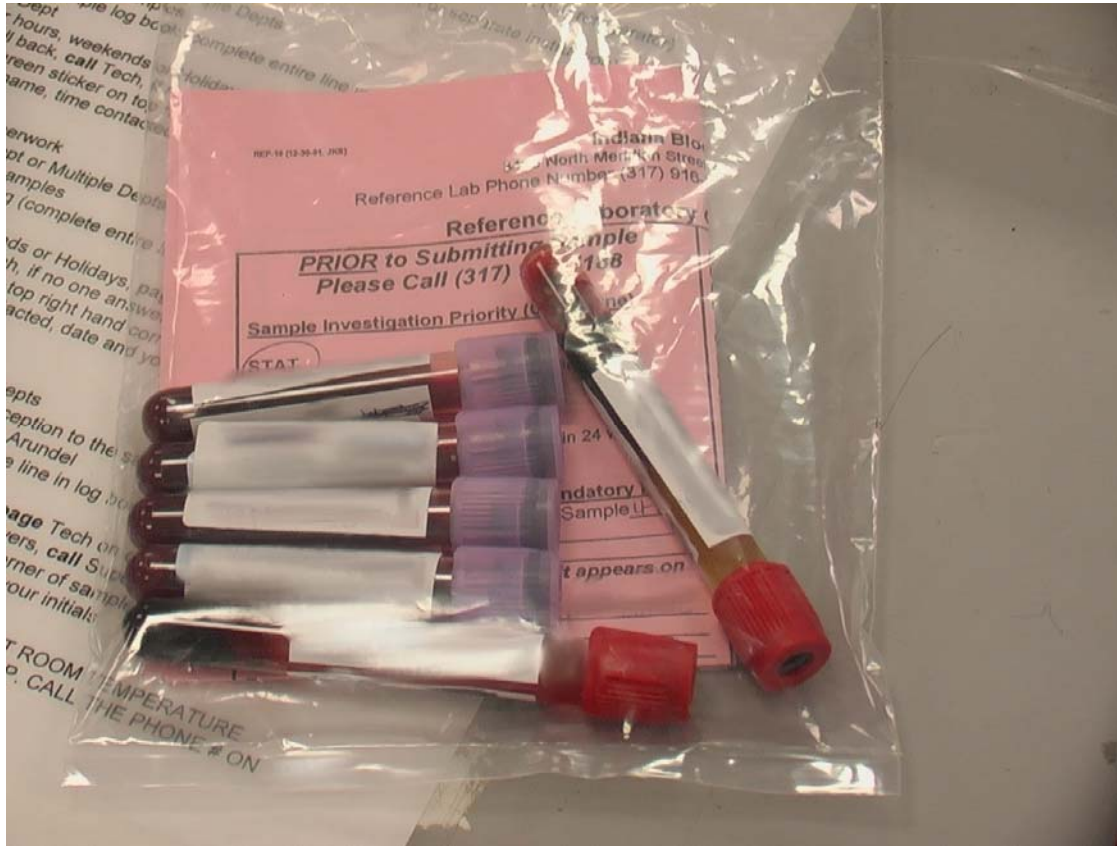
CORRECT



INCORRECT



ATTACHMENT D - CONTINUED



ATTACHMENT E

Indiana Blood Center
Indianapolis, IN 46208

Testing Laboratory Surround Client Information Worksheet

1	Implementation Date: _____	
2	(Check one) <input type="checkbox"/> New <input type="checkbox"/> Change <input type="checkbox"/> Deactivate	
3	Client Name: _____	
4	Contact Name (s): _____	
	Address: _____	
	Phone Number (s): _____	
	Do you wish to be contacted following a transfer? <input type="checkbox"/> YES <input type="checkbox"/> NO	
5	Prefixes	_____
6	Transfer initials results? (Check one)	<input type="checkbox"/> YES <input type="checkbox"/> NO
7	Routine Test Panel (Check each applicable test)	<input type="checkbox"/> HBsAg <input type="checkbox"/> HCV <input type="checkbox"/> HIV <input type="checkbox"/> HBc <input type="checkbox"/> HTLV <input type="checkbox"/> AbScr <input type="checkbox"/> STS (Syph) <input type="checkbox"/> CMV <input type="checkbox"/> ABORh <input type="checkbox"/> CHOI <input type="checkbox"/> MPX (only) <input type="checkbox"/> MPX (w/HIN & HCN) <input type="checkbox"/> WNV <input type="checkbox"/> CHA <input type="checkbox"/> PHENO (C, c, E, e)
8	Transfer default tests only? (Check one)	<input type="checkbox"/> YES <input type="checkbox"/> NO
9	Primary transfer method (Check one)	<input type="checkbox"/> FAX <input type="checkbox"/> EMAIL <input type="checkbox"/> MODEM <input type="checkbox"/> NETWORK <input type="checkbox"/> PRINT/MAIL
10	Secondary transfer method (Check one)	<input type="checkbox"/> FAX <input type="checkbox"/> EMAIL <input type="checkbox"/> MODEM <input type="checkbox"/> NETWORK <input type="checkbox"/> PRINT/MAIL
11	E-mail address (if applicable)	_____
12	Fax number(s) (if applicable)	_____
	Do you need results faxed to multiple numbers? <input type="checkbox"/> YES <input type="checkbox"/> NO	
13	Network transfer information (if applicable)	Network address: _____ User ID: _____ Password: _____ File name: _____ Create unique file name? (Check one) <input type="checkbox"/> YES <input type="checkbox"/> NO

- 14 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.

ATTACHMENT E - CONTINUED

Indiana Blood Center
Indianapolis, IN 46208

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

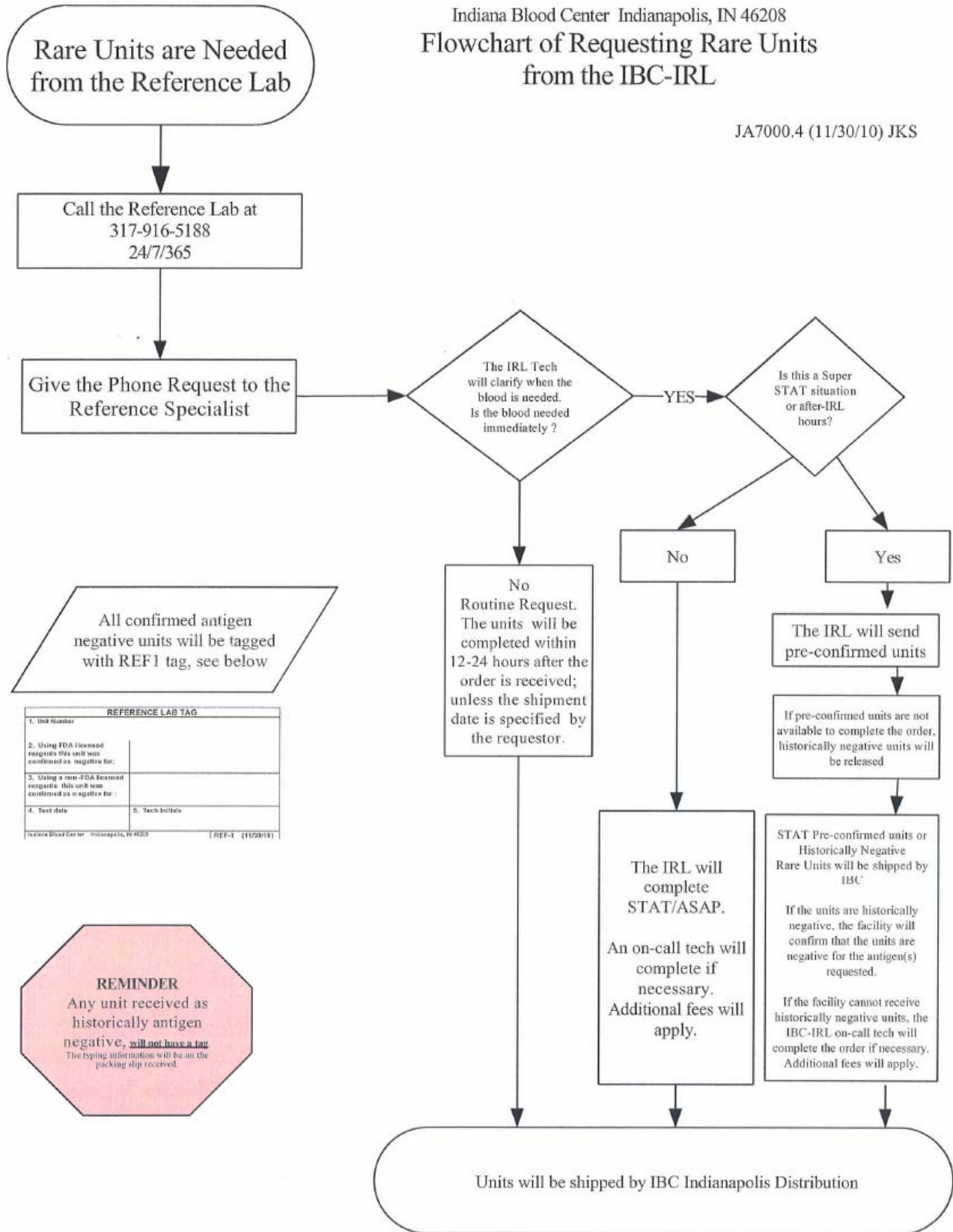
1. Implementation date—the date the client expects the action (new transfer, change, or deactivation) to occur
2. Mark the appropriate box:
 - New—a test panel is being established for a new client
 - Change—an existing client panel is being revised. Only the client name, the implementation date, and 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 contacts. 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 initials 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.
 - If NAT MPX testing (HIV/HCV combo) is requested, the MPX result is required. The client may choose whether or not they wish to receive the individual HIV and HCV results (MPX (w/HIN & HCN)).
8. Transfer default test only—the client only wants to receive results for tests marked on the test panel.
 - Optional or occasional tests (i.e. CMV or Chagas) will not transfer if this option is selected.
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.

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

REFERENCE LAB TAG	
1. Unit Number	
2. Using FDA licensed reagents this unit was confirmed as negative for:	
3. Using a non-FDA licensed reagent, this unit was confirmed as negative for:	
4. Test date	5. Tech initials

Indiana Blood Center Indianapolis, IN 46208 REF-1 (11/30/10)

REMINDER
 Any unit received as historically antigen negative, will not have a tag. The typing information will be on the packing slip received.

Flowchart of Submitting Samples to the IBC-IRL

JA7000.3 JKS (9/21/07)

