



Current Information on the Tests and Test Kits Used by LABS

21 CFR Part 1271.80(c) & 1271.85 Requirements for Donor Testing
 REGISTRATIONS & CERTIFICATIONS (21 CFR Part 1271.80(c))
 FDA Registration Numbers for HCT/PS & Blood Establishment:
 LABS-Colorado (LABS-CO) FEI: 1000477683
 LABS-Northeast (LABS-NE) FEI: 3007203928
 LABS-Midwest (LABS-MW) FEI: 3007072964 (HCT/PS Only)

CLIA Certification Numbers:
 LABS-CO 06D0717586
 LABS-NE 39D1088340
 LABS-MW 26D1086087

Manufacturer	HIV 1/2 Antibody		Hepatitis B Surface Antigen		Hepatitis B Core Antibody		Hepatitis C Antibody		HTLV I/II Antibody		Syphilis		CMV Antibody		NAT HIV-1, HCV & HBV (all 3 viruses unless otherwise noted)		NAT - WNV		
	Bio-Rad	Abbott (LABS-CO)	Bio-Rad	Abbott (LABS-CO)	Ortho	Abbott (LABS-CO)	Ortho	Abbott (LABS-CO)	Abbott (LABS-CO)	PRISM Anti-HTLV-I/II ChLIA	Arlington Scientific, Inc.	Immucor	Novartis (LABS-CO, LABS-NE) Roche AmpliScreen (LABS-MW-HIV/HCV)	Novartis (LABS-CO, LABS-NE) Roche AmpliScreen (LABS-MW-HIV/HCV)	Procleix Ultra Tigris (LABS-CO, LABS-NE) COBAS AmpliScreen (LABS-MW-HIV/HCV)	Procleix WNV (LABS-CO)	Novartis (LABS-CO)		
Test Kit	GS HIV-1/2 Plus O EIA	GS HBsAg 3.0 EIA	GS HBsAg 3.0 EIA	PRISM HBsAg ChLIA	Anti-HBcore Total EIA	Anti-HCV 3.0 EIA	PRISM Anti-HCV ChLIA	PRISM Anti-HTLV-I/II ChLIA	PRISM Anti-HTLV-I/II ChLIA	ASIR RPR Flocculation	Capture-CMV AB (Total)	Novartis (LABS-CO, LABS-NE) Roche AmpliScreen (LABS-MW-HIV/HCV)	Procleix Ultra Tigris (LABS-CO, LABS-NE) COBAS AmpliScreen (LABS-MW-HIV/HCV)	Procleix WNV (LABS-CO)					
	PRISM HIV 1/2 Plus O ChLIA	PRISM HBsAg ChLIA	PRISM Anti-HBcore ChLIA	PRISM Anti-HCV ChLIA	PRISM Anti-HTLV-I/II ChLIA	PRISM Anti-HCV ChLIA	PRISM Anti-HCV ChLIA	PRISM Anti-HTLV-I/II ChLIA	PRISM Anti-HTLV-I/II ChLIA	ASIR RPR Flocculation	Capture-CMV AB (Total)	Novartis (LABS-CO, LABS-NE) Roche AmpliScreen (LABS-MW-HIV/HCV)	Procleix Ultra Tigris (LABS-CO, LABS-NE) COBAS AmpliScreen (LABS-MW-HIV/HCV)	Procleix WNV (LABS-CO)					
Type of Test	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	Screening	
Is the Test Kit FDA-Licensed, Approved or Cleared for Donor Screening?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Is the Test Kit Specifically Labeled for Cadaveric Specimens?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
**Confirmatory Tests/Manufacturer	Bio-Rad HIV-1 Western Blot HIV-2 EIA send-out, Not a confirmation test only)	Bio-Rad GS HBsAg Neutralization	Bio-Rad GS HBsAg Neutralization	Prism HBsAg Confirmatory	None Available (BioRad Hbc Igm may be requested to determine acute infection.)	Strip Immunoblot Assay (SIA) / Chiron RIBA HCV 3.0 SIA	Inno-LIA HTLV I/II (send-out Supplemental test Research Use Only)	Inno-LIA HTLV I/II (send-out Supplemental test Research Use Only)	Inno-LIA HTLV I/II (send-out Supplemental test Research Use Only)	**FTA-ABS / Scimedx IFA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

COMMENTS:
 *Acceptable for cadaveric donors, provided there is not a test with cadaveric approval.
 **Most confirmatory tests are not FDA approved to reverse a reactive result of a donor screening test. Of the LABS-offered confirmatory tests, only the FTA-ABS can reverse a reactive screening result. Confirmatory tests are only performed at the written request of the client.
 *** A Draft Notice for Industry, issued by the FDA on April 2008 describes the need for WNV nucleic acid testing for HCT/PS.
 PLEASE NOTE: Unless otherwise noted, test kits identified in the "Manufacturer" and "Test Kit" rows above are used at each of the LABS, Inc. facilities.
 Package inserts, Registration, and Certification documents are available at www.labs-inc.org