CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-automated	Various	Monitors hemoglobin level in blood
84830	Ovulation tests by visual color comparison for human luteinizing hormone	Various	Detection of ovulation (optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia
85651	Erythrocyte sedimentation rate – non-automated	Various	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

CPT CODE(S)	TEST NAME		MANUFACTURER	<u>USE</u>
80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW		bott i-STAT Chem8+ Cartridge /hole Blood}	i-STAT Corporation	Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
80048QW	1.	Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc	Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen in whole blood
	2.	Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc	
80051QW	1.	Abaxis Piccolo Blood Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	Measures carbon dioxide, chloride, potassium, and sodium in whole blood
	2.	Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
80053QW	1.	Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	Measures alanine amino transferase, aspartate amino transferase, albumin, total bilirubin, total calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, and urea nitrogen in whole blood
	2.	Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	

CPT CODE(S)	TEST NAME	MANUFACTURI	ER USE
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	Abaxis, Piccolo xpr Analyzer {Lipid Pa Disc} (Whole Blood	anel Reagent	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	 Infopia USA LipidF and glucose measur (LipidPro Lipid Pro 	ing system	
	3. Jant Pharmacal Corp Professional Lipid F Glucose Measuring (LipidPlus Lipid Pro	Profile and System	
	4. Piccolo Point of Car Analyzer (Lipid Par Disc) (Whole Blood	nel Reagent	
	5. Polymer Technolog CardioChek PA An Panels Lipid Panel	alyzer {PTS Systems, Inc.	
	6. Poylmer Technolog Inc., CardioChek He Systems (CardioChe Panel test strips)	ome Test Systems, Inc.	
	7. Poylmer Technolog Inc., CardioChek Pl Systems (PTS Pane test strips)	lus Test Systems, Inc.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	Jant Pharmacal Lipi Profile and Glucose System		Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
80061QW, 82465QW (cont.)(Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	2. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	3. Infopia USA LipidPro lipid profile and glucose measuring system	Infopia Co., Ltd.	
	 Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System 	Infopia Co., Ltd	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW	Alere Cholestech LDX {Whole Blood}	Alere, Inc.	Measures alanine aminotransferase, aspartate aminotransferase, total cholesterol, HDL cholesterol, glucose, and triglycerides in whole blood
80069QW	 Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel) {Whole Blood} 	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and urea nitrogen in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
80305QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems and analytes.	Various	Screening test for the presence/detection of any number of drug classes in urine
81003QW	Dipstick or tablet reagent urinalysis – automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems.	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81003QW, 82044QW, 82570QW	Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine
81003QW, 82044QW, 82570QW, 84703QW	Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	

CPT CODE(S)	TI	EST NAME	MANUFACTURER	<u>USE</u>
81003QW, 82044QW, 82570QW, 84703QW	3.	Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
81007QW	1.	Diatech Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
	2.	Jant Pharmacal Corporation Accutest Uriscreen (Bacteriuria)	Savyon Diagnostics Ltd	
82010QW		S Bioscanner (for OTC use) - for od ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	1.	Abbott Laboratories, Medisense Products Precision TM Xtra TM Advanced Diabetes Management System (K983504)	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
	2.	Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories	
	3.	Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System	Nova Biomedical Corp.	
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	An	axis Piccolo Blood Chemistry alyzer (General Chemistry 13 nel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood

<u>CPT CODE(S)</u>	TEST NAME	MANUFACTURER	<u>USE</u>
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW,	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood
82977QW, 84075QW,			
84155 QW, 84450QW, 84460QW, 84520QW, 84550QW			
82040QW, 82150QW, 82247QW,	Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and
82977QW, 84075QW, 84155QW, 84450QW, 84460QW	Plus Reagent Disc) { whole blood}		total protein levels in whole blood
	 Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood) 	Abaxis, Inc	
82040QW, 82310QW, 82565QW, 82947QW,	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1)	Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82950QW, 82951QW, 82952QW, 84520QW	{Whole Blood}		
82043QW	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW, 82570QW	Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine))	ACON Laboratories, Inc.	Semi-quantitative measurement of albumin and creatinine in urine
82120QW, 83986QW	Litmus Concepts FemExam TestCard (from vaginal swab)	Litmus Concepts, Inc.	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82271QW	1. Aerscher Hemaprompt FG	Aerscher Diagnostics	Rapid screening test to detect the presence of gastric occult blood

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
82271QW (cont.)	2. SmithKline Gastroccult	SmithKline	Rapid screening test to detect the presence of gastric occult blood
82271QW, 83986QW	Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates
82274QW G0328QW	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems.	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	 Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood} 	Abaxis, Inc.	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and urea nitrogen (BUN) in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc	
82435QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Abbott i-STAT 6+ Cartridge {Whole Blood}	i-Stat Corporation	Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
82465QW (Contact your Medicare carrier for claims instructions.)	1. Advanced Care	Johnson & Johnson	Cholesterol monitoring
	Boehringer Mannheim Accu-Chek InstantPlus Cholesterol	Boehringer Mannheim	
	3. ChemTrak AccuMeter	ChemTrak	
	4. ENA.C.T Total Cholesterol Test	ActiMed Laboratories, Inc.	
	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	

CPT CODE(S)	<u>T</u>	EST NAME	MANUFACTURER	<u>USE</u>
82465QW (cont.) (Contact your Medicare carrier for claims instructions.)	6.	Lifestream Technologies Cholesterol Monitor	Lifestream Technologies, Inc.	Cholesterol monitoring
	7.	Lifestream Technologies Personal Cholesterol Monitor	Lifestream Technologies, Inc.	
	8.	Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	
	9.	PTS Bioscanner Test Strips Chloesterol	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW	1.	Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+Glu test strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, and glucose in whole blood
	2.	Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+Glu test strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW	1.	Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	2.	Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL test strips)		
	3.	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	
	4.	Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	

CPT CODE(S)	<u>T</u>]	EST NAME	MANUFACTURER	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW (cont.)	5.	Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	6.	Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL test strips)	Polymer Technology Systems, Inc.	
	7.	Roche Diagnostics AccuChek Instant Plus Dual Testing System	Roche Diagnostics	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	1.	Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
	2.	Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	3.	Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	4.	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 80061QW	Cholestech LDX	Cholestech Corp.	Measures total cholesterol, glucose, HDL cholesterol, and triglycerides in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	Wako APOLOWAKO Analyzer (Whole Blood)	Wako Chemicals USA, Inc.	Measures total cholesterol, hemoglobin A1c, glucose, and triglycerides in whole blood
82465QW(Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW	Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)}	Abaxis, Inc.	Measures cholesterol, HDL cholesterol, glucose, alanine aminotransferase, aspartate aminotransferase, and triglycerides in whole blood
82523QW	Ostex International Osteomark NTX Point of Care Prescription Home Use	Ostex International Inc.	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine
82565QW	Abbott i-STAT Crea Cartridge {Whole Blood}	i-Stat Corporation	Quantitative measurement of creatinine in whole blood
82565QW, 84520QW	Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of creatinine and urea nitrogen in whole blood

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW	 Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel) {Whole Blood} 	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, aspartate aminotransferase, creatinine, gamma glutamyltransferase, glucose and urea nitrogen in whole blood
	 Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel) {Whole Blood} 	Abaxis, Inc.	
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)	Unipath Limited	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception
82947QW, 82950QW, 82951QW, 82952QW	1. HemoCue B-Glucose Photometer	HemoCue, Inc.	Measures glucose levels in whole blood
82947QW, 82950QW, 82951QW, 82952QW (cont.)	 HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer 	HemoCue, Inc.	Measures glucose levels in whole blood
	3. Abbott i-STAT G Cartridge {Whole Blood}	i-Stat Corporation	
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW	Abbott i-STAT EC4+ Cartridge {Whole Blood}	i-Stat Corporation	Measures glucose, potassium, sodium, and hematocrit in whole blood
82962, 82465QW (Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	LXN Duet Glucose Control Monitoring System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period

<u>CPT CODE(S)</u>	TEST NAME	MANUFACTURER	<u>USE</u>
82962, 82985QW (cont.)	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period
82985QW	LXN Fructosamine Test System	LXN Corporation	Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)
82947 QW	 Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips) 	Polymer Technology Systems, Inc.	Measures glucose in whole blood
	 Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips) 	Polymer Technology Systems, Inc.	
	3. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips	Polymer Technology Systems, Inc.	
	4. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips)	Polymer Technology Systems, Inc.	
83001QW	Acon Laboratories, Inc. FSH Menopause Predictor Test	ACON Laboratories, Inc.	Detects follicle stimulating hormone in urine
	 Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use} 	ACON Laboratories, Inc.	
	3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use}	ACON Laboratories, Inc.	
	4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test	Applied Biotech, Inc.	
	5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device	ACON Laboratories, Inc.	

<u>CPT CODE(S)</u>	TES'	T NAME	MANUFACTURER	<u>USE</u>
83001QW (cont.)		Genosis Fertell Female Fertility Pest	Genosis, Inc.	Detects follicle stimulating hormone in urine
	7. G	Senua Menopause Monitor Test	Genua 1944 Inc	
		ynova Healthcare MenocheckPro Professional Use)	Applied Biotech, Inc.	
83036QW		axis-Shield Afinion AS100 analyzer	Axis-Shield Poc	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
		alere Technologies AS, Alere Afinion AS101 Analyzer	Axis-Shield Poc	
	3. B	Bayer AICNow+ Professional Use	Bayer Healthcare, LLC	
		iemens Medical Diagnostics OCA Vantage Analyzer	Siemens Healthcare Diagnostics, Inc.	
		TS Diagnostics A1CNow + trofessional Use	Polymer Technology Systems, Inc.	
	6. Si	iemens DCA 2000 Analyzer	Siemens Healthcare Diagnostics, Inc.	
	7. Si	iemens DCA 2000+ Analyzer	Siemens Healthcare Diagnostics, Inc	
83037QW		sayer A1CNow+ {For rofessional use}	Bayer Corp.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
	2. B	Sayer A1C Now SelfCheck	Bayer Healthcare, Llc.	
		SIO-RAD in2it (II) System Analyzer Prescription Home Use	Bio-Rad Laboratories, Inc.	
		Sio-Rad Micromat II Hemoglobin Alc Prescription Home Use Test	Bio-Rad Laboratories, Inc.	
		Cholestech GDX A1C Test Prescription Home Use)	Cholestech Corporation	
		rovalis Diagnostics Glycosal™ IbA1c Test	Provalis Diagnostics Ltd.	

<u>CPT CODE(S)</u>	TEST NAME	MANUFACTURER	<u>USE</u>
83037QW (cont.)	7. Provalis Diagnostics In2it In- Office Analyzer (II) Prescription Home Use Test System	Provalis Diagnostics Ltd	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
83516QW	 Rapid Pathogen Screening, Inc. InflammaDry 	Rapid Pathogen Screening, Inc.	Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye.
	 Quidel Corporation, InflammaDry* 	Quidel Corporation	
82044QW	Beckman Coulter ICON Microalb	Beckman Coulter, Inc.	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
	2. Boehringer Mannheim Chemstrip Micral	Boehringer Mannheim	
	3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test	Diagnostic Chemicals Limited	
	 Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick) 	Diagnostic Chemicals Limited (USA)	
	 Genzyme Diagnostics OSOM ImmunoDip Urinary Albumin Test 	Genzyme Diagnosites	
	6. Roche Diagnostics Chemstrip Micral (urine dipstick)	Roche Diagnostics Corporation	
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	ESA Biosciences, Inc.	Quantitative measurement of blood lead in whole blood
83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips)	Polymer Technology Systems, Inc.	Measures HDL cholesterol, triglycerides, and glucose in whole blood
83721 QW	Polymer Technology Systems Cardiochek PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
83861QW	TearLab Corporation TearLab Osmolarity System	TearLab Corporation	Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.
83880QW	 Biosite Triage Meter {Whole Blood} Biosite Triage Meter Plus {Whole Blood} 	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
83986QW	All qualitative color comparison pH testing - body fluids (other than blood)	Various	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates
83986QW	 Dale Medical Products, Inc. RightLevel pH 	EZ-NG, LLC.	Gastric pH detection (acid-base balance)
	2. Dale Medical Products, Inc. RightSpot pH	EZ-NG, LLC.	
	3. RightBio Metrics, RightSpot Infant pH Indicator	Right BioMetrics	
	4. RightBio Metrics, RightSpot pH Detector	Right BioMetrics	
	 RightBio Metrics, RightSpot pH Indicator 	Right BioMetrics	
83986QW	1. FemTek pHEM-ALERT®	FemTek, LLC	Vaginal pH detection (acid-base balance)
	2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test	Common Sense Ltd.	
	3. Common Sense Ltd. VA-Sense Kit	Common Sense, Ltd.	
	4. Common Sense Ltd. VS-Sense Test {qualitative}	Common Sense, Ltd	
	5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test	Lil' Drug Store Products Inc.	
	6. Teco Diagnostics OBGYN-VpH Vaginal pH Screening Kit	Teco Diagnosites	
84295QW, 84132QW, 85014QW	Abbott i-STAT E3+ Cartridge {Whole Blood}	i-Stat Corporation	Measures potassium, sodium, and hematocrit in whole blood

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
84443QW	 Aventir Biotech LLC, Forsure TSH Test {Whole Blood} 	Screening Devices Canada Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
	2. BTNX, Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette	Screening Devices Canada Inc.	
	3. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette	Screening Devices Canada Inc.	
	 CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood} 	Screening Devices Canada Inc.	
	Germaine Laboratories, Inc. AimStep Thyroid Screen {whole blood}	Screening Devices Canada Inc.	
	6. ThyroTec, Inc. ThyroTest Whole Blood TSH Test	ThyroTec, Inc.	
	7. Jant Pharmacal Accutest TSH {Whole Blood}	Screening Devices Canada Inc.	
	8. Qualigen, Inc. FastChek TSH {Whole blood}	Screening Devices Canada Inc.	
84450QW, 84520QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp.	Diagnosis of pregnancy
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	AimStrip Hb Hemoglobin (Hb) Testing System	Acon Laboratories, Inc.	Measures hemoglobin level in whole blood
	2. Alere HemoPoint H2 System	Stanbio Laboratory	

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
85018QW (cont.)	3. Biosafe Laboratories, Inc., Anemiapro Self Screener	Biosafe Laboratories, Inc.	Measures hemoglobin level in whole blood
	4. Clarity HbCheck Hemoglobin Testing System	Acon Laboratories, Inc.	
	5. HemoCue Donor Hemoglobin Checker System HemoCue	HemoCue, Inc.	
	6. HemoCue Hemoglobin System	HemoCue, Inc.	
	7. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)	HemoCue, Inc.	
	8. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	HemoCue, Inc.	
	9. HemoCue Hb 301 System	HemoCue, Inc.	
	10. GDS Diagnostics HemoSite Meterfor hemoglobin	GDS Technology, Inc.	
	 GDS Technology STAT-Site MHgb Test System 	GDS Technology	
85025QW	Sysmex XW-100*	Sysmex America, Inc.	Quantitative automated hematology analyzer intended using anticoagulated venous whole blood for WBC count, RBC count, hematocrit, hemoglobin, platelet count and WBC differential
85576QW	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation
85610QW (Contact your Medicare carrier for claims instructions.)	1. AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use}	Alere San Diego, Inc.	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	2. AvoSure PT System (prescription home use)	Avocet Medical, Inc.	
	3. AvoSure Pro (professional use)	Avocet Medical, Inc.	
	4. CoaguChek PST for Prothrombin Time	Boehringer Mannheim Corporation	

CPT CODE(S)	<u>T</u>]	EST NAME	MANUFACTURER	<u>USE</u>
85610QW (cont.) (Contact your Medicare carrier for claims instructions.)	5.	Coag-Sense Prothrombin Time (PT/INR) Monitoring system (Professional use)	CoaguSense, Inc.	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	6.	CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)	CoaguSense, Inc.	
	7.	HemoSense INRatio System	HemoSense, Inc.	
	8.	ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	9.	International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	10	. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	11	. Lifescan Harmony™ INR Monitoring System Prescription Home Use and Professional Use	Lifescan, Inc.	
	12	. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	
	13	. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	14	. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	
	15	. Roche Diagnostics CoaguChek XS	Roche Diagnostics	
	16	. Roche Diagnostics CoaguChek XS Plus System	Roche Diagnostics	

CPT CODE(S)	TEST NAME	<u>MANUFACTURER</u>	<u>USE</u>
86294QW	Bion Diagnostic Sciences BTA stat Test (for home use)	Bion Diagnostic Sciences, Inc.	Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients
	2. LifeSign Status BTA	Polymedco, Inc.	
86308QW	Screening test for mononucleosis (mono) categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems.	Various	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
86318QW	Immunoassay for <i>Helicobacter pylori</i> antibodies, single step method, categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems.	Various	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
86386QW	 Alere NMP22 BladderChek Test (Prescription Home Use) and (Professional Use) 	Alere	Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients
	 Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use 	Maritech, Inc.	
86618QW	Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay	Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to Borrelia burgdorferi (causative agent of Lyme disease) in whole blood
86701QW	1. bioLytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood}	BioLytical Laboratories, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
	 OraSure Technologies OraQuick Rapid HIV-1 Antibody Test 	OraSure Technologies, Inc	
	3. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood	OraSure Technologies, Inc.	

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
86701QW(cont.)	4. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)	Trinity Biotech	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
86780QW	Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood}	Diagnostics Direct LLC	Immunochromatographic assay for the detection of <i>Treponema pallidum</i> (syphilis) antibodies in whole blood
G0433QW	1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood , venipuncture whole blood and/or oral fluid specimens
	2. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid}	OraSure Technologies, Inc.	
	3. Chembio Diagnostic Systems, Inc, DPP HIV 1/2 Assay {Oral Fluid}	Chembio Diagnostic Systems, Inc.	
	 Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood} 	Chembio Diagnostic Systems, Inc.	
86803QW, G0472QW	OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference Panel	Orasure Technologies Inc.	Qualitative immunoassay to detect antibodies to hepatitis C virus in fingerstick whole blood and venipuncture whole blood specimens
87077QW	Ballard Medical Products CLOtest	Ballard Medical Products	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
	2. Delta West CLOtest	Delta West Tri-Med Specialties	
	3. GI Supply HP-FAST	Mycoscience Labs, Inc.	
	4. GI Supply, Div. Chek-Med Systems HP One	GI Supply	
	5. Jant Accutest Rapid Urease test (H. pylori detection)	ARJ Medical, Inc.	
	6. Medical Instruments Corporation Pronto Dry H. pylori	Medical Instruments Corporation	
	7. Serim Pyloritek Test Kit	Serim	

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
87210QW	Stesans Maybe?Mom Mini Ovulation Microscope	LEC Associates	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)
	2. O2 Unlimited Donna Ovulation Tester	O2 Unlimited Corp.	
87338QW	Meridian Bioscience Immunocard STAT! HpSA (Stool)	Meridian Bioscience, Inc.	Immunoassay for rapid, qualitative detection of <i>Helicobacter pylori</i> antigens in stool
87389QW[from December 5, 2014 to December 31, 2014], 87806QW [on and after January 1, 2015], G0475QW [on and after January 1, 2017]	Orgenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}		Detects antigen to HIV-1, and antibodies to HIV-1 and HIV-2 in whole blood
87449QW	ZymeTx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87502QW	 Alere i Influenza A & B Test {Direct Nasal swab only} 	Alere Scarborough, Inc.	Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology
	 RocheMolecular, cobas Liat System (cobas Liat Influenza A/B Assay) 	IQuum, Inc.	Real-time RT-PCR assay for detection and discrimination of Influenza A and Influenza B in nasopharyngeal swab specimens
87631QW	 Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress) Roche Molecular, cobas Liat 	Cepheid	Detection of influenza A, influenza B and respiratory syncytial virus (RSV) viral RNA by reverse transcriptase polymerase chain reaction assay
	System cobas Liat Influenza A/B & RSV Assay	IQUUM, INC.	
87633QW	BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids){Nasopharyngeal Swabs}	BioFire Diagnostics, LLC	Multiplexed nucleic acid test for detection and identification of multiple respiratory pathogen nucleic acids in nasopharyngeal swabs
87634QW	Alere i System Respiratory Syncytial Virus	Alere Scarborough, Inc.	Qualitative detection of RSV viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media utilizing isothermal nucleic acid amplification technology

CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>
87651QW	1. Alere i Instrument	Alere Scarborough, Inc.	Detection of Group A Strep bacterial nucleic acids utilizing isothermal nucleic acid amplification technology
	2. Roche Molecular, cobas Liat System	IQuum, Inc.	Detection of Streptococcus group A utilizing nucleic acid purification and polymerase chain reaction (PCR) technology (automation and integration of sample purification, nucleic acid amplification, and detection of the target sequence using real-time PCR) to detect Streptococcus pyogenes
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B
87804QW	Alere Influenza A & B Test (For use with nasal Swabs only.)	Alere Scarborough, Inc.	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
	 Alere BinaxNow Influenza A & B Card {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens} 	Alere Scarborough, Inc.	
	3. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}	Becton, Dickinson and Company	
	4. BinaxNow Influenza A & B Test, K092223	Binax, Inc	
	5. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	
	 BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126 	Binax, Inc.	
	7. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}	Binax, Inc.	

<u>CPT CODE(S)</u>	T NAME <u>MANUFACTURER</u> <u>USE</u>	
87804QW (cont.)	asopharyngeal swabs} Corporation swab, nasopl	etection of influenza type A and type B antigens from nasal arryngeal (NP) swab, nasal wash, nasal aspirate or nasal at does differentiate between influenza types A and B
	Ienry Schein OneStep+ Influenza Alere Scarborough, Inc.	
	ifeSign LLC, Status Flu A+B Princeton Biomeditech Nasal and Nasopharyngeal Corporation wabs}	
	AcKesson Consult Influenza A & Princeton Biomeditech S {Nasal and Nasopharyngeal Corporation wabs}	
	Princeton Biomeditech Cest {Nasal and Nasopharyngeal wabs} Princeton Biomeditech Corporation	
	BM Princeton Biomedical Corp. mmunoCard STAT! Flu A&B Nasal and Nasopharyngeal wabs} Princeton Biomeditech Corporation	
	Quidel Quickvue Influenza A+B Quidel Corporation	
	Quidel Sofia 2 {Sofia Influenza Quidel Corporation +B FIA}	
	ekisui Diagnostics LLC, OSOM Princeton Biomeditech Ultra Flu A&B Test {Nasal and Corporation Uasopharyngeal Swabs}	
	ofia Analyzer and Influenza A+B Quidel Corporation IA	
	ofia Analyzer and Influenza A+B Quidel Corporation (IA (for user with nasal swabs and asopharyngeal swabs)	
87804QW	Sinax Now® Flu A Test Binax, Inc. Qualitative dispecimens	etection of influenza type A antigen in nasopharyngeal
	TNX, Inc. Rapid Response SA Scientific, Inc. nfluenza A Test Cassette	

CPT CODE(S)	TEST !	NAME	MANUFACTURER	<u>USE</u>
87804QW (cont.)	3. Early	yDetect Pro Influenza A Test	SA Scientific, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	4. SAS Test	Scientific SAS Influenza A	SA Scientific, Inc.	
87804QW	1. Bina	ax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
		NX, Inc. Rapid Response uenza BTest Cassette	SA Scientific, Inc.	
	3. Early	yDetect Pro Influenza B Test	SA Scientific, Inc.	
	4. SAS Test	Scientific SAS Influenza B	SA Scientific, Inc.	
87807QW	1. Aler	e BinaxNOW RSV Card	Alere Scarborough, Inc.	Rapid immunoassay for the qualitative detection of RSV antigen
	Dete naso	Veritor System for Rapid ection of RSV (For use with opharyngeal cimens) [Includes a reader]	Becton, Dickinson and Company	
	3. Bina	ax NOW RSV Test (K021687)	Binax, Inc.	
		ax NOW RSV Test 32166/A005)	Binax, Inc.	
	5. Fishe Test	er Scientific Sure-Vue RSV	SA Scientific, Inc.	
	_	grated Biotechnology Quick RSV Test	Integrated Biotechnology Corp.	
	7. Quid	del Quick Vue RSV Test	Quidel Corporation	
	8. SA S	Scientific SAS RSV Alert	SA Scientific, Inc.	
	9. Sofia	a RSV	Quidel Corp.	
	10. Quid	del Sofia 2 {Sofia RSV FIA}	Quidel Corp.	
87808QW		zyme OSOM Trichomonas id Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs
		isui Diagnostics, LLC OSOM homonas Rapid Test	Genzyme Corp.	

	CPT CODE(S)	TEST NAME	MANUFACTURER	<u>USE</u>	
87809QW		1. AdenoPlus (human eye fluid)	Rapid Pathogen Screening, Inc.	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid	
		2. Quidel, AdenoPlus {Tear fluid}*	Quidel Corp.		
		3. Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid	
	87880QW	Streptococcus group A antigen detection by immunoassay with direct optical observation categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived test systems.	Various	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever	
	87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori antigens</i> in stool specimens	
	87905QW	Gryphus Diagnostics BVBlue	Gryphus Diagnosites, LLC	Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginais</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.	
	89300 QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	 Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility 	Embryotech Laboratories, Inc.	Screening test to measure sperm concentration	
		2. SpermCheck Vasectomy	Princeton BioMeditech Corp.	Detects sperm in semen following a vasectomy	
	89321QW	Fertell Male Fertility Test	Genosis Ltd.	Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml	