CMS Guidance Document	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Executive Guidance Number 0623	**Date: December 3, 2008**
Planned Web Site Address http://www.cms.hhs.gov/manuals/	**Release planned: December 17, 2008**

PROGRAM AREA: Laboratory Services

SUBJECT: New Waived Tests

APPLIES TO: Clinical Diagnostic Laboratories

I. SUMMARY OF DOCUMENT: This instruction informs contractors of new waived tests approved by the Food and Drug Administration under 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. This Recurring Update Notification (RUN) can be found in Chapter 16, ý 70.8 of the Internet Only Manual.

New / Revised Material
Effective Date: January 1, 2009
Implementation Date: January 5, 2009

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)
STATUS: R=REVISED, N=NEW, D=DELETED.

Status	**CHAPTER/SECTION/SUBSECTION/TITLE**
R	16//70/70.8 Certificate of Waiver

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Herb Kuhn/(410)786-4164/CMSO
Agency POC	Kathleen Todd/(410)786-3385/CMSO/SCG/DLS

IV. TYPE:

	Audit Guide
X	**Change Request**
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: Contractors need to be informed of new waived CLIA covered tests when they are approved by the FDA. The new tests are approved on a flow basis by the FDA which gives no advance notice of the approval to CMS. The tests are valid as soon as they are approved. We need this PM to notify the contractors to update their files with the attached list. This PM will list the new test(s). This information must be sent immediately to the contractors because the new tests are marketed as soon as the FDA approves them. That means a physician could submit a claim for a newly approved test shortly after CMS is informed of the FDA approval of the new test.

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal:	Date:	Change Request: 6287

SUBJECT: New Waived Tests

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

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	Effective Date	Description
83036QW	October 11, 2007	Siemens Medical Diagnostics DCA Vantage Analyzer
81003QW	May 28, 2008	Henry Schein OneStepPlus Urine Analyzer
82274QW G0328QW	July 1, 2008	Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test
82274QW G0328QW	July 1, 2008	Beckman Coulter Hemoccult ICT (K080812)
82274QW G0328QW	July 22, 2008	BTNX Inc.Rapid Response Immunological Fecal Occult Blood Test (IFOBT)
80101QW	July 31, 2008	Aventir Biotech LLC Home Check Multiple Drug Cup Test
80101QW	August 18, 2008	American Bio Medica Rapid TOX
83986QW	September 18, 2008	Common Sense Ltd. VA-SENSE Kit

For 2009, the new CPT code 87905 was developed for infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid) testing. Therefore, the CPT code assigned to the Gryphus Diagnostics BVBlue test and the Genzyme Diagnostics OSOM BVBlue Test is changed to 87905QW with an effective date of January 1, 2009.

This RUN can be found in Chapter 16, § 70.8 of the Internet Only Manual.

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 waived complexity under CLIA

in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6287.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	X			X						
6287.2	The Medicare contractor shall permit the use of code 87905QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2009.	X			X					X	
6287.3	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X			X						
6287.4	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.	X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6287.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ 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 one week of the availability of	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. 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.										

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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

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

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) and Carriers*:

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

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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 6287

TESTS GRANTED WAIVED STATUS UNDER CLIA

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

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	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. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
	3. 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
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)	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	Acon Laboratories, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	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	
	3. Phamatech QuickScreen One Step Cocaine 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 9068)	Phamatech	Screening test for the presence/detection of methamphetamines in urine
	2. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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
	2. Phamatech QuickScreen One Step PCP Screening 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) 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	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	Screening test for the presence/detection of phencyclidine (PCP) in urine
	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 PCP in urine
	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	
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, 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 THC, cocaine metabolites, opiates and methamphetamines in urine

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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, 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.	
	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	
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, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and PCP in urine
	2. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Innovacon	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and PCP in urine
	4. Innovacon Integrated E-Z Split Key Cup II {Professional Use}	Innovacon	
	5. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use}	Innovacon	
	6. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon	
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, THC, cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, and PCP in urine
80101QW (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, methylenedioxymethamphetamine, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	2. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device	Innovacon, Inc.	
	3. Abbott Diagnostics Signify ER Drug Screen Test	Innovacon, Inc.	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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, THC, cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Branan Medical Corporation, FasTox Multiple Drug Dipcard	Branan Medical Corporation	
	3. Branan Medical Corporation, QuickTox Drug Screen Dipcard	Branan Medical Corporation	
	4. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant View 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, methylenedioxymethamphetamine, morphine, PCP and tricyclic antidepressants in urine
	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	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.	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	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

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	American Bio Medica Rapid TOX*	American Bio Medica Corp.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methylenedioxymethamphetamine, methamphetamines, methadone, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
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	
81003QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Bayer	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
	2. Biosys Laboratories Optima Urine Anlayzer	Biosys Laboratories	
	3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Boehringer Mannheim Corporation	
	4. Henry Schein OneStepPlus Urine Analyzer*	Macherey-Nagel GmbH & Co., Kg.	
	5. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81003QW (cont.)	6. Physician Sales & Service, Inc. PSS Select Urine Analyzer	Biosys Laboratories, 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
	7. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	8. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer MannheimCorporation	
	9. Teco Diagnostics URITEK TC-101 Urine Strip Reader	Teco Diagnostics	
	10. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
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.
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	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82042QW, 82150QW, 82247QW, 82977QW, 84075QW, 84157QW, 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
	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	
82042QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 1) {Whole Blood}	Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82044QW, 82570QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine	Bayer Corp.	Semi-quantitative measurement of microablumin and creatinine in urine for the detection of patients at risk for developing kidney damage
	2. Bayer Diagnostics/ MICROALBUSTIX™ Reagent Strip	Bayer Inc.	
82247QW, 84075QW, 84157QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and total protein levels in whole blood

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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 Gastroccult	SmithKline	
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 Hemoccult ICT (K961062) & (K080812)*	Beckman Coulter, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	2. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc.	
	3. BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (IFOBT)*	Teco Diagnostics	
	4. BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc	
	5. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	Wampole Laboratories	
	6. Clearview Ultra FOB Test	RAC Medical Group, Inc.	

This list includes updates from Change Request 6287
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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82274QW G0328QW (cont.)	7. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	8. Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
	9. Enterix Insure II Fecal Immunochemical Test	Enterix, Inc.	
	10. Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test*	New Bay Bioresearch Co. Ltd.	
	11. immoCare Fecal Occult Blood Test	Care Diagnostic, Inc.	
	12. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	Immunostics, In	
	13. InSure Quik Fecal Immunochemical Test (F.I.T.)	Enterix, Inc.	
	14. OcculTech Fecal Occult Blood Rapid Test	YD Diagnositcs Corp.	
	15. Teco Rapid Fecal Occult Blood (FOB) Card Test	Teco Diagnostics	
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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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82465QW (cont.) (Contact your Medicare carrier for claims instructions.)	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	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.	
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		

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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
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
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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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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 in whole blood
82523QW	Ostex International Osteomark NTX Point of Care Prescription Home Use	Ostex International Inc.	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine
82565QW, 84520QW	Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of creatinine and urea nitrogen in whole blood
82042QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84157 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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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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	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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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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. Genosis Fertell Female Fertility Test	Genosis, Inc.	
	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-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. Siemens Medical Diagnostics DCA Vantage Analyzer*	Siemens Medical Solutions Diagnostics	
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.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
83037QW (cont.)	5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
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	
83520QW	HemoCue Albumin 201 System	Hemocue AB	Quantitative measurement of albumin in urine by immunoassay
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
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

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
83880QW	1. Biosite Triage Meter {Whole Blood} 2. Biosite Triage Meter Plus {Whole Blood}	Biosite Incorporated	Quantitative measurement of b-type natuiretic 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. VA-Sense Kit*	FemTek, LLC Common Sense, Ltd.	Vaginal pH detection (acid-base balance)
84443QW	1. ThyroTec, Inc. ThyroTest Whole Blood TSH Test 2. Jant Pharmacal Accutest TSH {Whole Blood}	ThyroTes, Inc. 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
84443QW (cont.)	3. Qualigen, Inc. FastChek TSH {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
84520QW, 84450QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
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	Biosafe Laboratories, Inc. HemoCue	Measures hemoglobin level in whole blood

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
85018QW (cont.)	3. HemoCue Hemoglobin System	HemoCue	Measures hemoglobin level in whole blood
	4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)	HemoCue	
	5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	HemoCue	
	6. HemoCue Hb 301 System	HemoCue	
	7. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	
	8. 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.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
85610QW (cont.) (Contact your Medicare carrier for claims instructions.)	9. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	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
	10. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	11. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	
	12. Roche Diagnostics CoaguChek XS	Roche Diagnostics	
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
86294QW (cont.)	2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	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. Acon Mononucleosis Rapid Test Device {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
	2. Acon Mononucleosis Rapid Test Strip {Whole Blood}	Acon Laboratories, Inc.	
	3. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	4. BioStar Acceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	5. Cardinal Health SP Brand Rapid Test Mono {Whole Blood}	Cardinal Health	
	6. Clearview MONO Whole Blood, K042272/A013	Inverness Medical Professional Diagnostics	
	7. Clearview MONO Whole Blood, K042272/A016	Innovacon	
	8. Clearview Mono-plus II	Applied Biotech, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW (cont.)	9. Genzyme Contrast Mono (whole blood)	Genzyme 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
	10. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	11. Icon Mono	Beckman Coulter, Inc.	
	12. Immuno Detector Mono {Whole Blood}	Princeton Biomeditech Corp.	
	13. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	Acon Laboratories, Inc.	
	14. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	Acon Laboratories, Inc.	
	15. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	16. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
	17. LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
	18. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	19. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
	20. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
	21. PerMaxim RediScreen Mononucleosis {Whole Blood}	Acon Laboratories, Inc.	
	22. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	23. Poly Stat Mono Test {Whole Blood}	Innovacon	
	24. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW (cont.)	25. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation	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
	26. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}	Acon Laboratories, Inc.	
	27. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	
	28. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	
	29. Signify Mono Cassette {Whole Blood}	Innovacon	
	30. Signify Mono Whole Blood	Inverness Medical Professional Diagnostics	
	31. Stanbio Rely Mono Rapid Test{Whole Blood}	Innovacon, Inc.	
	32. Wampole Mono-Plus WB	Wampole Laboratories	
	33. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	34. 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 *Helicobacter pylori* in whole blood
	2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood}	Innovacon	
	3. Abbott TestPack Plus H. pylori (for whole blood)	Abbott Laboratories	
	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.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86318QW (cont.)	7. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood	Beckman Coulter, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood
	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	
	11. Diagnostic Test Group Clarity H. pylori Rapid Test Device {Whole Blood}	Princeton Biomedical Corp.	
	12. Fisher Healthcare Sure-Vue H. pylori Test {Whole Blood}	Innovacon	
	13. Germaine Laboratories, Aimstep H. pylori {whole blood}	Acon Laboratories, Inc.	
	14. Henry Schein One Step+ H. Pylori Rapid Test Device (Whole Blood)	Innovacon	
	15. Immunostics Detector H. Pylori WB (H. pyloi Antibody Test) {Whole Blood}	Princeton Biomeditech Corp.	
	16. Instant Technologies iScreen H.pylori Rapid Test Device	Acon Laboratories, Inc.	
	17. Inverness Medical Clearview H. pylori Test {whole blood}	Innovacon	
	18. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	
	19. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	20. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86318QW (cont.)	21. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood
	22. Polymedco Poly Stat H. Pylori Test (Whole Blood)	Innovacon	
	23. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel	
	24. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation	
	25. Remel RIM® A.R.C. H.pylori Test	Remel	
	26. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.	
	27. Trinity Uni-Gold™ H.pylori	Trinity BioTech	
	28. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Applied Biotech , Inc.	
86618QW	Wampole PreVue™ *B. burgdorferi* Antibody Detection Assay	Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to Borrelia burgdorferi (causative agent of Lyme disease) in whole blood
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	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86703QW	1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood and venipuncture whole blood specimens
	2. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	
87077QW	1. Ballard Medical Products CLOtest	Ballard Medical Products	Presumptive identification of *Helicobacter pylori* 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
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, nasal aspirate or nasal specimens that does differentiate between influenza types A and B

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87804QW (cont.)	2. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
	3. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.	
	4. 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. 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-Vue RSV Test	SA Scientific, Inc.	
	4. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	5. Quidel Quick Vue RSV Test	Quidel Corp.	
	6. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87808QW	Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of *Trichomonas vaginalis* antigens from vaginal swabs

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87809QW	Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid
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. Abbott Laboratories Signify Strep A Dipstick	Innovacon	
	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.	
	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.	
	9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter	
	10. Becton Dickinson BD Chek Group A Strep A Test	Innovaconn, Inc.	
	11. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	12. Binax NOW Strep A Test	Binax	
	13. BioStar Acceava 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.	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	16. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	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
	17. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon	
	18. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	19. DE Healthcare Products TruView Strep A Cassette Test	Acon Laboratories, Inc.	
	20. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	
	21. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	22. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	23. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	24. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	25. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	26. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	27. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	28. Immunostics Detector Strep A Direct	Acon Laboratories, Inc	
	29. Immunostics Immuno/Strep A Detector	Acon Laboratories, Inc	
	30. Instant Technologies iStrep Strep A	Acon Laboratories, Inc	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	31. Inverness Medical BioStar Acceava 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
	32. Inverness Medical BioStar Acceava Strep A Twist	Innovacon, Inc.	
	33. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	34. Jant Pharmacal Accustrip Strep A Value+ Test Strip	Innovacon, Inc.	
	35. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	36. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	37. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	38. LifeSign LLC Status Strep A	Princeton BioMeditech	
	39. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	40. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	
	41. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	42. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon	
	43. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon	
	44. PSS World Medical Select Diagnostics Strep A Twist	Innovacon	
	45. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	46. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc	

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	47. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	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
	48. QuickVue® Dipstick Strep A	Quidel Corporation	
	49. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	50. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	51. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	52. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax	
	53. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	
	54. Stanbio QuStick Strep A	Stanbio Laboratory	
	55. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	56. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
87905QW	1. Gryphus Diagnostics BVBlue	Gryphus Diagnositcs, LLC	Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as *Gardnerella vaginais, Bacteroides* spp., *Prevotella* spp., and *Mobiluncus* spp.
	2. Genzyme Diagnostics OSOM BVBlue Test	Gryphus Diagnositcs, LLC	
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassy for the qualitative detection of *Helicobacter pylori 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

This list includes updates from Change Request 6287
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) (cont.)	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

This list includes updates from Change Request 6287
* Newly added waived test system

70.8 - Certificate of Waiver

(Rev.)

Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or certificate of accreditation to legally perform clinical laboratory testing on specimens from individuals in the United States.

The Food and Drug Administration approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

For a list of specific HCPCS codes subject to CLIA see
http://www.cms.hhs.gov/CLIA/downloads/waivetbl.pdf