CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12415	**Date: December 19, 2023**
	Change Request 13455

Transmittal 12381 issued November 24, 2023, is being rescinded and replaced by Transmittal 12415, dated December 19, 2023, to update the Background section to revise the QW code information among the 80 tests and to add 24 new waived tests with their corresponding QW codes approved by the FDA as of December 5, 2023. In addition, the attachment and CR summary has been updated. All other information remains the same.

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, the CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 104 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the Internet Only Manual (IOM).

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

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	N/A

III. FUNDING:

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.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 12415	Date: December 19, 2023	Change Request: 13455

Transmittal 12381 issued November 24, 2023, is being rescinded and replaced by Transmittal 12415, dated December 19, 2023, to update the Background section to revise the QW code information among the 80 tests and to add 24 new waived tests with their corresponding QW codes approved by the FDA as of December 5, 2023. In addition, the attachment and CR summary has been updated. All other information remains the same.

SUBJECT: New Waived Tests

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

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 (FDA) as waived tests under CLIA. The Healthcare Common Procedure Coding System (HCPCS) 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., HCPCS codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

The HCPCS code, effective date, and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

CODE EFFECTIVE DATE TEST/MANUFACTURER

- 87631QW May 5, 2023 Biofire Diagnostics SPOTFIRE Respiratory Panel Mini
- 80305QW May 15, 2023 American Screening Corporation Discover Plus Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation G-Card Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation G-Cup Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Onescreen Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Precision DX Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation Precision DX Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Precision Plus Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation Precision Plus Multi-Panel Drug Test Cup
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Marijuana test kit (THC urine test)
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Multi Drug Test Cup
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Multi Drug Test Panel
- 80305QW May 25, 2023 Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN CLICK CUP
- 80305QW May 25, 2023 Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN FLAT CUP

- 80305QW May 25, 2023 Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREENING CLICK CUP
- 80305QW May 25, 2023 Medical Distribution Group Bicycle Health CLIA WAIVED DRUG TEST
- 80305QW May 25, 2023 Neopharma Technologies Sdn. NEOTEST Drug Test Dip Card
- 80305QW May 25, 2023 Neopharma Technologies Sdn. NEOTEST Drug Test Multi Panel Cup (Urine)
- 80305QW May 31, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Cup
- 80305QW May 31, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Dip Card
- 80305QW June 5, 2023 Wal-Mart Stores Inc. Equate Multi Panel Urine Test Cup
- 87635QW June 20, 2023 Cue Health Inc. Cue Health Monitoring System (For use with Anterior Nasal Swabs)
- 80305QW June 22, 2023 Pregmate LLC ez level MARIJUANA THC DRUG TEST
- 80305QW June 22, 2023 Pregmate LLC ez level DRUG TEST
- 80305QW June 23, 2023 VivaChek Diagnostics Inc. BioSieve Multi-Drug Urine Test Cup
- 80305QW June 26, 2023 Walgreen Co. Walgreens Multi Panel Urine Test Cup
- 87420QW June 29, 2023 Healgen Scientific LLC Rapid Check RSV Antigen Test (Nasopharyngeal swabs)
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Cup
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Cup LC
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card LC
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW THC Urine Strip Test
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Cup
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Dip Card
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine DipCard
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana DipCard
- 80305QW July 11, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Buprenorphine (BUP))
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M300
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test
- 80305QW July 11, 2023 BTNX Inc. L-Cup Home Rapid Test (Urine)
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine DipCard
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M2000
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Oxycodone (OXY))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Morphine (MOP))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Methylenedioxymethamphetamine (MDMA))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Methamphetamine (MET))

- 85610QW July 27, 2023 ARKRAY USA Assure PT Care Prothrombin Time PT/INR Monitoring System Professional Use
- 87631QW July 27, 2023 Roche Molecular cobas Liat System {Cobas SARS-CoV-2 & Influenza A/B}
- 80305QW August 2, 2023 Easy Healthcare Corporation Easy@Home Single Drug Screen Test (Cocaine Urine Test)
- 80305QW August 3, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card
- 87635QW August 10, 2023 Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)
- 80305QW August 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO THC One Step Marijuana Test Dip Card
- 80305QW August 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi Panel Drug Urine Test Cup
- 80305QW August 15, 2023 Smartox SMARTEST Drug of Abuse Urine Test Cup
- 87420QW August 21, 2023 Versea Diagnostics LLC Versea Easy Lab PRO Rapid RSV Test
- 80305QW August 23, 2023 BTNX Inc. Rapid Response Multi-Drug One Step Cup
- 80305QW August 24, 2023 Clarity Diagnostics LLC. Clarity Multi-Drug Urine Test Cup (Urine)
- 80305QW August 24, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Compact Round Cup
- 80305QW August 24, 2023 Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Round Cup
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit For Cannabis
- 80305QW August 28, 2023 Citest Diagnostics Inc. Citest Multiplex DOA Home Test Cup (Urine)
- 80305QW August 28, 2023 Citest Diagnostics Inc. Citest Multiplex DOA Home Test Panel (Urine)
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Five (5) Drugs
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Twelve (12) Drugs
- 80305QW September 8, 2023 Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Panel 50
- 80305QW September 8, 2023 Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Strip 50
- 80061QW, 82465QW, 83718QW, 84478QW September 20, 2023 Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)
- 86769QW, 87426QW, 87811QW September 20, 2023 Quidel Sofia 2
- 83986QW September 22, 2023 Genabio Diagnostics Inc. GenaCheck Vaginal Health pH Screening Test
- 83036QW September 27, 2023 Abbott Diagnostics Technologies AS Afinion 2 analyzer {Afinion HbA1c}
- 83036QW September 27, 2023 Abbott Diagnostics Technologies AS AS100 Analyzer {Afinion HbA1c}
- 83036QW September 29, 2023 Siemens Healthcare Diagnostics Inc. DCA Vantage Analyzer {Siemens DCA Systems Hemoglobin A1c Reagent Kit}
- 85018QW October 2, 2023 Sanguina Inc. AnemoCheck Home
- 80305QW October 2, 2023 Dochek USA Inc. Amazewell Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife C-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife T-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife T-Dip Multi-Drug Urine Test Panel
- 80305QW October 18, 2023 McKesson Medical-Surgical Inc. McKesson Drugs of Abuse Test 14-Drug Panel with Adulterants
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 87420QW October 19, 2023 Clarity Diagnostics LLC Clarity RSV Antigen Test
- 85018QW October 20, 2023 Henry Schein OneStep+ Pro Hb System

- 80305QW October 24, 2023 FSA Store Inc. Caring Mill Amphetamine Tests Strip
- 80305QW October 26, 2023 Wondfo USA Co. Ltd. SAFElife T-Dip Amphetamine (AMP500) Urine Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Panel
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Drug Urine Test Cup
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Panel Urine Test
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Cup
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Panel
- 80305QW November 6, 2023 Hangzhou AllTest Biotech Co. Ltd. AllTest Fentanyl Urine Test Cassette
- 80305QW November 6, 2023 2San LLC. 2SAN Home Drug Test Cup
- 80305QW November 16, 2023 American Screening Corporation Discover Multi-Drug Rapid Test Cup (Urine)
- 80305QW November 16, 2023 Lendas UAB Exploro Highly Sensitive 5-Panel Urine Drug Test
- 80305QW November 16, 2023 VivaChek Biotech (Hangzhou) Co. Ltd. BioSieve Multi-Drug Urine Test Panel
- 86769QW, 87426QW, 87811QW November 17, 2023 ACON Laboratories Inc. Flowflex COVID-19 Antigen Home Test (For use with Anterior Nasal Swabs)
- 80305QW December 1, 2023 Medical Distribution Group Inc. DrugTect Fentanyl Urine Cassette
- 80305QW November 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Accurate Oral Fluid Drug Test COT

This Recurring Update Notification applies to Chapter 16, Section 70.8 of the IOM.

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

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13455.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X							
13455.2	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							
13455.3	Contractors shall not use the explanatory information under		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	the "Use" column in the attachment as the reason for rejecting a claim.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13455.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 1

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 (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 FFS13455

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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 blood urea nitrogen (BUN) in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Basic Metabolic Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Basic Metabolic Panel 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 Blood Chemistry Analyzer {Piccolo Electrolyte Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Electrolyte Panel 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 BUN in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel 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 BUN in whole blood

This list includes updates from FFS13455

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80053QW (cont.)	3. Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel Reagent Disc} (Whole Blood)		
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	Cholesterol level, HDL cholesterol level and triglycerides level. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	1. Infopia USA LipidPro lipid profile and glucose measuring system	Infopia Co., Ltd.	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)	Alere San Diego Inc.	
	3. Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	
	4. Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System	Infopia Co., Ltd.	

This list includes updates from FFS13455

* 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.), 82962, 83718QW, 84478QW (cont.)	5. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	6. KPI Healthcare Co., Ltd. CURO L5 Lipid Profile and Glucose Measuring System	Osang Healthcare Co., Ltd.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW 80069QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and BUN in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and BUN in whole blood

This list includes updates from FFS13455

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
80069QW (cont.)	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
80305QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Screening test for the presence/detection of any number of drug classes in urine
81003QW	Dipstick or tablet reagent urinalysis – automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81003QW, 82044QW, 82570QW	Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine

This list includes updates from FFS13455

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81003QW, 82044QW, 82570QW, 84703QW	1. Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	1. Diatech Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
	2. Jant Pharmacal Corporation Accutest Uriscreen (Bacteriuria)	Savyon Diagnostics Ltd	
81514QW	1.Cepheid GeneXpert Xpress System {Xpert Xpress MVP}*	Cepheid	This test is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis. The test is a qualitative real-time polymerase chain reaction (PCR) assay that amplifies specific DNA targets from the above-mentioned organisms via fluorogenic target-specific hybridization probes that detect and differentiate targeted DNA.
82010QW	1. AmVenturex, Inc., KetoCoach Blood Ketone Monitoring System	Apex BioTechnology Corp.	Measures ketones in whole blood
	2. Apex Biotechnology Corp., KET-1 Blood Ketone Monitoring System	Apex Biotechnology Corp.	
	3. PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	

This list includes updates from FFS13455

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82010QW, 82962	Monitoring of blood glucose levels and measures ketones - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Monitoring of blood glucose levels and measures ketones in whole blood
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	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-glutamyl transferase, glucose, total bilirubin, total protein, blood urea nitrogen (BUN) and uric acid in whole blood
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma-glutamyl transferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW	1. Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma-glutamyl transferase, total bilirubin and total protein levels in whole blood
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW (cont.)	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}	Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82043QW	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW, 82570QW	1. Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine))	ACON Laboratories, Inc.	Semi-quantitative measurement of albumin and creatinine in urine
	2. BTNX, Inc., Rapid Response U120S Urine Analyzer Test System (BTNX, Inc. Rapid Response Urinalysis Reagent Strips (Microablumin/Creatinine))	ACON Laboratories, Inc	
	3. Medline Industries, Inc., Medline 120 Mini Analyzer Test System (Medline Industries, Inc. Medline Urinalysis Reagent Strips)	ACON Laboratories, 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. GenaCheck Vaginal Health pH Screening Test*	Genabio Diagnostics Inc.	
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82271QW	1. Aerscher Hemaprompt FG	Aerscher Diagnostics	Rapid screening test to detect the presence of gastric occult blood
	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

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82274QW G0328QW	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc.	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and BUN in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.)	Cholesterol level. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Cholesterol monitoring
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW	1. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+Glu test strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, and glucose in whole blood

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
	2. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+Glu test strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW	Cholesterol level, and HDL cholesterol level. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various.	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, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	4. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 80061QW	ACON Laboratories Inc., Mission Lipid Panel Monitoring System (ACON Laboratories Inc., Mission Lipid Panel Test Cartridges)	ACON Laboratories Inc.	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood

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

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* Newly added waived test system

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-glutamyl transferase, 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, Inc.	Measures glucose levels in whole blood
82947QW, 82950QW, 82951QW, 82952QW (cont.)	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
	3. Abbott i-STAT G Cartridge {Whole Blood}	Abbott Point of Care	
82962, 82465QW (Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	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	
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)

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82947QW	1. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips)	Polymer Technology Systems, Inc.	Measures glucose in whole blood
	2. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips)	Polymer Technology Systems, Inc.	
	3. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips	Polymer Technology Systems, Inc.	
	4. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips)	Polymer Technology Systems, Inc.	
83001QW	Gonadotropin, follicle stimulating (reproductive hormone) level - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Detects follicle stimulating hormone in urine
83036QW	Hemoglobin A1C level - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes. This semi-automated, benchtop system also and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.
83037QW	Hemoglobin A1C level, by device for home use - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	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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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
83516QW	1. Rapid Pathogen Screening, Inc. InflammaDry	Rapid Pathogen Screening, Inc.	Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye.
	2. Quidel Corporation, InflammaDry	Quidel Corporation	
82044QW	Urine microalbumin (protein) analysis - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	ESA Biosciences, Inc.	Quantitative measurement of blood lead in whole blood
83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips)	Polymer Technology Systems, Inc.	Measures HDL cholesterol, triglycerides, and glucose in whole blood
83721QW	Polymer Technology Systems Cardiochek PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood
83861QW	TearLab Corporation TearLab Osmolarity System	TearLab Corporation	Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.
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
	1. Dale Medical Products, Inc. RightLevel pH	EZ-NG, LLC.	Gastric pH detection (acid-base balance)
	2. Dale Medical Products, Inc. RightSpot pH	EZ-NG, LLC.	

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* Newly added waived test system

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
83986QW(continued)	3. RightBio Metrics, RightSpot Infant pH Indicator	Right BioMetrics	
	4. RightBio Metrics, RightSpot pH Detector	Right BioMetrics	
83986QW (cont.)	5. RightBio Metrics, RightSpot pH Indicator	Right BioMetrics	Gastric pH detection (acid-base balance)
83986QW	Body fluid pH level, vaginal - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	Various	Vaginal pH detection (acid-base balance)
84443QW	Blood test, thyroid stimulating hormone (TSH) - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems and analytes.	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
84450QW, 84520QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84478QW	Germaine Laboratories Inc. AimStrip Tandem Lipid Profile and Glucose Measuring System (Germaine Laboratories Inc. AimStrip Tandem Triglycerides Test Strips)	Germaine Laboratories Inc.	Measures triglycerides in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp.	Diagnosis of pregnancy

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
84550QW	ForaCare, Inc. FORA MD6 Uric Acid Monitoring System (ForaCare, Inc. FORA MD6 Uric Acid Test Strips)	TaiDoc Technology Corp.	Measures blood uric acid in whole blood
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	Measures hemoglobin in whole blood. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various.	Tests for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2EDTA, K3EDTA, sodium citrate, lithium heparin, or sodium heparin) of adults.
85025QW	Sysmex XW-100	Sysmex America, Inc.	Quantitative automated hematology analyzer intended using anticoagulated venous whole blood for WBC count, RBC count, hematocrit, hemoglobin, platelet count and WBC differential
85576QW	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation
85610QW (Contact your Medicare carrier for claims instructions.)	Screening test for deficiency of prothrombin - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	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. Thet *in vitro* diagnostic test provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy.
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. LifeSign Status BTA	Polymedco, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW	Screening test for mononucleosis (mono) categorized as waived complexity - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
86318QW	Immunoassay for *Helicobacter pylori* antibodies, single step method, categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood
86386QW	1. Abbott Diagnostics Scarborough Inc. NMP22 BladderChek Test (Prescription Home Use) and (Professional Use)		Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients
	2. Alere NMP22 BladderChek Test (Professional Use)	Alere	
	3. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Maritech, Inc.	
86618QW	1. 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
	2. Quidel Sofia 2 {Fingerstick whole blood}	Quidel Corporation	
86701QW	1. bioLytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood}	BioLytical Laboratories, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
	2. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test	OraSure Technologies, Inc	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
	3. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood	OraSure Technologies, Inc.	
	4. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)	Trinity Biotech	
86769QW, 87426QW, 87811QW	1.Flowflex COVID-19 Antigen Home Test*	ACON Laboratories Inc.	Antigen Test is a visually read lateral flow immunoassay or immunofluorescent sandwich assay intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID19 within the first 6 days of symptom onset.
	2.Quidel Sofia 2*	Quidel Corporation	
86780QW	Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood}	Diagnostics Direct LLC	Immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in whole blood
86780QW, G0433QW	Chembio Diagnostic Systems, Inc., DPP HIV-Syphilis (Fingerstick whole blood)	Chembio Diagnostic Systems, Inc.	Immunoassay for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2), and/or Treponema pallidum bacteria
G0433QW	1. bioLytical Laboratories, INSTI HIV-1/HIV-2 Antibody Test {Fingerstick whole blood}	bioLytical Laboratories	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venipuncture whole blood and/or oral fluid specimens
	2. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	
	3. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid}	OraSure Technologies, Inc.	

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	4. Chembio Diagnostic Systems, Inc, DPP HIV 1/2 Assay {Oral Fluid}	Chembio Diagnostic Systems, Inc.	
	5. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	
86803QW, G0472QW	OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference Panel	Orasure Technologies Inc.	Qualitative immunoassay to detect antibodies to hepatitis C virus in fingerstick whole blood and venipuncture whole blood specimens
87077QW	Presumptive identification of *Helicobacter pylori* in gastric biopsy tissue - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Presumptive identification of *Helicobacter pylori* in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
87087QW-discontinued, see 87420QW			RSV antigen test
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.	
87338QW	Meridian Bioscience Immunocard STAT! HpSA (Stool)	Meridian Bioscience, Inc.	Immunoassay for rapid, qualitative detection of *Helicobacter pylori* antigens in stool
87389QW [from December 5, 2014 to December 31, 2014], 87806QW [on and after January 1, 2015], G0475QW [on and after January 1, 2017]	1. Orgenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}	Orgenics	Detects antigen to HIV-1, and antibodies to HIV-1 and HIV-2 in whole blood

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	2. Abbott Diagnostics Determine HIV-1/2 Ag/Ab Combo {Fingerstick whole blood}	Abbott Diagnostics	
87400QW	1. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}	Becton, Dickinson and Company	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that differentiates between influenza types A and B
	2. Quidel Sofia 2 {Sofia Influenza A+B FIA}	Quidel Corporation	
87420QW	1. BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens){Includes a reader}	Becton, Dickinson and Company	Rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens by lateral flow immunogold assay. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection.
	2. Quidel Sofia 2 {Sofia RSV FIA}	Quidel Corp.	
	3. Rapid Check RSV Antigen Test (Nasopharyngeal swabs)	Healgen Scientific LLC	
	4. Versea Easy Lab PRO Rapid RSV Test*	Versea Diagnostics LLC	
	5. Clarity RSV Antigen Test*	Clarity Diagnostics LLC	
87430QW	1.BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab)	Becton Dickinson and Company	Immunoassay for the detection of GAS antigen from throat swabs
	2.Quidel Sofia 2 {Sofia Strep A+ FIA} (from throat swab only)	Quidel Corporation	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87449QW	ZymeTx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87502QW	Detection test by nucleic acid for multiple types influenza virus - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology
87631QW	1. Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)	Cepheid	Tests for RNA by reverse transcriptase polymerase chain reaction assay multiplexed polymerase chain reaction (PCR) intended for use for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids (3-5 targets) in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection,
	2. Cepheid GeneXpert Xpress System (Xpert Xpress Flu/RSV Assay)(GeneXpert Xpress IV hub configuration)	Cepheid	
	3. Roche Molecular, cobas Liat System cobas Liat Influenza A/B & RSV Assay	IQUUM, INC.	
	4. SPOTFIRE Respiratory Panel Mini *	Biofire Diagnostics	
	5. cobas Liat System {Cobas SARS-CoV-2 & Influenza A/B}*	Roche Molecular	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87633QW	1. BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids){Nasopharyngeal Swabs}	BioFire Diagnostics, LLC	Multiplexed polymerase chain reaction (PCR) test for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) specimens (multiple types or subtypes, 12-25 targets) obtained from individuals with signs and symptoms of respiratory tract infection, including targets including Flu A and Flu B, RSV andCOVID-19.
87634QW	1. Alere i System Respiratory Syncytial Virus	Alere Scarborough, Inc.	Qualitative detection of RSV viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media utilizing isothermal nucleic acid amplification technology
	2. Alere ID NOW Instrument {Nasopharyngeal swabs}	Alere Scarborough, Inc.	
	3. Mesa Biotech Accula (Accula RSV Test)	Messa Biotech, Inc.	
	4. Sekisui Inc. Silaris Dock (Silaris RSV Test)	Messa Biotech, Inc.	
87635QW	1. Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)*	ABBOTT	Rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection.
	2. Cue Health Monitoring System (For use with Anterior Nasal Swabs)*	Cue Health Inc.	
87651QW	1. Alere i Instrument	Alere Scarborough, Inc.	Detection of Group A bacterial nucleic acids utilizing isothermal nucleic acid amplification technology
	2. Alere i Instrument (Alere i Strep A 2)	Alere Scarborough, Inc.	
	3. Cepheid GeneXpert Xpress System (Xpert Xpress Strep A)(GeneXpert Xpress IV hub configuration)	Cepheid	

This list includes updates from FFS13455

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87651QW (continued)	4. Mesa Biotech Accula {Accula Strep A Test}	Mesa Biotech	
	5. Roche Molecular, cobas Liat System	IQuum, Inc.	
87801QW	1. binx health io Instrument {For use with female vaginal swabs and male urine}	binx health limited	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA by polymerase chain reaction
	2. Visby Medical Sexual Health Click Test (For use with self-collected vaginal swabs)	Visby Medical	PCR-based assay for direct qualitative detection and differentiation of DNA from *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*.
	3. Visby Medical Sexual Health Test (For use with self-collected vaginal swabs)*	Visby Medical	PCR-based assay for direct qualitative detection and differentiation of DNA from Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis in self-collected female vaginal swab
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does not differentiate between influenza types A and B
87804QW	Qualitative detection of influenza type A and type B antigens that differentiates between influenza types A and B - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.	Various	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza A Test Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza A Test	SA Scientific, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	4. SA Scientific SAS Influenza A Test	SA Scientific, Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87804QW	1. Binax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza BTest Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza B Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	
87807QW	Qualitative detection of RSV antigen by immunoassay - Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the current waived complexity test systems.		Rapid immunoassay for the qualitative detection of RSV antigen
87808QW	1. Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of *Trichomonas vaginalis* antigens from vaginal swabs
	2. Sekisui Diagnostics, LLC OSOM Trichomonas Rapid Test	Genzyme Corp.	
87809QW	1. AdenoPlus (human eye fluid)	Rapid Pathogen Screening, Inc.	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid
	2. Quidel, AdenoPlus {Tear fluid}	Quidel Corp.	
	3. Quidel Corporation, QuickVue Adenoviral Conjunctivitis Test {Tear Fluid}	Quidel Corp.	
	4. Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW	Streptococcus group A antigen detection by immunoassay with direct optical observation categorized as waived complexity. Refer to the FDA website http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for the currently waived complexity test systems.	Various	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of *Helicobacter pylori antigens* in stool specimens
87905QW	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.
89300 QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	1. Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility	Embryotech Laboratories, Inc.	Screening test to measure sperm concentration
	2. SpermCheck Vasectomy	Princeton BioMeditech Corp.	Detects sperm in semen following a vasectomy
	3. BonrayBio LensHooke X1 Semen Quality Analyzer	Dynamic Biotech Inc.	Detects sperm in semen
89321QW	1. Fertell Male Fertility Test	Genosis Ltd.	Determines whether the concentration of sperm is above a cut-off level
	2. Labcorp OnDemand Men's Rapid Fertility Test	MEDTOX Diagnostics Inc.	

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