



## Reagent and Kit Specifications

<b>ABO</b>	
Name of Test	Reference Cells
Generation	None
FDA License	102707/0.0
Manufacturer	Immucor, Inc.
Introduced or Replaced	February, 1999
Method	Tube Agglutination

Name of Test	Anti-A series 1
Generation	None
FDA License	102691/0.0
Manufacturer	Immucor, Inc.
Introduced or Replaced	July 1, 1990
Method	Tube Agglutination

Name of Test	Anti-B series 3
Generation	None
FDA License	102692/1009
Manufacturer	Immucor, Inc.
Introduced or Replaced	Sept. 14, 2001
Method	Tube Agglutination

<b>Anti-D (Rh)</b>	
Name of Test	Anti-D series 4
Generation	None
FDA License	103523/0.0
Manufacturer	Immucor, Inc.
Introduced or Replaced	Dec. 23, 1997
Method	Tube Agglutination

<b>Antibody Screen</b>	
Name of Test	Hemantigen
Generation	None
FDA License	102707/0.0
Manufacturer	Immucor, Inc.
Introduced or Replaced	Dec. 28, 1982
Method	Tube Agglutination

<b>ALT</b>	
Name of Test	ALT IFCC
Generation	First
FDA License	U.S. License # K860748
Manufacturer	Roche
Introduced or Replaced	April 1986
Method	Enzymatic/Spectrophotometric

<b>HBcAb (Anti-Core IgG &amp; IgM)</b>	
Name of Test	Hepatitis B Virus Core Antigen (recombinant) ORTHO HBc ELISA Test System
Generation	None
FDA License	U.S. License # 1236
Manufacturer	ORTHO Clinical Diagnostics
Introduced or Replaced	Licensed April 18, 1991
Method	ELISA

<b>HBsAb (Anti-HBsAg) Qualitative</b>	
Name of Test	Abbott AUSAB by AxSYM
Generation	First Generation
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	August 2006
Method	Microparticle Enzyme Immunoassay (MEIA)

<b>HBsAb (Anti-HBsAg) Quantitative</b>	
Name of Test	Abbott AUSAB by AxSYM
Generation	First Generation
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	August, 2006
Method	Microparticle Enzyme Immunoassay (MEIA)

<b>HBsAg</b>	
Name of Test	Abbott PRISM HBsAg Kit
Generation	N/A
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	2007
Method	ChLIA

<b>HBsAg CONFIRMATORY ASSAY</b>	
Name of Test	Abbott PRISM HBsAg Confirmatory Kit
Generation	N/A
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	2007
Method	ChLIA

<b>HCVAB</b>	
Name of Test	Abbott HCV EIA 2.0
Generation	Third Generation
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	May 06, 1992
Method	EIA

<b>HCVAB</b>	
Name of Test	Abbott PRISM HCVAB Kit
Generation	N/A
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	2007
Method	ChLIA

<b>HCV PCR (NAT)</b>	
Name of Test	Cobas AmpliScreen HCV
Generation	Version 2.0
FDA License	125045/0
Manufacturer	Roche Molecular System, Inc.
Introduced or Replaced	Dec. 3, 2003
Method	PCR

<b>HIV-1/2 Antibody</b>	
Name of Test	HIVAB HIV-1/HIV-2 (rDNA) EIA
Generation	Third Generation
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	February 04, 1992
Method	EIA

<b>HIV-1 PCR (NAT)</b>	
Name of Test	Cobas AmpliScreen HIV-1
Generation	Version 1.5
FDA License	125059/0
Manufacturer	Roche Molecular System, Inc.
Introduced or Replaced	Dec. 3, 2002
Method	PCR

<b>HIV-1 IMMUNOBLOT</b>	
Name of Test	Genetic Systems HIV-1 Western Blot
Generation	None
FDA License	U.S. License # 1109
Manufacturer	BioRad
Introduced or Replaced	June, 1990
Method	Immunoblot

<b>HTLV I/II</b>	
Name of Test	Antibody To Human T-Cell Lymphotropic Virus Type I & II.
Generation	Third Generation
FDA License	U.S. License # 43
Manufacturer	Abbott Laboratories
Introduced or Replaced	August 15, 1997
Method	EIA

<b>Serum Protein Electrophoresis</b>	
Name of Test	Serum Protein Electrophoresis
Generation	None
FDA License	K-960029
Manufacturer	Sebia, Inc.
Introduced or Replaced	July 17, 1996
Method	Gel Electrophoresis

<b>Syphilis - Rapid Plasma Reagin Test (RPR)</b>	
Name of Test	ASI RPR
Generation	Initial
FDA License	510K K851504
Manufacturer	Arlington Scientific, Inc.
Introduced or Replaced	April 15, 1995
Method	Carbon Particle Agglutination

<b>Syphilis - TP-PA - Treponema Antigen</b>	
Name of Test	Serodia-TP-PA Syphilis
Generation	First Generation
FDA License	K971502
Manufacturer	Fujirebio Inc.
Introduced or Replaced	1999
Method	Passive Particle Agglutination

<b>Tetanus Toxoid Antibody</b>	
Name of Test	Bulk T. Tox
Generation	One
FDA License	None
Manufacturer	The Binding Site, Ltd.
Introduced or Replaced	August, 2003
Method	Enzyme Immunoassay