

Creative Testing Solutions

Blood Screening Assays

Anti-HIV-1/2 Plus O EIA

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

Nucleic Acid Testing (NAT) Procleix HIV-1/HCV/HBV (licensed for use with cadaveric samples)

Manufacturer: Gen-Probe Incorporation, San Diego, CA
Test Name: Procleix Ultrio Assay
License: U.S. License No. 1592

HTLV I/II (Prism)

Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Antibody to Human T-Lymphotropic Virus Type I and Type II (HTLV I/II)
License: U.S. License No. 43

HBsAg (Prism)

Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgM)
License: U.S. License No. 43

Anti-HBc (Prism)

Manufacturer: Abbott Laboratories, Abbott Park, IL
Test Name: Hepatitis B Virus Core Antigen (E. coli, Recombinant)
License: U.S. License No. 43

Anti-HCV EIA

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

T.cruzi Antibody EIA

Manufacturer: ORTHO-Clinical Diagnostics, Inc., Raritan, NJ
Test Name: Trypanosoma cruzi (T. cruzi) Whole Cell Lysate Antigen; Ortho T. cruzi ELISA Test System
License: U.S. License No. 1236

Nucleic Acid Testing (NAT) Procleix WNV RNA

Manufacturer: Gen-Probe Incorporation, San Diego, CA
Test Name: Procleix WNV Assay
License: U.S. License No. 1592

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Cholesterol

Manufacturer: Olympus Life & Material Science, Europa Gmb H, Co. Clare, Ireland
Test Name: Cholesterol
License: Information not available

Syphilis Serology

Manufacturer: Fujirebio Diagnostics, Inc. Malvern, PA for Olympus America Inc.
Test Name: Olympus PK TP Reagent System

License: PK7200 and PK7300 Automated Immunohematology Analyzers
BK060062

Cytomegalovirus (CMV) Screen

Manufacturer: Fujirebio Diagnostics, Inc. Malvern, PA for Olympus America Inc.
Test Name: Olympus PK CMV-PA Test System and Controls

License: PK7200 and PK7300 Automated Immunohematology Analyzers
BK070030

Alternate Cytomegalovirus (CMV) Screen

Manufacturer: ImmucorGamma, Norcross, GA
Test Name: Capture-CMV

License: Galileo Automated Blood Bank System
BK050050

ABO/Rh

Manufacturer: Diagast, Loos Cedex, France for Olympus America Inc.
Test Name: Olympus PK System Blood Grouping Reagents, Reagent Red Blood Cells and Bromelin

License: PK7200 and PK7300 Automated Immunohematology Analyzers
U.S. License No. 1744

Alternate ABO/Rh

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)

License: Galileo Automated Blood Bank System
U.S. License No. 0886

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Blood Screening Assays

Alternate ABO/Rh

Manufacturer: ImmucorGamma, Norcross, GA
Test Name: Reagent Red Blood Cells for ABO Serum Grouping
Blood Grouping Reagent Anti-A, -B, -A,B, -D Gamma-clone
Blood Grouping Reagent Anti-D

PK7200 Automated Immunohematology Analyzer
License: U.S. License No. 0886

Alternate ABO/Rh

Manufacturer: Micro Typing Systems, Inc. an Ortho-Diagnostics Company, Raritan, NJ
Test Name: A/B/D Monoclonal Grouping Card
A/B/D Monoclonal and Reverse Grouping Card
MTS Anti-IgG Card

ProVue Analyzer
License: U.S. License No. 1177

Antibody Screen

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

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

Antibody Identification

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

Manufacturer: ImmucorGamma., Norcross, GA
Test Name: Capture-R Ready ID, Extend I and Extend II
License: U.S. License No. 0886

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Parvovirus B19 Testing

Parvovirus B19 Molecular Beacon Assay

Manufacturer: Qualtex Laboratories
Test Name: Parvovirus B19 Molecular Beacon Assay
License: Information not available

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Supplemental/Confirmatory Assays and Alternate Screening Assays used in Special Testing

Nucleic Acid Testing (NAT) Procleix Discriminatory dHIV-1 (licensed for use with cadaveric samples)

Manufacturer: Gen-Probe Incorporation, San Diego, CA
Test Name: Procleix HIV-1 Assay
License: U.S. License No. 1592

Nucleic Acid Testing (NAT) Procleix Discriminatory dHCV (licensed for use with cadaveric samples)

Manufacturer: Gen-Probe Incorporation, San Diego, CA
Test Name: Procleix HCV Assay
License: U.S. License No. 1592

Nucleic Acid Testing (NAT) Procleix Discriminatory dHBV (licensed for use with cadaveric samples)

Manufacturer: Gen-Probe Incorporation, San Diego, CA
Test Name: Procleix HBV Assay
License: U.S. License No. 1592

Anti-HIV-1 IFA

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-1/2 Plus O EIA (licensed for use with cadaveric samples)

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-HIV-2 EIA

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

Anti-HTLV-I/II Supplemental Assay

Manufacturer: Innogenetics, N.V., Belgium
Test Name: INNO-LIA HTLV I/II Score
License: Not applicable

Creative Testing Solutions

Supplemental/Confirmatory Assays

HBsAg Neutralization (Prism)

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

HBsAg EIA (licensed for use with cadaveric samples)

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

HBsAg Neutralization

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

Anti-HBs EIA

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

Anti-HBc EIA

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-HCV EIA (licensed for use with cadaveric samples)

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-HCV RIBA

Manufacturer: Novartis Vaccines and Diagnostics, Inc., Emeryville, CA
Test Name: Chiron RIBA HCV 3.0 Strip Immunoblot Assay (SIA)
License: U.S. License No. 1106

T. cruzi Antibody EIA (licensed for use with cadaveric samples)

Manufacturer: ORTHO-Clinical Diagnostics, Inc., Raritan, NJ
Test Name: Trypanosoma cruzi (T. cruzi) Whole Cell Lysate Antigen; Ortho T. cruzi ELISA Test System
License: U.S. License No. 1236

Creative Testing Solutions

Supplemental/Confirmatory Assays

Syphilis-G EIA

Manufacturer: Trinity Biotech, Jamestown, NY
Test Name: CAPTIA™ Syph - G
License: Not Applicable

RPR and Quantitative RPR

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

Donor Screen- HLA Class I and II

Manufacturer: GTI Diagnostics
20925 Crossroads Circle, Suite 200, Waukesha, WI 53186-4054
Test Name: ™Donor Screen- HLA Class I and II
License: BK070045

Referral Testing Services

HCV PCR

Manufacturer: Roche Molecular Systems Inc., Branchburg, NJ
Test Name: Cobas Ampliscreen HCV
License: U.S. License No. 1636

HIV-1 PCR

Manufacturer: Roche Molecular Systems Inc., Branchburg, NJ
Test Name: Cobas Ampliscreen HIV-1
License: U.S. License No. 1636

HBV PCR

Manufacturer: Roche Molecular Systems Inc., Branchburg, NJ
Test Name: Cobas Ampliscreen HBV
License: U.S. License No. 1636

Unlicensed assay available through California Department of Health Services Laboratory

- **Anti-HIV-2 Western Blot**

Unlicensed assays available through Sonora Quest Laboratory

- **ALT**
- **Anti-HBc IgM**
- **T. cruzi Antibody RIPA Testing** (performed by Quest Diagnostics Inc. Nichols Institute)

- **WNV IgG Antibody**

Manufacturer: FOCUS Diagnostics
Test Name: West Nile Virus IgG DxSelect
License: Not Applicable

- **WNV IgM Antibody**

Manufacturer: FOCUS Diagnostics

Test Name: West Nile Virus IgM Capture DxSelect

License: Not Applicable

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Component Quality Control

WBC Counts on Leucoreduced Products

LeucoCOUNT Kit

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

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

Dade-Behring Multi-Fibren U Fibrinogen Assay

Manufacturer: Dade-Behring, Inc., Newark, DE
Test Name: Fibrinogen Assay
License: Information is not available

Dade-Behring Standard Human Plasma

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

Manufacturer: bioMérieux, Inc.
Test Name: BacT/ALERT
License: Information is not available

Blood Systems Laboratories

One Lambda Product

LABScreen Mixed Class I and II

Manufacturer: One Lambda, Inc.
21001 Kittridge Street, Canoga Park, CA 91303-2801
Test Name: LABScreen® Mixed Class I and II
Catalog #: LSM12
License: BK030069

Revision History

The following table represents the revision history of this document.

Date Revised	Reason for Change
01/17/12	▪ Added the Donor Screen HLA Class I and Class II
3/28/11	▪ Removed Bio-Rad Anti-HIV-1 EIA from Supplemental/Confirmatory Assays list.
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. ▪ Added NAT Discriminatory dHBV to Supplemental/Confirmatory Assays.
4/19/10	▪ Removed Abbott Anti-HTLV-I/II EIA from Supplemental/Confirmatory Assays.