

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 2745</b>	<b>Date: July 24, 2013</b>
	<b>Change Request 8301</b>

Transmittal 2734, dated June 28, 2013, is being rescinded and replaced by Transmittal 2745, dated July 24, 2013, to correct the name of the test in line number two in the background section from “B Henry Schein OneStep+ Influenza A&B Test” to “Henry Schein OneStep+ Influenza A&B Test”. All other information remains the same.

**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 4 newly added waived complexity tests. The initial release of this Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

**EFFECTIVE DATE: October 1, 2013**

**IMPLEMENTATION DATE: October 7, 2013**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**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 obliged 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**

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

## Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 2745	Date: July 24, 2013	Change Request: 8301
-------------	-------------------	---------------------	----------------------

Transmittal 2734, dated June 28, 2013, is being rescinded and replaced by Transmittal 2745, dated July 24, 2013, to correct the name of the test in line number two in the background section from “B Henry Schein OneStep+ Influenza A&B Test” to “Henry Schein OneStep+ Influenza A&B Test”. All other information remains the same.

**SUBJECT: New Waived Tests**

**EFFECTIVE DATE: October 1, 2013**

**IMPLEMENTATION DATE: October 7, 2013**

### 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:

1. 82274QW, G0328QW, January 3, 2013, OSOM iFOB Test OSOM iFOBT Contol Kit;
2. 87804QW, February 13, 2013, Henry Schein OneStep+ Influenza A&B Test;
3. G0434QW, February 27, 2013, American Screening Corporation Discover Drug Test Cards;
4. G0434QW, February 27, 2013, American Screening Corporation Discover Multi-panel Drug Test Cups;
5. 81003QW, March 15, 2013, Moore Medical, mooremedical Urine Analyzer U120; and
6. 82055QW, March 25, 2013, Chematics Inc. Alco-Screen Saliva Alcohol Test.

**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			D M E M A C	F I R E R	C A R R I E R	R H I	Shared-System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
8301.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X					X					
8301.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.		X					X					
8301.3	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.		X					X					

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			D M E M A C	F I R E R	C A R R I E R	R H I	Other
		A	B	H H H					
8301.4	MLN Article : A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X					X	

#### 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) or Contractor Manager, as applicable.

#### VI. FUNDING

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

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

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

**(Attachment 1)**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-automated	Various	Monitors hemoglobin level in blood
84830	Ovulation tests by visual color comparison for human luteinizing hormone	Various	Detection of ovulation (optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia
85651	Erythrocyte sedimentation rate – non-automated	Various	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

**This list includes updates from Change Request 8301**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80047QW, 82330QW, 82374QW, 82435QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	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 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)	Infopia Co., Ltd.	
	3. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	
	4. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	Jant Pharmcal LipidPlus Lipid Profile and Glucose Measuring System	Infopia Co., Ltd.	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
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

**This list includes updates from Change Request 8301**  
\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech QuickScreen One Step Amphetamine Test	Phamatech	Screening test for the presence/detection of amphetamine in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Cassette Amp/Amphetamine	BTNX Inc.	
	3. BTNX Inc Rapid Response X-Press Drug Test Strip Amp/Amphetamine	BTNX Inc.	
	4. Wondfo Amphetamine Urine Test { Cup Format }	Guangzhou Wondfo Biotech Co., Ltd.	
	5. Wondfo Amphetamine Urine Test { Dip card Format }	Guangzhou Wondfo Biotech Co., Ltd.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Secobarbital Urine Test {Cup Format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of barbiturates in urine
	2. Wondfo Secobarbital Urine Test {Dip card Format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0434QW (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.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine
	2. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	
	3. BTNX Inc Rapid Response X-Press Drug Test Cassette	BTNX Inc.	
	4. BTNX Inc Rapid Response X-Press Drug Test Strip	BTNX Inc.	
	5. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	ACON Laboratories, Inc.	
	6. Phamatech QuickScreen One Step THC Screening Test	Phamatech	
	7. Phamatech At Home Drug Test (Model 9078)	Phamatech	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

<b><u>CPT CODE(S)</u></b>	<b><u>TEST NAME</u></b>	<b><u>MANUFACTURER</u></b>	<b><u>USE</u></b>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	8. Phamatech At Home Drug Test (Model 9078T)	Phamatech	Screening test for the presence/detection of cannabinoids (THC) in urine
	9. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Cup format}	BTNX Inc.	Screening test for the presence/detection of cocaine metabolites in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (COC/Cocaine){Dip card format}	BTNX Inc.	
	3. Phamatech At Home Drug Test (Model 9073)	Phamatech	
	4. Phamatech At Home Drug Test (Model 9073T)	Phamatech	
	5. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	
G0434QW (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 (MTD/Methadone){Cup format}	BTNX Inc.	Screening test for the presence/detection of methadone in urine
	2. BTNX Inc Rapid Response X-Press Drug Test (MTD/Methadone){Dip card format}	BTNX Inc.	

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (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
G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. BTNX Inc Rapid Response X-Press Drug Test (MET/Methamphetamine){Dip card format}	BTNX Inc.	Screening test for the presence/detection of methamphetamines in urine
	3. Phamatech At Home Drug Test (Model 9068)	Phamatech	
	4. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	
G0434QW (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/Methylenedioxy methamphetamine){Cup format}	BTNX Inc.	Screening test for the presence/detection of 3,4-methylenedioxy methamphetamine HCl (MDMA) in urine
G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. BTNX Inc Rapid Response X-Press Drug Test (MDMA/Methylenedioxy methamphetamine){Dip card format}	BTNX Inc.	Screening test for the presence/detection of 3,4-methylenedioxy methamphetamine HCl (MDMA) in urine
G0434QW (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 (MOP/Morphine){Cup format}	BTNX Inc.	Screening test for the presence/detection of morphine in urine at a cutoff concentration of 300ng/ml
	2. BTNX Inc Rapid Response X-Press Drug Test (MOP/Morphine){Dip card format}	BTNX Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (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.	
G0434QW (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.	
G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. Mossman Associates, Inc. NicCheck I Test Strips	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
G0434QW (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 Nortiptyline{Cup format}	BTNX Inc.	Screening test for the presence/detection of nortiptyline (major metabolite of tricyclic antidepressants) in urine
	2. BTNX Inc Rapid Response X-Press Drug Test Nortiptyline{Dip card format}	BTNX Inc.	
G0434QW (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	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (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.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Oxycodone Urine Test {Dip card format}	Guangzhou Wondfo Biotech Co., Ltd.	Screening test for the presence/detection of oxycodone in urine
	2. Wondfo Oxycodone Urine Test {Cup format}	Guangzhou Wondfo Biotech Co., Ltd.	
G0434QW (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.	
	3. Phamatech At Home Drug Test (Model 9133)	Phamatech	
	4. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	
G0434QW (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.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) 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. Wondfo Cannabinoids Urine Test {Cup Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	6. Wondfo Cannabinoids Urine Test {Dip card Format}	Guangzhou Wondfu Biotech Co., Ltd.	
	7. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC)	Worldwide Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant-View Drug of Abuse Urine Cassette Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine
	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.	

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
G0434QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. Insight Medical Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of morphine and oxycodone in urine	
	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.		
	G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. ADC CLIA Waived Multiple Drug Test Card	ADC	Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and PCP in urine
		2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card	Advantage Diagnostics Corporation	
		3. AlateX Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Phamatech At Home Drug Test (Model 9150T)	Phamatech	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, and opiates in urine	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET)	Worldwide Medical Corporation	Screening test for the presence/detection of THC, cocaine metabolites, opiates and methamphetamines in urine
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	<ol style="list-style-type: none"> <li>1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine</li> <li>2. accutest Multi-Drug, Multi-Line Screen Test Device</li> <li>3. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)</li> <li>4. Alere iCassette Drug Screen</li> <li>5. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device</li> <li>6. iCassette Multi-Drug, Multi-Line Screen Test Device</li> <li>7. RediScreen Multi-Drug, Multi-Line Screen Test Device</li> <li>8. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}</li> </ol>	<ol style="list-style-type: none"> <li>1. Accu-Stat Diagnostics, Inc.</li> <li>2. ACON Laboratories, Inc.</li> <li>3. ACON Laboratories, Inc.</li> <li>4. Alere</li> <li>5. ACON Laboratories, Inc.</li> <li>6. ACON Laboratories, Inc.</li> <li>7. ACON Laboratories, Inc.</li> <li>8. Innovacon, Inc.</li> </ol>	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW (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	
G0434QW (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 benzodiazepines, barbiturates, MDMA, methadone, opiates, and oxycodone in urine
	2. Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests	Chemtron Biotech, Inc	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine
	2. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Innovacon, Inc.	
	3. First Check Diagnostics First Check Multi Drug Cup	First Check Diagnostics LLC	
	4. Innovacon Integrated E-Z Split Key Cup II {Professional Use}	Innovacon, Inc.	
	5. Noble Medical Inc. Split-Specimen Cup	ACON Laboratories, Inc.	
	6. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II	Biosite Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	7. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use }	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine (MDMA), opiates, and PCP in urine
	8. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon, Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Wondfo Multi-Drug Urine Test Cup {Cup Format }	Guangzhou wondfo Biotech Co., Ltd.	Screening test for the presence/detection of cocaine metabolites, methamphetamines, MDMA, morphine, methadone, PCP and tricyclic antidepressants in urine
	2. Wondfo Multi-Drug Urine Test Panel {Dip Card Format }		
G0434QW (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.	
G0434QW (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
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Innovacon Multi-Clin Drug Screen Test Device	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Instant Technologies, Inc. iCassette DX Drug Screen Test	Alere	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, MDMA, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	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.	
G0434QW (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
	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	
	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.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	9. Physicians' Test 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
	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.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	13. Total Diagnostic Solutions 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, morphine, oxycodone, PCP and tricyclic antidepressants in urine
	1. Aventir Biotech LLC Home Check Multiple Drug Test Cup	Tianjin New Bay Bioresearch Co. Ltd.	
	2. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd.	
	3. Medimpex United Inc. MedimpexQ Test Multi X Drug Cup Test	Tianjin New Bay Bioresearch Co. Ltd.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. Syntron Bioresearch Quikscreen 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, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	1. Amedica Biotech Amedica Drug Screen Test Cup	Amedica Biotech, Inc.	
	2. Amedica Biotech AmediCheck Instant Test Cup	Amedica Biotech, Inc.	
	3. Amedica Biotech Instant Test Cup	Amedica Biotech, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. Ameditech, Inc ImmuTest Drug Screen Cup	Biosite Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	5. Branan Medical Corporation, FasTox Multiple Drug Dipcard	Branan Medical Corporation	
	6. CLIAwaived, Inc. Rapid Drug Test	Biosite Inc.	
	7. CLIAwaived, Inc. Rapid Drug Test Cup {OTC}	Biosite Inc.	
	8. CLIAwaived Inc. Rapid Dip Drug Test	Branan Medical Corporation	
	9. CLIAwaived Inc. Single Drug Dipstick Test	Branan Medical Corporation	
	10. Express Diagnostics, DrugCheck Waive Cup	Biosite Inc.	
	11. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
	12. Instant Technologies, iCup DX Drug Screen Cup	Biosite Inc.	
	13. Jant Pharmacal Corporation ACCUTEST Drug Test Cup	Amedica Biotech, Inc	
	14. Millennium Laboratories Clinical Supply, Inc Multi-Drug Pain Med Screen Cup	Biosite Inc.	
	15. NexScreen LLC, NexScreen Cup	Amedica Biotech, Inc.	
	16. Noble Medical Inc. NOBLE 1 Step Cup {OTC}	Biosite Inc.	
	17. Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}	Biosite Inc.	

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	18. Redwood Toxicology Laboratory, Inc Reditest Freedom Cup	Biosite Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	19. Twin Spirit, Inc. DrugSmart Cup	Amedica Biotech, Inc.	
	20. US Diagnostics ProScreen Drugs of Abuse Cup {OTC}	Biosite Inc.	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methadone, methamphetamines, MDMA, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Branan Medical Corporation, QuickTox Drug Screen Dipcard	Branan Medical Corporation	
G0434QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. 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
	2. American Screening Corporation Discover Multi-panel Drug Test Cups*	UCP Biosciences, Inc	
	3. American Screening Corporation, Inc., Multi-Drug Testing Cards	UCP Biosciences, Inc	
	4. American Screening Corporation, Inc., Multi-Drug Testing Cups	UCP Biosciences, Inc	
	5. American Screening Corporation OneScreen Drug Test Cards	UCP Biosciences, Inc.	
	6. American Screening Corporation OneScreen Drug Test Cups	UCP Biosciences, Inc.	
	7. American Screening Corporation Reveal Multi-Drug Testing Cups	UCP Biosciences, Inc	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
G0434QW(cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	8. Diagnostic Test Group Clarity Multi-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
	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.	
	13. Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups	UCP Biosciences, Inc.	
	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. Multiple Drug Screen Cups	UCP Biosciences	
	17. UCP Biosciences, Inc. U-Checker Drug Screening Test Cups	UCP Biosciences, Inc.	
	18. UCP Biosciences, Inc. UCP Compact Drug Test Cards	UCP Biosciences, Inc	
	19. UCP Biosciences, Inc. UCP Compact Drug Test Cups	UCP Biosciences, Inc	
	20. UCP Biosciences, Inc., UCP Home Drug Screening Test Cards	UCP Biosciences, Inc.	
	21. Ultimate Analysis Cup UA Cups	UCP Biosciences, Inc.	
	22. American Bio Medica Rapid TOX	American Bio Medica Corp.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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.	
	3. Acon Mission U120 Urine Analyzer	Acon Laboratories, Inc.	
	4. Biosys Laboratories Optima Urine Analyzer	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 Laboratories, Inc.	
	11. Henry Schein OneStepPlus Urine Analyzer	Macherey-Nagel GmbH & Co., Kg.	
	12. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	13. Immunostics Inc., Detector Uristrip+ Analyzer	Acon Laboratories, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81003QW (cont.)	14. Jant Pharmacal Corporation Accustrip URS Reader	Jant Pharmacal Corporation	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
	15. McKesson 120 Urine Analyzer	Acon Laboratories, Inc.	
	16. Mediwatch urinewatch Urine Analyzer	Acon Laboratories, Inc.	
	17. Moore Medical, mooremedical Urine Analyzer U120*	Acon Laboratories, Inc.	
	18. Physician Sales & Service, Inc. PSS Select Urine Analyzer	BioSys Laboratories, Inc.	
	19. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	20. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer Mannheim Corporation	
	21. Stanbio Uri-Trak 120 Urine Analyzer	Acon Laboratories, Inc.	
	22. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
81003QW, 82044QW, 82570QW	Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine
81003QW, 82044QW, 82570QW, 84703QW	1. Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	Diatech Diagnostics Uriscreeen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
82010QW, 82962 (cont.)	2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
	3. Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System	Nova Biomedical Corp.	
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma glutamyltransferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	
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
	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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	<ol style="list-style-type: none"> <li>1. Beckman Coulter ICON Microalb</li> <li>2. Boehringer Mannheim Chemstrip Micral</li> <li>3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test</li> <li>4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)</li> <li>5. Genzyme Daignostics OSOM ImmunoDip Urinary Albumin Test</li> <li>6. Roche Diagnostics Chemstrip Micral (urine dipstick)</li> </ol>	<ol style="list-style-type: none"> <li>Beckman Coulter, Inc.</li> <li>Boehringer Mannheim</li> <li>Diagnostic Chemicals Limited</li> <li>Diagnostic Chemicals Limited (USA)</li> <li>Genzyme Diagnositcs</li> <li>Roche Diagnostics Corporation</li> </ol>	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	<ol style="list-style-type: none"> <li>1. Alere Toxicology services, iScreen Saliva Alcohol Test Strip</li> <li>2. Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip</li> <li>3. American Screening Corporation, Reveal Saliva Alcohol Test Strip</li> <li>4. Acon Laboratories Inc. Mission Saliva Alcohol Test Strip</li> <li>5. Chematics Inc. Alco-Screen Saliva Alcohol Test*</li> </ol>	<ol style="list-style-type: none"> <li>Acon Laboratories, Inc.</li> <li>Acon Laboratories, Inc.</li> <li>Acon Laboratories, Inc.</li> <li>Acon Laboratories, Inc.</li> <li>Chematics. Inc</li> </ol>	Quantitative determination of alcohol (ethanol) in saliva

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
82055QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	6. Chematics Inc. Alco-Screen 02 Saliva Alcohol Test	Chematics. Inc.	Quantitative determination of alcohol (ethanol) in saliva	
	7. CLIAwaived Inc. Rapid Saliva Alcohol Test	Acon Laboratories, Inc.		
	8. Germaine Laboratories AimStrip Alcohol Saliva	Acon Laboratories, Inc.		
	9. Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip	Acon Laboratories, Inc.		
	10. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test	OraSure Technologies, Inc.		
	11. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	OraSure Technologies, Inc.		
	12. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test	STC Technologies Inc.		
	13. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	STC Technologies Inc.		
	14. Teco Diagnostics Saliva Alcohol Test	Teco Diagnostics		
	82120QW, 83986QW	1. Litmus Concepts FemExam TestCard (from vaginal swab)	Litmus Concepts, Inc.	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
	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 Gastrocult	SmithKline	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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.	
	4. BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)	Ind Diagnostic Inc.	
	5. BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (iFOBT)	Teco Diagnostics	
	6. BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test	Alfa Scientific Designs, Inc	
	7. Care Diagnostics Clarity iFOB Test	Care Diagnostics, Inc.	
	8. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	Wampole Laboratories	
	9. Clearview Ultra FOB Test	RAC Medical Group, Inc.	
	10. Consult Diagnostics Immunochemical Fecal Occult Blood Test (iFOBT)	Immunostics, Inc.	
	11. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	
	12. Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
	13. Enterix Insure II Fecal Immunochemical Test	Enterix, Inc.	
	14. Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW G0328QW(cont.)	15. Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test	New Bay Bioresearch Co. Ltd.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	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.	
	19. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	Immunostics, In	
	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 One-Step Immunological Fecal Occult Blood Test	Ind Diagnostics Inc.	
	24. OC-Light iFOB Test	Polymedco, Inc	
	25. OSOM iFOB Test OSOM iFOBT Contol Kit*	Sekisui Diagnostics, Inc	
	26. OcculTech Fecal Occult Blood Rapid Test	YD Diagnosites Corp.	
	27. Polymedco Poly Stat OC-light FOB Test	Polymedco, Inc.	
	28. Teco Rapid Fecal Occult Blood (FOB) Card Test	Teco Diagnostics	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	<ol style="list-style-type: none"> <li>Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}</li> <li>Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}</li> </ol>	<p>Abaxis, Inc.</p> <p>Abaxis, Inc</p>	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and urea nitrogen (BUN) in whole blood
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.)	<ol style="list-style-type: none"> <li>Advanced Care</li> <li>Boehringer Mannheim Accu-Chek InstantPlus Cholesterol</li> <li>ChemTrak AccuMeter</li> <li>ENA.C.T Total Cholesterol Test</li> <li>ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)</li> <li>Lifestream Technologies Cholesterol Monitor</li> <li>Lifestream Technologies Personal Cholesterol Monitor</li> <li>Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol</li> <li>PTS Bioscanner Test Strips Cholesterol</li> </ol>	<p>Johnson &amp; Johnson</p> <p>Boehringer Mannheim</p> <p>ChemTrak</p> <p>ActiMed Laboratories, Inc.</p> <p>ActiMed Laboratories, Inc.</p> <p>Lifestream Technologies, Inc.</p> <p>Lifestream Technologies, Inc.</p> <p>Polymer Technology Systems, Inc.</p> <p>Polymer Technology Systems, Inc.</p>	Cholesterol monitoring

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 82962	1. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	Measures total cholesterol and monitors blood glucose levels
	2. Roche Diagnostics AccuChek Instant Plus Dual Testing System		
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW	1. Cholestech LDX	Cholestech Corp.	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood
	2. Infopia USA LipidPro lipid profile and glucose measuring system	Infopia CO., Ltd.	
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	Wako APOLOWAKO Analyzer (Whole Blood)	Wako Chemicals USA, Inc.	Measures total cholesterol, hemoglobin A1c, glucose, and triglycerides in whole blood
82465QW(Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW 82523QW	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
	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

**This list includes updates from Change Request 8301**

\* Newly added waived test system

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, aspartate aminotransferase, creatinine, gamma glutamyltransferase, glucose and urea nitrogen in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	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)

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82962, 82465QW(Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	1. LXN Duet Glucose Control Monitoring System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period
	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	
83001QW	1. Acon Laboratories, Inc. FSH Menopause Predictor Test	ACON Laboratories, Inc.	Detects follicle stimulating hormone in urine
	2. Acon Laboratories, Inc. FSH One Step Menopause Test Device {Professional Use}	ACON Laboratories, Inc.	
	3. Acon Laboratories, Inc. FSH One Step Menopause Test Strip {Professional Use}	ACON Laboratories, Inc.	
	4. Applied Biotech, Inc. RU25 Plus FSH Menopause Test	Applied Biotech, Inc.	
	5. Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device	ACON Laboratories, Inc.	
	6. Genosis Fertell Female Fertility Test	Genosis, Inc.	
	7. Genua Menopause Monitor Test	Genua 1944 Inc	
	8. Synova Healthcare MenocheckPro (Professional Use)	Applied Biotech, Inc.	
83036QW	1. Axis-Shield Afinion AS100 Analyzer	Axis-Sheild Poc As	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	2. Bayer AICNow+ Professional Use	Bayer Healthcare, LLC	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83036QW(cont.)	3. Siemens Medical Diagnostics DCA Vantage Analyzer	Siemens Healthcare Diagnostics, Inc.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	4. Siemens DCA 2000 Analyzer	Siemens Healthcare Diagnostics, Inc.	
	5. 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.	
	2. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories	
	3. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	
	4. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	ESA Biosciences, Inc.	Quantitative measurement of blood lead in whole blood
83718QW	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood
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

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83861QW	TearLab Corporation TearLab Osmolarity System	TearLab Corporation	Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.
83880QW	<ol style="list-style-type: none"> <li>1. Biosite Triage Meter {Whole Blood}</li> <li>2. Biosite Triage Meter Plus {Whole Blood}</li> </ol>	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
83986QW	All qualitative color comparison pH testing - body fluids (other than blood)	Various	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates
83986QW	<ol style="list-style-type: none"> <li>1. Dale Medical Products, Inc. RightLevel pH</li> <li>2. Dale Medical Products, Inc. RightSpot pH</li> </ol>	EZ-NG, LLC.	Gastric pH detection (acid-base balance)
83986QW	<ol style="list-style-type: none"> <li>1. FemTek pHEM-ALERT®</li> <li>2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test</li> <li>3. Common Sense Ltd. VA-Sense Kit</li> <li>4. Common Sense Ltd. VS-Sense Test {qualitative}</li> <li>5. Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test</li> </ol>	FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Common Sense, Ltd.	Vaginal pH detection (acid-base balance)
84295QW, 84132QW, 85014QW	Abbott i-STAT E3+ Cartridge {Whole Blood}	i-Stat Corporation	Measures potassium, sodium, and hematocrit in whole blood
84443QW	<ol style="list-style-type: none"> <li>1. Aventir Biotech LLC, Forsure TSH Test {Whole Blood}</li> <li>2. BTNX, Inc Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette</li> </ol>	Screening Devices Canada Inc. Screening Devices Canada Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
84443QW(cont.)	3. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette { Whole Blood}	Screening Devices Canada Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
	4. ThyroTec, Inc. ThyroTest Whole Blood TSH Test	ThyroTes, Inc.	
	5. Jant Pharmacal Accutest TSH { Whole Blood}	Screening Devices Canada Inc.	
	6. 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. Biosafe Laboratories, Inc., Anemiapro Self Screener	Biosafe Laboratories, Inc.	Measures hemoglobin level in whole blood
	2. HemoCue Donor Hemoglobin Checker System HemoCue	HemoCue, Inc.	
	3. HemoCue Hemoglobin System	HemoCue, Inc.	
	4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)	HemoCue, Inc.	
	5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System	HemoCue, Inc.	
	6. HemoCue Hb 301 System	HemoCue, Inc.	
	7. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	

**This list includes updates from Change Request 8301**  
 \* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
85018QW(cont.)	8. GDS Technology STAT-Site MHgb Test System	GDS Technology	Measures hemoglobin level in whole blood
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.	
	7. HemoSense INRatio System	HemoSense, Inc.	
	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	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
85610QW(cont.) (Contact your Medicare carrier for claims instructions.)	14. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	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
	2. Acceava Mono Cassette {For whole Blood}	Princeton BioMeditech Corp.	
	3. Acon Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	4. Acon Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	5. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	6. BioStar Acceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	7. Cardinal Health SP Brand Rapid Test Mono {Whole Blood}	Cardinal Health	
	8. Clearview MONO Whole Blood, K042272/A013	Inverness Medical Professional Diagnostics	
	9. Clearview MONO Whole Blood, K042272/A016	Innovacon, Inc.	
	10. Clearview Mono-plus II	Applied Biotech, Inc.	
	11. Consult Diagnostics Mononucleosis Cassette {Whole Blood}	Princeton BioMeditech Corp.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW (cont.)	12. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
	13. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	14. Icon Mono	Beckman Coulter, Inc.	
	15. Immuno Detector Mono {Whole Blood}	Princeton BioMeditech Corp.	
	16. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	17. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	18. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	19. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
	20. LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
	21. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	22. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
	23. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
	24. PerMaxim RediScreen Mononucleosis {Whole Blood}	ACON Laboratories, Inc.	
	25. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	26. Poly Stat Mono Test {Whole Blood}	Innovacon, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86318QW (cont.)	19. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	20. Inverness Medical Signify H. Pylori Whole Blood	Innovacon, Inc.	
	21. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	22. McKesson H. pylori Test (Whole Blood)	Alere	
	23. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	
	24. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	
	25. Polymedco Poly Stat H. Pylori Test (Whole Blood)	Innovacon, Inc.	
	26. Pro-Advantage by NDC H. pylori Device (Whole Blood)	Innovacon, Inc.	
	27. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel Corporation	
	28. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation	
	29. Remel RIM® A.R.C. H.pylori Test	Remel	
	30. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.	
	31. Stanbio Rely H. plyori Rapid Test (Whole Blood) (Finger-stick only)	Alere	
	32. Trinity Uni-Gold™ H.pylori	Trinity Biotech	
	33. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Applied Biotech , Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
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™ <i>B. burgdorferi</i> Antibody Detection Assay	Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood
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	
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. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	
86803QW	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

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87077QW	1. Ballard Medical Products CLOtest	Ballard Medical Products	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
	2. Delta West CLOtest	Delta West Tri-Med Specialties	
	3. GI Supply HP-FAST	Mycoscience Labs, Inc.	
	4. GI Supply, Div. Chek-Med Systems HP One	GI Supply	
	5. Medical Instruments Corporation Pronto Dry H. pylori	Medical Instruments Corporation	
	6. Serim Pyloritek Test Kit	Serim	
87210QW	1. Stesans Maybe?Mom Mini Ovulation Microscope	LEC Associates	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)
	2. O2 Unlimited Donna Ovulation Tester	O2 Unlimited Corp.	
87449QW	ZymeTx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does not differentiate between influenza types A and B
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	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>		
87804QW (cont.)	5. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens, K041049	Binax, Inc.	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B		
	6. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.			
	7. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}	Binax, Inc.			
	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 (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.			

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87807QW	1. Alere BinaxNOW RSV Card	Alere Scarborough, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. Binax NOW RSV Test (K021687)	Binax, Inc.	
	3. Binax NOW RSV Test (K032166/A005)	Binax, Inc.	
	4. Fisher Scientific Sure-Vue RSV Test	SA Scientific, Inc.	
	5. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	6. Quidel Quick Vue RSV Test	Quidel Corporation	
	7. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87808QW	1. Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> 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. Acon® Strep A Rapid Strip Test	ACON Laboratories, Inc.	
	4. Acon® Strep A Twist Rapid Test	ACON Laboratories, Inc.	
	5. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	6. Beckman Coulter ICON DS Strep A Test	Princeton BioMeditech Corp.	
	7. Beckman Coulter ICON SC Strep A Test	ACON Laboratories, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system



## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	8. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	ACON Laboratories, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter, Inc.	
	10. Becton Dickinson BD Chek Group A Strep A Test	Innovacon, Inc.	
	11. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	12. Binax NOW Strep A Test	Binax, Inc.	
	13. BioStar Aceeva Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	14. Biotechnostix Rapid Response Strep A Rapid Test Device	Acon Laboratories Co.	
	15. Biotechnostix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	
	16. BTNX Rapid Response Strep A Rapid Test Strips	Sa Scientific, Inc.	
	17. BTNX, Inc. Strep A Rapid Test	Sa Scientific, Inc.	
	18. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	Applied Biotech Inc.	
	19. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon, Inc.	
	20. CLIA waived inc Rapid Strep A Test	Sa Scientific, Inc.	
	21. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	22. DE Healthcare Products TruView Strep A Cassette Test	ACON Laboratories, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	23. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	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. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	25. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	26. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	27. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	28. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	29. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	30. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	31. Henry Schein Inc, One Step+ Strep A Dipstick Test	Henry Schein	
	32. Immunostics Detector Strep A Direct	ACON Laboratories, Inc.	
	33. Immunostics Immuno/Strep A Detector	ACON Laboratories, Inc.	
	34. Instant Technologies iStrep Strep A	ACON Laboratories, Inc.	
	35. Inverness Medical BioStar Aceava Strep A Test	Innovacon, Inc.	
	36. Inverness Medical BioStar Aceava Strep A Twist	Innovacon, Inc.	
	37. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)	Innovacon, Inc.	
	38. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	39. Jant Pharmacal Accustrip Strep A Value+ Test Strip	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. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	41. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	42. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	43. LifeSign LLC Status Strep A	Princeton BioMeditech	
	44. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	45. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	
	46. McKesson Strep A Test – Dipstick	Alere San Diego, Inc.	
	47. McKesson Strep A Test – Twist	Alere San Diego, Inc.	
	48. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	49. Mooremedical Strep A Rapid Test – Dipstick	Alere San Diego, Inc.	
	50. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon, Inc.	
	51. PSS Consult Diagnostics Strep A Dipstick	Innovacon, Inc.	
	52. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon, Inc.	
	53. PSS World Medical Select Diagnostics Strep A Twist	Innovacon, Inc.	
54. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.		
55. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc.		

**This list includes updates from Change Request 8301**

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW (cont.)	56. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	57. QuickVue® Dipstick Strep A	Quidel Corporation	
	58. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	59. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013)	Quidel Corporation	
	60. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	61. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	62. Sekisui Diagnostics LLC, OSOM Strep A Test{direct from throat swab}	Sekisui Diagnostics LLC	
	63. Sekisui Diagnostics LLC, OSOM Ultra Strep A Test	Sekisui Diagnostics LLC	
	64. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax, Inc.	
	65. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	
	66. Stanbio QuStick Strep A	Stanbio Laboratory	
	67. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	68. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
	87905QW	1. Gryphus Diagnostics BVBlue	
2. Genzyme Diagnostics OSOM BVBlue Test		Gryphus Diagnostics, LLC	
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens

**This list includes updates from Change Request 8301**

\* Newly added waived test system

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

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