



THE SPERM BANK OF CALIFORNIA
2115 Milvia Street Berkeley, California 94704-1157

DONOR SCREENING

Approved or Cleared 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/HIV-2 PLUS O ChLIA	Abbott PRISM HIV O Plus Assay Changed 12/08/10	09/18/2009	LABS
RPR-Non-Treponemal Diagnostic test (ASI RPR)	Arlington Scientific Inc. Changed 7/16/08	(1) Cleared	LABS
Anti-HTLV 1/2	Abbott PRISM HTLV I/II ChLIA	1/16/2008	LABS
Antibody to CMV IgG&IgM	Immunoassay (IA) Changed 6/11/14	(1) Cleared	Quest
Hepatitis B Virus Core Antibody	Abbott PRISM HB Core ChLIA Assay	10/13/2005	LABS
Hepatitis B Surface Antigen	Abbott PRISM HBsAg ChLIA Assay	7/18/2006	LABS
Hepatitis C Virus Encoded Antibody	Abbott PRISM HCV ChLIA Assay	7/11/2007	LABS
Urine Chlamydia/GC amplification	Aptima Genprobe Tigris (Aptima Combo 2 Assay) (PCR)	8/9/05	LABS
HIV-1/HCV/HBV NAT	Procleix ULTIO Triplex eSAS system	10/03/2006	LABS

(1) CMV and Syphilis test kits are not regulated by the new 21CFR Part 1271 FDA regulations. Prior to June 2014, donors were tested for CMV Total Antibody and positive donors were additionally tested for CMV by blood antibody CMV IgG&IgM (LABS or Quest Diagnostics). Starting June 2014, all donors are tested directly for blood antibody CMV IgG&IgM (Quest Diagnostics).

Quest Diagnostics

967 Maybury Road
San Jose CA 95133
CLIA Registry #: 05D0608832,
California State License: CLF 2582

OBI: Oklahoma Blood Institute

Sylvan N. Goldman Center
1001 N. Lincoln Blvd Oklahoma City OK 73104
FDA Registry#: 1626009, CLIA Registry#: 37D0470358

Laboratories at Bonfils (LABS)

717 Yosemite Street
Denver, Colorado 80230
CLIA Registry#: 06D0512796, California State License: COS 800123
FDA Blood and Tissue Establishment Registrant FEI 1000477683

ViroMed

FDA Registry#: 2183472, CLIA Registry#: 24DO400424
California State License (HIV) CLFH0025, (Other) CO5800057

Note: On January 22, 2007 THE SPERM BANK OF CALIFORNIA switched from using Oklahoma Blood Institute for blood testing and ViroMed through LabCorp for urine Chlamydia/GC, to using LABS for all donor screening.