Blood Screening Assays

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

<table>
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<tr>
<th>Code</th>
<th>Location</th>
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<td>P</td>
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<tr>
<td>T</td>
<td>performed in Tampa lab</td>
<td>3008082972</td>
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</table>

**ABO/Rh (P, D, T)**
- **Manufacturer:** Diagast, Loos Cedex, France for Beckman Coulter
- **Test Name:** Beckman Coulter PK System Blood Grouping and Phenotyping
- **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
  - Anti-A (Series 1), -B (Series 1), -B (Series 3), -A,B (Series 1), -D (Series 4), -D (Series 5)
- **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
Blood Screening Assays

Anti-HBc (ChLIA)  
(P, D, T)
manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® HBcore, Hepatitis B Virus Core Antigen (E. coli, Recombinant)
License: U.S. License No. 43

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

Anti-HTLV-I/HTLV-II (ChLIA)  
(P, D, T)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® HTLV-I/HTLV-II, Human T-Lymphotropic Virus Types I and II
License: U.S. License No. 43

Babesia  
(P, T)
Manufacturer: Immunetics, Inc.
Test Name: Babesia microti ELISA Kit
License: Information not available
NOTE: This assay is for investigational use only and requires IRB approval prior to implementation.

Cholesterol  
(P, D, T)
Manufacturer: Beckman Coulter, Inc.
Test Name: Cholesterol
License: Information not available

Cytomegalovirus (CMV) Screen  
(P, D, T)
Manufacturer: Fujirebio Diagnostics, Inc. Malvern, PA Beckman Coulter
Test Name: Beckman Coulter PK CMV-PA Test System and Controls
License: BK070030

Ferritin  
(P, D, T)
Manufacturer: Beckman Coulter, Inc.
Test Name: Ferritin
License: Information not available
Blood Screening Assays

**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

**Hemoglobin A1c**  (D)
Manufacturer: Beckman Coulter, Inc.
Test Name: HbA1c (Hemoglobin A1c)
License: U.S. License No. 862.1150

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

**Nucleic Acid Testing (NAT) Procleix WNV RNA**  (P, D, T)
Manufacturer: Hologic Inc., San Diego, CA
Test Name: Procleix WNV Assay
License: U.S. License No. 2037

**Rh + K Phenotyping**  (P, D, T)
Manufacturer: Diagast, 59374 Cedex Loos, France for Beckman Coulter PK Systems
Test Name: Blood Grouping Reagents (for the Beckman Coulter® PK® Systems)
License: U.S. License No. 1744

**Syphilis Serology**  (P, D, T)
Manufacturer: Fujirebio Diagnostics, Inc. Brea, CA for Beckman Coulter.
Test Name: Beckman Coulter PK TP System PK7200 and PK7300 Automated Immunohematology Analyzers
License: BK060062

**T. cruzi Antibody ChLIA**  (P, D, T)
Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Abbott PRISM® Chagas, Trypanosoma cruzi (E. coli, Recombinant) Antigen
License: U.S. License No. 43
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 Ultro Plus Assay
License: N/A

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

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

**Nucleic Acid Testing (NAT) Procleix® Ul tro Plus® Discriminatory dHIV-1 (licensed for use with cadaveric samples)**
Manufacturer: Hologic, Inc., San Diego, CA
Test Name: Procleix Ul tro 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
Referral Testing Services

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

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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<thead>
<tr>
<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>Removal of HTLV Inno-LIA</td>
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<td>11/23/15</td>
<td>Ferritin implementation Tampa</td>
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<tr>
<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>ABO/Rh</td>
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<td>Addition of Roche NAT HCV in Phoenix</td>
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<td>Addition of HbA1c in Dallas</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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<tr>
<td>04/01/15</td>
<td>Removed CTS Chicago and added Ferritin</td>
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<tr>
<td>03/23/15</td>
<td>Implementation of Rh, Kell in Tampa</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>09/23/14</td>
<td>Removed T. cruzi Antibody RIPA</td>
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<td>04/14/14</td>
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<td>Removal of Reference testing of Anti- HCV</td>
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<td>09/17/13</td>
<td>NEO implementation for Red Cell Testing</td>
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<td>07/15/13</td>
<td>Prism implementation for viral marker testing</td>
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<td>07/01/13</td>
<td>Prism implementation for T. Cruzi testing</td>
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<td>04/15/13</td>
<td>Implementation of Procleix® Ultrio plus® assay</td>
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<tr>
<td>03/11/13</td>
<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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<tr>
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<td>- Removed LabScreen Mixed Class I and II Antibodies</td>
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<td>- Removed HCV RIBA from Supplemental Assays</td>
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<td>- Added Anti-HCV ChLIA to Referral Testing</td>
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<td>- Updated the HTLV assays from Prism to Avioq.</td>
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<tr>
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<td>- Removed ALT assay from Supplemental/Confirmatory under Referral Assays.</td>
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<td>- Update Vendor Name from Olympus to Beckman Coulter</td>
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<tr>
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<td>- Updated the Anti-HBc and HBsAg assays from Prism to Ortho</td>
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<td>01/17/12</td>
<td>- Added the Donor Screen HLA Class I and Class II</td>
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<tr>
<td>10/28/10</td>
<td>- Moved Roche PCR assays from Supplemental/Confirmatory to Referral Assays.</td>
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<tr>
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<td>- Removed NAT Procleix HIV-1/HCV assay from Blood Screening Assays.</td>
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<tr>
<td>8/2/10</td>
<td>- Added NAT HIV-1/HCV/HBV Ultrio to Blood Screening Assays.</td>
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<td>- Added NAT Discriminatory dHBV to Supplemental/Confirmatory Assays.</td>
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<tr>
<td>4/19/10</td>
<td>- Removed Abbott Anti-HTLV-I/II EIA from Supplemental/Confirmatory Assays.</td>
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