

# TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<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

This list includes updates from Change Request 7349

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW 80048QW	Abbott i-STAT Chem8+ Cartridge {Whole Blood}	i-STAT Corporation	Measures ionized calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
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.	

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80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	1. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)	Infopia Co., Ltd.	
	3. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	
	4. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
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
80069QW	1. 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	

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Phamatech QuickScreen One Step Amphetamine Test	Phamatech	Screening test for the presence/detection of amphetamine in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	2. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	
	3. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	ACON Laboratories, Inc.	
	4. Phamatech QuickScreen One Step THC Screening Test	Phamatech	
	5. Phamatech At Home Drug Test (Model 9078)	Phamatech	
	6. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	7. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9073)	Phamatech	Screening test for the presence/detection of cocaine metabolites in urine

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G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Phamatech At Home Drug Test (Model 9073T)	Phamatech	Screening test for the presence/detection of cocaine metabolites in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. Phamatech QuickScreen One Step Cocaine Screening Test 1. Phamatech At Home Drug Test (Model 9068)	Phamatech Phamatech	Screening test for the presence/detection of methamphetamines in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Phamatech QuickScreen One Step Methamphetamine Test 1. DyanGen NicCheck II Test Strips	Phamatech DynaGen, Inc.	Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Mossman Associates, Inc. NicCheck I Test Strips 1. Phamatech At Home Drug Test (Model 9083)	Mossman Associates, Inc. Phamatech	Screening test for the presence/detection of opiates in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Phamatech QuickScreen One Step Opiate Screening Test	Phamatech	

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9133)	Phamatech	Screening test for the presence/detection of phencyclidine (PCP) in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	
	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	
	3. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	
	4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	
	5. Worldwide Medical Corporation, First Check@ Home Drug Test (THC-COC)	Worldwide Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine

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G0434QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. ADC CLIA Waived Multiple Drug Test Card	ADC	Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and PCP in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card	Advantage Diagnostics Corporation	
	3. Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Phamatech At Home Drug Test (Model 9150T)	Phamatech	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, and opiates in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET)	Worldwide Medical Corporation	Screening test for the presence/detection of THC, cocaine metabolites, opiates and methamphetamines in urine

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine
	2. accutest Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	3. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine
	4. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	5. iCassette Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	6. RediScreen Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	7. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}	Innovacon, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine

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G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, MDMA, opiates, and PCP in urine
	3. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	
	4. Innovacon Integrated E-Z Split Key Cup II {Professional Use}	Innovacon, Inc.	
	5. Noble Medical Inc. Split-Specimen Cup	ACON Laboratories, Inc.	
	6. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II	Biosite Inc.	
	7. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use}	Innovacon, Inc.	
	8. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Branan Medical Corporation ToxCup Drug Screen Cup	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Innovacon Multi-Clin Drug Screen Test Device	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Inverness Medical Innovations Signify ER Drug Screen	Biosite Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamine, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	3. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device	Innovacon, Inc.	
	4. Abbott Diagnostics Signify ER Drug Screen Test	Innovacon, Inc.	
	1. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamine, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	5. Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	6. Insight Medical Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	7. Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	

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G0434QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	8. Millenium Laboratories Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	9. Physicians' Test Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	10. On the Spot Drug Testing Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	11. Quik Test USA, Inc. Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	12. Screen Tox Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	13. Total Diagnostic Solutions Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Aventir Biotech LLC Home Check Multiple Drug Test Cup	Tianjin New Bay Bioresearch Co. Ltd.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, morphine, oxycodone, PCP and tricyclic antidepressants in urine
	2. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
	3. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Amedica Biotech Amedica Drug Screen Test Cup	Amedica Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Amedica Biotech AmediCheck Instant Test Cup	Amedica Biotech, Inc.	
	3. Ameditech, Inc ImmuTest Drug Screen Cup	Biosite Inc.	
	4. Branran Medical Corporation Fastest II Drug Screen Dipstick Test	Branran Medical Corporation	
	5. Branran Medical Corporation, FasTox Multiple Drug Dipcard	Branran Medical Corporation	
	6. Branran Medical Corporation, QuickTox Drug Screen Dipcard	Branran Medical Corporation	
	7. CLIAwaived, Inc. Rapid Drug Test	Biosite Inc.	
	8. Express Diagnostics, DrugCheck Waive Cup	Biosite Inc.	
	9. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
	10. Jant Pharmacal Corporation ACCUTEST Drug Test Cup	Amedica Biotech, Inc	
	11. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup	Biosite Inc.	
	12. NexScreen LLC, NexScreen Cup	Amedica Biotech, Inc.	
	13. Noble Medical Inc. NOBLE 1 Step Cup {OTC}	Biosite Inc.	

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G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	14. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup	Biosite Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	15. Twin Spirit, Inc. DrugSmart Cup	Amedica Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
	16. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}	Biosite Inc.	
	1. American Screening Corporation OneScreen Drug Test Cards	UCP Biosciences, Inc.	
	2. American Screening Corporation OneScreen Drug Test Cups	UCP Biosciences, Inc.	
	3. American Screening Corporation Reveal Multi-Drug Testing Cups	UCP Biosciences, Inc.	
	4. Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards	UCP Biosciences, Inc.	
	5. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups	UCP Biosciences, Inc.	
	6. UCP Biosciences, Inc. Drug Screening Test Cards	UCP Biosciences	
	7. UCP Biosciences, Inc. Multiple Drug Screen Cups	UCP Biosciences	
	8. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards	UCP Biosciences, Inc.	

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G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) 80178QW	American Bio Medica Rapid TOX	American Bio Medica Corp.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
81003QW	ReliaLAB Inc. InstaRead Lithium System {fingertick or venipuncture whole blood} 1. Biosys Laboratories Optima Urine Analyzer 2. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated 3. Cole-Taylor Marketing Inc. CTI-120 Urine Strip Analyzer 4. Consult diagnostics Urine Analyzer 5. Henry Schein OneStepPlus Urine Analyzer 6. Hypoguard Diascreen® Urine Chemistry Analyzer 7. Jant Pharmacal Corporation Accustrip URS Reader 8. Physician Sales & Service, Inc. PSS Select Urine Analyzer 9. Roche Diagnostics Urisys 1100 Urine Analyzer 10. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Akers Laboratories, Inc.  BioSys Laboratories, Inc.  Boehringer Mannheim Corporation  Acon Laboratories, Inc.  BioSys Laboratories, Inc. Macherey-Nagel GmbH & Co., Kg. Hypoguard USA, Inc.  BioSys Laboratories, Inc.  Roche Diagnostics Corp.  Roche Diagnostics/Boehringer Mannheim Corporation	Measures lithium blood levels in whole blood  Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections

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81003QW (cont.)	11. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	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	1. 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	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	Diatech Diagnostics Uriscreeen (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.
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	1. Abbott Laboratories, Medisense Products Precision™ Xtra™ 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.	

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82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW	1. Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood
82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)  Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}	Abaxis, Inc.  Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82043QW	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW	1. 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	
	4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)	Diagnostic Chemicals Limited (USA)	
	5. Genzyme Daignostics OSOM ImmunoDip Urinary Albumin Test	Genzyme Diagnostics	

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82044QW(cont.)	6. Roche Diagnostics Chemstrip Mical (urine dipstick)	Roche Diagnostics Corporation	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. OraSure Technologies Q.E.D. A- 150 Saliva Alcohol Test	OraSure Technologies, Inc.	Quantitative determination of alcohol (ethanol) in saliva
	2. OraSure Technologies Q.E.D. A- 350 Saliva Alcohol Test	OraSure Technologies, Inc.	
	3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test	STC Technologies Inc.	
	4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	STC Technologies Inc.	
82120QW, 83986QW	1. 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
	2. Quidel QuickVue Advance pH and Amines Test	Quidel Corporation	
82271QW	1. Aerscher Hemaprompt FG	Aerscher Diagnostics	Rapid screening test to detect the presence of gastric occult blood
	2. SmithKline Gastrocult	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	1. American IVD Biotechnology Services Inc. FOB/CRC Advanced+	Ind Diagnostic Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay

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# TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW G0328QW(cont.)	2. Beckman Coulter Hemocult ICT (K961062) & (K080812)	Beckman Coulter, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	3. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc.	
	4. BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)	Ind Diagnostic Inc.	
	5. BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (iFOBT)	Teco Diagnostics	
	6. BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc.	
	7. Care Diagnostics Clarity iFOB Test	Care Diagnostics, Inc.	
	8. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	Wampole Laboratories	
	9. Clearview Ultra FOB Test	RAC Medical Group, Inc.	
	10. Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT)	Immunostics, Inc.	
	11. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	
	12. Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
	13. Enterix InSure II Fecal Immunochemical Test	Enterix, Inc.	
	14. Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	
	15. Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test	New Bay Bioresearch Co. Ltd.	
	16. Henry Schein One Step+ iFOBT	Immunostics, Inc.	
	17. immoCare Fecal Occult Blood Test	Care Diagnostic, Inc.	

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# TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW	18. Immunostics, Inc., hema-screen	Immunostics, Inc.	Detection of blood in feces from whatever cause, benign or malignant
G0328QW(cont.)	Specific Immunochemical Fecal Occult Blood Test		(colorectal cancer screening) by immunoassay
	19. InSure Quik Fecal	Enterix, Inc.	
	Immunochemical Test (F.I.T.)		
	20. Inverness Medical Clearview	New Bay Research Co. Ltd.	
	iFOBT Complete Fecal Occult Blood Test		
	21. Jant Pharmacal Accutest	New Bay Bioresearch Co.	
	Immunological Fecal Occult Blood Test (iFOBT)	Ltd.	
	22. Occultech Fecal Occult Blood	YD Diagnostics Corp.	
	Rapid Test		
	23. Polymedco Poly Stat OC-light FOB	Polymedco, Inc.	
	Test*		
	24. Teco Rapid Fecal Occult Blood	Teco Diagnostics	
	(FOB) Card Test		
82374QW,	1. Abaxis Piccolo Blood Chemistry	Abaxis, Inc.	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium,
82435QW,	Analyzer (Piccolo Metlyte 8 Panel		total carbon dioxide and urea nitrogen (BUN) in whole blood
82550QW,	Reagent Disc) {Whole Blood}		
82565QW,			
82947QW,			
84132QW,			
84295QW,			
84520QW	2. Abaxis Piccolo xpress Chemistry	Abaxis, Inc.	
	Analyzer (Piccolo Metlyte 8 Panel		
	Reagent Disc) {Whole Blood}		

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# TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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
	2. 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.	
	6. Lifestream Technologies Cholesterol Monitor	Lifestream Technologies, Inc.	
	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 Cholesterol	Polymer Technology Systems, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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 CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 82962	1. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	Measures total cholesterol and monitors blood glucose levels
	2. Roche Diagnostics AccuChek Instant Plus Dual Testing System		
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 CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW	1. Cholestech LDX	Cholestech Corp.	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	2. Infopia USA LipidPro lipid profile and glucose measuring system Wako APOLOWAKO Analyzer (Whole Blood)	Infopia CO., Ltd. 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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	1. Abaxis Piccolo Blood 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
	2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW	1. 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
	2. 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 82947QW, 82950QW, 82951QW, 82952QW	Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)  1. HemoCue B-Glucose Photometer  2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer 3. Abbott i-STAT G Cartridge {Whole Blood}	Unipath Limited  HemoCue, Inc.  HemoCue, Inc.  i-Stat Corporation	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception  Measures glucose levels in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW 82985QW	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.)	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)
	Roche Diagnostics Accutrend Plus System {fingertstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	1. 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
	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	
83001QW	1. Acon Laboratories, Inc. FSH Menopause Predictor Test	ACON Laboratories, Inc.	Detects follicle stimulating hormone in urine
	2. 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.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83001QW(cont.)	6. Genosis Fertil Female Fertility Test	Genosis, Inc.	Detects follicle stimulating hormone in urine
	7. Genua Menopause Monitor Test	Genua 1944 Inc	
	8. Synova Healthcare MenocheckPro (Professional Use)	Applied Biotech, Inc.	
83036QW	1. Axis-Shield Afinion AS100 Analyzer	Axis-Shield Poc As	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	2. Siemens Medical Diagnostics DCA Vantage Analyzer	Siemens Healthcare Diagnostics, Inc.	
	3. Siemens DCA 2000 Analyzer	Siemens Healthcare Diagnostics, Inc.	
	4. Siemens DCA 2000+ Analyzer	Siemens Healthcare Diagnostics, Inc	
83037QW	1. Bayer A1CNow+ {For professional 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. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories	
	3. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	
	4. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	
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	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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
83721QW	Polymer Technology Systems CardioChek PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood
83880QW	1. Biosite Triage Meter {Whole Blood} 2. 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	1. FemTek pHEM-ALERT® 2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test 3. Common Sense Ltd. VA-Sense Kit 4. Common Sense Ltd. VS-Sense Test {qualitative} 5. Lil' Drug Store Products Inc. Vagi- Screen Vaginal Health Test	FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Common Sense, Ltd	Vaginal pH detection (acid-base balance)
84295QW, 84132QW, 85014QW 84443QW	Abbott i-STAT E3+ Cartridge {Whole Blood} 1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood} 2. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette	Lil' Drug Store Products Inc. i-Stat Corporation Screening Devices Canada Inc. Screening Devices Canada Inc.	Measures potassium, sodium, and hematocrit in whole blood  Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults

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84443QW (cont.)	3. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {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
	4. ThyroTec, Inc. ThyroTest Whole Blood TSH Test	ThyroTec, Inc.	
	5. Jant Pharmacal Accutest TSH {Whole Blood}	Screening Devices Canada Inc.	
	6. Qualigen, Inc. FastChek TSH {Whole blood}	Screening Devices Canada Inc.	
84520QW, 84450QW 84450QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood} Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
85014QW	Wampole STAT-CRIT Hct	Bayer Corp.	Diagnosis of pregnancy
		Wampole Laboratories	Screen for anemia
85018QW	1. Biosafe Laboratories, Inc., Anemiapro Self Screener	Biosafe Laboratories, Inc.	Measures hemoglobin level in whole blood
	2. HemoCue Donor Hemoglobin Checker System HemoCue	HemoCue, Inc.	
	3. HemoCue Hemoglobin System	HemoCue, Inc.	
	4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)	HemoCue, Inc.	
	5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	HemoCue, Inc.	
	6. HemoCue Hb 301 System	HemoCue, Inc.	

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85018QW(cont.)	7. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	Measures hemoglobin level in whole blood
85576QW	8. GDS Technology STAT-Site MHgb Test System	GDS Technology	
	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation
85610QW (Contact your Medicare carrier for claims instructions.)	1. AvoSure PT System (prescription home use)	Avocet Medical, 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 Pro (professional use)	Avocet Medical, Inc.	
	3. CoaguChek PST for Prothrombin Time	Boehringer Mannheim Corporation	
	4. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)	Coaguscense, Inc.	
	5. HemoSense INRatio System	HemoSense, Inc.	
	6. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	7. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	8. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	9. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.	
	10. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	

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85610QW(cont.) (Contact your Medicare carrier for claims instructions.)	11. Roche Diagnostics CoaguChek PST  12. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics  Roche Diagnostics	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
86294QW	13. Roche Diagnostics CoaguChek XS  1. Bion Diagnostic Sciences BTA stat Test (for home use)  2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Roche Diagnostics  Bion Diagnostic Sciences, Inc.  Maritech, 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
86308QW	1. Aceava Mono II {Whole Blood}  2. Aceava Mono Cassette {For whole Blood} 3. Acon Mononucleosis Rapid Test Device {Whole Blood} 4. Acon Mononucleosis Rapid Test Strip {Whole Blood} 5. Applied Biotech SureStep Mono Test (whole blood) 6. BioStar Aceava Mono Test (whole blood) 7. Cardinal Health SP Brand Rapid Test Mono {Whole Blood} 8. Clearview MONO Whole Blood, K042272/A013	Biosite Inc.  Princeton BioMeditech Corp. ACON Laboratories, Inc. ACON Laboratories, Inc. Applied Biotech, Inc. Wyntek Diagnostics, Inc. Cardinal Health Inverness Medical Professional Diagnostics	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

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86308QW (cont.)	9. Clearview MONO Whole Blood, K042272/A016	Innovacon, Inc.	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
	10. Clearview Mono-plus II	Applied Biotech, Inc.	
	11. Consult Diagnostics Mononucleosis Cassette {Whole Blood}	Princeton BioMeditech Corp.	
	12. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	13. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	14. Icon Mono	Beckman Coulter, Inc.	
	15. Immuno Detector Mono {Whole Blood}	Princeton BioMeditech Corp.	
	16. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	17. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	18. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	19. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
	20. LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
	21. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	22. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
	23. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW (cont.)	24. PerMaxim RediScreen Mononucleosis {Whole Blood}	ACON Laboratories, Inc.	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
	25. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	26. Poly Stat Mono Test {Whole Blood}	Innovacon, Inc.	
	27. ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only)	Biosite Inc.	
	28. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	
	29. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation	
	30. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	31. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	
	32. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	
	33. Signify Mono Cassette {Whole Blood}	Innovacon, Inc.	
	34. Signify Mono Whole Blood	Inverness Medical Professional Diagnostics	
	35. Stanbio Rely Mono Rapid Test {Whole Blood}	Innovacon, Inc.	
	36. Wampole Mono-Plus WB	Wampole Laboratories	
	37. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	38. Wyntek Signify Mono Test	Wyntek Diagnostics, Inc.	
86318QW	1. Abbott FlexPak HP Test for whole blood	SmithKline Diagnostics, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood}	Innovacon, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86318QW (cont.)	3. Abbott TestPack Plus H. pylori (for whole blood)	Abbott Laboratories	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	4. Acon® H. pylori Test Device	ACON Laboratories, Inc.	
	5. Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test	Alfa Scientific Designs, Inc.	
	6. Applied Biotech SureStep H. pylori WB Test (whole blood)	Applied Biotech, Inc.	
	7. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood	Beckman Coulter, Inc.	
	8. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)	Cortecs Diagnostics Limited	
	9. Cardinal Health SP Brand Rapid Test H. pylori (K990892)	Applied Biotech Inc.	
	10. Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood} (K024350/A15)	Innovacon, Inc.	
	11. Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood}	Princeton BioMeditech Corp.	
	12. EarlyDetect H. Pylori Whole Blood Rapid Test	Alpha Scientific Designs, Inc.	
	13. Fisher Healthcare Sure-Vue H. pylori Test {Whole Blood}	Innovacon, Inc.	
	14. Germaine Laboratories, Aimstep H. pylori {whole blood}	ACON Laboratories, Inc.	
	15. Henry Schein One Step+ H. Pylori Rapid Test Device (Whole Blood)	Innovacon, Inc.	
	16. Immunostics Detector H. Pylori WB (H. pyloi Antibody Test) {Whole Blood}	Princeton BioMeditech Corp.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86318QW (cont.)	17. Instant Technologies iScreen H.pylori Rapid Test Device	ACON Laboratories, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	18. Inverness Medical Clearview H. pylori Test {whole blood}	Innovacon, Inc.	
	19. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	
	20. Inverness Medical Signify H. Pylori Whole Blood	Innovacon, Inc.	
	21. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	22. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	
	23. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	
	24. Polymedco Poly Stat H. Pylori Test (Whole Blood)	Innovacon, Inc.	
	25. Pro-Advantage by NDC H. pylori Device (Whole Blood)	Innovacon, Inc.	
	26. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel Corporation	
	27. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation	
	28. Remel RIM® A.R.C. H.pylori Test	Remel	
	29. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.	
	30. Trinity Uni-Gold™ H.pylori	Trinity Biotech	
	31. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Applied Biotech, Inc.	
86618QW	Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay	Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86701QW	<ol style="list-style-type: none"> <li>1. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test</li> <li>2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood</li> <li>3. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)</li> </ol>	<p>OraSure Technologies, Inc.</p> <p>OraSure Technologies, Inc.</p> <p>Trinity Biotech</p>	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
G0433QW	<ol style="list-style-type: none"> <li>1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}</li> <li>2. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}</li> </ol>	<p>OraSure Technologies, Inc.</p> <p>Chembio Diagnostic Systems, Inc.</p>	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
87077QW	<ol style="list-style-type: none"> <li>1. Ballard Medical Products CLOtest</li> <li>2. Delta West CLOtest</li> <li>3. GI Supply HP-FAST</li> <li>4. GI Supply, Div. Chek-Med Systems HP One</li> <li>5. Medical Instruments Corporation Pronto Dry H. pylori</li> <li>6. Serim Pyloritek Test Kit</li> </ol>	<p>Ballard Medical Products</p> <p>Delta West</p> <p>Tri-Med Specialties</p> <p>Mycoscience Labs, Inc.</p> <p>GI Supply</p> <p>Medical Instruments Corporation</p> <p>Serim</p>	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
87210QW	<ol style="list-style-type: none"> <li>1. Stesans Maybe?Mom Mini Ovulation Microscope</li> <li>2. O2 Unlimited Donna Ovulation Tester</li> </ol>	<p>LEC Associates</p> <p>O2 Unlimited Corp.</p>	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)
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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	1. Quidel Quickvue Influenza A+B Test	Quidel Corporation	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
	2. BinaxNow Influenza A & B Test, K092223	Binax, Inc	
	3. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	
	4. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.	
	5. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}	Binax, Inc.	
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza A Test Cassette*	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza A Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza A Test	SA Scientific, Inc.	
87804QW	1. Binax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza B Test Cassette*	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza B Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87807QW	1. Binax NOW RSV Test (K021687)	Binax, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. Binax NOW RSV Test (K032166/A005)	Binax, Inc.	
	3. Fisher Scientific Sure-Vue RSV Test	SA Scientific, Inc.	
87808QW	4. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs
	5. Quidel Quick Vue RSV Test	Quidel Corporation	
	6. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87809QW	Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs
	Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	
	1. Abbott Signify Strep A Test (from throat swab only)	Wyntek Diagnostics, Inc.	
87880QW	2. Abbott Laboratories Signify Strep A Dipstick	Innovacon, Inc.	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
	3. Acon® Strep A Rapid Strip Test	ACON Laboratories, Inc.	
	4. Acon® Strep A Twist Rapid Test	ACON Laboratories, Inc.	
	5. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	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
	6. Beckman Coulter ICON DS Strep A Test	Princeton BioMeditech Corp.	
	7. Beckman Coulter ICON SC Strep A Test	ACON Laboratories, Inc.	
	8. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	ACON Laboratories, Inc.	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
	9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A	Beckman Coulter, Inc.	
	Immunochemical Strep A Test		

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	10. Becton Dickinson BD Chek Group A Strep A Test	Innovacon, Inc.	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
	11. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	12. Binax NOW Strep A Test	Binax, Inc.	
	13. BioStar Aceava Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	14. Biotechnostix Rapid Response Strep A Rapid Test Device	Acon Laboratories Co.	
	15. Biotechnostix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	
	16. BTNX, Inc. Strep A Rapid Test	Sa Scientific, Inc.	
	17. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	Applied Biotech Inc.	
	18. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon, Inc.	
	19. CLIA waived inc Rapid Strep A Test	Sa Scientific, Inc.	
	20. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	21. DE Healthcare Products TruView Strep A Cassette Test	ACON Laboratories, Inc.	
	22. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	
	23. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	24. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	25. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	26. Genzyme OSOM Ultra Strep A Test	Genzyme General	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
	27. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	28. Germaine Laboratories Strep ADM Tower	Germaine Laboratories, Inc.	
	29. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	30. Henry Schein Inc, One Step+ Strep A Dipstick Test	Henry Schein	
	31. Immunostics Detector Strep A Direct	ACON Laboratories, Inc.	
	32. Immunostics Immuno/Strep A Detector	ACON Laboratories, Inc.	
	33. Instant Technologies iStrep Strep A	ACON Laboratories, Inc.	
	34. Inverness Medical BioStar Aceava Strep A Test	Innovacon, Inc.	
	35. Inverness Medical BioStar Aceava Strep A Twist	Innovacon, Inc.	
	36. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)	Innovacon, Inc.	
	37. Jant Pharmal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	38. Jant Pharmal Accustrip Strep A Value+ Test Strip	Innovacon, Inc.	
	39. Jant Pharmal Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	40. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	41. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	

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87880QW (cont.)	42. LifeSign LLC Status Strep A	Princeton BioMeditech	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
	43. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	44. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	
	45. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	46. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon, Inc.	
	47. PSS Consult Diagnostics Strep A Dipstick	Innovacon, Inc.	
	48. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon, Inc.	
	49. PSS World Medical Select Diagnostics Strep A Twist	Innovacon, Inc.	
	50. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	51. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc.	
	52. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	53. QuickVue® Dipstick Strep A	Quidel Corporation	
	54. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	55. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013)	Quidel Corporation	
	56. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	57. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	

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87880QW (cont.)	58. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax, Inc.	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
	59. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	
	60. Stanbio QuStick Strep A	Stanbio Laboratory	
	61. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc.	
	62. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
87905QW	1. Gryphus Diagnostics BVBBlue	Gryphus Diagnostics, LLC	Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.
87899QW	2. Genzyme Diagnostics OSOM BVBBlue Test	Gryphus Diagnostics, LLC	
	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens
89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	1. 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

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