



DONOR ELIGIBILITY TESTS: TEST KIT INFORMATION

ANALYTE TYPE	METHOD	TEST KIT NAME	MANUFACTURER	TEST TYPE	FDA-LICENSED, APPROVED OR CLEARED FOR DONOR SCREENING	CE Mark Affixed to Test Kit
HIV 1/2 Antibody	Automated/Manual	GS HIV-1/2 Plus O EIA	Bio-Rad	Screening	Yes BL125030	No
Hepatitis B Surface Antigen	Automated/Manual	GS HBsAg 3.0 EIA	Bio-Rad	Screening	Yes BL103590	No
Hepatitis B Core Antibody	Automated/Manual	Anti-HBcore Total ELISA	Ortho	Screening	Yes BL103062	No
Hepatitis C Antibody	Automated/Manual	Anti-HCV 3.0 ELISA	Ortho	Screening	Yes BL103065	No
HTLV I/II Antibody	Automated/Manual	Anti-HTLV I/II ELISA	Avioq	Screening	Yes BL125394	No
Syphilis	Automated	ASI Automated RPR	Arlington Scientific, Inc.	Screening	Yes BK200488	Yes
	Manual	CAPTIA-G	Trinity BioTech	Screening	Yes K014233	Yes
CMV Antibody	Automated/Manual	Capture-CMV AB (Total)	Immucor	Screening	Yes BK180247	Yes
NAT HIV- 1/2, HCV & HBV	Automated	Procleix Ultrio Elite Assay Panther	Grifols	Screening	Yes BL125652	Yes
NAT - WNV	Automated	Procleix WNV Assay Panther	Grifols	Screening	Yes BL125121	Yes
Chagas	Automated	Ortho <i>T. cruzi</i> ELISA Test System	Ortho	Screening	Yes BL125161	Yes
Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC)	Automated	GEN-PROBE® Aptima Combo 2® Assay	Hologic	Detection	* 510K K180681	No

*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)).