

Table: FDA-Approved HIV, HAV, HBV, HCV, and STD Diagnostic or Monitoring Assays by Manufacturer and Platform^a

	Serologic Assays							
	Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, <i>Mycoplasma genitalium</i>	
	Abbott	ARCHITECT System	HIV Ag/Ab Combo	Anti-HAV IgG, Anti-HAV IgM	Anti-HBs, HBsAg (Qual), HBsAg (Qual Conf.), Anti-HBc, Anti-HBc IgM,	Anti-HCV	Syphilis TP (Treponemal)	
		Alinity <i>i</i>	HIV Ag/Ab Combo	HAVAB IgG, HAVAB IgM	Anti-Hbc, Anti-HBc IgM, Anti-HBs, HbsAg, HBsAg Confirmatory	Anti-HCV	Syphilis TP (Treponemal)	
	Avioq	Manual	Avioq HIV-1 Microelisa System, VioOne HIV Profile Supplemental Assay					
	Bio-Rad	EVOLIS	GS HIV Combo Ag/Ab EIA, GS HIV-1/HIV-2 <i>Plus O</i> EIA, HIV-2 EIA			MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc EIA, MONOLISA Anti-HBc IgM EIA		Syphilis IgG (Treponemal)
		BioPlex 2200	BioPlex 2200 HIV Ag-Ab					Syphilis Total & RPR assay (Treponemal and Nontreponemal)
		Geenius	Geenius HIV 1/2 Supplemental Assay					
		Manual	GS HIV Combo Ag/Ab EIA, GS HIV-1/HIV-2 Plus O EIA, HIV-1 Western Blot, HIV-2 EIA	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc EIA, GS HBs Ag EIA, GS HBs Ag Confirmatory	ORTHO HCV v3.0 ELISA		
	Diasorin	LIAISON XL	MUREX HIV Ab/Ag HT (Ag/Ab)	Anti-HAV, HAV IgM	MUREX Anti-Hbe, MUREX HBsAg Qual, MUREX Anti HBc, MUREX Anti-HBs	MUREX HCV Ab	Treponema Assay Kit (IgG and IgM)	
	Ortho-Clinical Diagnostics	VITROS ECI/ECIQ, 3600, 5600 and XT 7600	Anti-HIV1+2, VITROS HIV Combo (Ag/Ab)	Anti-HAV IgM, Anti-HAV Total	Anti-HBc, Anti-HBc IgM, Anti-HBe, Anti-HBs	Anti-HCV		
	Roche	Cobas e 411 or Cobas e 601		Elecsys Anti-HAV IgM, Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, HBe Ag, HBs Ag II, HBs Ag II quant II	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)	
		Cobas e 602	Elecsys HIV Combi PT (Ag/Ab)	Elecsys Anti-HAV IgM and Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, HBe Ag, HBs Ag II, HBs Ag II quant II	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)	
		Cobas e 801	Elecsys HIV Duo (Ag/Ab)	Elecsys Anti-HAV IgM and Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-HBe, HBe Ag, HBs Ag II, HBs Ag II quant II, HBsAg II Auto Confirm	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)	
	Siemens	ADVIA Centaur XPT/XP	HIV Ag/Ab Combo, HIV 1/O/2 Enhanced	HAV IgM, HAV Total	Anti-HBs2, HBc IgM, HBc Total, HBe Ag, HBs Ag Confirmatory, HBs AgII	HCV Assay	Syphilis (Treponemal)	
		ADVIA Centaur CP	HIV 1/O/2 Enhanced	HAV IgM, HAV Total	Anti-HBs2, HBc IgM, HBc Total, HBs Ag, HBs Ag Confirmatory	HCV Assay	Syphilis (Treponemal)	
		Atellica IM	HIV Ag/Ab Combo, HIV 1/O/2 Enhanced	HAV IgM, HAV Total	HBsAg II, Anti-HBs2, HBc IgM, HBc Total, HBsAg Confirmatory	HCV Assay	Syphilis (Treponemal)	
	Molecular Assays							
	Manufacturer	Platform	HIV	HAV	HBV	HCV	STD	
	Abbott	<i>m</i> 2000	RealTime HIV-1 Viral Load			RealTime HBV (Viral Load)	RealTime HCV Viral Load, RealTime HCV Genotype II (Genotyping)	RealTime CT/NG, RealTime CT
		Alinity <i>m</i>	Alinity <i>m</i> HIV-1 (Viral Load)			Alinity <i>m</i> HBV (Viral Load)	Alinity <i>m</i> HCV (Viral Load)	CT/NG/TV/M. genitalium
		ABI 3130	ViroSeq HIV-1 Genotyping System v2.0 ^c (Genotyping)					
	Roche	cobas 6800/8800	cobas HIV-1 (Viral Load), cobas HIV-1/HIV-2 Qual (Diagnosis)			cobas HBV (Viral-Load)	cobas HCV (Diagnosis and Viral Load)	cobas CT/NG, cobas TV/MG
		cobas 4800				cobas HBV (Viral-Load)	cobas HCV (Diagnosis and Viral Load)	cobas 4800 CT/NG
		COBAS TaqMan Analyzer/ COBAS TaqMan 48 Analyzer	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 (Viral Load)			COBAS AmpliPrep/COBAS Taqman HBV Test, v2.0 (Viral Load), COBAS TaqMan HBV Test For Use With The High Pure System (Viral Load) ^b	COBAS AmpliPrep/COBAS Taqman HCV Test, v2.0 (Diagnosis and Viral Load)	
		Manual				COBAS Taqman HBV Test (Viral Load)	COBAS Taqman HCV Test (Viral Load)	
	Hologic	Panther	Aptima HIV-1 Quant Dx (Diagnosis and Viral Load)			Aptima HBV Quant (Viral Load)	Aptima HCV Quant Dx (Diagnosis and Viral Load)	Aptima Combo2 for CT/NG, Aptima TV, Aptima Mycoplasma genitalium
Manual		Aptima HIV-1 RNA Qual (Diagnosis)				Aptima HCV RNA Qual (Diagnosis)		
Siemens	Auto-LiPA 48/AutoBlot 3000H					VERSANT HCV Genotype 2.0 (LiPA) (Genotyping)		
Vela Diagnostics	Sentosa SX101 and SQ 301 Instruments	Sentosa SQ HIV-1 Genotyping Assay (Genotyping)						

a. Note that this document was created to compile all HIV and HCV serologic and molecular assays by Manufacturer and Platform. We have also added any assays on these platforms that detect Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), *Treponema pallidum* (Syphilis), *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV). There may be other manufacturers and/or platforms that have assays that detect these pathogens but if they don't also have an HIV and/or HCV test available they were not included at this time. b. This assay is only available on the COBAS TaqMan 48 Analyzer. c. The Abbott Viroseq HIV-1 Genotyping System will be discontinued December 31, 2021. This document was supported by Cooperative Agreement # 5NU600E000103 funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services. Updated August 2021. For any questions please contact anne.gaynor@aphl.org.