

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, <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	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	Geenius 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					"Toluidine 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, <i>Mycoplasma genitalium</i>
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, <i>Mycoplasma genitalium</i>
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
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 # 5NU600E000103 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<p>Whole Blood:</p> <ul style="list-style-type: none"> Up to two days at 15–30°C Up to seven days at 2–8°C <p>Serum/Plasma:</p> <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<p>Serum or Plasma:</p> <ul style="list-style-type: none"> 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) <p>Dried Blood Spots:</p> <ul style="list-style-type: none"> Up to ninety days at 2–8°C or 15–30°C (humidity must be <50%) For long term storage: store at –20°C or colder (humidity must be <50%) <p>Oral Fluid Specimens:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<p>Fingerstick Whole Blood: Test immediately after collection</p> <p>Venous Whole Blood: Up to three days at 2–8°C</p> <p>Serum/Plasma:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Up to six hours at 15–30°C Up to 24 hours at 2–8°C Plasma: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> Up to one day at 15–30°C Up to two days at 2–8°C Whole Blood (Serum): <ul style="list-style-type: none"> Up to 12 hours at 15–30°C Up to two days at 2–8°C Serum/Plasma: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Batched testing Kit Size(s): 96 tests LoD: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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-HCV²¹	Diagnostic	Serum/Plasma	150 µL	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Utilizes disposable pipette tips Random access testing Kit size(s): 100 tests Age restrictions: Not evaluated for use in patients <2 years old 	86803
Qidel Ortho-clinical Diagnostics	Vitros Eci, 3600, 5700, XT7600	Vitros Immunodiagnosics Anti-HCV ²⁴	Diagnostic	Serum/Plasma	20 µL + system required dead volume	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<p>Whole Blood: Up to six hours at 2–30°C</p> <p>Serum/Plasma:</p> <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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)	<p>Whole Blood:</p> <ul style="list-style-type: none"> Up to four hours at 15–30°C Up to three days at 2–8°C <p>Serum/Plasma:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)	<p>Whole Blood: Up to four hours at 2–30°C</p>	<ul style="list-style-type: none"> 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 Dx³¹	Diagnostic Viral Load	Serum/Plasma	700–1,200 µL (dependent on tube type)	<p>Prior to plasma/serum preparation: Up to six hours at 2–30°C</p> <p>Centrifuged in primary collection tube:</p> <ul style="list-style-type: none"> • Up to five days at 2–8°C • Up to 24 hours at 2–25°C <p>In secondary tube: Up to 60 days at -20°C (do not exceed three freeze/thaws)</p>	<ul style="list-style-type: none"> • 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 HCV³²	Diagnostic Viral Load	Serum/Plasma	650 µL	<p>Prior to plasma/serum preparation: Up to 24 hours at 2–25°C</p> <p>After separation from cells:</p> <ul style="list-style-type: none"> • Up to six days at 2–8°C • Up to 12 weeks at ≤ -18°C <p>Long-term storage (up to six months): Temperatures at ≤ -60°C are recommended; stable for up to four freeze/thaws.</p>	<ul style="list-style-type: none"> • 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	<p>All Specimens: Up to five days at 2–8°C</p> <p>Serum:</p> <ul style="list-style-type: none"> • Test within five days of collection • To store longer than five days, remove from red cells and keep at -20°C or below <p>Plasma Only: Do not store samples longer than five days at 2-8°C due to potential false reactive results</p>	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Up to five days at 2–8°C • Serum: Once removed from clot or separated from cells or gel, store at -20°C 	<ul style="list-style-type: none"> • 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	<p>Serum</p> <ul style="list-style-type: none"> • Up to five days at 2–8°C • Once removed from clot or separated from cells or gel, store at -20°C <p>Plasma: Up to 24 hours at 2–8°C</p>	<ul style="list-style-type: none"> • Manual batched test • Qualitative and Quantitative • Kit size(s): <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> Up to seven days at 2–8°C Up to 14 days at or below -20°C (no more than two freeze thaw cycles) 	<ul style="list-style-type: none"> Batched testing Qualitative and semi-quantitative Kit size: 480 and 16, 320 tests Target antigens: Cardioliipin, 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: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Batched testing Qualitative and quantitative Kit size(s): 150/500/5,000/10,000 tests Target antigens: Cardioliipin, cholesterol and phosphatidylcholine Age restrictions: None specified 	86592 86593
Teco Diagnostics	Manual	Teco Diagnostics RPR ³⁸	Diagnostic	Serum/Plasma	50 µL	Serum: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Batched testing Qualitative and quantitative Kit size(s): 500 tests Target antigens: Cardioliipin, 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Random access testing Kit size(s): 100/500 tests Qualitative Target antigens: <i>T. pallidum</i> recombinant antigens TpN15, TpN17 and TpN47 Age restrictions: None specified 	86780
Diasorin	Liaison	Treponema Assay ⁴¹	Diagnostic	Serum	220 µL	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Automated random access or batched testing Qualitative Kit size: 200 tests Target antigens: <i>T. pallidum</i> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Test within 48 hours of collection Do not inactivate or freeze 	<ul style="list-style-type: none"> Manual batched testing Qualitative Kit size(s): 100/220 tests Target Antigens: Lyophilized preparation of colored gelatin particles sensitized <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Batched testing Qualitative Kit size(s): 60/200 tests Target antigens: <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Random access testing Qualitative Kit size(s): 300 tests Target antigens: <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Random access testing Qualitative Kit size(s): 200 tests Target antigens: <i>T. pallidum</i> recombinant antigens TpN15 and TpN17 Age restrictions: Not evaluated for use in neonatal patients 	86780
Siemens	Atellica™ IM	Syphilis (Syph) ⁴⁶	Diagnostic	Serum/Plasma	100 µL plus instrument dead volume	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Random access testing Qualitative Kit size(s): 200 tests Target antigens: <i>T. pallidum</i> recombinant antigen TpN17 Age restrictions: None specified 	86780
Siemens	Immulin 2000	Syphilis Screen ⁴⁷	Diagnostic	Serum/Plasma	100 µL	<ul style="list-style-type: none"> Up to three days at 2–8°C Once removed from clot or separated from cells or gel: store at -20°C 	<ul style="list-style-type: none"> Random access testing Qualitative Kit size(s): 200 tests Target antigens: <i>T. pallidum</i> 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	Captia™ Syphilis IgG EIA ⁴⁸	Diagnostic Donor Screening	Serum/Plasma	10-50 µL	Serum: <ul style="list-style-type: none"> Up to five days at 2–8°C Once removed from clot or separated from cells or gel: store at -20°C Plasma: <ul style="list-style-type: none"> Up to 48 hours at 2–8°C Should not be frozen due to fibrin clot formation 	<ul style="list-style-type: none"> Batched testing Qualitative Kit size(s): 96/960 tests Target antigens: Antigens from sonicated <i>T. pallidum</i> cells Age restrictions: None specified 	86780
Trinity Biotech	Manual or automated	Trep-Sure™ Syphilis Total Antibody EIA ⁴⁹ (Phoenix Bio-tech)	Diagnostic	Serum/Plasma	100 µL	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Batched testing Qualitative Kit size(s): 96/960/1920 tests Target antigens: Recombinant <i>T. antigens</i>; exact antigens are not specified Age restrictions: None specified 	86780
Zeus Scientific, Inc.	Manual	FTA-ABS Test System ⁵⁰	Diagnostic	Serum	50 µL	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Batched testing Qualitative Kit size(s): 100 tests Target antigens: <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Automated random access or batched testing Qualitative Kit size(s): 96 tests Target antigens: <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Batched testing Qualitative Kit size(s): 96 tests Target antigens: <i>T. pallidum</i> 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	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Random access testing Kit size(s): 100 tests Target antigens: <ul style="list-style-type: none"> Nontreponemal: Cardiolipin, cholesterol, phosphatidylcholine Treponemal: <i>T. pallidum</i> 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 Kit¹	Diagnostic	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i> <i>Mycoplasma genitalium</i>	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)	<ul style="list-style-type: none"> Up to 14 days at 2 to 30°C Up to 60 days at -25 to -15°C 	<ul style="list-style-type: none"> 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 <i>M. genitalium</i> infection is suspected. Targets: ribosomal RNA (CT) and DNA (GC) 	0402U
Abbott	M2000	Abbott RealTime CT/NG²	Diagnostic	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	Endocervical swab Vaginal swab (patient and clinician collected) Male urethral swab Female and male urine	Abbott multi-Collect Specimen Collection Kit	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Batched testing Kit size(s): 192 tests Age Restrictions: None specified in package insert intended use or limitations. Targets: two regions on cryptic plasmid DNA (CT) and the <i>Opa</i> gene (GC) 	87491 87591
Becton Dickinson	BD COR or BD MAX	CT/GC/TV2³	Diagnostic	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i>	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	<ul style="list-style-type: none"> 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 Buffer Tube or Molecular Aliquot Tube Up to 4 days after pierceable cap is punctured within 21 days at 2 to 30°C 	<ul style="list-style-type: none"> Batched testing Kit size(s): 16 - 96 well plates Age Restrictions: None specified in package insert intended use or limitations. Targets: two proprietary targets 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	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	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	<ul style="list-style-type: none"> • 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	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	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)	<ul style="list-style-type: none"> • 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 <i>Neisseria gonorrhoeae</i> Assay ⁶	Diagnostic	<i>Neisseria gonorrhoeae</i>	Male Urine	Aptima® Urine Collection Kit	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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 <i>Chlamydia trachomatis</i> Assay ⁷	Diagnostic	<i>Chlamydia trachomatis</i>	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)	<ul style="list-style-type: none"> • 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	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	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	<ul style="list-style-type: none"> 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 <i>ompA</i> 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	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>	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	<ul style="list-style-type: none"> 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 <i>ompA</i> 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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7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 | 240.485.2745 | www.aphl.org

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