

DONOR SCREENING TESTS

FDA Registry #3003343209, CLIA Registry #05DO602416, California Tissue Bank License: CNC80010,

California Clinical Lab License: #CLF10970, NY Tissue Bank ID #:GA023, Maryland Tissue Bank Permit: #TB839. Maryland Medical Lab. Permit: #839

TEST	KIT	FDA APPROVED	LOCATION
HIV-1(Groups M and O)/HIV-2 EIA	Abbott Alinity s HIV Ag/Ab Kit	(1) (2) (3) 7/23/2019	ViroMed
Treponema pallidum (Syphilis)	Beckman Coulter PK TP Kit	(3) (5) (8) 2/21/2003	ViroMed
HTLV I/II Ab	Abbott Alinity s HTLV-I/HTLV-II Kit	(1) (3) 6/26/2019	ViroMed
CMV Total Antibody (IgG and IgM)	Immucor Capture CMV Solid Phase System	(4) 11/20/2018	ViroMed
Hepatitis B Virus Core Antibody	Abbott Alinity s HBCore	(1) (3) 8/2/2019	ViroMed
Hepatitis B Surface Antigen	Abbott Alinity s HBsAg	(1) (3) 6/14/2019	ViroMed
Hepatitis C Virus Encoded Antibody	Abbott Alinity s HCV	(1) (3) 7/9/2019	ViroMed
Urine Chlamydia/GC amplification	Gen-Probe Aptima Combo 2 Kit	(6) 8/9/2005	ViroMed
HIV-1/HIV-2/HCV/HBV NAT	COBAS MPX Kit	(3) 9/21/2017	ViroMed
West Nile Virus	COBAS WNV Kit	(3) (7) 11/2/2016	ViroMed
Syphilis RPR non-treponemal	Arlington Scientific ASI Evolution-AT	(8) (9) 9/30/2020	Eurofins CellTx

(1) As of 2/21/2022 ViroMed laboratories has updated kit information to reflect change from Abbott Prism system to Abbott Alinity s. (2) FDA supplement approval 9/11/2020. (3) From 1/11/2016 - 9/11/2019 these tests were performed at Eurofins Donor & Product Testing or Eurofins DPT formerly VRL Eurofins / LABS, Inc using FDA approved tests for donor screening on other platforms. (4) During the period between 6/2014 and 1/ 2016 all donors were tested directly for CMV anti-IgG and anti-IgM at Quest Diagnostics. (5) Prior to 9/11/2019 donors were screened for syphilis using a FDA approved RPR-non treponemal test. (6) From 6/18/2018 - 9/11/2019 this test was performed using the BD Probe Tec CT/GC Assay at VRL Eurofins/ LABS, Inc. (7) WNV is tested seasonally on donors from June 1st through October 31st. (8) From 10/19/20 to currently DD/KD syphilis testing performed using FDA approved non-treponemal test with reflex to Treponema pallidum test. (9) Previously run at Eurofins DPT 7/1/2018-9/10/19, 10/19/20-4/23]

ViroMed (LabCorp) [9/11/19-current]

1447 York Court Room 105 Burlington, NC 27215-3361 CLIA # 24D0400424, CA License #COS800057 FDA Registration # 2183472

Quest Diagnostics [6/2014- 1/2016]

967 Maybury Road San Jose, CA 95133 CLIA # 05D0608832, CA License # CLF 2582

Eurofins CellTx [4/14/23-current]

9052 S Rita Rd, Suite 1400 Tucson, AZ 85747 CLIA# 03D2269071, CA License #COS90008933 FDA Registration # 3025981313

OBI: Oklahoma Blood Institute [Before 1/22/2007] 1001 N. Lincoln Blvd. Oklahoma City, OK 73104 CLIA # 37D0470358, FDA # 162009

LABS, Inc [1/22/2007-6/30/2018]

6933 S. Revere Parkway Centennial, CO 80112 CLIA # 06D0717586, CA License # COS800123 FDA Registration # 3007203928

Eurofins DPT [7/1/2018-9/10/19, 10/19/20-4/14/23]

6665 S. Kenton St., Suite 205 Centennial, CO 80111 CLIA# 06D0717586, CA License #00800123 FDA Registration # 1000477683

S:\mastercopies\Donor Screening Tests\DONOR SCREENING TESTS revision 09 2023