

Blood Screening Assays

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

D= performed in Dallas lab	FEI: 3002580251
P= performed in Phoenix lab	FEI: 3000204058
T= performed in Tampa lab	FEI: 3008082972

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

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

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: Immunitics, 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 PK7200 and PK7300 Automated Immunohematology Analyzers
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) cobas® TaqScreen MPX Test, Version 2.0 (T) (licensed for use with cadaveric samples)

Manufacturer: Roche Diagnostics, Brachburg, NJ
Test Name: cobas® TaqScreen MPX Test, Version 2.0
License: U.S. License No. 1636

Nucleic Acid Testing (NAT) cobas® TaqScreen West Nile Virus (T)

Manufacturer: Roche Diagnostics, Brachburg, NJ
Test Name: cobas® TaqScreen West Nile Virus Test
License: U.S. License No. 1636

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

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 Immunochemistry 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 (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® 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, Norcross, 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
ReagentsPK7200 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

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® Ultrio Plus® Discriminatory dHBV (P, T) (licensed for use with cadaveric samples)

Manufacturer: Hologic, Inc., San Diego, CA
Test Name: Procleix Ultrio Plus dHBV Assay
License: U.S. License No. 2037

Nucleic Acid Testing (NAT) Procleix® Ultrio Plus® Discriminatory dHCV (P, T) (licensed for use with cadaveric samples)

Manufacturer: Hologic, Inc., San Diego, CA
Test Name: Procleix Ultrio Plus dHCV Assay
License: U.S. License No. 2037

Nucleic Acid Testing (NAT) Procleix® Ultrio Plus® Discriminatory dHIV-1 (P, T) (licensed for use with cadaveric samples)

Manufacturer: Hologic, Inc., San Diego, CA
Test Name: Procleix Ultrio 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

•

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

Revision History

The following table represents the revision history of this document.

Date Revised	Reason for Change
01/25/17	<ul style="list-style-type: none"> ▪ Updated manufacturer and license number for NAT Procleix Ultrio Plus and Procleix WNV
12/19/16	<ul style="list-style-type: none"> ▪ Discontinuation of HIV-2 Western Blot ▪ Implementation of Geenius HIV-1/2 Supplemental Assay
07/01/16	<ul style="list-style-type: none"> ▪ Addition cobas Taqscreen MPX 2.0 ▪ Discontinuation of AmpliScreen and FTA
05/17/16	<ul style="list-style-type: none"> ▪ Addition of MP HLTV Western Blot 2.4 ▪ Removal of HTLV Inno-LIA
11/23/15	<ul style="list-style-type: none"> ▪ Ferritin implementation Tampa
09/21/15	<ul style="list-style-type: none"> ▪ Removed Alternate CMV on Galileo platform ▪ Added Babesia ▪ Added Tampa site to Ferritin ▪ Added Source Plasma section: <ul style="list-style-type: none"> ▪ Anti HIV 1/HIV 2 ▪ Anti-HCV ▪ HbsAg ▪ Procleix® Ultrio plus® assay ▪ ABO/Rh ▪ Antibody Screen ▪ RPR ▪ Serum Protein Electrophoresis ▪ Total Protein
08/20/15	<ul style="list-style-type: none"> ▪ Addition of Roche NAT HCV in Phoenix ▪ Addition of HbA1c in Dallas ▪ Addition of Generation HCV ChLIA and HbsAg EIA
07/10/15	<ul style="list-style-type: none"> ▪ Removed Referral testing from Illinois Department of Health
04/01/15	<ul style="list-style-type: none"> ▪ Removed CTS Chicago and added Ferritin
03/23/15	<ul style="list-style-type: none"> ▪ Implementation of Rh, kell in Tampa
11/04/14	<ul style="list-style-type: none"> ▪ Addition of T. Cruzi ESA ▪ Addition of Syphilis FTA ▪ Addition of Phoenix location to HLA Screen Class I and II
09/23/14	<ul style="list-style-type: none"> ▪ Removed T. cruzi Antibody RIPA
04/14/14	<ul style="list-style-type: none"> ▪ Removed Dallas and Tampa locations from Antibody ID assay
02/03/14	<ul style="list-style-type: none"> ▪ Addition of Reference testing of Anti-T Cruzi ▪ Removal of Reference testing of Anti- HCV
09/17/13	<ul style="list-style-type: none"> ▪ NEO implementation for Red Cell Testing
07/15/13	<ul style="list-style-type: none"> ▪ Prism implementation for viral marker testing
07/01/13	<ul style="list-style-type: none"> ▪ Prism implementation for T. Cruzi testing
04/15/13	<ul style="list-style-type: none"> ▪ Implementation of Procleix® Ultrio plus® assay
03/11/13	<ul style="list-style-type: none"> ▪ Updated Supplemental/Confirmatory section to reflect consolidation of Tampa and Phoenix Special Testing
01/01/13	<ul style="list-style-type: none"> ▪ Added assays performed by CTS Chicago ▪ Updated Parvo B19 assay to Roche
11/06/12	<ul style="list-style-type: none"> ▪ Removed LabScreen Mixed Class I and II Antibodies ▪ Removed HCV RIBA from Supplemental Assays ▪ Added Anti-HCV ChLIA to Referral Testing

05/21/12	<ul style="list-style-type: none"> ▪ Updated the HTLV assays from Prism to Avioq.
04/26/12	<ul style="list-style-type: none"> ▪ Removed ALT assay from Supplemental/Confirmatory under Referral Assays.
04/17/12	<ul style="list-style-type: none"> ▪ Update Vendor Name from Olympus to Beckman Coulter
03/19/12	<ul style="list-style-type: none"> ▪ Updated the Anti-HBc and HBsAg assays from Prism to Ortho
01/17/12	<ul style="list-style-type: none"> ▪ Added the Donor Screen HLA Class I and Class II
3/28/11	<ul style="list-style-type: none"> ▪ Removed Bio-Rad Anti-HIV-1 EIA from Supplemental/Confirmatory Assays list.
10/28/10	<ul style="list-style-type: none"> ▪ Moved Roche PCR assays from Supplemental/Confirmatory to Referral Assays.
10/13/10	<ul style="list-style-type: none"> ▪ Removed NAT Procleix HIV-1/HCV assay from Blood Screening Assays.
8/2/10	<ul style="list-style-type: none"> ▪ Added NAT HIV-1/HCV/HBV Ultrio to Blood Screening Assays. ▪ Added NAT Discriminatory dHBV to Supplemental/Confirmatory Assays.
4/19/10	<ul style="list-style-type: none"> ▪ Removed Abbott Anti-HTLV-I/II EIA from Supplemental/Confirmatory Assays.