CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3550	**Date: June 24, 2016**
	Change Request 9687

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This change will inform contractors of new CLIA waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 29 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

EFFECTIVE DATE: October 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2016

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:
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: 3550	Date: June 24, 2016	Change Request: 9687

SUBJECT: New Waived Tests

EFFECTIVE DATE: October 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2016

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 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, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

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

- G0434QW [from August 21, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Healgen Scientific LLC, Healgen Multi-Drug Urine Test Dip Card;
- G0477QW, March 8, 2016, Tanner Scientific Multi-Panel Drug Test Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Cassette;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Dip Card;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Cassette;

- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Dip Card;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Cassette;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Dip Card;
- 87338QW, March 22, 2016, Meridian Bioscience Immunocard STAT! HpSA (Stool);
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Turn-Key Split Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Turn-Key Split Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Turn-Key Split Cup;
- G0477QW, April 21, 2016, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup Tests; and
- G0477QW, April 21, 2016, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup with OPI 2000 Tests.

The new waived complexity code 87338QW [Qualitative or semiquantitative detection test for helicobacter pylori in stool, multiple-step method] was assigned for the detection of Helicobacter pylori antigens in stool performed using the Meridian Bioscience Immunocard STAT! HpSA (Stool) test.

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	
9687.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X							
9687.2	The Medicare contractor shall permit the use of code 87338QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 22, 2016.		X						X	
9687.3	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							
9687.4	Contractors shall not use the explanatory information under the “Use” column in the attachment as the reason for rejecting a claim.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9687.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are		X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

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 FFS9687

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 FFS9687
* 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. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)	Infopia Co., Ltd.	
	3. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System (LipidPlus Lipid Profile test strips)	Infopia Co., Ltd.	
	4. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	
	5. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
	6. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips)	Polymer Technology Systems, Inc.	
	7. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Lipid Panel test strips)	Polymer Technology Systems, Inc.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	1. Jant Pharmacal LipidPlus 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

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* 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	2. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	3. Infopia USA LipidPro lipid profile and glucose measuring system	Infopia Co., Ltd.	
	4. Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW	Alere Cholestech LDX {Whole Blood}	Alere, Inc.	Measures alanine aminotransferase, aspartate aminotransferase, total cholesterol, HDL cholesterol, glucose, and triglycerides in whole blood
80069QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and urea nitrogen in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card*	Assure Tech Co., Ltd.	Screening test for the presence/detection of amphetamine in urine
	2. Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card*	Assure Tech Co., Ltd.	
	3. Assure Tech Co., Ltd. AssureTech Amphetamine Strip*	Assure Tech Co., Ltd.	
	4. Assure Tech Co., Ltd. AssureTech Amphetamine Turn-Key Split Cup*	Assure Tech Co., Ltd.	
	5. BTNX Inc Rapid Response X-Press Drug Test Cassette Amp/Amphetamine	BTNX Inc.	
	6. BTNX Inc Rapid Response X-Press Drug Test Strip Amp/Amphetamine	BTNX Inc.	
	7. Healgen Amphetamine Test Cassette	LSI International Inc.	
	8. Healgen Amphetamine Test Cup	LSI International Inc.	
	9. Healgen Amphetamine Test Dip Card	LSI International Inc.	
	10. Healgen Amphetamine Test Strip		
	11. Phamatech QuickScreen One Step Amphetamine Test	Phamatech	
	12. Wondfo Amphetamine Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	
	13. Wondfo Amphetamine Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. AssureTech Co. Ltd, AssureTech Secobarbital Strip {OTC}	AssureTech Co. Ltd	Screening test for the presence/detection of barbiturates in urine
	2. W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Cup Test	LSI International	
	3. W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Dip Card Test	LSI International	
	4. Wondfo Secobarbital Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	
	5. Wondfo Secobarbital Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Oxazepam Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of benzodiazepines in urine
	2. Wondfo Oxazepam Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Assure Tech Co., Ltd AssureTech Buprenorphine Strip	LSI International	Screening test for the presence/detection of buprenorphine in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	2. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	
	3. BTNX Inc Rapid Response X-Press Drug Test Cassette	BTNX Inc.	

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* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. BTNX Inc Rapid Response X-Press Drug Test Strip	BTNX Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	5. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	ACON Laboratories, Inc.	
	6. Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Easy Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	7. Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Cassette*	Hangzhou Clongene Biotech Co., Ltd.	
	8. Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Dip Card*	Hangzhou Clongene Biotech Co., Ltd.	
	9. Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Split Key Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	10. Healgen THC One Step Marijuana Test Cassette	Healgen Scientific, LLC	
	11. Healgen THC One Step Marijuana Test Cup	Healgen Scientific, LLC	
	12. Healgen THC One Step Marijuana Test Dip Card	Healgen Scientific, LLC	
	13. Healgen THC One Step Marijuana Test Strip	Healgen Scientific, LLC	
	14. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cassette	LSI International Inc.	
	15. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) Cup	LSI International Inc.	

This list includes updates from Change Request FFS9687
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	16. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test Marijuana (THC) DipCard	LSI International Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	17. Phamatech QuickScreen One Step THC Screening Test	Phamatech	
	18. Phamatech At Home Drug Test (Model 9078)	Phamatech	
	19. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	20. Polymed Therapeutics FaStep Marijuana Panel Dip	PolyMed Therapeutics, Inc.	
	21. Polymed Therapeutics FaStep Marijuana Quick Cup	PolyMed Therapeutics, Inc.	
	22. Polymed Therapeutics FaStep Marijuana Strip	PolyMed Therapeutics, Inc.	
	23. Polymed Therapeutics FaStep Marijuana Turn-Key Split Cup	PolyMed Therapeutics, Inc.	
	24. SCI International Inc. New Choice At Home Drug Test: Marijuana (Strip Format)	Ind Diagnostic Inc.	
	25. Wondfo Cannabinoids Urine Test {Cup Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	26. Wondfo Cannabinoids Urine Test {Dip card Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	27. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Assure Tech Co., Ltd. AssureTech Cocaine Dip Card*	Assure Tech Co., Ltd.	Screening test for the presence/detection of cocaine metabolites in urine
	2. Assure Tech Co., Ltd. AssureTech Cocaine Quick Cup*	Assure Tech Co., Ltd.	
	3. Assure Tech Co., Ltd. AssureTech Cocaine Strip*	Assure Tech Co., Ltd.	
	4. Assure Tech Co., Ltd. AssureTech Cocaine Turn-Key Split Cup*	Assure Tech Co., Ltd.	
	5. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Cup format}	BTNX Inc.	
	6. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Dip card format}	BTNX Inc.	
	7. Healgen COC One Step Cocaine Test Cassette	Healgen Scientific LLC	
	8. Healgen COC One Step Cocaine Test Cup	Healgen Scientific LLC	
	9. Healgen COC One Step Cocaine Test Dip Card	Healgen Scientific LLC	
	10. Healgen COC One Step Cocaine Test Strip	Healgen Scientific LLC	
	11. Phamatech At Home Drug Test (Model 9073)	Phamatech	
	12. Phamatech At Home Drug Test (Model 9073T)	Phamatech	
	13. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Assure Tech Co., Ltd AssureTech Methadone Strip	LSI International	Screening test for the presence/detection of methadone in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Cup format}	BTNX Inc.	
	3. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Dip card format}	BTNX Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (MET/Methamphetamine) {Cup format}	BTNX Inc.	Screening test for the presence/detection of methamphetamines in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MET/Methamphetamine){Dip card format}	BTNX Inc.	
	3. Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Easy Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	4. Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Split Key Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	5. Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Cassette*	Hangzhou Clongene Biotech Co., Ltd.	
	6. Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Dip Card*	Hangzhou Clongene Biotech Co., Ltd.	
	7. Healgen mAMP One Step Methamphetamine Test Cassette	Healgen Scientific, LLC	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	8. Healgen mAMP One Step Methamphetamine Test Cup	Healgen Scientific, LLC	Screening test for the presence/detection of methamphetamines in urine
	9. Healgen mAMP One Step Methamphetamine Test Dip Card	Healgen Scientific, LLC	
	10. Healgen mAMP One Step Methamphetamine Test Strip	Healgen Scientific, LLC	
	11. Phamatech At Home Drug Test (Model 9068)	Phamatech	
	12. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	
	13. Polymed Therapeutics FaStep Methamphetamine Panel Dip	Polymed Therapeutics, Inc.	
	14. Polymed Therapeutics FaStep Methamphetamine Quick Cup	Polymed Therapeutics, Inc.	
	15. Polymed Therapeutics FaStep Methamphetamine Strip	Polymed Therapeutics, Inc.	
	16. Polymed Therapeutics FaStep Methamphetamine Turn-Key Split Cup	Polymed Therapeutics, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine){Cup format}	BTNX Inc.	Screening test for the presence/detection of 3,4-methylenedioxymethamphetamine HCl (MDMA) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxymethamphetamine){Dip card format}	BTNX Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA Cup	LSI International Inc.	Screening test for the presence/detection of 3,4-methylenedioxymethamphetamine HCl (MDMA) in urine
	4. Nantong Egens Biotechnology Co., Ltd., EGENS Urine Test MDMA DipCard	LSI International Inc.	
	5. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Cassette	LSI International Inc.	
	6. Healgen Scientific LLC Healgen MDMA (Ecstasy)Test Cup	LSI International Inc.	
	7. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Dip Card	LSI International Inc.	
	8. Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Strip	LSI International Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Assure Tech Co., Ltd. AssureTech Morphine Dip Card*	Assure Tech Co., Ltd.	Screening test for the presence/detection of morphine in urine
	2. Assure Tech Co., Ltd. AssureTech Morphine Quick Cup*	Assure Tech Co., Ltd.	
	3. Assure Tech Co., Ltd. AssureTech Morphine Strip*	Assure Tech Co., Ltd.	
	4. Assure Tech Co., Ltd. AssureTech Morphine Strip*	Assure Tech Co., Ltd.	
	5. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine){Cup format}	BTNX Inc.	

This list includes updates from Change Request FFS9687
* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	6. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine){Dip card format}	BTNX Inc.	Screening test for the presence/detection of morphine in urine
	7. Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Easy Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	8. Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Split Key Cup*	Hangzhou Clongene Biotech Co., Ltd.	
	9. Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Cassette*	Hangzhou Clongene Biotech Co., Ltd.	
	10. Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Dip Card*	Hangzhou Clongene Biotech Co., Ltd.	
	11. Healgen Morphine Test Cassette	Healgen Scientific LLC	
	12. Healgen Morphine Test Cup	Healgen Scientific LLC	
	13. Healgen Morphine Test Dip Card	Healgen Scientific LLC	
	14. Healgen Morphine Test Strip	Healgen Scientific LLC	
	15. Healgen MOP One Step Morphine Test Cassette	Healgen Scientific LLC	
	16. Healgen MOP One Step Morphine Test Cup	Healgen Scientific LLC	
	17. Healgen MOP One Step Morphine Test Dip Card	Healgen Scientific LLC	
	18. Healgen MOP One Step Morphine Test Strip	Healgen Scientific LLC	
	19. W.H.P.M., Inc. First Sign® Drug of Abuse Morphine Dip Card Test	LSI International	

This list includes updates from Change Request FFS9687
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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Cup format}	BTNX Inc.	Screening test for the presence/detection of morphine in urine at a cutoff concentration of 2000ng/ml
	2. BTNX Inc Rapid Response X-Press Drug Test Morphine (2000){Dip card format}	BTNX Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. CLIAwaived Inc. Instant Nicotine Detection Test	Mossman Associates, 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
	2. DyanGen NicCheck II Test Strips	DynaGen, Inc.	
	3. Mossman Associates, Inc. NicCheck I Test Strips	Mossman Associates, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Notriptyline{Cup format}	BTNX Inc.	Screening test for the presence/detection of notriptyline (major metabolite of tricyclic antidepressants) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Notriptyline{Dip card format}	BTNX Inc.	
G0477QW (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	
	3. Quest Products, Inc. DrugHAWK Buprenorphine Drug Test Cup	S.D. biotek, LLC	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Cassette	BTNX Inc.	Screening test for the presence/detection of oxazepam (major metabolite of benzodiazepines) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Oxazepam Strip	BTNX Inc.	
	3. Healgen Oxazepam Test Cassette	Healgen Scientific LLC	
	4. Healgen Oxazepam Test Cup	Healgen Scientific LLC	
	5. Healgen Oxazepam Test Dip Card	Healgen Scientific LLC	
	6. Healgen Oxazepam Test Strip	Healgen Scientific LLC	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. AssureTech Co. LTD, AssureTech Oxycodone Strip {OTC}	LSI International Inc	Screening test for the presence/detection of oxycodone in urine
	2. Healgen Oxycodone Test Cassette	LSI International Inc	
	3. Healgen Oxycodone Test Cup	LSI International Inc.	
	4. Healgen Oxycodone Test Dip Card	LSI International Inc.	
	5. Healgen Oxycodone Test Strip	LSI International Inc.	
	6. Wondfo Oxycodone Urine Test {Dip card format}	Guangzhou Wondfo Biotech Co., Ltd.	
	7. Wondfo Oxycodone Urine Test {Cup format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Cup format}	BTNX Inc.	Screening test for the presence/detection of phencyclidine (PCP) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (PCP/Phencyclidine){Dip card format}	BTNX Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. Healgen Scientific LLC Healgen Phencyclidine Test Cassette	LSI International Inc.	Screening test for the presence/detection of phencyclidine (PCP) in urine
	4. Healgen Scientific LLC Healgen Phencyclidine Test Cup	LSI International Inc.	
	5. Healgen Scientific LLC Healgen Phencyclidine Test Dip Card	LSI International Inc.	
	6. Healgen Scientific LLC Healgen Phencyclidine Test Strip	LSI International Inc.	
	7. Phamatech At Home Drug Test (Model 9133)	Phamatech	
	8. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Cassette	BTNX Inc.	Screening test for the presence/detection of secobarbital (major metabolite of barbiturates) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Secobarbital Strip	BTNX Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Panel Dip {OTC}	LSI International	Screening test for the presence/detection of barbiturates and oxycodone
	2. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Quick Cup {OTC}	LSI International	
	3. AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Turn Key-Split Cup {OTC}	LSI International	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Panel Dip	LSI International	Screening test for the presence/detection of buprenorphine and methadone
	2. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Quick Cup	LSI International	
	3. Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Turn Key-Split Cup	LSI International	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	
	3. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	
	4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	
	5. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC)	Worldwide Medical Corporation	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc.	Screening test for the presence/detection of buprenorphine and tricyclic antidepressants
	2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests	Chemtron Biotech, Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Quest Products, Inc. DrugHAWK MDMA and OPI Drug Test Cup (Urine){Cup format}	S.D.biotek, LLC	Screening test for the presence/detection of MDMA and opiates in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine
	2. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	3. Insight Medical Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	
	4. Insight Medical Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	5. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	6. Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	
	7. Jant Pharmacal Accutest Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	8. Jant Pharmacal Accutest Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	
	9. Total Diagnostic Solutions Drug of Abuse Urine (Cassette) Test	Alfa Scientific Designs, Inc.	
	10. Total Diagnostic Solutions Drug of Abuse Urine (Cup) Test	Alfa Scientific Designs, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (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	
G0477QW (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
G0477QW (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
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Alfa Scientific Designs, Inc. Confidential Drug Test – Multi Drugs of Abuse Urine Test (OTC)	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, MDMA and morphine in urine
G0477QW (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. Alere iCassette Drug Screen	Alere	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	5. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine
	6. iCassette Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	7. RediScreen Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	8. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}	Innovacon, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests	Chemtron Biotech, Inc	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, morphine, and PCP in urine
	2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip	Chemtron Biotech, Inc	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests	Chemtron Biotech, Inc	Screening test for the presence/detection of benzodiazeprines, barbiturates, MDMA, methadone, opiates, and oxycodone in urine
	2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere Toxicology Service, Inc. Tox Screen Drugs of Abuse Test Cup	Alere	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine
	3. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Innovacon, Inc.	
	4. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	
	5. Innovacon Integrated E-Z Split Key Cup II {Professional Use}	Innovacon, Inc.	
	6. Noble Medical Inc. Split-Specimen Cup	ACON Laboratories, Inc.	
	7. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II	Biosite Inc.	
	8. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use}	Innovacon, Inc.	
	9. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Wondfo Multi-Drug Urine Test Panel {Dip Card Format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, methadone, methamphetamines, MDMA, morphine, oxycodone, PCP and tricyclic antidepressants in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Nobel Medical Inc. INSTA-SCREEN Multi-Drug Urine Test Cup	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of cocaine metabolites, methamphetamines, MDMA, morphine, methadone, opiates, PCP and tricyclic antidepressants in urine

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Branan Medical Corporation ToxCup Drug Screen Cup	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	2. Express Diagnostic Int'l Inc DrugCheck Waive RT (Model 9308z)	Phamatech, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere Toxicology Services Alere iCassette DX Drug Screen	Alere	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine
	2. Phamatech At Home 12 Drug Test (Model 9308T)	Phamatech, Inc.	
	3. Phamatech At Home 12 Drug Test (Model 9308Z)	Phamatech, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Innovacon Multi-Clin Drug Screen Test Device	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	2. Instant Technologies, Inc. iCassette DX Drug Screen Test	Alere	
	3. Inverness Medical Innovations Signify ER Drug Screen	Biosite Inc.	
	4. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device	Innovacon, Inc.	
	5. Abbott Diagnostics Signify ER Drug Screen Test	Innovacon, Inc.	
G0477QW (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, MDMA, morphine, PCP and tricyclic antidepressants in urine

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	5. Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	6. Insight Medical Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	7. Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	8. Millenium Laboratories Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc	
	9. Physicians' Test Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	10. On the Spot Drug Testing Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	11. Quik Test USA, Inc. Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	12. Screen Tox Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	
	13. Total Diagnostic Solutions Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc	
	14. Aventir Biotech LLC Home Check Multiple Drug Test Cup	Tianjin New Bay Bioresearch Co. Ltd.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	15. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, MDMA, morphine, PCP and tricyclic antidepressants in urine
	16. Medimpex United Inc. MedimpexQ Test Multi X Drug Cup Test	Tianjin New Bay Bioresearch Co. Ltd	
	17. Quest Products, Inc. DrugHAWK Drug Test Cup	S.D.biotek, LLC.	
	18. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card Tests	. Chemtron Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, morphine, opiates, oxycodone and PCP in urine
	2. Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card with OPI 2000 Tests	Chemtron Biotech, Inc.	
	3. Native Diagnostics International, DrugSmart Dip Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Amedica Biotech Amedica Drug Screen Test Cup	Amedica Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Amedica Biotech AmediCheck Instant Test Cup	Amedica Biotech, Inc.	
	3. Amedica Biotech Instant Test Cup	Amedica Biotech, Inc.	
	4. Ameditech, Inc ImmuTest Drug Screen Cup	Biosite Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	5. Branan Medical Corporation, FasTox Multiple Drug Dipcard	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	6. CLIAwaived, Inc. Rapid Drug Test	Biosite Inc.	
	7. CLIAwaived, Inc. Rapid Drug Test Cup	Alere	
	8. CLIAwaived, Inc. Rapid Drug Test Cup {OTC}	Biosite Inc.	
	9. CLIAwaived Inc. Rapid Dip Drug Test	Branan Medical Corporation	
	10. CLIAwaived Inc. Single Drug Dipstick Test	Branan Medical Corporation	
	11. Clinical Reference Laboratory, Inc. Intelligent Transport Cup	Alere	
	12. Express Diagnostics, DrugCheck Waive Cup	Biosite Inc.	
	13. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
	14. Instant Technologies, iCup DX Drug Screen Cup	Biosite Inc.	
	15. Jant Pharmacal Corporation ACCUTEST Drug Test Cup	Amedica Biotech, Inc	
	16. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup	Biosite Inc.	
	17. NexScreen LLC, NexScreen Cup	Amedica Biotech, Inc.	
	18. Noble Medical Inc. NOBLE 1 Step Cup {OTC}	Alere	
	19. Noble Medical Inc. NOBLE 1 Step Cup {OTC}	Biosite Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	20. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}	Alere	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	21. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}	Biosite Inc.	
	22. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup	Biosite Inc.	
	23. Twin Spirit, Inc. DrugSmart Cup	Amedica Biotech, Inc.	
	24. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}	Alere	
	25. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}	Biosite Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. American Institute of Toxicology, Inc., AIT Laboratories Drug of Abuse Cup	Guangzhou Wondfo Biotech Co. LTD	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, morphine, oxycodone, PCP and tricyclic antidepressants in urine
	2. BTNX Inc. Rapid Response Multi-Drug Urine Test Cup	Guangzhou Wondfo Biotech Co. LTD	
	3. BTNX Inc. Rapid Response Multi-Drug Urine Test Panel	Guangzhou Wondfo Biotech Co. LTD	
	4. uVera Diagnostics, Inc. CR2 Multi-Drug Urine Test Cup	Guangzhou Wondfo Biotech Co. LTD	
	5. uVera Diagnostics, Inc. CR3 Multi-Drug Urine Test Cup	Guangzhou Wondfo Biotech Co. LTD	
	6. uVera Diagnostics, Inc. SMARTOX U3 Multi-Drug Urine Test Cup	Guangzhou Wondfo Biotech Co. LTD	
	7. Wal-Mart Stores, Inc. ReliOn Home Drug Urine Cup Test	Alfa Scientific Designs, Inc.	

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G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Micro Distributing II, LTD One Step Multi-Drug Urine Test Panel	Guangzhou Wondfo Biotech Co. LTD	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methamphetamines, MDMA, morphine, opiates, oxycodone and PCP in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test DipCard	LSI International Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, and PCP in urine
	2. Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test Cup	LSI International Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Healgen Scientific LLC, Healgen Multi-Drug Urine Test Dip Card*	Healgen Scientific LLC	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, morphines, oxycodone, and PCP in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere iScreen DX Multi-Drugs of Abuse Dip Test	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Alere iScreen DX Single Dip Card {The Alere iScreen DX Single Dip Card may include a maximum of four drugs in any combination of the 13 claimed drugs}		
	3. Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	
	4. Branan Medical Corporation, QuickTox Drug Screen Dipcard	Branan Medical Corporation	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Advin Multi-Drug Screen Test	Advin Biotech	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. American Screening Corporation Discover Drug Test Cards	UCP Biosciences, Inc	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
	3. American Screening Corporation Discover Multi-panel Drug Test Cups	UCP Biosciences, Inc	
	4. American Screening Corporation, Inc., Multi-Drug Testing Cards	UCP Biosciences, Inc	
	5. American Screening Corporation, Inc., Multi-Drug Testing Cups	UCP Biosciences, Inc	
	6. American Screening Corporation OneScreen Drug Test Cards	UCP Biosciences, Inc.	
	7. American Screening Corporation OneScreen Drug Test Cups	UCP Biosciences, Inc.	
	8. Diagnostic Test Group Clarity Multi-Drug Test Cards	UCP Biosciences, Inc	
	9. Diagnostic Test Group Clarity Multiple Drug Screen Cards	UCP Biosciences, Inc.	
	10. Diagnostic Test Group Clarity Multiple Drug Screen Cups	UCP Biosciences, Inc.	
	11. Diagnostic Test Group Clarity Simple Drug Screening Cups	UCP Biosciences, Inc.	
	12. Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards	UCP Biosciences, Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	13. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, and tricyclic antidepressants in urine
	14. UCP Biosciences, Inc. Drug Screening Test Cards	UCP Biosciences	
	15. UCP Biosciences, Inc. Drug Screening Test Cups	UCP Biosciences, Inc.	
	16. UCP Biosciences, Inc. U-Checker Drug Screening Test Cups	UCP Biosciences, Inc.	
	17. Ultimate Analysis Cup UA Cups	UCP Biosciences, Inc.	
	18. American Bio Medica Rapid TOX	American Bio Medica Corp.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests	Chemtron Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, and tricyclic antidepressants in urine
	2. Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests with OPI 2000	Chemtron Biotech, Inc.	
	3. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup Tests*	Chemtron Biotech, Inc	
	4. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup with OPI 2000 Tests*	Chemtron Biotech, Inc	
	5. Clarity Diagnostics Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc.	
	6. Clarity Diagnostics Multi-Panel Drug Screen Dip Card with OPI 2000 Tests	Chemtron Biotech, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	7. Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card with OPI 2000 Tests	Chemtron Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, and tricyclic antidepressants in urine
	8. Native Diagnostics International; DrugSmart Drug Screen Cup Tests with OPI 2000	Chemtron Biotech, Inc.	
	9. Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests	Chemtron Biotech, Inc.	
	10. Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests with OPI 2000	Chemtron Biotech, Inc.	
	11. On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc.	
	12. On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card with OPI 2000 Tests	Chemtron Biotech, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere iCup DX 14 {Cassette Dip Card format}	Branan Medical Corp.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	2. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc.	
	3. Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card with OPI 2000 Test	Chemtron Biotech, Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. CLIAwaived Inc. Rapid Drug Test Cup {Cassette Dip Card format}	Branan Medical Corp.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	5. Coastline Medical Management Coastline Explorer Cup {Cassette Dip Card Format	Branan Medical Corp.	
	6. Noble Medical Inc. Noble 1 Step + Cup	Branan Medical Corp.	
	7. PTox Drug Screen Cup {Cassette Dip Card format}	Branan Medical Corp.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. UCP Biosciences, Inc. UCP Multi-Drug Test Key Cups	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. American Screening Corporation, Inc. Discover Drug Test Cards	UCP Biosciences, Inc	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	2. American Screening Corporation, Inc. Discover Multi-Panel Drug Test Cups	UCP Biosciences, Inc	
	3. American Screening Corporation, Inc. Discover Plus Drug Test Cards	UCP Biosciences, Inc	
	4. American Screening Corporation, Inc. Discover Plus Multi-Panel Drug Test Cups	UCP Biosciences, Inc	
	5. American Screening Corporation One Screen Drug Test Cards	UCP Biosciences, Inc.	
	6. American Screening Corporation, Reveal Mini Drug Test Cups	UCP Biosciences, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	7. American Screening Corporation Reveal Multi-Drug Testing Cups	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	8. Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards	UCP Biosciences, Inc.	
	9. Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards	UCP Biosciences, Inc.	
	10. Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cards	Medical Distribution Group Inc.	
	11. Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cups	Medical Distribution Group Inc.	
	12. Tanner Scientific, Platinum Line® Multi-Panel Drug Test Cup	UCP Biosciences, Inc.	
	13. Transmetron, Inc. Invitro Pro Drug Test Cards	UCP Biosciences, Inc.	
	14. Transmetron Invitro Pro Drug Test Cups	UCP Biosciences, Inc.	
	15. UCP Biosciences, Inc. UCP Compact Drug Test Cards	UCP Biosciences, Inc.	
	16. UCP Biosciences, Inc. UCP Compact Drug Test Cups	UCP Biosciences, Inc.	
	17. UCP Biosciences, Inc. UCP Drug Test Mini Cups	UCP Biosciences, Inc.	
	18. UCP Biosciences, Inc. Multiple Drug Screen Cups	UCP Biosciences	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	19. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards	UCP Biosciences, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
	20. UCP Biosciences, Inc., UCP Home Drug Screening Test Cups	UCP Biosciences, Inc.	
	21. UCP Biosciences, Inc. U-Cup Drug Test Cards	UCP Biosciences, Inc.	
	22. UCP Biosciences, Inc. U-Card Drug Test Cups	UCP Biosciences, Inc.	
	23. Ultimate Analysis Cup Inc. UA Cups	UCP Biosciences, Inc.	
	24. Ultimate Analysis Cup Inc. UA Cups Test Cards	UCP Biosciences, Inc.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Premier BIOTECH Premier Bio-Cup & Bio-Dip	Advin Biochemicals	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, EDDP (methadone metabolite), MDMA, methamphetamines, methadone, morphine, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	Tanner Scientific Multi-Panel Drug Test Cup*	Co-Innovation Biotech Co., Ltd.	
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
81003QW	1. Acon Laboratories, Inc. Foresight U120 Urine Analyzer	Acon 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
	2. Acon Laboratories, Inc. Insight U120 Urine Analyzer	Acon Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81003QW(cont.)	3. Acon Mission U120 Urine Analyzer	Acon 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
	4. Biosys Laboratories Optima Urine Anlayzer	BioSys Laboratories, Inc.	
	5. BTNX Rapid Response U120 Urine Analyzer	Acon Laboratories, Inc.	
	6. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Boehringer Mannheim Corporation	
	7. CLIAwaived Inc. Automated Urinalysis Test System	Acon Laboratories, Inc.	
	8. Cole-Talyor Marketing Inc. CTI-120 Urine Strip Analyzer	Acon Laboratories, Inc.	
	9. Consult diagnostics Urine Analyzer	BioSys Laboratories, Inc.	
	10. Germaine Laboratories Inc. AimStrip Urine Analyzer	Acon Labortories, Inc.	
	11. Henry Schein OneStepPlus Urine Analyzer	Macherey-Nagel GmbH & Co., Kg.	
	12. Henry Schein Urispec Plus Urine Analyzer	Macherey-Nagel GmgH & Co., Kg.	
	13. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	14. Immunostics Inc., Detector Uristrip+ Analyzer	Acon Laboratories, Inc.	
	15. Jant Pharmacal Corporation Accustrip URS Reader	Jant Pharmacal Corporation	
	16. Medline 120 Urine Analyzer	Acon Laboratories, Inc.	
	17. McKesson 120 Urine Analyzer	Acon Labortories, Inc.	
	18. Mediwatch urinewatch Urine Analyzer	Acon Labortories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
81003QW(cont.)	19. Moore Medical, mooremedical Urine Analyzer U120	Acon Labortories, 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
	20. Physician Sales & Service, Inc. PSS Select Urine Analyzer	BioSys Laboratories, Inc.	
	21. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	22. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer MannheimCorporation	
	23. Stanbio Uri-Trak 120 Urine Analyzer	Acon Labortories, Inc.	
	24. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
81003QW, 82044QW, 82570QW	1. Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine
81003QW, 82044QW, 82570QW, 84703QW	1. Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	1. Diatech Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
	2. Jant Pharmacal Corporation Accutest Uriscreen (Bacteriuria)	Savyon Diagnostics Ltd	
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82010QW, 82962	1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
	2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories	
82010QW, 82962 (cont.)	3. Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System	Nova Biomedical Corp.	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 glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen 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 glutamyltransferase, 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 glutamyltransferase, total bilirubin and total protein levels in whole blood

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood
82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	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	1. Beckman Coulter ICON Microalb	Beckman Coulter, Inc.	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
	2. Boehringer Mannheim Chemstrip Micral	Boehringer Mannheim	
	3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test	Diagnostic Chemicals Limited	
	4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)	Diagnostic Chemicals Limited (USA)	
	5. Genzyme Daignostics OSOM ImmunoDip Urinary Albumin Test	Genzyme Diagnositcs	
	6. Roche Diagnostics Chemstrip Micral (urine dipstick)	Roche Diagnostics Corporation	
82947QW	1. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips)	Polymer Technology Systems, Inc.	Measures glucose in whole blood

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82947QW (cont.)	2. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips)	Polymer Technology Systems, Inc.	Measures glucose in whole blood
	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.	
G0477QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alere Toxicology services, iScreen Saliva Alcohol Test Strip	Acon Laboratories, Inc.	Quantitative determination of alcohol (ethanol) in saliva
	2. Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip	Acon Laboratories, Inc.	
	3. American Screening Corporation, Reveal Saliva Alcohol Test Strip	Acon Laboratories, Inc.	
	4. Acon Laboratories Inc. Mission Saliva Alcohol Test Strip	Acon Laboratories, Inc.	
	5. Chematics Inc. Alco-Screen Saliva Alcohol Test	Chematics. Inc	
	6. Chematics Inc. Alco-Screen 02 Saliva Alcohol Test	Chematics. Inc.	
	7. CLIAwaived Inc. Rapid Saliva Alcohol Test	Acon Laboratories, Inc.	
	8. Express Diagnostics International, Incorporated Saliva Alcohol Test	Teco Diagnostics	
	9. Germaine Laboratories AimStrip Alcohol Saliva	Acon Laboratories, Inc.	
	10. Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip	Acon Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
G0477QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	11. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test	OraSure Technologies, Inc.	Quantitative determination of alcohol (ethanol) in saliva
	12. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	OraSure Technologies, Inc.	
	13. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test	STC Technologies Inc.	
	14. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	STC Technologies Inc.	
	15. Teco Diagnostics Saliva Alcohol Test	Teco Diagnostics	
82120QW, 83986QW	Litmus Concepts FemExam TestCard (from vaginal swab)	Litmus Concepts, Inc.	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82271QW	1. Aerscher Hemaprompt FG	Aerscher Diagnostics	Rapid screening test to detect the presence of gastric occult blood
	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. American IVD Biotechnology Services Inc. FOB/CRC Advanced+	Ind Diagnostic Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	2. Beckman Coulter Hemoccult ICT (K961062) & (K080812)	Beckman Coulter, Inc.	
	3. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc.	

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

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82274QW G0328QW(cont.)	19. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	Immunostics, In	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	20. InSure Quik Fecal Immunochemical Test (F.I.T.)	Enterix, Inc.	
	21. Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test	New Bay Research Co. Ltd.	
	22. Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	
	23. Medline iFOB Test	Princeton BioMeditech Corp.	
	24. Medline iFOB One-Step Immunological Fecal Occult Blood Test	Ind Diagnostics Inc.	
	25. OC-Light iFOB Test	Polymedco, Inc	
	26. OSOM iFOB Test OSOM iFOBT Contol Kit	Sekisui Diagnostics, Inc	
	27. OcculTech Fecal Occult Blood Rapid Test	YD Diagnositcs Corp.	
	28. Polymedco Poly Stat OC-light FOB Test	Polymedco, Inc.	
	29. Rapid Response(TM) FIT-Fecal Immunochemical Test	Orient Gene Biotech	
	30. Sekisui Diagnostics, LLC OSOM iFOB Test	Princeton BioMeditech Corp.	
	31. Tanner Scientific iFOB One Step Rapid Test	Zhejiang Orient Gene Biotech Co., Ltd	
	32. Teco Rapid Fecal Occult Blood (FOB) Card Test	Teco Diagnostics	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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 urea nitrogen (BUN) in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc	
82435QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Abbott i-STAT 6+ Cartridge {Whole Blood}	i-Stat Corporation	Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood
82465QW (Contact your Medicare carrier for claims instructions.)	1. Advanced Care	Johnson & Johnson	Cholesterol monitoring
	2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol	Boehringer Mannheim	
	3. ChemTrak AccuMeter	ChemTrak	
	4. ENA.C.T Total Cholesterol Test	ActiMed Laboratories, Inc.	
	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	
	6. Lifestream Technologies Cholesterol Monitor	Lifestream Technologies, Inc.	
	7. Lifestream Technologies Personal Cholesterol Monitor	Lifestream Technologies, Inc.	
	8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	
	9. PTS Bioscanner Test Strips Chloesterol	Polymer Technology Systems, Inc.	

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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.), 83718QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	
	4. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	
	5. Roche Diagnostics AccuChek Instant Plus Dual Testing System		
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	

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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	1. 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	1. 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	1. Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)}	Abaxis, Inc.	Measures cholesterol, HDL cholesterol, glucose, alanine aminotransferase, aspartate aminotransferase, and triglycerides in whole blood
82523QW	Ostex International Osteomark NTX Point of Care Prescription Home Use	Ostex International Inc.	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine
82565QW	Abbott i-STAT Crea Cartridge {Whole Blood}	i-Stat Corporation	Quantitative measurement of creatinine in whole blood
82565QW, 84520QW	Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of creatinine and urea nitrogen in whole blood

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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, Inc.	Measures glucose levels in whole blood
	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
	3. Abbott i-STAT G Cartridge {Whole Blood}	i-Stat Corporation	
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW	Abbott i-STAT EC4+ Cartridge {Whole Blood}	i-Stat Corporation	Measures glucose, potassium, sodium, and hematocrit in whole blood
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, 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

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TESTS GRANTED WAIVED STATUS UNDER CLIA

CPT CODE(S)	TEST NAME	MANUFACTURER	USE
82962, 82985QW	1. LXN Duet Glucose Control Monitoring System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period
	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	
83001QW	1. Acon Laboratories, Inc. FSH Menopause Predictor Test	ACON Laboratories, Inc.	Detects follicle stimulating hormone in urine
	2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use}	ACON Laboratories, Inc.	
	3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use}	ACON Laboratories, Inc.	
	4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test	Applied Biotech, Inc.	
	5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device	ACON Laboratories, Inc.	
	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-Shield Poc	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	2. Alere Technologies AS, Alere Afinion AS101 Analyzer	Axis-Shield Poc	
	3. Bayer AICNow+ Professional Use	Bayer Healthcare, LLC	
	4. Siemens Medical Diagnostics DCA Vantage Analyzer	Siemens Healthcare Diagnostics, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
83036QW (cont.)	5. PTS Diagnostics A1CNow + Professional Use	Polymer Technology Systems, Inc.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	6. Siemens DCA 2000 Analyzer	Siemens Healthcare Diagnostics, Inc.	
	7. Siemens DCA 2000+ Analyzer	Siemens Healthcare Diagnostics, Inc	
83037QW	1. Bayer A1CNow+ {For professional use}	Bayer Corp.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
	2. Bayer A1C Now SelfCheck	Bayer Healthcare, Llc.	
	3. BIO-RAD in2it (II) System Analyzer Prescription Home Use	Bio-Rad Laboratories, Inc.	
	4. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories, Inc.	
	5. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	
	6. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	7. Provalis Diagnostics In2it In-Office Analyzer (II) Prescription Home Use Test System	Provalis Diagnostics Ltd	
83516QW	Rapid Pathogen Screening, Inc. InflammaDry	Rapid Pathogen Screening, Inc.	Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye.
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

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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}	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
	2. Biosite Triage Meter Plus {Whole Blood}		
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. Dale Medical Products, Inc. RightLevel pH	EZ-NG, LLC.	Gastric pH detection (acid-base balance)
	2. Dale Medical Products, Inc. RightSpot pH	EZ-NG, LLC.	
	3. RightBio Metrics, RightSpot Infant pH Indicator	Right BioMetrics	
	4. RightBio Metrics, RightSpot pH Detector	Right BioMetrics	
	5. RightBio Metrics, RightSpot pH Indicator	Right BioMetrics	
83986QW	1. FemTek pHEM-ALERT®	FemTek, LLC	Vaginal pH detection (acid-base balance)
	2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test	Common Sense Ltd.	
	3. Common Sense Ltd. VA-Sense Kit	Common Sense, Ltd.	
	4. Common Sense Ltd. VS-Sense Test {qualitative}	Common Sense, Ltd	
	5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test	Lil' Drug Store Products Inc.	
84295QW, 84132QW, 85014QW	Abbott i-STAT E3+ Cartridge {Whole Blood}	i-Stat Corporation	Measures potassium, sodium, and hematocrit in whole blood
84443QW	1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood}	Screening Devices Canada Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
84443QW (cont.)	2. BTNX, Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette	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
	3. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette	Screening Devices Canada Inc.	
	4. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood}	Screening Devices Canada Inc.	
	5. Germaine Laboratories, Inc. AimStep Thyroid Screen {whole blood}	Screening Devices Canada Inc.	
	6. ThyroTec, Inc. ThyroTest Whole Blood TSH Test	ThyroTec, Inc.	
	7. Jant Pharmacal Accutest TSH {Whole Blood}	Screening Devices Canada Inc.	
	8. Qualigen, Inc. FastChek TSH {Whole blood}	Screening Devices Canada Inc.	
84450QW, 84520QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp.	Diagnosis of pregnancy
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	1. AimStrip Hb Hemoglobin (Hb) Testing System	Acon Laboratories, Inc.	Measures hemoglobin level in whole blood
	2. Alere HemoPoint H2 System	Stanbio Laboratory	
	3. Biosafe Laboratories, Inc., Anemiapro Self Screener	Biosafe Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
85018QW (cont.)	4. Clarity HbCheck Hemoglobin Testing System	Acon Laboratories, Inc.	Measures hemoglobin level in whole blood
	5. HemoCue Donor Hemoglobin Checker System HemoCue	HemoCue, Inc.	
	6. HemoCue Hemoglobin System	HemoCue, Inc.	
	7. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)	HemoCue, Inc.	
	8. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	HemoCue, Inc.	
	9. HemoCue Hb 301 System	HemoCue, Inc.	
	10. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	
	11. 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. AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use}	Alere San Diego, Inc.	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	2. AvoSure PT System (prescription home use)	Avocet Medical, Inc.	
	3. AvoSure Pro (professional use)	Avocet Medical, Inc.	
	4. CoaguChek PST for Prothrombin Time	Boehringer Mannheim Corporation	
	5. Coag-Sense Prothrombin Time (PT/INR) Monitoring system (Professional use)	CoaguSense, Inc.	
	6. CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)	CoaguSense, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
85610QW(cont.) (Contact your Medicare carrier for claims instructions.)	7. HemoSense INRatio System	HemoSense, 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
	8. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	9. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	10. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	11. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.	
	12. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	
	13. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	14. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	
	15. Roche Diagnostics CoaguChek XS	Roche Diagnostics	
	16. Roche Diagnostics CoaguChek XS Plus System	Roche Diagnostics	
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.	
86308QW	1. Acceava Mono II {Whole Blood}	Biosite 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

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW (cont.)	2. Acceava Mono Cassette {For whole Blood}	Princeton BioMeditech Corp.	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
	3. Acon Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	4. Acon Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	5. AimStep Mono {Whole Blood}	Princeton BioMeditech Corp.	
	6. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	7. BioStar Acceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	8. Cardinal Health SP Brand Rapid Test Mono {Whole Blood}	Cardinal Health	
	9. Clearview MONO Whole Blood, K042272/A013	Inverness Medical Professional Diagnostics	
	10. Clearview MONO Whole Blood, K042272/A016	Innovacon, Inc.	
	11. Clearview Mono-plus II	Applied Biotech, Inc.	
	12. Consult Diagnostics Mononucleosis Cassette {Whole Blood}	Princeton BioMeditech Corp.	
	13. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	14. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	15. Henry Schein OneStep Pro+ Mono {Whole Blood}	Princeton BioMeditech Corp.	
	16. Icon Mono	Beckman Coulter, Inc.	
	17. Immuno Detector Mono {Whole Blood}	Princeton BioMeditech Corp.	
	18. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW (cont.)	19. Instant Technologies iScreen Mononucleosis Rapid Test Strip {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
	20. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	21. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
	22. Jant Pharmacal Corp. Accutest Rapid Mono Test {Whole Blood}	Princeton BioMeditech Corp.	
	23. LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
	24. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	25. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
	26. Medline Mono Test Cassette {Whole Blood}	Princeton BioMeditech Corp.	
	27. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
	28. PerMaxim RediScreen Mononucleosis {Whole Blood}	ACON Laboratories, Inc.	
	29. Polymedco Polystat Mono {whole blood}	Princeton BioMeditech Corp.	
	30. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	31. Poly Stat Mono Test {Whole Blood}	Innovacon, Inc.	
	32. ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only)	Biosite Inc.	
	33. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86308QW (cont.)	34. 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
	35. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	36. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	
	37. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	
	38. Signify Mono Cassette {Whole Blood}	Innovacon, Inc.	
	39. Signify Mono Whole Blood	Inverness Medical Professional Diagnostics	
	40. Stanbio Rely Mono Rapid Test{Whole Blood}	Innovacon, Inc.	
	41. Wampole Mono-Plus WB	Wampole Laboratories	
	42. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	43. 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, Inc.	
	3. Abbott TestPack Plus H. pylori (for whole blood)	Abbott Laboratories	
	4. Acon® H. pylori Test Device	ACON Laboratories, Inc.	
	5. Alere Clearview H. pylori Whole Blood Only {Whole Blood}	Alere San Diego, Inc.	
	6. Alere Signify H. pylori Whole Blood Only {Whole Blood}	Alere San Diego, Inc.	

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

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
86318QW (cont.)	21. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood
	22. Inverness Medical Signify H. Pylori Whole Blood	Innovacon, Inc.	
	23. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	24. McKesson H. pylori Test (Whole Blood)	Alere	
	25. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	
	26. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	
	27. Polymedco Poly Stat H. Pylori Test (Whole Blood)	Innovacon, Inc.	
	28. Pro-Advantage by NDC H. pylori Device (Whole Blood)	Innovacon, Inc.	
	29. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel Corporation	
	30. Quidel QuickVue H. pylori gII (For whole blood)	Quidel Corporation	
	31. Remel RIM® A.R.C. H.pylori Test	Remel	
	32. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.	
	33. Stanbio Rely H. plyori Rapid Test (Whole Blood) (Finger-stick only)	Alere	
	34. Trinity Uni-Gold™ H.pylori	Trinity Biotech	
	35. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Applied Biotech , Inc.	

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86386QW	1. Alere NMP22 BladderChek Test (Prescription Home Use) and (Professional Use)	Alere	Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients
	2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Maritech, 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. 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	
	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	
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
G0433QW	1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood , venipuncture whole blood and/or oral fluid specimens
	2. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid}	OraSure Technologies, Inc.	
	3. Chembio Diagnostic Systems, Inc, DPP HIV 1/2 Assay {Oral Fluid}	Chembio Diagnostic Systems, Inc.	
	4. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
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	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. Jant Accutest Rapid Urease test (H. pylori detection)	ARJ Medical, Inc.	
	6. Medical Instruments Corporation Pronto Dry H. pylori	Medical Instruments Corporation	
	7. Serim Pyloritek Test Kit	Serim	
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.	
87388QW	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]	Oregenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}		Detects antigen to HIV-1, and antibodies to HIV-1 and HIV-2 in whole blood
87449QW	ZymeTx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87502QW	1. Alere i Influenza A & B Test {Direct Nasal swab only}	Alere Scarborough, Inc.	Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology
	2. RocheMolecular, cobas Liat System (cobas Liat Influenza A/B Assay)	IQuum, Inc.	Real-time RT-PCR assay for detection and discrimination of Influenza A and Influenza B in nasopharyngeal swab specimens

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87631QW	Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)	Cepheid	Detection of influenza A, influenza B and respiratory syncytial virus viral RNA by reverse transcriptase polymerase chain reaction assay
87651QW	1. Alere i Instrument	Alere Scarborough, Inc.	Detection of Group A Strep bacterial nucleic acids utilizing isothermal nucleic acid amplification technology
	2. Roche Molecular, cobas Liat System	IQuum, Inc.	Detection of Streptococcus group A utilizing nucleic acid purification and polymerase chain reaction (PCR) technology (automation and integration of sample purification, nucleic acid amplification, and detection of the target sequence using real-time PCR) to detect Streptococcus pyogenes
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B
87804QW	1. Alere Influenza A & B Test (For use with nasal Swabs only.)	Alere Scarborough, Inc.	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
	2. Alere BinaxNow Influenza A & B Card {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}	Alere Scarborough, Inc.	
	3. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}	Becton, Dickinson and Company	
	4. BinaxNow Influenza A & B Test, K092223	Binax, Inc	
	5. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	
	6. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87804QW (cont.)	7. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}	Binax, Inc.	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
	8. Henry Schein OneStep+ Influenza A&B Test	Alere Scarborough, Inc.	
	9. Quidel Quickvue Influenza A+B Test	Quidel Corporation	
	10. Sofia Analyzer and Influenza A+B FIA	Quidel Corporation	
	11. Sofia Analyzer and Influenza A+B FIA (for user with nasal swabs and nasopharyngeal swabs)	Quidel Corporation	
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza A Test Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza A Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza A Test	SA Scientific, Inc.	
87804QW	1. Binax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza 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	1. Alere BinaxNOW RSV Card	Alere Scarborough, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens){Includes a reader}	Becton, Dickinson and Company	
	3. Binax NOW RSV Test (K021687)	Binax, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87807QW (cont.)	4. Binax NOW RSV Test (K032166/A005)	Binax, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	5. Fisher Scientific Sure-Vue RSV Test	SA Scientific, Inc.	
	6. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	7. Quidel Quick Vue RSV Test	Quidel Corporation	
	8. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
	9. Sofia RSV	Quidel Corp.	
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. Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid
	2. AdenoPlus (human eye fluid)	Rapid Pathogen Screening, Inc.	
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, Inc.	
	3. Accustrip Strep A {Specimen type (Throat Swab)}	Princeton Biomeditech Corp.	
	4. Acon® Strep A Rapid Strip Test	ACON Laboratories, Inc.	
	5. Acon® Strep A Twist Rapid Test	ACON Laboratories, Inc.	
	6. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	7. Beckman Coulter ICON DS Strep A Test	Princeton BioMeditech Corp.	
	8. Beckman Coulter ICON SC Strep A Test	ACON Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	9. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	ACON Laboratories, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	10. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter, Inc.	
	11. Becton Dickinson BD Chek Group A Strep A Test	Innovacon, Inc.	
	12. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	13. BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab)	Becton Dickinson and Company	
	14. Binax NOW Strep A Test	Binax, Inc.	
	15. BioStar Acceava Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	16. Biotechnostix Rapid Response Strep A Rapid Test Device	Acon Laboratories Co.	
	17. Biotechnostix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	
	18. BTNX Rapid Response Strep A Rapid Test Strips	Sa Scientific, Inc.	
	19. BTNX, Inc. Strep A Rapid Test	Sa Scientific, Inc.	
	20. Cardinal Health Strep A Dipstick – Rapid Test (Throat Swab Specimen)	Alere SD	
	21. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	Applied Biotech Inc.	
	22. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	23. CLIA waived inc Rapid Strep A Test	Sa Scientific, 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
	24. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	25. DE Healthcare Products TruView Strep A Cassette Test	ACON Laboratories, Inc.	
	26. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	
	27. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	28. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	29. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	30. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	31. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	32. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	33. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	34. Henry Schein Inc, One Step+ Strep A Dipstick Test	Henry Schein	
	35. Henry Schein OneStep Pro+ Strep A Cassette	Princeton Biomeditech Corp.	
	36. Immunostics Detector Strep A Direct	ACON Laboratories, Inc.	
	37. Immunostics Immuno/Strep A Detector	ACON Laboratories, Inc.	
	38. Instant Technologies iStrep Strep A	ACON Laboratories, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	39. 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
	40. Inverness Medical BioStar Acceava Strep A Twist	Innovacon, Inc.	
	41. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)	Innovacon, Inc.	
	42. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	43. Jant Pharmacal Accustrip Strep A Value+ Test Strip	Innovacon, Inc.	
	44. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	45. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	46. LABSCO Advantage Strep A	Princeton BioMeditech Corp,	
	47. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	48. LifeSign LLC Status Strep A	Princeton BioMeditech	
	49. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	50. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	
	51. McKesson Strep A Test – Dipstick	Alere San Diego, Inc.	
	52. McKesson Strep A Test – Twist	Alere San Diego, Inc.	
	53. Medline Strep A Test Strip {Throat Swab}	Alere, Inc.	
	54. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	55. Mooremedical Strep A Rapid Test – Dipstick	Alere San Diego, Inc.	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	56. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	57. Poly stat Strep A Strip Test {Specimen type (Throat Swab)}	Princeton Biomeditech Corp.	
	58. Poly stat Strep A Flip Test	Princeton Biomeditech Corp.	
	59. PSS Consult Diagnostics Strep A Dipstick	Innovacon, Inc.	
	60. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon, Inc.	
	61. PSS World Medical Select Diagnostics Strep A Twist	Innovacon, Inc.	
	62. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	63. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc	
	64. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	65. QuickVue® Dipstick Strep A	Quidel Corporation	
	66. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	67. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013)	Quidel Corporation	
	68. Quidel Sofia Strep A+FIA {from throat swab only}	Quidel Corporation	
	69. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	70. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	71. Sekisui Diagnostics LLC, OSOM Strep A Test{direct from throat swab}	Sekisui Diagnostics LLC	
	72. Sekisui Diagnostics LLC, OSOM Ultra Strep A Test	Sekisui Diagnostics LLC	

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CPT CODE(S)	TEST NAME	MANUFACTURER	USE
87880QW (cont.)	73. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	74. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	
	75. Stanbio QuStick Strep A	Stanbio Laboratory	
	76. StrepAim {Specimen type (Throat Swab)}	Princeton Biomeditech Corp.	
	77. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	78. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
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.
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay 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
	2. SpermCheck Vasectomy	Princeton BioMeditech Corp.	Detects sperm in semen following a vasectomy
89321QW	Fertell Male Fertility Test	Genosis Ltd.	Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml

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