FDA-authorized Assays for HIV, HAV, HBV, HCV and STD Diagnostics or Monitoring (by Manufacturer and Platform)

Serologic Assays

Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, *Mycoplasma genitalium*
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	HIV Ag/Ab Combo	HAVAB IgG, HAVAB IgM	Anti-Hbc, Anti-HBc IgM, Anti-HBs, HbsAg, HBsAg confirmatory	Anti-HCV	Syphilis TP (Treponemal)
	Manual	Determine HIV-1/2 Ag/Ab Combo				
Arlington Scientific	**ASI Evolution**					Automated RPR (Nontreponemal)
	Manual					RPR Card Test fo Syphilis (Nontreponemal)
Avioq	**Manual**	Avioq HIV-1 Microelisa System, VioOne HIV Profile Supplemental Assay				
Beckman Coulter	**ACCESS**	HIV Ag/Ab combo				
Becton Dickinson	**Manual**					Macro-Vue RPR Card Tests (Nontreponemal)
Bio-Rad	**EVOLIS**	" GS HIV Combo Ag/Ab EIA, GS HIV-1/HIV-2 Plus O EIA, HIV-2 EIA"	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc, MONOLISA Anti-HBc IgM EIA	ORTHO HCV v3.0 ELISA	Syphilis IgG (Treponemal)
	BioPlex 2200	BioPlex 2200 HIV Ag-Ab				"Syphilis Total & RPR assay (Treponemal and Nontreponemal)"
	Manual	GS HIV Combo Ag/Ab EIA, GS HIV-1/ HIV-2 Plus O EIA, HIV-1 Western Blot, HIV-2 EIA Geenius HIV-1/2 Confirmatory Assay	MONOLISA Anti-HAV EIA, MONOLISA Anti-HAV IgM EIA	MONOLISA Anti-HBs EIA, MONOLISA Anti-HBc, GS HBsAG EIA, GS HBsAG Confirmatory	ORTHO HCV v3.0 ELISA	
	Geenius	Geenious HIV 1/2 Supplemental Assay				
Diasorin	**LIAISON XL**	MUREX HIV Ab/Ag HT	LIAISON Anit-HAV, LIAISON HAV IgM	HBsAg, HBsAg Confirmatory, Anti-HBc, HBc IgM, Anti-HBs, Anti-Hbe, HBeAg	MUREX HCV Ab	Treponema Assay (Treponemal)

Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, *Mycoplasma genitalium*
Diesse Diagnostica	**Manual**					Enzy-Well Syphilis IgG
EKA Diagnostics	**Manual**					Stanbio Quicktest RPR (Nontreponemal)
Fujirebio	**Manual**					Serodia TPPA
	Lumipulse G1200					Lumipulse G TP-N (Treponemal)
Gold Standard Diagnostics	**AiX1000**					Rapid Plasma Reagin (RPR) (Nontreponemal)
Hemagen Diagnostics Inc.	**Manual**					VIRGO FTA-ABS IgG DA (Treponemal)
New Horizons Diagnostics	**Manual**					"Toludine Red Unheated Serum Test (TRUST) (Nontreponemal)"
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 e 601**		Elecsys Anti-HAV IgM, Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-Hbe, HBsAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
	cobas e 602	Elecsys HIV Combi PT (Ag/Ab)	Elecsys Anti-HAV IgM, Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-Hbe, HBsAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	Elecsys Anti-HCV II	Elecsys Syphilis (Treponemal)
	cobas e 402 or e 801	Elecsys HIV Duo (Ag/Ab)	Elecsys Anti-HAV IgM, Anti-HAV II	Elecsys Anti-HBs II, Anti-HBc II, HBc Ag, Anti-Hbe, HBsAg, HBsAg II, HBsAg II Auto Confirm, Anti-HBc IgM	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 Ag/AB Combo, 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 Screen (Treponemal)
Teco Diagnostics	**Manual**					Teco Diagnostics RPR (Nontreponemal)
Trinity Biotech	**Manual**					Captia Syphilis IgG EIA (Treponemal)
	Manual					Trep-Sure Syphilis Total Antibody EIA (Treponemal)

Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, *Mycoplasma genitalium*
Zeus Scientific Inc.	**Manual**					FTA-ABS Test System (Treponemal)
	AtheNA Multi-Lyte					Treponema Pallidum IgG Test System (Treponemal)
	ELISA					Treponema Pallidum IgG Test System (Treponemal)

Molecular Assays

Manufacturer	Platform	HIV	HAV	HBV	HCV	Chlamydia, Gonorrhea, Syphilis, *Mycoplasma genitalium*
Abbott	**m 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 m	Alinity m HIV-1 (Viral Load)		Alinity m HBV (Viral Load)	Alinity m HCV (Viral Load)	CT/NG /TV/ M. genitalium
Becton Dickinson	**BD COR or BD MAX**					CT/GC/TV2
Cepheid	**GeneXpert Express**				Xpert HCV	
	Gene Xpert					Xpert CT/NG
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 CT, Aptima GC, APTIMA TV, Aptima Mycoplasma genitalium
	Manual	Aptima HIV-1 RNA Qual (Diagnosis)			Aptima HCV RNA Qual (Diagnosis)	
Roche	**cobas 5800/6800/8800**	"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 4800 CT/NG
Siemens	**Auto-LiPA 48 (? Now Fujirebio)**				"VERSANT HCV Genotype 2.0 (LiPa) (Genotyping)"	

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. This document was supported by Cooperative Agreement # 5NU60OE000103 funded by the US 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 March 2026. For any questions please contact sarah.buss@aphl.org.

FDA-authorized Assays for HIV Diagnostics and Monitoring

The following assays have been authorized by the US Food and Drug Administration (FDA) for the purpose of diagnosing or monitoring HIV. Contents have been broken up into Serologic Assays (page 4) and Molecular (RNA) Assays (page 9).

View a comparison chart of these assays and more for information on FDA clearance to test for Hepatitis A, B or C, Syphilis and other STD diagnostic or monitoring assays.

Serologic Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**Architect**	**HIV Ag/Ab Combo**[1]	Diagnostic	Serum/Plasma	150 µL	• Up to three days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel store at -20°C (no more than five freeze/thaws)	• Utilizes reusable probe for sampling • Random access testing • Kit Size(s): 100/500 tests • Age Restrictions: Not evaluated for use in patients <2 years old • Assay cannot distinguish between detection of HIV-1 p24 antigen and antibodies to HIV-1/HIV-2	87389
Abbott	**Alinity i**	**HIV Ag/Ab Combo**[2]	Diagnostic	Serum/Plasma	First Test: 150 µL Each Additional Test: 100 µL	• Up to three days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel store at -20°C (no more than five freeze/thaws)	• Utilizes reusable probe for sampling • Random access testing • Kit Size(s): 200/1200 tests • Age Restrictions: Not evaluated for use in patients <2 years old • Assay cannot distinguish between detection of HIV-1 p24 antigen and antibodies to HIV-1/HIV-2	87389
Abbott	**Manual**	**Determine HIV-1/2 Ag/Ab Combo**[3]	Diagnostic	Whole Blood, Serum and Plasma	50 µL	**Whole Blood:** • Up to two days at 15–30°C • Up to seven days at 2–8°C **Serum/Plasma:** • Up to two days at 15–30°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel store at -20°C (no more than three freeze/thaws)	• Point of care test • Kit Size(s): 25 tests • Age Restrictions: Not intended for use in patients less than 12 years of age • Detection of p24 may be inhibited by biotin in the sample, causing false negative results in acute infection; therefore, do not test samples from patients taking biotin • Distinguishes between HIV-1 p24 antigen and antibodies to HIV-1/HIV-2	87806
Avioq	**96 well microplate** **Manual or semi-automated plate reader**	**VioOne™ HIV Profile™ Supplemental Assay**[4]	Diagnostic (Supplemental) Confirmation and differentiation of antibodies to HIV-1 and HIV-2	Serum/Plasma	160 µL	• Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C up to twelve months (no more than five freeze/thaws)	• Batched testing • Intended for confirmation and differentiation of antibodies to HIV-1 and HIV-2. Not intended for use as a first line diagnostic test • Kit Size(s): 24 tests • Age Restrictions: Not evaluated for use in patients <2 years old	86701 86702

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Avioq	**96 well microplate** **Amenable to manual or semi-automated plate reader**	**HIV-1 Microelisa System**[5]	Diagnostic	Serum, plasma, dried blood spots or oral fluid specimens obtained with the Orasure® HIV-1 Oral Specimen Collection Device	Serum/Plasma: 10 µL Dried blood spots: 25 µL Oral fluid specimen: 75 µL	**Serum or Plasma:** • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at –20°C (no more than five freeze/thaws) **Dried Blood Spots:** • Up to ninety days at 2–8°or 15–30°C (humidity must be <50%) • For long term storage: store at –20°C or colder (humidity must be <50%) **Oral Fluid Specimens:** • Up to 21 days at 2–37°C • Up to six weeks at –20°C or colder • For long term storage: store off the pad in cryovials at –20°C or colder	• Batched testing • Kit Size(s): 384/960/9600 tests • Age Restrictions: None Specified	86701 G0433*
Beckman Coulter	**ACCESS**	**HIV Ag/Ab combo**[6]	Diagnostic	Serum/Plasma	60 µL plus instrument dead volume (varies by sample container type)	• Up to 72 hours at 20–25°C • Up to seven days at 2–8°C • Up to 30 days at -20°C, once removed from clot or separated from cells or gel (no more than five freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Assay does not distinguish between HIV-1 and HIV-2 infection • Kit Size(s): 2 packs of 100 tests • Age Restrictions: Not evaluated for use in patients <2 years old	87389
Bio-Rad	**EVOLIS™, Manual**	**Genetic Systems™ HIV-1/HIV-2 PLUS O EIA**[7]	Diagnostic/ Donor Screening	Serum/Plasma	Manual: 75 µL EVOLIS: 175 µL	• Up to two days at 20–25°C • Up to seven days at 2–8°C • For long-term storage, store at store at -20°C or colder (no more than five freeze/thaws)	• Utilizes disposable pipette tips • Batched testing • Kit Size(s): 192/960 tests • Age Restrictions: Not intended for use in patients <2 years old	87389
Bio-Rad	**BioPlex 2200**	**HIV Ag-Ab**[8]	Diagnostic	Serum/Plasma	40 µL plus instrument dead volume (varies by sample container type)	• Up to four days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: Store at -20°C (no more than four freeze/thaws)	• Utilizes reusable probe for sampling • Random access testing • Kit Size(s): 200 tests • Age Restrictions: Not intended for use in patients <2 years old • False positive results may occur if plasma remains with the cells for >24 hours • In addition to reporting an overall HIV Antigen-Antibody Screen result, simultaneously detects and reports individual results for HIV-1 p24 Antigen, HIV-1 Antibody and HIV-2 Antibody	86701 (HIV-1 Ab) 87602 (HIV-2 Ab) 87390 (HIV-1 p24 Ag) 87389
Bio-Rad	**Geenius**	**Geenius HIV 1/2 Supplemental Assay**[9]	Diagnostic (Supplemental)	Whole Blood, Serum or Plasma	Whole Blood: 15 µL Serum/Plasma: 5 µL	**Fingerstick Whole Blood:** Test immediately after collection **Venous Whole Blood:** Up to three days at 2–8°C **Serum/Plasma:** • Up to 48 hours at 18-30°C • Up to seven days at 2–8°C • For long-term storage, store at -20°C or colder (no more than five freeze/thaws); centrifuge thawed specimens to remove gross particulate matter	• Single use assay • Kit Size(s): 20 tests • Age Restrictions: Not intended for use in patients <2 years old • Intended for confirmation and differentiation of antibodies to HIV-1 and HIV-2	86701 86702

* Specifically for HIV-1 and/or 2 ELISA test

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Diasorin	**LIAISON XL**	**MUREX HIV Ab/Ag HT**[10]	Diagnostic	Serum/Plasma	350 µL	• Up to three days at 18 - 30°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: Store at -20°C (no more than seven freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Assay cannot distinguish between the detection of HIV p24 antigen and HIV-1/HIV-2 antibodies • Kit Size(s): 200 tests • Age Restrictions: Not intended for use in patients <2 years old	87389
Quidel Ortho-clinical diagnostics	**VITROS ECi, 3500, 5600, XT7600**	**HIV Combo**[11]	Diagnostic	Serum/Plasma	80 µL plus instrument dead volume (varies by sample container type)	• Up to 24 hours at up to 30°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than five freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Assay cannot distinguish between the detection of HIV p24 antigen and HIV-1/HIV-2 antibodies • Kit Size(s): 100 tests • Age Restrictions: Not intended for use in patients <2 years old	87389
Roche	**cobas e 402** **cobas e 801**	**Elecsys HIV Duo**[12]	Diagnostic/ Donor Screening	Serum/Plasma	30 µL plus instrument dead volume (varies by sample container type)	• Up to seven days at 20–25°C • Up to four weeks at 2–8°C • Up to three months at -20°C, once removed from clot or separated from cells or gel (no more than five freeze/ thaws)	• Utilizes disposable pipette tips • Random access testing • Kit Size(s): 300 tests • Age Restrictions: Not intended for use in patients <2 years old • Provides separate results for HIV-1 p24 antigen and antibodies to HIV-1/HIV-2	87389
Roche	**cobas e 602**	**Elecsys HIV combi PT**[13]	Diagnostic/ Donor Screening	Serum/Plasma	40 µL plus instrument dead volume (varies by sample container type)	• Up to seven days at 20–25°C • Up to four weeks at 2–8°C • Up to three months at -20°C, once removed from clot or separated from cells or gel (no more than five freeze/ thaws)	• Utilizes disposable pipette tips • Random access testing • Kit Size(s): 100 tests • Age Restrictions: Not intended for use in patients <2 years old • Assay does not distinguish between HIV-1 antigen and HIV-1/ HIV-2 antibodies	87389
Siemens	**ADVIA Centaur**	**HIV Ag/Ab Combo**[14]	Diagnostic	Serum/Plasma	100 µL plus instrument dead volume (varies by sample container type)	• Up to 24 hours at 20–25°C • Up to 14 days at 2–8°C • Up to eight months at -20°C, once removed from clot or separated from cells or gel (no more than five freeze/ thaws)	• Utilizes disposable pipette tips • Random access testing • Kit Size(s): 100 tests • Age Restrictions: Not evaluated for use in patients <2 years old	87389
Siemens	**Atellica® IM** **Atellica® CI**	**HIV Ag/Ab Combo (CHIV)**[15]	Diagnostic	Serum/Plasma	100 µL plus instrument dead volume (varies by sample container type)	• Up to 24 hours at 20–25°C • Up to 14 days at 2–8°C • Up to eight months at -20°C, once removed from clot or separated from cells or gel (no more than five freeze/ thaws)	• Utilizes disposable pipette tips • Random access testing • Kit Size(s): 100 tests • Age Restrictions: Not intended for use in patients <2 years old	87389

Molecular (RNA) Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**m2000**	**RealTime HIV-1**[16]	Viral Load	Plasma	0.7–1.8 mL (dependent on tube type and sample volume used)	**Whole Blood:** • Up to six hours at 15–30°C • Up to 24 hours at 2-8°C **Plasma:** • Up to 24 hours at 15-30°C • Up to 5 days at 2-8°C • Up to 60 days at -20°C (no more than three freeze/thaws)	• Batched testing • Kit Size(s): 96 tests • LoD plasma: 40 copies/mL (for 1.0 mL and 0.6 mL sample volume) • LLoQ plasma: 40 copies/mL (for 1.0 mL and 0.6 mL sample volume)	87536
Abbott	**Alinity m**	**HIV-1 AMP Kit**[17]	Diagnostic Viral Load	**Quantitative:** Plasma **Qualitative:** Serum/Plasma	0.75–1.0 mL (dependent on tube type)	**Whole Blood (Plasma):** • Up to one day at 15–30°C • Up to two days at 2-8°C **Whole Blood (Serum):** • Up to 12 hours at 15–30°C • Up to two days at 2-8°C **Serum/Plasma:** • Up to 12 hrs (serum) or one day (plasma) at 15–30°C • Up to three days at 2-8°C • Up to 30 days (serum) or sixty days (plasma) at -20°C, once removed from clot or separated from cells or gel (no more than two [plasma] or three [serum] freeze/thaws) • Up to six months at -70°C, once removed from clot or separated from cells or gel (no more than two [plasma] or three [serum] freeze/thaws)	• Random Access • Kit Size(s): 192 tests • LoD serum/plasma: 20 Copies/mL • LLoQ serum/plasma: 20 Copies/mL	87535 87536
Hologic	**Panther**	**Aptima® HIV-1 Quant Dx**[18]	Diagnostic Viral Load	Quantitative: Plasma Qualitative: Serum/Plasma	700–1,200 µL (dependent on tube type)	**Whole Blood:** Up to 24 hours at 2–30°C **Serum/Plasma:** • Up to three days (plasma) and five days (serum) at 2-8°C in primary tube • Up to five days at 2-8°C in secondary tube • Up to 90 days at -20 to -70°C, once removed from clot or separated from cells or gel (no more than three freeze/thaws)	• Random access • Kit Size(s): 100 tests • LoD plasma: 12 copies/mL (35 IU/mL) • LoD serum: 8.9 copies/mL (25 IU/mL) • LLoQ plasma: 30 copies/mL (1.17 log10 copies/mL) • Performance of this test has not been evaluated for use in pregnant women or in a pediatric population	87535 87536
Roche	**cobas® 5800/6800/8800**	**cobas® HIV-1/ HIV-2 Qualitative**[19]	Diagnostic	Serum/Plasma	650 µL	**Whole Blood:** Up to 24 hours at 2–25°C **Serum/Plasma (Secondary Tube):** • Up to 24 hours at 30°C • Up to five days at 2-8°C • Up to six weeks at -20°C (no more than three freeze/thaws) • For long term storage at or below -60°C is recommended	• Batched testing • Kit Size(s): 96 tests • LoD: ○ HIV-1 Grp M – 12.8 (plasma/serum) ○ HIV-1 Grp O – 15.4 (plasma), 13.3 (serum) ○ HIV-2 – 35.4 (plasma), 26.3 (serum) • Detection and differentiation of HIV-1 and HIV-2 RNA	87535 87538
Roche	**cobas® 5800/6800/8800**	**cobas® HIV-1 Quantitative nucleic acid test**[20]	Viral Load	Plasma	350–650 µL	**Whole Blood (Plasma):** Up to 24 hours at 2–25°C **Plasma:** • Up to six days at 2-8°C • Up to 12 weeks at -18°C (no more than four freeze/thaws) • For long term storage at or below -60°C is recommended	• Batched testing • Kit Size(s): 192 tests • LoD: 20 copies/mL	87536

FDA-authorized Assays for Hepatitis C Diagnostics and Monitoring

The following assays have been authorized by the US Food and Drug Administration (FDA) for the purpose of diagnosing or monitoring Hepatitis C Virus (HCV). Contents have been broken up into Serologic (Antibody) Assays (page 8) and Molecular (RNA) Assays (page 2). View a comparison chart of these assays and more for information on FDA clearance to test for HIV, Hepatitis A, B or C, Syphilis and other STD diagnostic or monitoring assays.

Serologic (Antibody) Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**Architect**	**ARCHITECT anti-HCV**[21]	Diagnostic	Serum/Plasma	150 µL	• Up to three days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than three freeze/thaws)	• Utilizes reusable probe for sampling • Random access testing • Kit Size(s): 100/500 tests • Age Restrictions: Assay performance has not been established for newborns, infants or children	86803 (G0472)
Abbott	**Alinity i**	**Alinity I Anti-HCV**[22]	Diagnostic	Serum/Plasma	150 µL	• Up to three days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than three freeze/thaws)	• Utilizes reusable probe for sampling • Random access testing • Kit Size(s): 200 tests • Age Restrictions: Assay performance has not been established for newborns, infants or children	86803
Diasorin	**LIAISON® XL**	**Murex HCV Ab**[23]	Diagnostic	Serum/Plasma	175 µL	• Up to four days at 18–30°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C for up to three months (no more than seven freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Kit size(s): 100 tests • Age restrictions: Not evaluated for use in patients <2 years old	86803
Quidel Ortho-clinical Diagnostics	***Vitros* Eci, 3600, 5700, XT7600**	***Vitros* Immunodiagnostics Anti-HCV**[24]	Diagnostic	Serum/Plasma	20 µL + system required dead volume	• Up to eight hours at 22°C • Up to two days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C up to three months (no more than one freeze/thaw)	• Utilizes disposable pipette tips • Random access testing • Kit size(s): 100 tests • Age Restrictions: Not evaluated for use in patients < 10 years old	86803
Roche	**cobas® e 402** **cobas® e 411** **cobas® e 601** **cobas® e 602** **cobas® e 801**	**Elecsys Anti-HCV II**[25]	Diagnostic	Serum/Plasma	50 µL + system required dead volume	• Up to seven days at 20–25°C • Up to 14 days at 2–8°C • Up to three months at -20°C (no more than six freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Kit size(s): 200 tests • Samples should not be taken from patients receiving therapy with high biotin doses (i.e., > 5 mg/day) until at least eight hours following the last biotin administration • Age Restrictions: None listed	86803

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Siemens	**Advia Centaur**	**HCV (aHCV)[26]**	Diagnostic	Serum/Plasma	30 µL + system required dead volume	• Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than four freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Kit size(s): 200 tests • Age Restrictions: Not evaluated for use in patients < 18 months old	86803
Siemens	**Atellica® CI**	**Hepatitis C (aHCV)[27]**	Diagnostic	Serum/Plasma	30 µL + system required dead volume	• Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than four freeze/thaws)	• Utilizes disposable pipette tips • Random access testing • Kit size(s): 200 tests • Age Restrictions: Assay performance has not been evaluated in specimens from neonatal patients	86803

Molecular (RNA) Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**m2000sp** **m2000rt**	**RealTime HCV Viral Load[28]**	Viral Load	Serum/Plasma	900 µL	**Whole Blood:** Up to six hours at 2–30°C **Serum/Plasma:** • Up to 24 hours at 15–30°C • Up to 5 days at 2–8°C • Up to 60 days at -10 – -30°C • Up to 60 days at -70°C (no more than three freeze/thaws)	• Batched testing • Kit Size(s): 96 tests • LoD serum/plasma: 12.0 IU/mL • LLoQ serum/plasma: 12.0 IU/mL	87522
Abbott	**Alinity m**	**Alinity m HCV AMP Kit[29]**	Diagnostic Viral Load	Serum/Plasma	0.75–1.0 mL (dependent on tube type)	**Whole Blood:** • Up to four hours at 15–30°C • Up to three days at 2–8°C **Serum/Plasma:** • Up to 20 hours at 15–30°C • Up to three days at 2–8°C • Up to 60 days at -20°C (do not exceed two freeze/thaws [plasma] or three freeze/thaws [serum]) • Long term storage at -70°C	• Random Access • Kit Size(s): 192 tests • LoD serum: 7.96 IU/mL • LoD plasma: 8.5 IU/mL • LLoQ: 12 IU/mL	87522
Cepheid	**GeneXpert Xpress**	**Xpert® HCV[30]**	Diagnostic (qualitative)	Fingerstick Whole blood (collected in K2EDTA microtainer)	100 µL (minimum of 250-500 µL of blood must be collected in microtainer, BD part number 365974)	**Whole Blood:** Up to four hours at 2–30°C	• Point of care waived test • Kit size: 10 tests • LoD (IU/mL): 32.2 - 136.4 depending on genotype • Age Restrictions: Performance only evaluated in patients ≥ 22 years of age • Performance not established in pregnant people	87521-QW

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Hologic	**Panther**	HCV Quant Dx[31]	Diagnostic Viral Load	Serum/Plasma	700–1,200 µL (dependent on tube type)	**Prior to plasma/serum preparation:** Up to six hours at 2–30°C **Centrifuged in primary collection tube:** • Up to five days at 2–8°C • Up to 24 hours at 2-25°C **In secondary tube:** Up to 60 days at -20°C (do not exceed three freeze/thaws)	• Random access testing • Kit size(s): 100 tests • LoD serum: 3.4 IU/mL • LoD plasma: 3.9 IU/mL • LLoQ serum/plasma: 10.0 IU/mL • Age Restrictions: None listed	87522
Roche	**Cobas 5800** **Cobas 6800** **Cobas 8800**	cobas HCV[32]	Diagnostic Viral Load	Serum/Plasma	650 µL	**Prior to plasma/serum preparation:** Up to 24 hours at 2–25°C **After separation from cells:** • Up to six days at 2–8°C • Up to 12 weeks at ≤ -18°C **Long-term storage (up to six months):** Temperatures at ≤ -60°C are recommended; stable for up to four freeze/thaws.	• Random access testing • Kit size(s): 192 tests • LoD serum: 13.7 IU/mL • LoD plasma: 12.0 IU/mL • LLoQ serum/plasma: 15.0 IU/mL • Age Restrictions: None listed	87522

FDA-authorized Assays for Syphilis Diagnostics and Monitoring

The following serologic assays have been authorized by the US Food and Drug Administration (FDA) for the purpose of diagnosing or monitoring syphilis. Contents have been broken up into Nontreponemal (Lipoidal Antigen) Assays (page 11), Treponemal Assays (page 2) and Combined Nontreponemal and Treponemal Assays (page 4). View a comparison chart of these assays and more for information on FDA clearance to test for HIV, Hepatitis A, B or C, Syphilis and other STD diagnostic or monitoring assays.

Nontreponemal (Lipoidal Antigen) Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Arlington Scientific Inc.	**ASI Evolution**	**Automated RPR**[33]	Diagnostic	Serum/Plasma	300 µL	**All Specimens:** Up to five days at 2–8°C **Serum:** • Test within five days of collection • To store longer than five days, remove from red cells and keep at -20°C or below **Plasma Only:** Do not store samples longer than five days at 2-8°C due to potential false reactive results	• Automated batched testing • Qualitative and quantitative • Kit size(s): 480/4800 tests • Target antigens: Cardiolipin, cholesterol, phosphatidylcholine • Age restrictions: None specified • This device should not be used for syphilis testing with the Reverse Testing Algorithm	86592 86593
Arlington Scientific Inc.	**Manual**	**RPR Card Test for Syphilis**[34]	Diagnostic	Serum/Plasma	Qualitative test: 50 µL Semiquantitative test (if needed): 50 µL	• Up to five days at 2–8°C • **Serum:** Once removed from clot or separated from cells or gel, store at -20°C	• Manual batched test • Qualitative and quantitative • Kit size(s): 25/100/500/5,000/10,000 tests • Target antigens: Cardiolipin, cholesterol, phosphatidylcholine • Age restrictions: None specified	86592 86593
Becton Dickinson	**Manual**	**Macro-Vue™ RPR Card Tests**[35]	Diagnostic	Serum/Plasma	Qualitative test: 50 µL Quantitative test (if needed): 50 µL	**Serum** • Up to five days at 2–8°C • Once removed from clot or separated from cells or gel, store at -20°C **Plasma:** Up to 24 hours at 2–8°C	• Manual batched test • Qualitative and Quantitative • Kit size(s): ○ Qualitative: 150/300/500/5,000/10,000 tests ○ Quantitative: 150 • Target antigens: Cardiolipin, cholesterol, phosphatidylcholine • Age restrictions: None specified • When testing plasma: if a baseline is to be established from which changes in titer can be determined, test should be repeated on unheated serum.	86592 86593
EKA Diagnostics USA	**Manual**	**Stanbio Quick-test RPR**	Diagnostic	Serum/Plasma	Detailed assay information not publicly available or package insert not accessible			

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Gold Standard Diagnostics	**Automated**	**AiX1000 Rapid Plasma Reagin (RPR)[36]**	Diagnostic	Serum	300µL to perform screen and titer	• Up to seven days at 2–8°C • Up to 14 days at or below -20°C (no more than two freeze thaw cycles)	• Batched testing • Qualitative and semi-quantitative • Kit size: 480 and 16, 320 tests • Target antigens: Cardiolipin, cholesterol and phosphatidylcholine • Turbid or hemolyzed samples are not acceptable • Age restrictions: None specified	86592 86593
New Horizons Diagnostics	**Manual**	**Toludine Red Unheated Serum Test (TRUST)[37]**	Diagnostic	Serum/Plasma	Qualitative test: 50 µL Quantitative test (if needed): 50 µL	**Serum:** • Up to five days at 2–8°C once removed from clot • Once removed from clot or separated from cells or gel, store at -20°C **Plasma:** Up to 24 hours at 2–8°C	• Batched testing • Qualitative and quantitative • Kit size(s): 150/500/5,000/10,000 tests • Target antigens: Cardiolipin, cholesterol and phosphatidylcholine • Age restrictions: None specified	86592 86593
Teco Diagnostics	**Manual**	**Teco Diagnostics RPR[38]**	Diagnostic	Serum/Plasma	50 µL	**Serum:** • Up to five days at 2–8°C once removed from clot • Once removed from clot or separated from cells or gel, store at -20°C **Plasma:** Test within 48 hours of collection	• Batched testing • Qualitative and quantitative • Kit size(s): 500 tests • Target antigens: Cardiolipin, lecithin and cholesterol • Age restrictions: None specified	86592 86593

Treponemal Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**Alinity i**	**Syphilis TP[39]**	Diagnostic	Serum/Plasma	150 µL	• Up to 72 hours at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: Store at -20°C for up to 30 days (no more than six freeze/thaw cycles)	• Random access testing • Kit size(s): 200/1,200 tests • Qualitative • Age restrictions: performance characteristics have not been established for newborns, infants, children or population of immunocompromised or immunosuppressed patients.	86780
Abbott	**Architect**	**Syphilis TP[40]**	Diagnostic	Serum/Plasma	150 µL	• Up to 72 hours at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: Store at -20°C for up to 30 days (no more than six freeze/thaw cycles)	• Random access testing • Kit size(s): 100/500 tests • Qualitative • Target antigens: *T. pallidum* recombinant antigens TpN15, TpN17 and TpN47 • Age restrictions: None specified	86780
Diasorin	**Liaison**	**Treponema Assay[41]**	Diagnostic	Serum	220 µL	• Up to seven days at 2–8°C, once separated from the clot • Once removed from clot or separated from cells or gel: Store at -20°C for up to 30 days (no more than four freeze/thaw cycles)	• Automated random access or batched testing • Qualitative • Kit size: 200 tests • Target antigens: *T. pallidum* recombinant antigens TpN17 • Age restrictions: None specified	
Diesse Diagnostica	**Manual**	**Enzy-Well Syphilis IgG**	Diagnostic	Serum/Plasma	Detailed assay information not publicly available or package insert not accessible			

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Fujirebio	**Manual**	**Serodia® TPPA[42]**	Diagnostic	Serum/Plasma	100 µL	**Serum:** • Up to five days at 2–8°C • Once removed from clot: store at -20°C (no more than one freeze/thaw cycle) • Heat inactivated (56°C, 30 min.) is acceptable **Plasma:** • Test within 48 hours of collection • Do not inactivate or freeze	• Manual batched testing • Qualitative • Kit size(s): 100/220 tests • Target Antigens: Lyophilized preparation of colored gelatin particles sensitized *T. pallidum* antigen • Age restrictions: None specified	86780
Fujirebio	**Lumipulse G1200**	**Lumipulse® G TP-N**	Diagnostic	Serum/Plasma	Detailed assay information not publicly available or package insert not accessible			
Hemagen Diagnostics Inc.	**Manual**	**VIRGO® FTA-ABS IgG IFA[43]**	Diagnostic Confirmation	Serum	50 µL	• Up to 24 hours at 20–25°C • Up to three days at 2–8°C • Once removed from clot: store at -20°C or below (avoid multiple freeze/thaw cycles)	• Batched testing • Qualitative • Kit size(s): 60/200 tests • Target antigens: *T. pallidum* fixed to a glass slide • Age restrictions: None specified • Not intended for routine use or as a screening procedure; used to distinguish true-positive nontreponemal results from false positive results and to establish the diagnosis of late latent or late syphilis	86780
Roche	**cobas® e 402** **cobas® e 411** **cobas® e 601** **cobas® e 602** **cobas® e 801**	**Elecsys Syphilis[44]**	Diagnostic Donor Screening	Serum/Plasma	10 µL plus instrument dead volume	• Up to seven days at 20–25°C • Up to 14 days at 2–8°C • Once removed from clot or separated from cells or gel: store for up to 12 months at -20°C (no more than five freeze/thaw cycles)	• Random access testing • Qualitative • Kit size(s): 300 tests • Target antigens: *T. pallidum* recombinant antigens TpN15, TpN17 and TpN47 • Age restrictions: None specified	86780
Siemens	**Advia Centaur® (XP and XPT)**	**Syphilis (SYPH)[45]**	Diagnostic	Serum/Plasma	100 µL plus instrument dead volume	• Centrifuge within 24 hours • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than six freeze/thaw cycles)	• Random access testing • Qualitative • Kit size(s): 200 tests • Target antigens: *T. pallidum* recombinant antigens TpN15 and TpN17 • Age restrictions: Not evaluated for use in neonatal patients	86780
Siemens	**AtellicaTM IM**	**Syphilis (Syph)[46]**	Diagnostic	Serum/Plasma	100 µL plus instrument dead volume	• Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (no more than six freeze/thaw cycles)	• Random access testing • Qualitative • Kit size(s): 200 tests • Target antigens: *T. pallidum* recombinant antigen TpN17 • Age restrictions: None specified	86780
Siemens	**Immulite 2000**	**Syphilis Screen[47]**	Diagnostic	Serum/Plasma	100 µL	• Up to three days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C	• Random access testing • Qualitative • Kit size(s): 200 tests • Target antigens: *T. pallidum* recombinant antigens TpN15 and TpN17 • Age restrictions: Not evaluated for use in neonatal patients	86780

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Trinity Biotech	**Performed manually or used with a variety of automatic or semi-automatic processors/ liquid handling systems**	**CaptiaTM Syphilis IgG EIA[48]**	Diagnostic Donor Screening	Serum/Plasma	10-50 µL	**Serum:** • Up to five days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C **Plasma:** • Up to 48 hours at 2–8°C • Should not be frozen due to fibrin clot formation	• Batched testing • Qualitative • Kit size(s): 96/960 tests • Target antigens: Antigens from sonicated *T. pallidum* cells • Age restrictions: None specified	86780
Trinity Biotech	**Manual or automated**	**Trep-SureTM Syphilis Total Antibody EIA[49] (Phoenix Bio-tech)**	Diagnostic	Serum/Plasma	100 µL	• Up to eight hours at 20-25°C • Up to 48 hours at 2–8°C • On clot, up to five days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (avoid repeat freeze/thaw cycles)	• Batched testing • Qualitative • Kit size(s): 96/960/1920 tests • Target antigens: Recombinant *T. antigens;* exact antigens are not specified • Age restrictions: None specified	86780
Zeus Scientific, Inc.	**Manual**	**FTA-ABS Test System[50]**	Diagnostic	Serum	50 µL	• Up to eight hours at 20-25°C • Up to 48 hours at 2–8°C • Once removed from clot: store at -20°C (avoid repeat freeze/thaw cycles)	• Batched testing • Qualitative • Kit size(s): 100 tests • Target antigens: *T. pallidum* fixed to a glass slide • Age restrictions: None specified	86780
Zeus Scientific, Inc.	**AtheNA Multi-Lyte**	**Treponema Pallidum IgG Test System[51]**	Diagnostic	Serum	10 µL	• Up to eight hours at 20-25°C • Up to 48 hours at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (avoid repeat freeze/thaw cycles)	• Automated random access or batched testing • Qualitative • Kit size(s): 96 tests • Target antigens: *T. pallidum* recombinant antigen TpN17 • Age restrictions: None specified • Do not perform as a screening procedure for general population	86780
Zeus Scientific, Inc.	**ELISA**	**Treponema Pallidum IgG Test System[52]**	Diagnostic	Serum	10 µL	• Up to eight hours at 20-25°C • Up to 48 hours at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C (avoid repeat freeze/thaw cycles)	• Batched testing • Qualitative • Kit size(s): 96 tests • Target antigens: *T. pallidum* recombinant antigen TpN17 • Age restrictions: None specified	86780

Combined Nontreponemal and Treponemal Assays

Manufacturer	Platform	Assay	Type of Claim	Specimen Types Accepted	Specimen Volume	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Bio-Rad	**BioPlex 2200**	**Syphilis Total & RPR[53]**	Diagnostic	Serum/Plasma	40–200 µL	• Up to three days at 20–25°C • Up to seven days at 2–8°C • Once removed from clot or separated from cells or gel: store at -20°C or below (no more than three freeze/ thaw cycles)	• Random access testing • Kit size(s): 100 tests • Target antigens: ○ Nontreponemal: Cardiolipin, cholesterol, phosphatidylcholine ○ Treponemal: *T. pallidum* recombinant antigens TpN17 and TpN47 • Age restrictions: None specified	86592 86780

FDA-authorized Assays for CT/GC Diagnostics

The following assays have been authorized by the US Food and Drug Administration (FDA) for the purpose of diagnosing. View a comparison chart of these assays and more for information on FDA clearance to test for HIV, Hepatitis A, B or C, Syphilis and other STD diagnostic or monitoring assays.

Manufacturer	Platform	Assay	Type of Claim	Pathogens Detected	Specimen Types Accepted	Specimen Preparation	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Abbott	**Alinity m**	**STI AMP Kit**[1]	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae* *Trichomonas vaginalis* *Mycoplasma genitalium*	Vaginal swabs (patient and clinician collected) Endocervical swabs Female urine (CT, GC and TV only) Male urine Oropharyngeal swabs (CT and GC only) Rectal swabs (CT and GC only) Gynecological specimens in ThinPrep® PreservCyt® Solution (CT and GC only)	Alinity m multi-Collect Specimen Collection Kit simpli-COLLECT Urine and Swab Kits (approved for self-collection and transport of vaginal swabs and urine)	• Up to 14 days at 2 to 30°C • Up to 60 days at -25 to -15°C	• Random access testing • Kit size(s): 384 tests • Age Restrictions: Assay has not been evaluated for patients younger than 14 years of age. • A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher clinical sensitivity compared to endocervical swabs. If endocervical swab specimens test negative, testing with a vaginal swab may be indicated if *M. genitalium* infection is suspected. • Targets: ribosomal RNA (CT) and DNA (GC)	0402U
Abbott	**M2000**	**Abbott RealTime CT/NG**[2]	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae*	Endocervical swab Vaginal swab (patient and clinician collected) Male urethral swab Female and male urine	Abbott multi-Collect Specimen Collection Kit	• Up to 14 days at 2 to 30°C • Up to 90 days at -10°C or colder. Specimens should not undergo more than four freeze/thaw cycles.	• Batched testing • Kit size(s): 192 tests • Age Restrictions: None specified in package insert intended use or limitations. • Targets: two regoins on cryptic plasmid DNA (CT) and the *Opa* gene (GC)	87491 87591
Becton Dickinson	**BD COR or BD MAX**	**CT/GC/TV2**[3]	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae* *Trichomonas vaginalis*	Vaginal swab (patient and clinician collected) Female and male urine Endocervical swab (CT and GC only) Liquid-Based Cytology (LBC) specimens in ThinPrep® PreservCyt®	BD Molecular Swab Collection Kit BD Molecular Urine Transport Kit BD Molecular LBC Sample Buffer Tube	• In BD Molecular Swab or Urine Sample Buffer Tube • Up to 21 days at 2 to 30°C • Up to 4 days after pierceable cap is punctured within 21 days at 2 to 30°C • PreservCyt® LBC Specimen • Up to 14 days at 2 to 30°C prior to transfer to BD Molecular LBC Sample Buffer Tube or Molecular Aliquot Tube • Up to 21 days at 2 to 30°C after transferred to BD Molecular LBC Sample Suffer Tube or Molecular Aliquot Tube • Up to 4 days after pierceable cap is punctured within 21 days at 2 to 30°C	• Batched testing • Kit size(s): 16 - 96 well plates • Age Restrictions: None specified in package insert intended use or limitations. • Targets: two proprietary tagets each for CT (one required for positivity) and GC (both required for positivity)	87590 87490 87660

Manufacturer	Platform	Assay	Type of Claim	Pathogens Detected	Specimen Types Accepted	Specimen Preparation	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Cepheid	**GeneXpert**	**Xpert® CT/NG[4]**	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae*	Endocervical swab Vaginal swab (Patient and clinician collected) Female and male urine Pharyngeal swabs Rectal swabs	Xpert Vaginal/ Endocervical Specimen Collection Kit Xpert Urine Specimen Collection Kit Xpert Swab Specimen Collection Kit	**Urine (unpreserved)** • Up to 3 days at 25 to 30°C • Up to 8 days at 2 to 6°C **Urine (preserved)** • Female: Up to 45 days at 2 to 15°C or up to 3 days at 2 to 30°C • Male: Up to 45 days at 2 to 30°C **Xpert swab specimens** • Up to 60 days at 2 to 30°C	• Random access testing • Kit size(s): 10/120 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Targets: Chromosomal sequences CT1 (CT). NG2 and NG4 (GC)	87491 87591
Hologic	**Panther**	**Aptima Combo 2[5]**	Diagnostic	*Neisseria gonorrhoeae*	Endocervical swabs Vaginal swabs (patient and clinician collected) Throat swabs Rectal swabs Male urethral swabs Female and male urine PreservCyt® Solution liquid Pap specimens	Aptima® Multitest Swab Specimen Kit (vaginal, throat and rectal swab specimens) Aptima® Unisex Swab Specimen Collection Kit (endocervical and male urethral swabs) Aptima® Urine Collection Kit	**Urogenital Swab Specimens (in specimen transport tubes)** • Up to 60 days at 2 to 30°C • Up to 12 months at -20 to -70°C (if frozen within 7 days of collection) **Throat and Rectal Swab Specimens (in specimen transport tubes)** • Up to 60 days at 4 to 30°C • Up to 60 days at -20 to -70°C **Urine Specimens** • Transfer into the Aptima urine specimen transport tube within 24 hours of collection. • Up to 30 days at 2 to 30°C • Up to 12 months at -20 to -70°C (if frozen within 7 days of collection) PreservCyt® Solution Liquid Pap Specimens (transferred to Aptima® specimen transfer tube)	• Random access testing • Kit size(s): 100/250 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Targets: 23S rRNA from CT and 16S rRNA from GC	87491 87591
Hologic	**Panther**	**Aptima *Neisseria gonorrhoeae* Assay[6]**	Diagnostic	*Neisseria gonorrhoeae*	Male Urine	Aptima® Urine Collection Kit	• Transfer specimen into the Aptima urine specimen transport tube within 24 hours of collection. • Up to 30 days at 2 to 30°C • Up to 12 months at -20 to -70°C (if frozen within 7 days of collection)	• Random access testing • Kit size(s): 100 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Target: specific region of 16S ribosomal RNA	87591
Hologic	**Panther**	**Aptima *Chlamydia trachomatis* Assay[7]**	Diagnostic	*Chlamydia trachomatis*	Patient collected vaginal specimens (in a clinical setting) Female and Male Urine specimens	Aptima® Multitest Swab Specimen Kit (vaginal specimen) Aptima® Urine Collection Kit	**Urogenital Swab Specimens (in specimen transport tubes)** • Up to 60 days at 2 to 30°C • Up to 12 months at -20 to -70°C (if frozen within 7 days of collection) **Urine Specimens** • Transfer into the Aptima urine specimen transport tube within 24 hours of collection. • Up to 30 days at 2 to 30°C • Up to 12 months at -20 to -70°C (if frozen within 7 days of collection)	• Random access testing • Kit size(s): 100 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Target: specific region of 16S ribosomal RNA	87491

Manufacturer	Platform	Assay	Type of Claim	Pathogens Detected	Specimen Types Accepted	Specimen Preparation	Specimen Stability	Special Notes (Including Age Restrictions)	CPT Code
Roche	**cobas 4800**	**cobas® CT/NG v2.0 Test**[8]	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae*	Endocervical swabs Vaginal swabs (patient and clinician collected) Female and male urine Cervical specimens collected in PreservCyt® solution.	Cobas® PCR Female Swab Sample Kit cobas® PCR Urine Sample Kit	**Specimens stabilized in cobas® PCR Media** • Up to 12 months at 2 to 30°C **Cervical specimens collected in PreservCyt® solution** • Up to 4 weeks at 2 to 30°C	• Batched testing • Kit size(s): 240/960 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Targets: CT cryptic plasmid DNA, CT genomic *ompA* gene DNA, and GC genomic DNA sequences A and B with DR-9 region	87491 87591
Roche	**cobas 5800/ 6800/8800**	**cobas® CT/NG**[9]	Diagnostic	*Chlamydia trachomatis* *Neisseria gonorrhoeae*	Endocervical swabs Vaginal swabs (patient and clinician collected) Oropharyngeal swabs Anorectal swabs Female and male urine Cervical specimens collected in PreservCyt® solution	cobas® PCR Media	**Specimens stabilized in cobas® PCR Media** • Up to 12 months at 2 to 30°C **Cervical specimens collected in PreservCyt® solution (in collection device)** • Up to 12 months at 2 to 30°C	• Batched testing • Kit size(s): 480 tests • Age Restrictions: Assay has not been evaluated for patients less than 14 years of age. • Targets: CT cryptic plasmid DNA, CT genomic *ompA* gene DNA, and GC genomic DNA sequences A and B with DR-9 region	87491 87591

a. Specimens are clinician collected unless otherwise specified b. Refer to manufacturer package insert for each assay to confirm specimen stability by sample type and specimen collection and/or transport device

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