



DONOR ELIGIBILITY TESTS: TEST KIT INFORMATION

ANALYTE	METHOD	TEST KIT NAME	MANUFACTURER	TEST TYPE	FDA-LICENSED, APPROVED OR CLEARED	CE Mark Or Equivalency Established	US Product Code	CE-IVDR EU and Canadian Product Code
HIV 1/2 Antibody	Automated - ECLIA	Elecsys HIV Duo	Roche Diagnostics, US License 2305	Screening	Yes 125778	** Yes	8836973162	8836973190
Hepatitis B Surface Antigen & Confirmation	Automated - ECLIA	Elecsys HBsAg II & HBsAg II Auto Confirm	Roche Diagnostics, US License 2305	Screening	Yes 125802	** Yes	8814848162, 8741034162	8814848190, 8741000000
Hepatitis B Core Antibody	Automated - ECLIA	Elecsys Anti-HBc II	Roche Diagnostics, US License 2305	Screening	Yes 125804	** Yes	9014926162	9014926190
Hepatitis C Antibody	Automated - ECLIA	Elecsys Anti-HCV II	Roche Diagnostics, US License 2305	Screening	Yes 125803	** Yes	8837058162	8837058190
HTLV I/II Antibody	Automated - ECLIA	Elecsys HTLV-I/II	Roche Diagnostics, US License 2305	Screening	Yes 125792/0	** Yes	9015272162	9015272190
Syphilis	Automated	ASI Automated RPR	Arlington Scientific, Inc.	Screening	Yes BK200488	Yes	N/A	N/A
	Manual	CAPTIA-G	Trinity BioTech	Screening	Yes K014233	Yes	N/A	N/A
CMV Antibody	Automated/Manual	Capture-CMV AB (Total)	Immucor	Screening	Yes BK180247	** Yes	9118551162	9118551190
	Automated ECLIA	Elecsys Anti-CMV	Roche Diagnostics, US License 2305	Screening	*510K BK230840	No	N/A	N/A
NAT HIV- 1/2, HCV & HBV	Automated	Procleix Ultrio Elite Assay Panther	Grifols	Screening	Yes BL125652	Yes	N/A	N/A
NAT - WNV	Automated	Procleix WNV Assay Panther	Grifols	Screening	Yes BL125121	Yes	N/A	N/A
Chagas	Automated	Elecsys Chagas	Roche Diagnostics, US License 2305	Screening	Yes 125799	** Yes	9015582162	9015582190
Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC)	Automated	GEN-PROBE® Aptima Combo 2® Assay	Hologic	Detection	* 510K K180681	No	N/A	NA

*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)).

**Equivalency of Roche Elecsys Blood Screening Serology reagents in US and CE Markets. Roche Elecsys blood screening assays sold in the US, Canadian, and EU Markets have the same reagent formulation and are manufactured at the same Roche locations, Roche Diagnostics GmH, Nonnenwald 2, D-82377 Penzberg Germany.