FDA-Approved HIV-1&2 Enzyme-Linked Immunosorbent Assays (ELISA or EIAs)

October 15, 2008

	FDA Approval Received	Specimen Type	Antigen Detected	Sensitivity* (95% CI)	Specificity* (95% CI)	Manufacturer	Kit Size**
Abbott HIVAB HIV-1/HIV-2 (rDNA) EIA	2/14/92	Serum	Recombinant HIV-1 *env* and *gag* HIV-2 *env* proteins	100% (99.15-100)	99.9% (99.83-99.94)	Abbott Laboratories www.abbottdiagnostics.com	100/
		Plasma					1000/
		Cadaveric Serum					
Genetic Systems HIV-1/HIV-2 Plus O EIA	8/5/03	Serum	gp 160 and p24 recombinant proteins and gp 36 synthetic peptides (Groups M and O)	100% (99.84-100)	99.89% (99.83-99.96)	Bio-Rad Laboratories, Inc. www.biorad.com	480/
		Plasma		100% (99.84-100)	99.89% (99.83-99.96)		960/
		Cadaveric Serum		100% (99.47, 100)	100% (99.47, 100)		4800/
Genetic Systems rLAV EIA [HIV-1]	6/29/98	Serum	Viral lysate and E-coli recombinant antigen	100% (99.75-100)	99.96% (99.91-100)	Bio-Rad Laboratories Blood Virus Division www.biorad.com	480/
		Plasma		100% (99.75-100)	99.96% (99.91-100)		960/
		Dried Blood Spot		100% (99.81-100)	100% (99.97-100)		4800/
Maxim HIV-1 Urine EIA	8/6/96	Urine Screen	gp160 recombinant antigen	98.7% (97.9-99.0)	99.14% (n/a)	Maxim Biomedical, Inc. www.mbidiagnostic.com	192/
							480/

*Sensitivity is the probability that the test results will be reactive if the specimen is a true positive; specificity is the probability that the test results will be nonreactive if the specimen is a true negative. Data from manufacturers' package insert claims.

****** Contact manufacturers for prices, which may vary based on purchasing agreements

Note: Trade names are for identification purposes only and do not imply endorsement.

Sources: Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays, U.S. Food and Drug Administration; manufacturers' package inserts

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