



Testing is performed by VRL, which is under contract with Fairfax Cryobank and Cryogenic Laboratories, Inc.
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Trade Name	Test Name	Format	Sample	Use	FDA Approval Date	License Number	Manufacturer/ Device Identifier
<u>Capture – CMV Total Ab</u>	CMV	Solid phase red cell adherence	Serum, Plasma	Donor	12/22/95	US: 886 Canada: 1084 EU: List B – NA (CE 0088)	Immucor/ 0066206, 0066216, 0066238, 0066239
<u>BD ProbeTec ET Chlamydia trachomatis and Neisseria gonorrhea</u>	CT/GC	SDA	Urine	Donor	9/18/01	US: K033861 (510k) Canada: 15611 (CE0336)	Becton, Dickinson & Co./ 440450, 440705
<u>FTA-ABS Test System</u>	FTA	Treponemal	Serum	Donor	N/A – cleared confirmatory test	US: N/A	Scimedx Corporation/ 8100L, 8400L
<u>Ortho HbC ELISA Test System</u>	HBc Total	EIA	Serum, Plasma	Donor	4/18/91	US: 1236 Canada: 13610	Ortho-Clinical Diagnostics/ 933245, 933275
<u>Genetic Systems HBsAg EIA 3.0</u>	HBsAg	EIA	Serum, plasma	Donor	1/23/03	US: 1109 Canada: 721	Bio-Rad Laboratories / 32591, 32592, 25258
<u>Ortho HCV Version 3.0 ELISA Test System</u>	HCV	EIA	Serum, Plasma	Donor	2/18/09	US: 1236 Canada: 9958	Ortho-Clinical Diagnostics/ 930740, 933730
<u>Genetic Systems HIV-1/HIV-2 Plus O EIA</u>	HIV 1/2 Ab + O	EIA	Serum, Plasma	Donor	8/5/03	US:1109 Canada: 60386	Bio-Rad Laboratories / 32588, 32589, 32590
<u>Procleix Ultrio</u>	HIV-1/ HCV/ HBV NAT	Nucleic Acid Test (TMA)	Plasma, Serum	Donor	10/3/06	US: 1592 Canada: 77437	Gen-Probe, Inc./ P/N 301103, P/N 301105
<u>HTLV I/II EIA Avioq</u>	HTLV-I/II	EIA	Serum, Plasma	Donor	3/26/12	US: 1856 Canada: 091672	Avioq/ 500192, 500576, 509600, 559879, 559880
<u>MacroVue RPR</u>	RPR	Non-treponemal	Serum	Diagnostic	N/A – approved pre-amendment device	US: K760040 (510K) Canada: 11405	Becton, Dickinson & Co./ 275110, 275115, 175130, 274449, 275005, 275239, 275539
For Canadian compliance:							
<u>Trep-Sure</u>	Anti-Treponema EIA Screen	EIA	Serum	Donor	N/A – Health Canada approved	US: K053570 (510K) Canada: 72043	Phoenix Bio-Tech/TS-96. TS-960, TS-1920

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