Blood Screening Assays

CTS lab locations where assays are performed are indicated by alpha codes D, P, and T.

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<tr>
<th>Code</th>
<th>Location</th>
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<td>performed in Dallas lab</td>
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<td>P</td>
<td>performed in Phoenix lab</td>
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<tr>
<td>T</td>
<td>performed in Tampa lab</td>
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ABO/Rh (P, D, T)
Manufacturer: Diagast, Loos Cedex, France for Beckman Coulter
Test Name: Beckman Coulter PK System Blood Grouping and Phenotyping
ReagentsPK7200 and PK7300 Automated Immunohematology Analyzers
License: U.S. License No. 1744

Alternate ABO/Rh (P, D, T)
Manufacturer: ImmucorGamma, Norcross, GA
Test Name: Reagent Red Blood Cells for ABO Serum Grouping, Blood Grouping
Reagents Anti-A (Series 1), -B (Series 1), -B (Series 3), -A,B (Series 1), -D (Series 4), -D (Series 5)
Galileo /Neo Automated Blood Bank System
License: U.S. License No. 0886

Antibody Identification (P)
Manufacturer: Micro Typing Systems, Inc. an Ortho Clinical-Diagnostics Company, Raritan NJ
Test Name: MTS Anti-IgG Card
Reagent Red Blood Cells 0.8% Resolve Panel A and Panel B
ProVue Analyzer
License: U.S. License No. 1177 and 1236

Alternate Antibody Identification (P)
Manufacturer: ImmucorGamma., Norcross, GA
Test Name: Capture-R Ready ID, Extend I and Extend II
License: U.S. License No. 0886

Antibody Screen (P, D, T)
Manufacturer: ImmucorGamma., Norcross, GA
Test Name: Capture-R Ready Screen (Pooled)
License: U.S. License No. 0886 for Capture-R Ready Screen test wells only and BK890012

Alternate Antibody Screen (P, D, T)
Manufacturer: Micro Typing Systems, Inc. an Ortho Clinical-Diagnostics Company, Raritan NJ
Test Name: MTS Anti-IgG Card
Reagent Red Blood Cells 0.8% Surgiscreen
ProVue Analyzer
License: U.S. License No. 1177 and 1236
<table>
<thead>
<tr>
<th>Assay</th>
<th>Manufacturer</th>
<th>Test Name</th>
<th>License</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Anti-HBc (ChLIA) (P, D, T)</td>
<td>Abbott Laboratories</td>
<td>Abbott PRISM® HBcore, Hepatitis B Virus Core Antigen (E. coli, Recombinant)</td>
<td>U.S. License No. 43</td>
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<td>Anti-HCV (ChLIA) (P, D, T)</td>
<td>Abbott Laboratories</td>
<td>Abbott PRISM® HCV, Hepatitis C Virus Encoded Antigens (Recombinant c100-3, HCr43, NS5)</td>
<td>U.S. License No. 43</td>
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<tr>
<td>Anti-HIV-1/HIV-2 (ChLIA)</td>
<td>Abbott Laboratories</td>
<td>Abbott PRISM® HIV O Plus, Human Immunodeficiency Virus Types 1 and 2 (E. coli, B. megaterium, Recombinant) Antigen and Synthetic Peptide</td>
<td>U.S. License No. 43</td>
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<tr>
<td>Anti-HTLV-I/HTLV-II (ChLIA)</td>
<td>Abbott Laboratories</td>
<td>Abbott PRISM® HTLV-I/HTLV-II, Human T-Lymphotropic Virus Types I and II</td>
<td>U.S. License No. 43</td>
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<tr>
<td>Babesia (P, T)</td>
<td>Immunetics, Inc.</td>
<td>Babesia microti ELISA Kit</td>
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<td>NOTE: This assay is for investigational use only and requires IRB approval prior to implementation.</td>
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<td>Cholesterol (P, D, T)</td>
<td>Beckman Coulter, Inc.</td>
<td>Cholesterol</td>
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<tr>
<td>Cytomegalovirus (CMV) Screen (P, D, T)</td>
<td>Fujirebio Diagnostics, Inc. Malvern, PA Beckman Coulter</td>
<td>Beckman Coulter PK CMV-PA Test System and Controls PK7200 and PK7300 Automated Immunohematology Analyzers</td>
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<td>Ferritin (P, D, T)</td>
<td>Beckman Coulter, Inc.</td>
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## Blood Screening Assays

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<tr>
<th>Test Name</th>
<th>Manufacturer</th>
<th>License</th>
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<tr>
<td><strong>HBsAg (ChLIA)</strong></td>
<td>Abbott Laboratories, Abbott Park, IL</td>
<td>U.S. License No. 43</td>
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<tr>
<td><strong>Hemoglobin A1c</strong></td>
<td>Beckman Coulter, Inc.</td>
<td>U.S. License No. 862.1150</td>
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<tr>
<td><strong>Nucleic Acid Testing (NAT) Procleix® Ultrio Plus®</strong></td>
<td>Hologic Inc., San Diego, CA</td>
<td>U.S. License No. 2037</td>
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<tr>
<td><strong>Nucleic Acid Testing (NAT) Procleix WNV RNA</strong></td>
<td>Hologic Inc., San Diego, CA</td>
<td>U.S. License No. 2037</td>
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<td><strong>Rh + K Phenotyping</strong></td>
<td>Diagast, 59374 Cedex Loos, France for Beckman Coulter PK Systems</td>
<td>U.S. License No. 1744</td>
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<td><strong>Syphilis Serology</strong></td>
<td>Fujirebio Diagnostics, Inc. Brea, CA for Beckman Coulter.</td>
<td>BK060062</td>
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<tr>
<td><strong>T. cruzi Antibody ChLIA</strong></td>
<td>Abbott Laboratories, Abbott Park, IL</td>
<td>U.S. License No. 43</td>
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</table>
Parvovirus B19 / HAV Testing

Parvovirus B19  (P)
Manufacturer: Roche Molecular Systems, Inc.
Test Name: cobas® TaqScreen DPX Test
License: Information not available

Parvovirus B19 / HAV  (P)
Manufacturer: Roche Molecular Systems, Inc.
Test Name: cobas® TaqScreen DPX Test
License: Information not available

TRALI Mitigation Testing

Donor Screen- HLA Class I and II  (D, P, T)
Manufacturer: GTI Diagnostics
             20925 Crossroads Circle, Suite 200, Waukesha, WI 53186-4054
Test Name: ™Donor Screen- HLA Class I and II
License: BK070045
Source Plasma

Anti-HCV (ChLIA)  (P, D, T)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® HCV, Hepatitis C Virus Encoded Antigens (Recombinant c100-3, HCr43, NS5)
License: U.S. License No. 43
Generation: 2

Anti-HIV-1/HIV-2 ChLIA  (P, D, T)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® HIV O Plus, Human Immunodeficiency Virus Types 1 and 2 (E. coli, B. megaterium, Recombinant) Antigen and Synthetic Peptide
License: U.S. License No. 43

HBsAg (ChLIA)  (P, D, T)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® HBsAg, Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgM)
License: U.S. License No. 43

Nucleic Acid Testing (NAT) Procleix® Parvo/HAV Assay  (D)
Manufacturer: Hologic, Inc, San Diego, CA
Test Name: Procleix Ultrio Plus Assay
License: N/A

Nucleic Acid Testing (NAT) Procleix® Ultrio Plus®  (P, D, T)
(licensed for use with cadaveric samples)
Manufacturer: Hologic, Inc, San Diego, CA
Test Name: Procleix Ultrio Plus Assay
License: U.S. License No. 2037
Source Plasma Ancillary Testing

**RPR (P, T)**
Manufacturer: Arlington Scientific, Inc., Springville, UT 84663
Test Name: ASI RPR Card Test for Syphilis
License: Not Applicable

**Serum Protein Electrophoresis (P)**
Manufacturer: Sebia Electrophoresis, Norcoss, GA
Test Name: Capillarys Protein (E) 6
License: Not Applicable

**Total Protein (P)**
Manufacturer: Beckman Coulter, Inc.
Test Name: Total Protein
License: Not Applicable

**ABO/Rh (P, D, T)**
Manufacturer: Diagast, Loos Cedex, France for Beckman Coulter
Test Name: Beckman Coulter PK System Blood Grouping and Phenotyping Reagents PK7200 and PK7300 Automated Immunohematology Analyzers
License: U.S. License No. 1744

**Antibody Screen (P, D, T)**
Manufacturer: ImmucorGamma., Norcross, GA
Test Name: Capture-R Ready Screen (Pooled)
License: U.S. License No. 0886 for Capture-R Ready Screen test wells only and BK890012
Supplemental/Confirmatory Assays and Alternate Screening Assays

Anti-HBc EIA (P)
Manufacturer: ORTHO-Clinical Diagnostics, Inc., Raritan, NJ
Test Name: ORTHO Hepatitis B Virus Core Antigen (Recombinant) ORTHO HBc ELISA Test System
License: U.S. License No. 1236

Anti-HBs EIA (P)
Manufacturer: Bio-Rad Laboratories, Redmond, WA
Test Name: Monolisa Anti-HBs EIA
License: Not applicable

Anti-HCV EIA (licensed for use with cadaveric samples) (P)
Manufacturer: ORTHO-Clinical Diagnostics, Inc., Raritan, NJ
Test Name: Hepatitis C Virus Encoded Antigen (Recombinant c22-3, C200 and NS5) ORTHO HCV Version 3.0 ELISA Test System
License: U.S. License No. 1236

Anti-HIV-1 IFA (P)
Manufacturer: Sanochemia Pharmazeutika AG Vienna, Austria
Test Name: Immunodeficiency Virus Type 1 (HIV-1): Fluorognost™ HIV-1 IFA
License: U.S. License No. 1631

Anti-HIV-2 EIA (P)
Manufacturer: Bio-Rad Laboratories Blood Virus Division Redmond, WA
Test Name: Human Immunodeficiency Virus Type 2, GS
License: U.S. License No. 1109

Anti-HIV-1/2 Plus O EIA (licensed for use with cadaveric samples) (P)
Manufacturer: Bio-Rad Laboratories Blood Virus Division Redmond, WA
Test Name: Human Immunodeficiency Virus Types 1 and 2 (Recombinant and Synthetic Peptides) GS HIV-1/HIV-2 Plus O EIA
License: U.S. License No. 1109

Anti-HTLV-I/II Confirmatory Assay (P)
Manufacturer: MP Biomedicals Asia Pacific Pte. LTD
Test Name: HTLV Blot 2.4 Western Blot Assay
License: Not applicable
US Patent 5,066,579; 5,614,366; 5,763,572 ; 5,814,441 ; 5,871,933 ; 5,643,714; 6.110.662.

Geenius HIV 1//2 Supplemental Assay (P)
Manufacturer: Bio-Rad Laboratories, Inc.
Test Name: Geenius HIV 1/2 Supplemental Assay
License: Not applicable

HBsAg Confirmatory ChLIA (P)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® Antibody to Hepatitis B Surface Antigen (Human)
License: U.S. License No. 43

HBsAg EIA (licensed for use with cadaveric samples) (P)
Manufacturer: Bio-Rad Laboratories Blood Virus Division, Redmond, WA
Test Name: Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal):GS HBsAg EIA 3.0
License: U.S. License No. 1109, Generation 3
**Supplemental/Confirmatory Assays and Alternate Screening Assays**

### HBsAg EIA Neutralization  (P)
- **Manufacturer:** Bio-Rad Laboratories Blood Virus Division Redmond, WA
- **Test Name:** Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal) GS HBsAg Confirmatory Assay 3.0
- **License:** U.S. License No. 1109

### HTLV I/II EIA (Avioq)  (P)
- **Manufacturer:** Avioq, Inc., Research Triangle Park, North Carolina
- **Test Name:** Avioq HTLV-I/II Microelisa System
- **License:** U.S. License No. 1856

### Nucleic Acid Testing (NAT) Procleix® Ultro Plus® Discriminatory dHBV  (P, T)
(licensed for use with cadaveric samples)
- **Manufacturer:** Hologic, Inc., San Diego, CA
- **Test Name:** Procleix Ultro Plus dHBV Assay
- **License:** U.S. License No. 2037

### Nucleic Acid Testing (NAT) Procleix® Ultro Plus® Discriminatory dHCV  (P, T)
(licensed for use with cadaveric samples)
- **Manufacturer:** Hologic, Inc., San Diego, CA
- **Test Name:** Procleix Ultro Plus dHCV Assay
- **License:** U.S. License No. 2037

### Nucleic Acid Testing (NAT) Procleix® Ultro Plus® Discriminatory dHIV-1  (P, T)
(licensed for use with cadaveric samples)
- **Manufacturer:** Hologic, Inc., San Diego, CA
- **Test Name:** Procleix Ultro Plus dHIV-1 Assay
- **License:** U.S. License No. 2037

### RPR and Quantitative RPR  (P, T)
- **Manufacturer:** Arlington Scientific, Inc., Springville, UT 84663
- **Test Name:** ASI RPR Card Test for Syphilis
- **License:** Not Applicable

### Syphilis-G EIA  (P)
- **Manufacturer:** Trinity Biotech, Jamestown, NY
- **Test Name:** CAPTIA™ Syph - G
- **License:** Not Applicable

### T. cruzi Antigen ESA  (P)
- **Manufacturer:** Abbott Laboratories, Abbott Park, IL
- **Test Name:** Abbott ESA Chagas, Trypanosoma cruzi (E. coli, Recombinant) Antigen
- **License:** U.S. License No. 43
Supplemental/Confirmatory Assays and
Alternate Screening Assays

Referral Testing Services

Assay available through Memorial Blood Centers
- Anti-T Cruzi EIA

Assay available through Bloodworks Northwest
- Nucleic Acid Testing (NAT) cobas®

Unlicensed assays available through Quest Laboratories
- Anti-HBc IgM
- EBV IgG
- Toxoplasma IgG (Toxoplasma Gondii)
- WNV IgG Antibody
- WNV IgM Antibody
Component Quality Control

WBC Counts on Leucoreduced Products

**LeucoCOUNT Kit (P)**
- Manufacturer: Becton Dickinson Immunocytometry Systems, San Jose, CA
- Test Name: LeucoCOUNT™ Kit
- License: Information is not available

Factor VIII and Fibrinogen on Cryoprecipitated and Fresh Frozen Plasma Units

**Dade-Behring Factor VIII Chromogenic Assay (P)**
- Manufacturer: Dade-Behring, Inc., Newark, DE
- Test Name: Factor VIII Chromogenic Assay
- License: Information is not available

**Dade-Behring Multi-Fibren U Fibrinogen Assay (P)**
- Manufacturer: Dade-Behring, Inc., Newark, DE
- Test Name: Fibrinogen Assay
- License: Information is not available

**Dade-Behring Standard Human Plasma (P)**
- Manufacturer: Dade-Behring, Inc., Newark, DE
- Test Name: Factor VIII Chromogenic Assay
- License: Information is not available

Bacterial Detection for Leukoreduced Platelet Components

**BacT/ALERT®SA (P)**
- Manufacturer: bioMérieux, Inc.
- Test Name: BacT/ALERT
- License: Information is not available
The following table represents the revision history of this document.

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<th>Date Revised</th>
<th>Reason for Change</th>
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<tr>
<td>10/08/17</td>
<td>Removed Roche NAT and WNV</td>
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<tr>
<td>06/06/17</td>
<td>Added NAT Procleix Parvo/HAV Assay</td>
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<td>01/25/17</td>
<td>Updated manufacturer and license number for NAT Procleix Ultrio Plus and Procleix WNV</td>
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<td>12/19/16</td>
<td>Discontinuation of HIV-2 Western Blot</td>
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<td>Implementation of Geenius HIV-1/2 Supplemental Assay</td>
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<td>Addition cobas Taqscreen MPX 2.0</td>
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<td>11/23/15</td>
<td>Ferritin implementation Tampa</td>
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<td>09/21/15</td>
<td>Removed Alternate CMV on Galileo platform</td>
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<td>Added Babesia</td>
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<td>Added Tampa site to Ferritin</td>
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<td>Added Source Plasma section:</td>
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<td>- Anti HIV 1/HIV 2</td>
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<td>- Procleix® Ultrio plus® assay</td>
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<td>Addition of Generation HCV ChLIA and HbsAg EIA</td>
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<td>07/10/15</td>
<td>Removed Referral testing from Illinois Department of Health</td>
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<td>04/01/15</td>
<td>Removed CTS Chicago and added Ferritin</td>
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<td>03/23/15</td>
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<td>11/04/14</td>
<td>Addition of T. Cruzi ESA</td>
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<td>Addition of Syphilis FTA</td>
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<td>Addition of Phoenix location to HLA Screen Class I and II</td>
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<td>Removed T. cruzi Antibody RIPA</td>
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<td>09/17/13</td>
<td>NEO implementation for Red Cell Testing</td>
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<td>Prism implementation for viral marker testing</td>
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<td>04/15/13</td>
<td>Implementation of Procleix® Ultrio plus® assay</td>
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<td>Updated Supplemental/Confirmatory section to reflect consolidation of Tampa and Phoenix Special Testing</td>
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<td>Added assays performed by CTS Chicago</td>
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<td>Updated Parvo B19 assay to Roche</td>
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<td>Date</td>
<td>Changes</td>
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| 11/06/12   | - Removed LabScreen Mixed Class I and II Antibodies  
           | - Removed HCV RIBA from Supplemental Assays  
           | - Added Anti-HCV ChLIA to Referral Testing                                                      |
| 05/21/12   | - Updated the HTLV assays from Prism to Avioq.                                                    |
| 04/26/12   | - Removed ALT assay from Supplemental/Confirmatory under Referral Assays.                       |
| 04/17/12   | - Updated Vendor Name from Olympus to Beckman Coulter                                            |
| 03/19/12   | - Updated the Anti-HBc and HBsAg assays from Prism to Ortho                                      |
| 01/17/12   | - Added the Donor Screen HLA Class I and Class II                                                |
| 10/28/10   | - Moved Roche PCR assays from Supplemental/Confirmatory to Referral Assays.                     |
| 10/13/10   | - Removed NAT Procleix HIV-1/HCV assay from Blood Screening Assays.                              |
| 8/2/10     | - Added NAT HIV-1/HCV/HBV Ultrio to Blood Screening Assays.                                      |
| 4/19/10    | - Added NAT Discriminatory dHBV to Supplemental/Confirmatory Assays.                             |
|            | - Removed Abbott Anti-HTLV-I/II EIA from Supplemental/Confirmatory Assays.                       |