Fairfax Cryobank

List of Medical Tests

Testing is performed by Eurofins CellTX, which is under contract with Fairfax Cryobank, Inc.
Eurofins CellTX: 9052 S. Rita Rd. Tucson, AZ 85747, CLIA ID # 03D2269071

Trade Name	Test Name	Format	Sample	Use	FDA Approval	License Number	Manufacturer
Roche Elecsys Anti CMV	CMV	ECLIA	Serum, Plasma	Donor	11/03/2023	US: 2305 STN: BK230840 Canada: 82601	Roche Donor Serology Pro Platform
Gold Standard Diagnostics CMV IgG Ab (EIA)	CMV IgG	EIA	Serum	Donor	02/23/96	STN: K954191	Quest
GEN-PROBE Aptima Combo 2 Assay Chlamydia trachomatis and Neisseria gonorrhea	CT/GC	Nucleic Acid Test (TMA)	Urine	Donor	N/A	* 510K K180681 Canada: 61047	Hologic
Roche Elecsys Anti-HBc II	HBc Total	ECLIA	Serum, Plasma	Donor	02/27/24	US: 2305 STN: 125804 Canada:38081	Roche Donor Serology Pro Platform
Roche Elecsys HBsAg II	HBsAg	ECLIA	Serum, plasma	Donor	02/21/24	US: 2305 STN: 125802 Canada: 38084	Roche Donor Serology Pro Platform
Roche Elecsys Anti-HCV II	HCV	ECLIA	Serum, Plasma	Donor	02/28/24	US: 2305 STN: 125803 Canada: 112209	Roche Donor Serology Pro Platform
Roche Elecsys HIV Duo	HIV 1/2 Ab	ECLIA	Serum, Plasma	Donor	06/13/23	US: 2305 STN: 125778 Canada: 102118	Roche Donor Serology Pro Platform
Procleix Ultrio Elite	HIV-1/HIV-2/HCV/ HBV NAT	Nucleic Acid Test (TMA)	Plasma, Serum	Donor	05/03/18	US: 2032 STN: BL125652 Canada: 98929	Grifols Diagnostics Solutions
Roche Elecsys HTLV-I/II	HTLV-I/II	ECLIA	Serum, Plasma	Donor	10/17/23	US: 2305 STN: BL125792 Canada: 97727	Roche Donor Serology Pro Platform
ASI Evolution Automated Syphilis Screening	RPR	Non-treponemal	Serum, Plasma	Donor	02/02/21	STN: BK200539	Arlington Scientific
CAPTIA Syphilis-G	Treponema	EIA	Serum, Plasma	Donor	01/24/02	STN: K014233	Trinity Biotech
Procleix – WNV	WNV	Nucleic Acid Test (TMA)	Plasma	Donor	12/01/05	US: 2032 STN: BL125121 Canada: 73972	Grifols Diagnostics Solutions

***Although there are diagnostic tests available, there are currently no FDA-licensed, approved, or cleared tests for donor screening. In the absence of such screening tests, you must use an FDA-licensed, approved, or cleared diagnostic test labeled for the detection of these organisms in an asymptomatic, low-prevalence population (§ 1271.80(c)). The use of Chlamydia trachomatis and Neisseria gonorrhoeae tests utilizing NAT technology adequately and appropriately reduces the risk of transmission of these relevant communicable disease agents (§ 1271.80(c)).**