



DONOR SCREENING TESTS

TEST	KIT	FDA APPROVED	LOCATION
HIV-1(Groups M and O)/ HIV-2 EIA	Abbott Alinity s HIV Ag/Ab Combo	7/23/2019 (1) (2) (3)	ViroMed
Treponema pallidum (Syphilis)	Beckman Coulter PK TP	2/21/2003 (3) (5) (8)	ViroMed
HTLV I/II Ab	Abbott Alinity s HTLV-I/HTLV-II	6/26/2019 (1) (3)	ViroMed
CMV Total Antibody (IgG and IgM)	Immucor Capture CMV w/reflex	11/20/2018 (4)	ViroMed
Hepatitis B Virus Core Antibody	Abbott Alinity s HBCore	8/2/2019 (1) (3)	ViroMed
Hepatitis B Surface Antigen	Abbott Alinity s HBsAg	6/14/2019 (1) (3)	ViroMed
Hepatitis C Virus Encoded Antibody	Abbott Alinity s HCV	7/9/2019 (1) (3)	ViroMed
Urine Chlamydia/GC	Hologic (formerly Gen-Probe) Aptima Combo 2	8/9/2005 (6)	ViroMed
HIV-1/HIV-2/HCV/HBV NAT	Procleix Ultrio Elite Assay	5/3/2018 (3)	ViroMed
West Nile Virus	Procleix West Nile Virus Assay	12/1/2005 (3) (7)	ViroMed
Syphilis RPR non-treponemal	Arlington Scientific ASI Evolution- AT	9/30/2020 (8) (9) (10)	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 (and after 5/2025) donors were screened for syphilis using an 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. (10) From 6/2025 to currently donor syphilis testing performed using an FDA approved non-treponemal test with reflex to Treponema pallidum test.

TSBC LICENSING AND REGISTRATION:

FDA FEI 3003343209, CLIA 05DO602416, CA Tissue Bank CNC80010, CA Clinical Lab CLF10970,
 NY Tissue Bank ID GA023, MD Tissue Bank Permit TB839, MD Medical Lab Permit 839

TESTING LABS:

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

1447 York Court Room 105
 Burlington, NC 27215-3361
 CLIA 24D0400424
 CA Lic COS800057
 FDA FEI 2183472

Eurofins CellTx [4/14/23-current]

9052 S Rita Rd, Suite 1400
 Tucson, AZ 85747
 CLIA 03D2269071
 CA Lic COS90008933
 FDA FEI 3025981313

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

6933 S. Revere Parkway
 Centennial, CO 80112
 CLIA 06D0717586
 CA Lic COS800123
 FDA FEI 3007203928

Quest Diagnostics [6/2014-1/2016]

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

OBI [Before 1/22/2007]

1001 N. Lincoln Blvd.
 Oklahoma City, OK 73104
 CLIA 37D0470358, FDA 162009

Eurofins [7/2018-9/2019, 10/2020-4/2023]

6665 S. Kenton St., Suite 205
 Centennial, CO 80111
 CLIA 06D0717586, CA Lic 00800123
 FDA FEI 1000477683