

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1115	Date: November 24, 2006
	Change Request 5404

Subject: New Waived Tests

I. SUMMARY OF CHANGES: This instruction informs contractors of new waived tests approved by the Food and Drug Administration under the Clinical Laboratory Improvement Amendments of 1988. Since these tests are marketed immediately after approval, the Centers for Medicare and Medicaid Services must notify its contractors of the new tests so that the contractors can accurately process claims.

New/Revised Material

Effective Date: January 1, 2007

Implementation Date: January 2, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1115	Date: November 24, 2006	Change Request: 5404
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SUBJECT: New Waived Tests

Effective Date: January 1, 2007

Implementation Date: January 2, 2007

I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below are the latest tests approved by the Food and Drug Administration as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the attached list (i.e., CPT codes: 81002, 81025, 82270, 82272, G0394, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

CPT Code/Modifier	Effective Date	Description
82274QW, G0328QW	June 15, 2006	Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test
87899QW	June 30, 2006	Gryphus Diagnostics BVBlue
83655QW	September 18, 2006	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)

The new waived CPT/HCPCS code, 83655QW, has been assigned for the blood lead test performed using the ESA Biosciences LeadCare II Blood Lead Testing System (whole blood).

For 2007, the new CPT/HCPCS code 87808QW (Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis) replaces the code 87899QW that was assigned to the Genzyme OSOM Trichomonas Rapid Test.

As mentioned in Transmittal 1062, Change Request 5292 dated September 22, 2006, the HCPCS code G0107 (Colorectal Cancer Screening; fecal-occult blood test, 1-3 simultaneous determinations) was retired effective January 1, 2007 and has been replaced with CPT code 82270 [Blood, occult, by peroxidase activity (e.g., Guaiac) qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)].

For 2007, the new CPT/HCPCS code G0394 is for Blood occult test (e.g., guaiac), feces, for single determination for colorectal neoplasm (i.e., patient was provided three cards or single triple card for consecutive collection). This code does not require a QW modifier.

B. Policy: The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as

III. PROVIDER EDUCATION

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B	DME	FI	CARRIE	DMERC	RHI	Shared-System Maintainers				OTHER
		MACC	MACC					FIS	MSS	VMS	CWF	
5404.7	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticle shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Kathy Todd (410) 786-3385

Post-Implementation Contact(s): Kathy Todd (410) 786-3385

VI. FUNDING

A. For TITLE XVIII Contractors, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. For Medicare Administrative Contractors (MAC), use only one of the following statements:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachment

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 G0394 (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 5404

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9063)	Phamatech	Screening test for the presence/detection of amphetamine in urine
	2. Phamatech QuickScreen One Step Amphetamine Test	Phamatech	
80101QW (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 At Home Drug Test (Model 9078)	Phamatech	
	5. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	6. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
80101QW (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
	2. Phamatech At Home Drug Test (Model 9073T)	Phamatech	

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* Newly added waived test system

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) (cont.)	3. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	Screening test for the presence/detection of cocaine metabolites in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9068)	Phamatech	Screening test for the presence/detection of methamphetamines in urine
	2. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	DynaGen NicCheck I Test Strips	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
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9083)	Phamatech	Screening test for the presence/detection of opiates in urine
	2. Phamatech QuickScreen One Step Opiate Screening Test	Phamatech	
80101QW (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 in urine

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.) (cont.)	2. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	Screening test for the presence/detection of phencyclidine in urine
80101QW (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) 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	
80101QW (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 phencyclidine (PCP) in urine
	2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card	Advantage Diagnostics Corporation	
	3. Alatec Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80101QW (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, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine
80101QW (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 cannabinoids (THC), cocaine metabolites, opiates and methamphetamines in urine
80101QW (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, cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and phencyclidine 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.	
	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.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80101QW (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, cannabinoids (THC), cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and phencyclidine in urine
	2. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	
80101QW (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, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, and phencyclidine in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, phencyclidine and tricyclic antidepressants in urine
	2. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
81002, 82570QW	1. Bayer Multistick Pro 7G Reagent Strips	Bayer 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 and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
	2. Bayer Multistick Pro 10LS Reagent Strips	Bayer Diagnostics	
	3. Bayer Multistick Pro 11 Reagent Strips	Bayer Diagnostics	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81003QW	<ol style="list-style-type: none"> 1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated 2. Biosys Laboratories Optima Urine Analyzer 3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated 4. Hypoguard Diascreen® Urine Chemistry Analyzer 5. Physician Sales & Service, Inc. PSS Select Urine Analyzer 6. Roche Diagnostics Urisys 1100 Urine Analyzer 7. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer 8. Teco Diagnostics URITEK TC-101 Urine Strip Reader 9. ThermoBiostar™ PocketChem™ UA 	<p>Bayer</p> <p>Biosys Laboratories</p> <p>Boehringer Mannheim Corporation</p> <p>Hypoguard USA, Inc.</p> <p>Biosys Laboratories, Inc.</p> <p>Roche Diagnostics Corp.</p> <p>Roche Diagnostics/Boehringer Mannheim Corporation</p> <p>Teco Diagnostics</p> <p>ThermoBiostar™</p>	<p>Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections</p>
81003QW, 82570QW	Bayer Clinitek Status Urine Chemistry Analyzer	Bayer Healthcare, LLC	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 semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
81007QW	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.

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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, Inc.	Monitoring of blood glucose levels and measures ketones in whole blood
	2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories, Inc	
82044QW, 82570QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine	Bayer Corp.	Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage
	2. Bayer Diagnostics/ MICROALBUSTIX™ Reagent Strip	Bayer Inc.	
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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82271QW (cont.)	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. Beckman Coulter Hemocult ICT	Beckman Coulter, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	2. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	Wampole Laboratories	
	3. Clearview Ultra FOB Test	RAC Medical Group, Inc.	
	4. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	
	5. Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
	6. immoCare Fecal Occult Blood Test	Care Diagnostic, Inc.	
	7. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test*		
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.	

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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.) (cont.)	8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	Cholesterol monitoring
	9. PTS Bioscanner Test Strips Chloesterol	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 80061QW	1. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid 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	Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood

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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	Cholestech LDX	Cholestech	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels 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
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	Measures glucose levels in whole blood
	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
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)
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	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	
	6. Genua Menopause Monitor Test	Genua 1944 Inc	
	7. Synova Healthcare MenocheckPro (Professional Use)	Applied Biotech, Inc.	
83036QW	1. Axis-Shield Afinion AS100 Analyzer	Axis-Sheild 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. Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c)	Bayer Corp.	
	3. Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c)	Bayer Corp.	
	4. Metrika A1c Now™ - Professional Use (K000887)	Metrika, Inc.	
	5. Metrika A1c Now for Professional Use (K020235)	Metrika, Inc.	
	6. Metrika DRx® HbA1c (Professional Use Test System)	Metrika, Inc.	
83037QW	1. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories	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

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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>
83037QW (cont.)	2. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	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
	3. Metrika A1c Now for Prescription Home Use (K020234)	Metrika, Inc.	
	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	
83518QW	1. Beckman Coulter ICON Microalb	Beckman Coulter	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. 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	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood
83721QW	Polymer Technology Systems Cardiochek PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	FemTek pHEM-ALERT®	FemTek, LLC	Vaginal pH detection (acid-base balance)
84443QW	ThyroTec, Inc. ThyroTest Whole Blood TSH Test	ThyroTes, Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
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
84478QW	PTS, Inc. Bioscanner 2000 for Triglycerides	Polymer Technology Systems, Inc.	Measures triglycerides 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	1. Biosafe Laboratories, Inc., Anemiapro Self Screener 2. HemoCue Donor Hemoglobin Checker System HemoCue 3. HemoCue Hemoglobin System 4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood) 5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	Biosafe Laboratories, Inc. HemoCue HemoCue HemoCue HemoCue	Measures hemoglobin level in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
85018QW (cont.)	6. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	Measures hemoglobin level in whole blood
	7. GDS Technology STAT-Site MHgb Test System	GDS Technology	
85576QW	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. HemoSense INRatio System	HemoSense, Inc.	
	5. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	7. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	8. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.	
	9. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	
	10. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	11. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics Corporation	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86294QW	1. 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. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Maritech, Inc.	
86308QW	1. Acon Mononucleosis Rapid Test Device {Whole Blood}		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
	2. Acon Mononucleosis Rapid Test Strip {Whole Blood}		
	3. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	4. BioStar Aceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	5. Clearview Mono-plus II	Applied Biotech, Inc.	
	6. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	7. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	8. Icon Mono	Beckman Coulter, Inc.	
	9. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	Acon Laboratories, Inc.	
	10. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	Acon Laboratories, Inc.	
	11. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	12. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	13. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	

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86308QW (cont.)	14. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, 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		
	15. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.			
	16. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation			
	17. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation			
	18. RAC Medical Clarity MONO Mononucleosis Rapid Test Device { Whole Blood }	Acon Laboratories, Inc.			
	19. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.			
	20. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics			
	21. Wampole Mono-Plus WB	Wampole Laboratories			
	22. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.			
	23. 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 TestPack Plus H. pylori (for whole blood)		Abbott Laboratories	
		3. Acon® H. pylori Test Device		ACON Laboratories, Inc.	
4. Applied Biotech SureStep H. pylori WB Test (whole blood)		Applied Biotech, Inc.			
5. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood		Beckman Coulter, Inc.			
6. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)		Cortecs Diagnostics Limited			

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86318QW (cont.)	7. Cardinal Health SP Brand Rapid Test H. pylori	Applied Biotech Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood		
	8. Germaine Laboratories, Aimstep H. pylori {whole blood}	Acon Laboratories, Inc.			
	9. Instant Technologies iScreen H.pylori Rapid Test Device	Acon Laboratories, Inc.			
	10. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.			
	11. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech			
	12. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.			
	13. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.			
	14. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel			
	15. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation			
	16. Remel RIM® A.R.C. H.pylori Test	Remel			
	17. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.			
	18. Trinity Uni-Gold™ H.pylori	Trinity BioTech			
	19. 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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86701QW	1. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
	2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood	OraSure Technologies, Inc.	
	3. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)	Trinity Biotech	
86703QW	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 oral fluid, fingerstick whole blood and venipuncture whole blood specimens
87077QW	1. 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. Medical Instruments Corporation Pronto Dry H. pylori	Medical Instruments Corporation	
	6. Serim Pyloritek Test Kit	Serim	
87210QW	1. 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.	
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
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

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87804QW	1. Quidel Quickvue Influenza A+B Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does differentiate between influenza types A and B
	2. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	
	3. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.	
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. 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. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	
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-View RSV Test	SA Scientific, Inc.	
	4. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	5. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87808QW	Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW	1. Abbott Signify Strep A Test (from throat swab only)	Wyntek Diagnostics, 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
	2. Acon® Strep A Rapid Strip Test	Acon Laboratories, Inc.	
	3. Acon® Strep A Twist Rapid Test	Acon Laboratories, Inc.	
	4. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	5. Beckman Coulter ICON DS Strep A Test	Princeton BioMeditech Corp.	
	6. Beckman Coulter ICON SC Strep A Test	Acon Laboratories, Inc	
	7. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	Acon Laboratories, Inc.	
	8. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter	
	9. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	10. Binax NOW Strep A Test	Binax	
	11. BioStar Aceeva Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	12. Biotechnostix Rapid Response Strep A Rapid Test Device	Acon Laboratories Co.	
	13. Biotechnostix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	
	14. Cardinal Health SP Brand Rapid Test Strep A Dipstick	Applied Biotech Inc.	
	15. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	16. DE Healthcare Products TruView Strep A Cassette Test	Acon Laboratories, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	17. Fisher HealthCare Sure-Vue Strep A (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
	18. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	19. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	20. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	21. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	22. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	23. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	24. Immunostics Detector Strep A Direct	Acon Laboratories, Inc	
	25. Immunostics Immuno/Strep A Detector	Acon Laboratories, Inc	
	26. Instant Technologies iStrep Strep A	Acon Laboratories, Inc	
	27. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	28. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	29. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	30. LifeSign LLC Status Strep A	Princeton BioMeditech	
	31. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	32. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>		
87880QW (cont.)	33. Meridian Diagnostics ImmunoCard STAT Strep A (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		
	34. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.			
	35. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc			
	36. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation			
	37. QuickVue® Dipstick Strep A	Quidel Corporation			
	38. Quidel QuickVue® In-Line Strep A	Quidel Corporation			
	39. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.			
	40. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.			
	41. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax			
	42. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.			
	43. Stanbio QuStick Strep A	Stanbio Laboratory			
	44. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc			
	45. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.			
	87899QW	Gryphus Diagnostics BVBlue*		Gryphus Diagnostics, LLC	Enzyme activity test for use in the detection of vaginal fluid specimens for sialidase activity, 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	Meridian Bioscience Immunocard STAT! HpSA {Stool}		Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens

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89300QW(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

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