



National Institute of Transplantation
NIT Administration
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National Institute of Transplantation

INTRODUCTION

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Mendez
**NATIONAL
INSTITUTE
of TRANSPLANTATION**
at the S. Mark Taper Foundation Transplant Center



National Institute of Transplantation
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National Institute of Transplantation

NIT – AN INTRODUCTION

The National Institute of Transplantation (NIT) was created to advance the science and practice of organ transplant therapy. In 1985, in affiliation with the University of Southern California (USC) School of Medicine Keck School and the Daughters of Charity Health System, the NIT was formed as the Los Angeles Transplant Institute. In 1989, the Los Angeles Transplant Institute became the National Institute of Transplantation (NIT).

The NIT, a public non-profit corporation based in Los Angeles, has a very clear mission:

The National Institute of Transplantation (NIT) is a non-profit organization advancing the science and practice of organ transplantation.

To accomplish its mission, the NIT performs several functions;

- It conducts basic research in such critical areas as minimizing organ rejection.
- It engages in clinical research to develop new and innovative approaches to organ transplantation.
- It trains surgeons from around the world so that they may develop and enhance local transplant programs.
- It conducts community education programs to teach populations particularly at risk to organ failure how to avoid such problems and inform them about transplantation as a treatment option.

The affiliation with USC and the Daughters of Charity Health System continues to this day, but NIT remains an independent organization, unrelated to or connected with any other private organization or any government agency.

* * *

RESEARCH

Basic research has been a priority at the NIT since it was founded. The Institute is constantly seeking new ways to cope with the human body's natural instinct to reject anything implanted in it. Another area of focus is the pursuit of scientific breakthroughs on hepatitis and diabetes, the leading cause of kidney failure.

Specifically, research initiatives at NIT focus on analyzing and understanding what triggers a transplant recipient to develop specific infections or graft rejection. To do so, scientists analyze markers in both the transplanted organ and the transplant recipient that may predispose some recipients to reject a graft. Identifying these markers may further the collective understanding of immunosuppressive therapies to help limit disease and rejection.

Still in its early stages, another research project – conducted with researchers at USC -- aims to apply small interfering RNA (siRNA) technology to organ transplantation. The siRNA technology essentially “silences” the genetic makeup of donor tissue, potentially allowing bone marrow or solid organ transplantation between a donor and recipient who may not otherwise match. This idea could revolutionize the way organs are allocated and could have a beneficial impact on patients, who could be relieved from a daunting immunosuppressive regimen.



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CLINICAL RESEARCH

In the field of clinical research, the NIT holds the distinction of being one of the largest transplantation clinical trials sites in the US. NIT Clinical Research partners with large multi national pharmaceutical firms to explore novel approaches and medicines to improve the lives of transplanted patients. The Institute continues to be interested in revitalizing and successfully using organs that once would have been considered unusable for transplantation.

Clinical research studies at NIT aim to study an individual's genetic makeup to formulate predictions about how a transplant patient will respond to a new organ and how well he or she will tolerate specific immunosuppressive drug regimens.

NIT is regularly invited to test new drugs for approval by the Food and Drug Administration. This relationship has resulted in the gradual improvement of immunosuppressive medication and in the markedly improved rate of graft survival among transplant patients in recent years.

TECHNOLOGY

NIT Data Services has developed and maintains a unique and comprehensive transplant patient tracking service (TranTrak) to allow for the day-to-day capture and analysis of massive amounts of patient data for on-going medical evaluation, pre and post transplant research, and other patient-centered purposes.

When a patient is accepted onto the national waiting list for an organ transplant, he or she must submit to regular blood tests at their transplant center. These routine tests continue after transplant to help physicians and transplant coordinators monitor drug values in a patient's blood and make necessary adjustments to a person's anti-rejection medications.

TranTrak, an arm of NIT, takes the clinical data collection a step further. Founded over a decade ago, Trantrak works in conjunction with transplant centers to collect and analyze clinical data and provide immediate and long-term support to transplant centers:

- When transplant coordinators run blood tests on their patients, they share the results with TranTrak's database. These results for both pre- and post-transplant patients are analyzed on a daily basis. When unusual values are found, they are reported immediately to the transplant center to help physicians and coordinators make immediate decisions to prevent recurrent illnesses and help stave off rejection.
- TranTrak monitors thousands of patients from the time they are referred for transplant and for their lifetime. With this massive amount of data, TranTrak analyzes factors that led to successful graft survival as well as conditions that led to poor outcomes. This collection of data helps physicians and surgeons make predictions about clinical factors that lead to successful outcomes and drug regimens that have shown to extend the life of recipients.

LABORATORY SERVICES

The NIT Histocompatibility Laboratory tests donor/recipient pairs for HLA genetic compatibility. Matching of the donor antigens in the recipient improves chances for long-term graft survival, lower rejection rates, and lower infection because of less use of



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immunosuppression. This laboratory is involved in the assessment of immunosuppressiveness of the transplant recipient by looking at HLA antibody profiles. This provides helpful information for clinicians to treat patients. Also, this lab is working on projects to genetically modulate HLA expression.

The NIT Serology and Molecular (Clinical) Laboratory is a clinical laboratory providing testing services 24-hours/365 days a year. Testing is performed in specialty areas including chemistry, hematology, serology, and molecular (nucleic acid testing). Most of our patient samples tested are transplant patients and/or potential donors (living and cadaveric). This laboratory is one of the only laboratories in the US to provide this type of specialty testing with results within 6-8 hours. This commitment by NIT to provide testing results 2-3 times faster than other labs greatly increase overall organ transplant outcome.

PATIENT EDUCATION / COMMUNITY OUTREACH

The NIT maintains a Community Outreach and Patient Education program in the Southern California service area. These programs have several objectives:

- To reduce the incidence of end-stage renal disease by identifying populations at risk for diabetes and hypertension and educating them in the prevention of these afflictions.
- To increase awareness of and access to organ transplantation as a treatment option that can lead to improved quality of life.
- To encourage patients to maintain their health while waiting for an organ and become more proactive in their healthcare.
- To make residents aware of the importance of donating organs so that others may live.
- To improve the survival rate of transplanted organs by making recipients well informed about the commitment they must make in caring for the new organ.

The NIT's scope of operations is both broad and deep; but its reach has never exceeded its grasp. The Institute remains committed to its mission and has dedicated itself to broaden its scope both geographically and technologically.



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National Institute of Transplantation
GENERAL NIT INFORMATION

Administrative and Billing Information	National Institute of Transplantation 2200 West Third Street, Suite 100 Los Angeles, CA. 90057
Telephone Numbers (GENERAL)	213.413.2779 213.484.6652 - FAX
Contact Name	James Schellenberg – COO 310.710.1816 – cell James.Schellenberg@transplantation.com
NIT Federal ID Tax Number	95-3952658
NIT State ID Tax Number	910-3890
NIT Serology Laboratory (Delivery of Specimens)	National Institute of Transplantation Serology Laboratory 221 South Figueroa Street, Suite 510 Los Angeles, CA. 90012
Telephone Numbers (LABORATORY)	213.229.3654 213.229.3659 – FAX
Laboratory Contact	Dem Brucal – Lab Manager DemBrucal@transplantation.com
Courier Information	Simply, the nurses/coordinators will contact a courier and the courier will be responsible for the pick up and delivery to NIT.
STERLING COURIER	www.quickintl.com/ - 800.633.6666
AMERIFLIGHT	www.ameriflight.com – 800.800.4538
AIRNET	www.airnet.com – 888.888.8463
Laboratory (Specimen) Requirements	3 Tubes 2 - 10ml Red Tops AND 1 – 5 ml Lavender Top



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National Institute of Transplantation DUTIES AND RESPONSIBILITIES

OPO's Responsibilities:

1. Transportation of the blood samples to NIT Lab shall be the responsibility of OPO's.
2. Blood for serology testing is to be drawn and placed in two, 10 ml red top tubes. In situations where only a small aliquot of pre-transfusion serum is available, acceptable sample tubes are submissible in the preferred top-color type in the order: 1) red top, 2) tiger top, 3) purple top tube.
3. Sample labels utilizing the donor hospital labels must include donor's full first and last name, date of birth (mm/dd/yy), UNOS/OPTN ID number, donor hospital name, date and time sample was drawn and initials of the person drawing the blood. The only exception to this is when UNOS/OPTN ID may not be available at the time of sending a sample, subsequent to the release of any report by NIT, an OPO's Placement Coordinator will generate a UNOS/OPTN ID and forward the UNET print-out to NIT via fax (see NIT Lab Responsibilities #6).
4. A requisition form for each set of serologies must be attached and sent with the samples; the requisition must be appropriately labeled as either pre or post transfusion sample.
5. The OPO's Placement Coordinator will notify the on-call NIT Laboratory personnel of the estimated time of arrival of the sample and donor hospital from where it is coming. Packaging of samples will meet commercial airline transportation requirements.
6. Submitted samples will be processed on a "stat" basis unless the lab is notified by the placement coordinator to hold the sample for later processing.

NIT Lab Responsibilities:

1. Submitted samples will be processed 24 hours a day/7 days a week on a "stat" basis unless NIT Lab is notified by the placement coordinator to hold the sample for later processing. Current turn around time requirements are 8 hours or less from the time the donor's blood sample is received at the NIT Lab.
2. These tests shall be performed by a Clinical Laboratory Scientist (CLS) and a laboratory technician in accordance with established NIT Lab policies and procedures.
3. Each sample's hold status (yes or no) will be confirmed with a telephone call from the OPO's placement coordinator and documented by the NIT lab personnel on OPO's RS110.1, *Serology Test Request* form. Serology samples will be held at the NIT lab for up to 72 hours following this notification. Upon additional telephone request, samples will be held but not run for an additional 2 days, for a total of 5 days maximum from the time of original submission.
4. The following FDA licensed tests will be performed on all donors with adequate sample submitted.
 - 4.1 Hepatitis B Surface antigen (HBsAg); then if positive, confirmatory testing is performed as follows: HBsAg neutralization test is the only confirmatory test if HBcAb is also reactive. If HBcAb was non-reactive, then three additional tests: HBsAg neutralization, Hepatitis B surface antibody (HBsAb), and HBc IgM are performed
 - 4.2 Hepatitis B core antibody (HbcAb); then if positive, an in-house confirmatory HBc IgM is performed



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- 4.3 Hepatitis C antibody (HCV Ab); then if reactive, the confirmatory HCV Ag RIBA (send-out) is performed only if the Anti-HCV assay result has a signal/cut-off ratio of 3.7 or below and the HIC/HCV NAT combo is non-reactive or HIV/HCV NAT combo is reactive and HCV NAT confirmatory is negative. Anti-HCV assays with a signal/cut-off ratio is 3.8 or higher will be considered positive.
 - 4.4 HIV I/II antibody (anti-HIV); then if positive, a confirmatory HIV 1/2 Western Blot (send-out) is performed only if the HIV/HCV NAT combo is non-reactive or HIV/HCV NAT combo is reactive and HIV NAT confirmatory is negative.
 - 4.5 HIV/HCV NAT Combo Assay (TMA); then if reactive, separate in-house confirmatory HIV-1 and HCV NAT assays are both performed.
 - 4.6 HTLV I/II antibody (HTLV I/II Ab); then if positive, HTLV I/II Western Blot (send-out) is performed.
 - 4.7 CMV antibody screen. (Acceptable specimen: **ONLY SERUM**)
 - 4.7.1 CMV IgG by *Wampole Diagnostics*
 - 4.7.2 CMV IgM by *Wampole Diagnostics*
 - 4.8 Epstein-Barr Virus Epstein Barr Virus (EBV). (Acceptable specimen: ONLY SERUM)
 - 4.8.1 Viral Capsid Antigen (VCA) IgG by *Wampole Diagnostics*
 - 4.8.2 Viral Capsid Antigen (VCA) IgM by *Wampole Diagnostics*
 - 4.8.3 Nuclear Antigen (EBNA) by *Trinity Biotech (July 1,2007)*
 - 4.9 RPR test for syphilis by *Becton Dickinson*; then if reactive, a confirmatory MHA/TPPA by *Fujirebio Diagnostics, Inc.* is performed.
 - 4.10 Confirmatory ABO and Rh typing with A1/A2 subgroup testing for Blood Group A by *Ortho Clinical Diagnostics Inc.*
 - 4.11 *T. cruzi (Chagas)* antibody; then if reactive, a confirmatory *T. cruzi* by IFA or RIPA (send-out) will be performed from a CLIA certified laboratory.*** Please make note here that this assay is done to some OPO not to all.
5. In situations where only a small aliquot of pre-transfusion serum is submitted, acceptable sample tubes will be utilized in the preferred top-color type in the order: 1) red top, 2) tiger top, and then 3) purple top tube.). If only a small aliquot of pre-transfusion serum is available, the order of priority for OPO's testing is the HIV antibody (Anti-HIV 1/2), Hepatitis C antibody (Anti-HCV), Hepatitis B surface antigen (HBsAg), and HIV/HCV NAT Combo Assay (TMA).
 6. OPO's requires that a UNOS ID # be verified and included in the reports produced by NIT and that all testing results be reported on a single page for each organ donor sample submitted, including the contingency for multiple reactive/confirmatory testing results. The display format for the reporting will show the NORMAL (negative/non-reactive) results in one column and the ABNORMAL (positive/reactive) results in a different column as well as the REFERENCE RANGE results in a third column.
 7. NIT Lab staff will fax confirmed test reports to OPO's placement staff designated on OPO's RS110.1, *Serology Test Request* form. Delays in reporting, which may result from reactive test results being confirmed by retesting, should be reported immediately to the placement coordinator with an estimated time to expect results.



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8. NIT Lab will respond to requests for changes to the reporting formats as required by OPO's.
9. NIT Lab will produce the completed documentation of OPO's RS110.1, *Serology Test Request* form upon request.
10. OPO's requires that no further testing of its samples be performed outside of its laboratory service agreement with NIT without a separate written agreement with OPO's.
11. OPO's requires that NIT provide complete copies of its licensures/accreditations and validated tests (both screening and confirmatory) per this laboratory service agreement including the current manufacturer and testing kit version to ensure compliance with all applicable laboratory reporting standards (UNOS, CLIA, FDA, etc.).
12. OPO's requires a sufficient advance notification (within 30 days) in writing from NIT in the event that NIT becomes aware of a change in the current status of its licensures or accredited status affecting any laboratory test or its availability mentioned in this agreement.
13. NIT will continue to archive all OPO's donor samples and in the event of an inability to archive a sample (insufficient quantity), NIT will notify OPO's.
14. In the event NIT is no longer a contracted service then OPO's obtains all rights to recover all archived samples.



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National Institute of Transplantation
 Laboratory Verification Checklist
 21 CFR Part 1271 Compliance
 Laboratory Registration and Test Type

CLIA ID: 05D0962012

REGISTRATION

Is your organization currently registered with the FDA? Yes No
 If yes, what is your FDA Establishment Registration Number? 3004732463
 Has a copy of your current validated FDA registration been included? Yes No
 If no, does your organization plan to register with the FDA in the near future? Yes No
Not Applicable

TESTING

<i>Test</i>	<i>Test Kit Name</i>	<i>Test Kit Manufacturer</i>	<i>Screening or Diagnostics Test</i>	<i>Licensed for Cadaveric Samples</i>	<i>Package Insert Included</i>
Anti-HIV-1/2	Genetic System™ Human Immunodeficiency Virus Types 1 and 2 Plus O	BIO-RAD Laboratories	Screening	Yes	Yes
Anti-HTLV I/II	Human T-Lymphotropic Virus Types I and II	Abbott Laboratories	Screening	No	Yes
Anti-HCV	Hepatitis C Virus Encoded Antigen (Ver. 3.0)	Ortho Diagnostics	Screening	No	Yes
Anti-HBc (IgG+IgM)	Hepatitis B Virus Core Antigen (Recombinant) ORTHO® HBc ELISA Test System	Ortho Diagnostics	Screening	No	Yes
HBsAg	Genetic System™ Antibody to Hepatitis B surface Antigen v 3.0	BIO-RAD Laboratories	Screening	Yes	Yes
HIV-1 NAT	Procleix HIV-1/HCV Assay	Chiron	Screening	Yes	Yes
HCV NAT	Procleix HIV-1/HCV Assay	Chiron	Screening	Yes	Yes
Syphilis	RPR Card Test	ASI	Diagnostic	No	Yes
T. pallidum	Serodia® - TP . PA	Fujirebio	Diagnsotics	No	Yes
Anti-CMV (IgG/IgM)	Cytomegalovirus IgG/IgM	Wampole Laboratories	Screening	No	Yes

Note: No tests or assays are set-up or perform in triplicate testing for organ or tissue donors.



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 NIT Serology Laboratory
 221 South Figueroa Street, Suite 510
 Los Angeles, CA. 90012
 Tel 213.229.3654 Fax 213.229.3659
 Medical Director: Mian Hardy, MD, FACP
 CLIA #: 05D0962012

Patient Demographics

Patient name: _____	NIT USE ONLY:
Date of Birth: _____ Age: _____ UNOS #: _____	

Specimen Information:

Draw Date: _____	Case #: _____
Draw Time: _____	<input type="checkbox"/> Pre <input type="checkbox"/> Post

OPO / Client

<input type="checkbox"/> OneLegacy	<input type="checkbox"/> GSDS	<input type="checkbox"/> IDS	<input type="checkbox"/> NMDS
<input type="checkbox"/> CTDN	<input type="checkbox"/> Lifesharing	<input type="checkbox"/> NDN	<input type="checkbox"/> WCC Late

Contact Information:

Coordinator: _____	
Tel #: _____	Fax #: _____

Tests:

<input type="checkbox"/> PANEL I - ABO/Rh; HBe Ag; HBe Ab; HCV Ab; HIV 1/2 Ab, HTLV I/II Ab; CMV Ig G & IgM; EBV IgG & IgM; RPR, NAT (HIV-1/HCV)	<input type="checkbox"/> NAT (HIV-1/HCV) Nucleic Acid Testing for HIV- 1/HCV	<input type="checkbox"/> Chagas Testing T. cruzi antibody - EIA
<input type="checkbox"/> Hgb A1c Quantitative Hgb A1c	<input type="checkbox"/> NAT (WNV) Nucleic Acid testing for West Nile Virus	<input type="checkbox"/>

NIT USE ONLY

___Red	___Yellow	___EDTA	___Tiger	___Pawl	___Green	___Blue	___Gold	___Purple	___Brown
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Date/Time Received: _____ Received by: _____

Comments: _____

Rev date: 08/307



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OPO DONOR PRICING SCHEDULE

Blood Organ Donor Serology Testing ABO/RH Total HBc Ab HBs Ag HCV Ab Screen HIV ½ Ab Screen HTLV I & II CMV (igG & IgM) RPR HBsAB – Hepatitis B EBV (IgG, IgM, and EBNA)	<p style="text-align: center;">\$1,950.00</p> <p style="text-align: center;">See information below for out-of-area pricing</p>
NAT – Nucleic Acid Testing (includes discriminatory testing for HIV & HCV)	<p style="text-align: center;">\$765.00</p>
Chagas	<p style="text-align: center;">\$285.00</p>
HgbA1c	<p style="text-align: center;">\$75.00</p>
West Nile Virus (includes both a NAT and ELISA (Enzyme-linked immunosorbent assay) Test)	<p style="text-align: center;">\$415.00</p>
Pricing schedule effective June 1, 2009	

All OPO Donor Testing is performed on an NIT '**STAT**' basis. That is, NIT will begin testing as soon as the specimen is received. Preparations begin when the NIT Laboratory receives notification from the OPO that a specimen(s) is being delivered.

National Institute of Transplantation (NIT) provides its out-of-area (Los Angeles) OPO clients a flat rate allowance of \$275 on 'Blood Organ Donor Serology Testing' Panel in consideration of the courier and other transportation expenses associated with delivering specimen to the NIT Laboratory in Los Angeles. The flat rate allowance is \$275 from the listed price of \$1,950; or \$1,675. (For NAT testing only clients, the transportation allowance is \$137.50, \$627.50.)

NIT's stated goal for results for OPO Donor is between 6 - 8 hours from the time of NIT Laboratory receipt.



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**COMPLETE LISTS OF TESTS
SOLID ORGAN DONORS**

1. ABO/Rh Typing – Gel Method/Tube Method by *Ortho Clinical Diagnostics*
 - a. A1/A2 – if ABO - Type A or AB
2. CMV
 - a. CMV IgG by *Wampole Diagnostics*
 - b. CMV IgM by *Wampole Diagnostics*
3. Epstein Barr Virus (EBV)
 - a. Viral Capsid Antigen (VCA) IgG by *Wampole Diagnostics*
 - b. Viral Capsid Antigen (VCA) IgM by *Wampole Diagnostics*
 - c. Nuclear Antigen (EBNA) IgG by *Wampole Diagnostics*
4. RPR (Syphilis-Qualitative) Latex Agglutination by *ASI*
5. Hepatitis B surface Antigen (HBsAg) EIA by *Bio-Rad*
6. Hepatitis B surface Antibody (HBsAb) EIA by *Bio-Rad*
7. Hepatitis B core Antibody (HBc Ab) EIA by *Ortho Clinical Diagnostics*
8. Hepatitis C Antibody ver. 3.0 (HCV Ab) EIA by *Ortho Clinical Diagnostics*
9. HTLV I/II Ab EIA by *Abbott*
10. HIV 1/2 Plus O Ab EIA by *Bio-Rad*
11. Procleix® HIV-1/HCV Assay by *Chiron/Novartis* (Qualitative)
12. T. cruzi (*CHAGAS*) EIA by *Ortho Clinical Diagnostics*
13. West Nile Virus (WNV) ELISA by *Focus Diagnostics* (**June 1, 2009**)
14. West Nile Virus Assay (NAT) by *Chiron/Novartis* (**June 1, 2009**)
15. Hemoglobin A1c (Hgb A1c) by *Bio-Rad* (*HPLC*)



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CONFIRMATORY TESTING: (IN –HOUSE)

1. Hepatitis B core - IgM (**If HBc Ab is Reactive**) EIA by *Bio-Rad*
2. Hepatitis B surface Ag Confirmatory (**If HBs Ag is Reactive**) – EIA by *Bio-Rad*
3. Procleix® HIV-1 Discriminatory Assay (**If Procleix® HIV-1/HCV Assay is Reactive**) by *Chiron/Novartis*
4. Procleix® HCV Discriminatory Assay (**If Procleix® HIV-1/HCV Assay is Reactive**) by *Chiron/Novartis*
5. HTLV I/II Western Blot (**If HTLV I/II Ab is Positive**) by *Genelabs*
6. MHA-TP (Serodia™) (**If RPR Screening is Reactive**) by *Fujirebio*
7. HIV-1 Western Blot (**If HIV ½ Ab is Positive**) if the NAT discriminatory HIV-1 does not agree to HIV ½ Plus O Ab by EIA by Bio-Rad

CONFIRMATORY TESTING WILL BE SENT OUT TO

1. **FOCUS Diagnostics**
5785 Corporate Avenue
Cypress, CA 90630-4750
2. **QUEST Diagnostics – West Hills**
8401 Fallbrook Avenue
West Hills, CA 91304-3226
3. **QUEST Diagnostics**
Nichols Institute Chantilly, Virginia
14225 Newbrook Drive
Chantilly, VA 20153
4. **QUEST Diagnostics**
Nichols Institute San Juan Capistrano, California
33608 Ortega Hwy.



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San Juan Capistrano, CA 92675

5. California Department of Public Health
Viral and Rickettsial Disease Laboratory
850 Marina Bay Parkway
Richmond, California

TESTS FOR SEND-OUT

1. HCV by RIBA® See CDC Guidelines for Laboratory testing and Result Reporting of Antibody to Hepatitis C Virus
2. T. cruzi (CHAGAS) by RIPA (If T. cruzi Ab by EIA is Reactive)
3. West Nile Virus Western Blot (If ELISA is repeatedly equivocal) by Department of Health – San Francisco



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ORGAN DONOR TESTS PERFORMED **(IN-HOUSE)**

Revised: 03/09/2009
Effective Date: 03/09/2009

ABO/Rh Typing

(Tube/Gel Method)
(Ortho Clinical Diagnostics)

FDA Approved

Qualitative Tests with Blended Monoclonal Antibodies for Recognition of the A Antigen and its Subgroups and/or the B Antigen on Human Red Blood Cells. The procedures used with these reagents are based on the principle of agglutination. Normal human red blood cells possessing antigens will agglutinate in the presence of antibody directed toward the antigens. The results of red blood cell grouping should be confirmed by reverse (serum) grouping, i.e. testing individual's serum with known A₁ and B red blood cells.

Cytomegalovirus Antibody IgG and IgM EIA

(CMV IgG and CMV IgM)
(Wampole Laboratories®)

The Wampole Laboratories Cytomegalovirus (CMV IgG and CMV IgM) ELISA test system is an enzyme linked immunosorbent assay (ELISA) for the qualitative detection of IgG and IgM class of antibodies to CMV in humans serum. The test system is intended to be used to evaluate serological evidence of previous or primary infection with CMV. This product is not FDA cleared (approved) for use in testing blood and plasma.

Epstein Bar Virus Viral Capsid Antigen IgG and IgM

(EBV VCA IgG and EBV VCA IgM)
(Wampole Laboratories®)
FDA Approved

The Wampole Laboratories Epstein Bar Virus (EBV) Viral Capsid Antigen (VCA) IgG and IgM ELISA test system is an enzyme linked immunosorbent assay (ELISA) designed for qualitative detection of IgG and IgM class antibodies to Epstein Bar Virus viral capsid antigen (EBV-VCA) in human serum. The test system is intended to be used to evaluate serological evidence of infection with EBV, and it is for in-vitro diagnostic use.

Epstein Bar Virus Viral Nuclear Antigen-1 IgG

(EBNA IgG)
(Wampole Laboratories)
FDA Approved

The Wampole Laboratories EBNA-1 IgG ELISA test system provides a means for the qualitative detection of IgG to the nuclear antigen-1 of Epstein-Barr virus (EBNA-1) in human sera. When performed according to these instructions, the results of this test together with other testing, such as heterophile test, and the EBV-VCA IgG and IgM tests, may aid in the diagnosis of, and provide information of infectious mononucleosis (IM), that may be of value in patient management and treatment. *For in vitro diagnosis use.*



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ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (Mouse Monoclonal)

(Genetic Systems™ HBsAg EIA 3.0)

(BIO-RAD)

FDA Approved

Genetic Systems™ HBsAg EIA 3.0 is a qualitative enzyme immunoassay for detection of Hepatitis B Surface Antigen (HBsAg) in human serum or plasma, and also in *cadaveric serum specimens*. The HBsAg EIA 3.0 is intended to be used for screening blood and blood products intended for transfusion or for further manufacture into plasma products

HBV is a major public health problem worldwide, with significant transmission of the virus occurring through use of contaminated blood and blood products. Also of concern is the transmission of HBV and other infectious disease through tissue and organ transplantation.

Because the presence of infection, screening for HBsAg is used to detect potentially infectious blood and plasma. Enzyme immunoassays to detect HBsAg have replaced relatively sensitive to radioimmunoassay methods. This test uses the mouse monoclonal antibodies to detect HBsAg in human serum, plasma or cadaveric specimens.

HEPATITIS B SURFACE ANTIBODY (anti-HBs)

(Monolisa™ Anti-HBs EIA)

(Bio-Rad)

Not FDA Approved

The Bio-Rad MONOLISA™ Anti-HBs EIA is a qualitative and quantitative enzyme immunoassay for the detection of antibody to hepatitis B surface antigen in human serum and EDTA or citrated plasma. The assay results may be used as an aid in the determination of susceptibility to hepatitis B virus (HBV) infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.

WARNING: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. Federal law restricts this device to sale by or on the order of a physician. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations.

ANTIBODY TO HEPATITIS B CORE ANTIGEN

(Monolisa™ anti-HBc)

(Ortho Clinical Diagnostics)

FDA Approved

Ortho HBc ELISA Test System is a qualitative enzyme-linked immunosorbent assay for the detection of total antibody to hepatitis B core antigen (anti-HBc) in human serum or plasma indicated for the screening of blood and blood products intended for transfusion and as an aid in the diagnosis of ongoing or previous hepatitis B virus infection.

ANTIBODY to HEPATITIS C VIRUS ENCODED ANTIGENS (HCV Ab)

(Recombinant c22-3, c200 and NS5)

(Ortho® Version 3.0 ELISA)

FDA Approved



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Ortho® HCV Version 3.0 ELISA Test System is a qualitative, enzyme-linked, immunosorbent assay for the detection of antibody to hepatitis C virus (anti-HCV) in human serum or plasma. The primary purpose of this assay is to screen blood donations so that donors/units containing HCV antibody can be identified and eliminated from the blood supply. Although the presence of anti-HCV does not constitute a diagnosis of HCV infection, the determination of anti-HCV may be used as an aid in the diagnosis of hepatitis C and in the differential diagnosis of non-A, non-B hepatitis in conjunction with determination of liver enzymes, additional serological markers and clinical evaluation.

This an ELISA Test System, which utilizes microwells coated with Hepatitis C virus encoded antigens in solid phase. ELISA technology utilizes the principle that antigens or antibodies, which become bound to the solid phase, can be detected by complimentary antibody or antigen respectively, which is labeled with an enzyme capable of acting on a chromogenic substrate.

The primary purpose of this assay is to detect antibodies of HCV found in blood and blood products. Although the presence of anti-HCV does not constitute a diagnosis of HCV infection, the determination of anti-HCV may be used as an aid in the diagnosis of hepatitis C and in differential diagnosis of non-A, non-B hepatitis in conjunction with determination of liver enzymes, additional serological markers, and clinical evaluations.

Human Immunodeficiency Virus Types 1 and 2 Plus O Antibody (HIV 1 and 2 Plus O Ab)

(Genetic Systems™ HIV-1/HIV-2 Plus O EIA)

(BIO-RAD)

FDA Approved

The *Genetic Systems™ HIV-1/HIV-2 Plus O EIA* is an enzyme immunoassay utilizing recombinant proteins and synthetic peptides for the detection of antibodies to HIV-1 (Group M and O) and/or HIV-2 in human serum and plasma. It is indicated as a screening test for serum or plasma and as an aid in the diagnosis of infection with HIV-1 and/or HIV-2.

The *Genetic Systems™ HIV-1/HIV-2 Plus O EIA* is an enzyme immunoassay based on the principle of direct antibody sandwich technique. Microwell strip plates (solid phase) are coated with purified antigens: gp160 and p24 recombinant proteins derived from HIV-1; a peptide representing the immunodominant region the HIV-2 transmembrane glycoprotein, gp36; and a synthetic polypeptide mimicking an artificial HIV-1 group O specific epitope.

HTLV-I/HTLV-II EIA Ab

(HTLV-I/HTLV-II EIA)

(Abbott Laboratories Diagnostics Division)

FDA Approved

Abbott HTLV-I/HTLV-II EIA is an in vitro enzyme immunoassay for the qualitative detection of antibodies to Human T-lymphotropic Virus Type I and /or Type II (HTLV-I/HTLV-II) in serum or plasma. The *Abbott* HTLV-I/HTLV-II EIA is intended to be used as a screen for *donated blood* to prevent transmission of HTLV-I and HTLV-II to recipients of cellular blood components and as an aid in the clinical diagnosis of HTLV-I/HTLV-II infection and related diseases.

Human T Lymphocytic Viruses are associated with neoplastic condition and demyelinating neurologic disorders. Infections are endemic in the Caribbean, southeastern Japan, and in central and south America.

The test utilizes enzyme immunoassay technology to detect specific antibodies present in patients' serum or plasma. Beads are coated with sonicated or detergent inactivated HTLV-I and HTLV-II proteins grown from human T-Lymphocyte cell line



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RAPID PLASMA REAGIN (RPR)

(Syphilis Testing)
(ASI)
FDA Approved

Rapid Plasma Reagin card is used for the detection of nonspecific antibody for syphilis. The antigen is carbon particle coated with cardiolipin, lecithin and cholesterol. Reagin-like antibodies will react with the carbon particle causing a macroscopic flocculation that appears as black clumps on a white plastic card. Positive screening test should be confirmed by using tests specific for *Treponema pallidum* antibody such as the FTA-ABS.

HIV-1/HCV RNA by TMA (Screening Assay)

(Procleix® HIV-1/HCV Assay)

(Chiron/Novartis)
FDA Approved

The *Procleix® HIV-1/HCV Assay* is a qualitative in vitro nucleic acid assay system for the detection of human immunodeficiency virus type 1 (HIV-1) and/or hepatitis C virus (HCV) RNA in human plasma specimens from individual blood donors, including donors of whole blood and blood components, source plasma and other living donors. It is also intended for use in testing plasma to screen organ donors when specimens are obtained while donor's heart is still beating, and from blood specimens from cadaveric (non-heart beating) donors. It is not intended for use on samples of blood cord.

The assay is intended for use in screening individual donor samples of all specimens type, pools of human plasma comprised of equal aliquots of not more than 16 individual donations for donors of whole blood, blood components, or source plasma. This assay is intended to be used in conjunction with licensed test for detecting antibodies to HIV-1 and HCV.

HIV-1 RNA by TMA

(Procleix® HIV-1 Discriminatory Assay)

(Chiron/Novartis)
FDA Approved

The *Procleix® HIV-1 Discriminatory Assay* is a qualitative in vitro nucleic acid assay system for the detection of human immunodeficiency virus type 1 RNA in human plasma specimens from individual blood donors, including donors of whole blood and blood components, source plasma and other living donors. It is also intended for use in testing plasma to screen organ donors when specimens are obtained while donor's heart is still beating, and from blood specimens from cadaveric (non-heart beating) donors. It is not intended for use on samples of blood cord.

The assay is intended for use in screening individual donor samples of all specimens type, pools of human plasma comprised of equal aliquots of not more than 16 individual donations for donors of whole blood, blood components, or source plasma. This assay is intended to be used in conjunction with licensed test for detecting antibodies to HIV-1.

HCV RNA by TMA

(Procleix® HCV Discriminatory Assay)

(Chiron/Novartis)



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FDA Approved

The *Procleix® HCV Discriminatory Assay* is a qualitative in vitro nucleic acid assay system for the detection of hepatitis C RNA in human plasma specimens from individual blood donors, including donors of whole blood and blood components, source plasma and other living donors. It is also intended for use in testing plasma to screen organ donors when specimens are obtained while donor's heart is still beating, and from blood specimens from cadaveric (non-heart beating) donors. It is not intended for use on samples of blood cord.

The assay is intended for use in screening individual donor samples of all specimens type, pools of human plasma comprised of equal aliquots of not more than 16 individual donations for donors of whole blood, blood components, or source plasma. This assay is intended to be used in conjunction with licensed test for detecting antibodies to HCV.

T. cruzi (Chagas) by EIA

(Ortho Clinical Diagnostic)

FDA Approved

ORTHO *T. cruzi* ELISA Test System is an enzyme-linked immunosorbent assay for the qualitative detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*) in human serum and plasma specimens.

This product is intended for use as a donor screening test to detect antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of whole blood components or source plasma, and other living donors. It is also intended for use to screen organ and tissue donors when specimens are obtained while the donor's heart is still beating. This test is not intended for use with specimens from cadaveric (non-heart-beating) donors. This test is not intended for use on samples of cord blood.

The ORTHO *T. cruzi* ELISA Test System is intended for use in a fully manual mode, in semi-automated mode using the Ortho Summit Sample Handling System (Summit) or in automated mode with the Ortho Summit System (OSS).

This assay is not intended for use as an aid in diagnosis.

Hemoglobin A1 (Hgb A1c) by HPLC

(BIO-RAD Laboratories)

The Bio-Rad D-10™ Hemoglobin A_{1c} Program is intended for the determination of hemoglobin A_{1c} in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The D-10 Hemoglobin A_{1c} Program is intended for use only with the Bio-Rad D-10™ Hemoglobin Testing System.

For In Vitro Diagnostic Use.

West Nile Virus IgM Capture DxSelect by ELISA

(Focus Diagnostics)

The Focus Diagnostics West Nile Virus IgM Capture DxSelect™ is intended for qualitatively detecting IgM antibodies to West Nile virus in human serum. In conjunction with the Focus Diagnostics West Nile Virus IgG DxSelect, the test is indicated for testing persons having symptoms of meningoencephalitis, as an aid in the presumptive laboratory diagnosis of West Nile virus infection. Positive results must be tested using the background subtraction method (either on the initial test or on a repeat test). Positive results must be



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confirmed by neutralization test, or by using the current CDC guidelines for diagnosing West Nile encephalitis. This test is not intended for self-testing, and this test is not FDA cleared nor approved for testing blood or plasma donors. Assay performance characteristics have not been established for automated instruments.

Procleix® WNV Assay

(Chiron/Novartis)

FDA Approved

The PROCLEIX® WNV Assay is a qualitative *in vitro* nucleic acid assay system for the detection of West Nile Virus (WNV) RNA in plasma specimens from individual human donors, including volunteer donors of whole blood and blood components, and other living donors. It is also intended for use in testing plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens to screen cadaveric (non-heart-beating) donors. It is not intended for use on cord blood specimens.

This assay is not intended for use as an aid in the diagnosis of West Nile Virus infection.

CONFIRMATORY TESTING (IN-HOUSE)

ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (HUMAN)

(Genetic Systems™ HBsAg Confirmatory Assay 3.0)

(BIO-RAD)

FDA Approved

Genetic Systems™ HBsAg Confirmatory Assay 3.0 is a qualitative assay intended for the confirmation of HBsAg reactive specimens detected in the *Genetic Systems™ HBsAg EIA 3.0*.

HEPATITIS B CORE IgM

(Monolisa™ Anti-HBc IgM EIA)

(Ortho-Clinical Diagnostics)

NOT FDA Approved

The MONOLISA™ Anti-HBc IgM EIA is an enzyme immunoassay intended for use in the qualitative detection of IgM antibodies to Hepatitis B core antigen (anti-HBc IgM) in human serum or plasma (potassium EDTA, sodium citrate, ACD (acid citrate dextrose), lithium heparin and sodium heparin). Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection.

This assay has not been FDA cleared or approved for the screening of blood or plasma donors. Federal law restricts this device to sale by or on the order of a physician. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing their own assay performance characteristics in these populations.

HTLV – 1/II WB

(HTLV-I/II WB)

(Genelabs Diagnostics®)



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NOT FDA Approved

The MP Diagnostics (MPD) HTLV BLOT2.4 is a qualitative enzyme immunoassay for the in vitro detection of antibodies to HTLV-I and HTLV-II in human serum or plasma samples. This test kit is supplied for research purposes only. It is not intended for use in diagnosis or prognosis of disease. In particular, this test cannot be used to evaluate blood specimens for purposes of donor screening or as a confirmatory diagnostic.

This assay was performed using reagents labeled "For Research Use Only" by the manufacturer. This laboratory is certified under the Clinical Laboratory Improvement Amendment (CLIA) to perform high complexity clinical laboratory testing. These results have been generated using a test that has not been approved by FDA. The performance characteristics of this test have been established by the NIT Laboratory.

HIV-1 Western Blot

(HIV-1 WB)

(Bio-Rad)

FDA APPROVED

The GS HIV-1 Western Blot Kit is an in vitro qualitative assay for the detection and identification of antibodies to Human Immunodeficiency Virus Type (HIV-1) in human serum, plasma, or dried blood spots. It is intended for use with persons of unknown risk as an additional, more specific test on human serum, plasma, or dried blood spot specimens found to be repeatedly reactive using a screening procedure, such as Enzyme-Linked Immunosorbent Assay (ELISA), and as an additional, more specific test use with serum, plasma, or dried blood spot specimens obtained from subjects found to be reactive using rapid HIV-1 tests.

MHA-TP

(MHA-TP (Serodia)

(Fujirebioa Inc.)

NOT FDA APPROVED

Serodia® - TP.PA is a qualitative gelatin particle agglutination assay intended to be used for the detection of *Treponema pallidum* antibodies in human serum or plasma as an aid in the diagnosis of syphilis. This product is not cleared or approved by the U.S. Food and Drug Administration (FDA) for use in screening blood or plasma donors.

This assay was performed using reagents labeled "For Research Use Only" by the manufacturer. This laboratory is certified under the Clinical Laboratory Improvement Amendment (CLIA) to perform high complexity clinical laboratory testing. These results have been generated using a test that has not been approved by FDA. The performance characteristics of this test have been established by the NIT Laboratory.



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Testing Notification Protocol

- a. OPO Coordinator/Distributor calls NIT Serology Lab (213.229.3654) to state that sample is being prepared for shipment.
- b. Basic information is communicated from the OPO to NIT to prepare for the sample.
- c. Requisition is completed by OPO and sent with sample to NIT Lab.
- d. NIT Lab estimates ETA (estimated time of arrival) of sample to Laboratory.
- e. One to one and a half hours (1 – 1.5 hours) from ETA NIT Lab begins thawing of reagents for STAT Serology and NAT testing.
- f. When sample is received it is logged (time and condition of sample).
- g. Serology and NAT testing begins in parallel.
- h. Communication with OPO Coordinator/Distributor is maintain throughout testing process to keep them current on results and/or any complications with the testing process.
- i. When tests are available they are immediately communicated to the coordinator.
- j. At the same time results are communicated, they are faxed to appropriate fax number – typically location of OPO coordinator/distributor.