

<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 1857</b>	<b>Date: November 20, 2009</b>
	<b>Change Request 6685</b>

**Subject: New Waived Tests**

**I. SUMMARY OF CHANGES:** This instruction informs contractors of new waived tests approved by the Food and Drug Administration under Clinical Laboratory Improvement Amendments of 1988. Since these tests are marketed immediately after approval, the Centers for Medicare and Medicaid Services must notify its contractors of the new tests so that the contractors can accurately process claims. This Recurring Update Notification (RUN) can be found in Chapter 16, § 70.8 of the Internet Only Manual (IOM).

**New / Revised Material**

**Effective Date: January 1, 2010**

**Implementation Date: January 4, 2010**

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

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

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

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

**III. FUNDING:**

**SECTION A:** For Fiscal Intermediaries and Carriers:

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

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

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

**IV. ATTACHMENTS:**

**Recurring Update Notification**

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

# Attachment – Recurring Update Notification

<b>Pub. 100-04</b>	<b>Transmittal: 1857</b>	<b>Date: November 20, 2009</b>	<b>Change Request: 6685</b>
--------------------	--------------------------	--------------------------------	-----------------------------

**SUBJECT:** New Waived Tests

**Effective Date:** January 1, 2010

**Implementation Date:** January 4, 2010

## I. GENERAL INFORMATION

### A. Background:

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

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

CPT Code	Effective Date	Description
80101QW	March 10, 2009	Amedica Biotech Amedica Drug Screen Test Cup
80101QW	May 11, 2009	Twin Spirit, Inc. DrugSmart Cup
84443QW	June 3, 2009	CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood}
86308QW	July 16, 2009	ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only)
86318QW	August 7, 2009	Pro-Advantage by NDC H. pylori Device (Whole Blood)
87804QW	August 18, 2009	BinaxNOW Influenza A & B Test, K092223

For 2009, the description for the CPT code 84155 was modified from “Protein, total, except by refractometry; serum” to “Protein, total, except by refractometry; serum, plasma or whole blood.” Therefore, the CPT codes assigned for the total protein test performed on the following test systems have been changed from 84157QW to 84155QW:

- Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood},
- Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood},
- Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood},
- Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood), and
- Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2){Whole Blood}.

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

**B. Policy:** The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

## II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M A C	F I  M A C	C A R I E R	R H I  S S	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
6685.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	X			X						
6685.2	The Medicare contractor shall permit the use of codes 84155QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2009.	X			X						X
6685.3	The Medicare contractor shall deny the use of code 84157QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2010.	X			X						X
6685.4	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						
6685.5	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.	X			X						

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M A C	F I  M A C	C A R I E R	R H I  S S	Shared-System Maintainers				OTH ER
							F I S S	M C S	V M S	C W F	
6685.6	A provider education article related to this instruction will be available at	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
		M A C	M A C				F I S S	M C S	V M S	C W F	
	<a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/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 site 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 your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

**IV. SUPPORTING INFORMATION**

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

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

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

**V. CONTACTS**

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

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

**VI. FUNDING**

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

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

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

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

**Attachment – TESTS GRANTED WAIVED STATUS UNDER CLIA**

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<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 6685**

**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 6685**  
\* 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. Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc) (Whole Blood)	Abaxis, Incorporated	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Abaxis, Piccolo xpress Chemistry Analyzer {Lipid Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
	3. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood
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	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) in urine

**This list includes updates from Change Request 6685**  
\* 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>
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	Screening test for the presence/detection of cannabinoids (THC) in urine
	3. First Check Diagnostics LLC, First Check Home Drug Test Marijuana	ACON Laboratories, Inc.	
	4. Phamatech At Home Drug Test (Model 9078)	Phamatech	
	5. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	6. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
	80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9073)	
	2. Phamatech At Home Drug Test (Model 9073T)	Phamatech	
	3. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9068)	Phamatech	Screening test for the presence/detection of methamphetamines in urine
	2. Phamatech QuickScreen One Step Methamphetamine Test	Phamatech	

**This list includes updates from Change Request 6685**  
 \* 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>
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. DyanGen NicCheck II Test Strips	DynaGen, Inc.	Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer
	2. Mossman Associates, Inc. NicCheck I Test Strips	Mossman Associates, Inc.	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9083)	Phamatech	Screening test for the presence/detection of opiates in urine
	2. Phamatech QuickScreen One Step Opiate Screening Test	Phamatech	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9133)	Phamatech	Screening test for the presence/detection of phencyclidine in urine
	2. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	

**This list includes updates from Change Request 6685**

\* 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>
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	Screening test for the presence/detection of phencyclidine (PCP) in urine
	2. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC)	Worldwide Medical Corporation	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. ADC CLIA Waived Multiple Drug Test Card	ADC	Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and PCP in urine
	2. Advantage Diagnostics Corporation ADC Multiple Drug Test Card	Advantage Diagnostics Corporation	
	3. Alatec Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Phamatec At Home Drug Test (Model 9150T)	Phamatec	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, and opiates in urine

**This list includes updates from Change Request 6685**

\* 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>
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET)	Worldwide Medical Corporation	Screening test for the presence/detection of THC, cocaine metabolites, opiates and methamphetamines in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, opiates, and PCP in urine
	2. accutest Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	3. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)	ACON Laboratories, Inc.	
	4. Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	5. iCassette Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	6. RediScreen Multi-Drug, Multi-Line Screen Test Device	ACON Laboratories, Inc.	
	7. Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use}	Innovacon, Inc.	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup	ACON Laboratories, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and PCP in urine

**This list includes updates from Change Request 6685**

\* 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>
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	2. Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, THC, cocaine metabolites, methamphetamines, methylenedioxymethamphetamine, opiates, and PCP in urine
	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. 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II	Biosite Inc.	
	6. Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use}	Innovacon, Inc.	
	7. Wolfe Drug Testing RealityCheck Integrated Specimen Cup	Innovacon, Inc.	
	80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Branan Medical Corporation ToxCup Drug Screen Cup	Branan Medical Corporation
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Innovacon Multi-Clin Drug Screen Test Device	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methylenedioxymethamphetamine, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
	2. Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device	Innovacon, Inc.	

**This list includes updates from Change Request 6685**

\* 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>
80101QW (cont.) (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	3. Abbott Diagnostics Signify ER Drug Screen Test	Innovacon, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methylenedioxymethamphetamine, opiates, oxycodone, PCP, propoxyphene and tricyclic antidepressants in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Amedica Biotech Amedica Drug Screen Test Cup*	Amedica Biotech, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, PCP and tricyclic antidepressants in urine
	2. Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	
	3. Branan Medical Corporation, FasTox Multiple Drug Dipcard	Branan Medical Corporation	
	4. Branan Medical Corporation, QuickTox Drug Screen Dipcard	Branan Medical Corporation	
	5. First Check Diagnostics First Check 12 Drug Test	First Check Diagnostics LLC	
	6. Twin Spirit, Inc. DrugSmart Cup*		
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, methylenedioxymethamphetamine, morphine, PCP and tricyclic antidepressants in urine
	2. Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test	Alfa Scientific Designs, Inc.	
	3. BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	

**This list includes updates from Change Request 6685**

\* 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>
80101QW (cont.)(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	4. BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine)	Alfa Scientific Designs, Inc.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, methylenedioxymethamphetamine, morphine, PCP and tricyclic antidepressants in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Aventir Biotech LLC Home Check Multiple Drug Test Cup	Tianjin New Bay Bioresearch Co. Ltd.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, THC, cocaine metabolites, methamphetamines, methadone, morphine, oxycodone, PCP and tricyclic antidepressants in urine
	2. Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
	3. Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version}	Tianjin New Bay Bioresearch Co. Ltd	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	American Bio Medica Rapid TOX	American Bio Medica Corp.	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, buprenorphine, THC, cocaine metabolites, methylenedioxymethamphetamine, methamphetamines, methadone, opiates, oxycodone, PCP, propoxyphene, and tricyclic antidepressants in urine
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
81002, 82570QW	1. Bayer Multistick Pro 7G Reagent Strips	Bayer Corp.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
	2. Bayer Multistick Pro 10LS Reagent Strips	Bayer Corp.	
	3. Bayer Multistick Pro 11 Reagent Strips	Bayer Corp.	

**This list includes updates from Change Request 6685**

\* 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	1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Bayer Corp.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
	2. Biosys Laboratories Optima Urine Analyzer	BioSys Laboratories, Inc.	
	3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Boehringer Mannheim Corporation	
	4. Consult diagnostics Urine Analyzer	BioSys Laboratories, Inc.	
	5. Henry Schein OneStepPlus Urine Analyzer	Macherey-Nagel GmbH & Co., Kg.	
	6. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	7. Jant Pharmacal Corporation Accustrip URS Reader		
	8. Physician Sales & Service, Inc. PSS Select Urine Analyzer	BioSys Laboratories, Inc.	
	9. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	10. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer Mannheim Corporation	
	11. Teco Diagnostics URITEK TC-101 Urine Strip Reader	Teco Diagnostics	
	12. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	

**This list includes updates from Change Request 6685**

\* 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, 82570QW	Bayer Clinitek Status Urine Chemistry Analyzer	Bayer Healthcare, LLC	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
81003QW, 82044QW, 82570QW, 84703QW	Siemens Clinitek Status 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 the semi-quantitative measurement for albumin and creatinine in urine, and the diagnosis of pregnancy
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.
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	<ol style="list-style-type: none"> <li>Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)</li> <li>Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)</li> </ol>	Abbott Laboratories	Monitoring of blood glucose levels and measures ketones in whole blood
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW	<ol style="list-style-type: none"> <li>Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){ whole blood}</li> <li>Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)</li> </ol>	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma glutamyltransferase, total bilirubin and total protein levels in whole blood

**This list includes updates from Change Request 6685**

\* 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 82043QW	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
	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW, 82570QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine 2. Bayer Diagnostics/ MICROALBUSTIX™ Reagent Strip	Bayer Corp.  Bayer Corp.	Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) { Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test  2. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test 3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test 4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	OraSure Technologies, Inc.  OraSure Technologies, Inc. STC Technologies Inc. STC Technologies Inc.	Quantitative determination of alcohol (ethanol) in saliva

**This list includes updates from Change Request 6685**  
\* 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>
82120QW, 83986QW	<ol style="list-style-type: none"> <li>1. Litmus Concepts FemExam TestCard (from vaginal swab)</li> <li>2. Quidel QuickVue Advance pH and Amines Test</li> </ol>	<p>Litmus Concepts, Inc.</p> <p>Quidel Corporation</p>	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82271QW	<ol style="list-style-type: none"> <li>1. Aerscher Hemaprompt FG</li> <li>2. SmithKline Gastrocult</li> </ol>	<p>Aerscher Diagnostics</p> <p>SmithKline</p>	Rapid screening test to detect the presence of gastric occult blood
82271QW, 83986QW	Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates
82274QW G0328QW	<ol style="list-style-type: none"> <li>1. Beckman Coulter Hemocult ICT (K961062) &amp; (K080812)</li> <li>2. BTNX Inc. Know Fecal Occult Blood (FOB) Self Test</li> <li>3. BTNX Inc. Rapid Response Immunological Fecal Occult Blood Test (iFOBT)</li> <li>4. BTNX Inc. Rapid Response Fecal Occult Blood (FOB) Self Test</li> <li>5. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test</li> <li>6. Clearview Ultra FOB Test</li> <li>7. Enterix InSure™ Fecal Occult Blood Test</li> <li>8. Enterix InSure Fecal Immunochemical Test</li> <li>9. Enterix InSure II Fecal Immunochemical Test</li> <li>10. Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test</li> <li>11. Henry Schein One Step+ iFOBT</li> </ol>	<p>Beckman Coulter, Inc.</p> <p>Alfa Scientific Designs, Inc.</p> <p>Teco Diagnostics</p> <p>Alfa Scientific Designs, Inc</p> <p>Wampole Laboratories</p> <p>RAC Medical Group, Inc.</p> <p>Enterix, Inc.</p> <p>Enterix, Inc.</p> <p>Enterix, Inc.</p> <p>New Bay Bioresearch Co. Ltd.</p> <p>Immunostics, Inc.</p>	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay

**This list includes updates from Change Request 6685**

\* 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>
82274QW G0328QW (cont.)	12. immoCare Fecal Occult Blood Test	Care Diagnostic, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	13. Immunostics, Inc., hema-screen Specific Immunochemical Fecal Occult Blood Test	Immunostics, In	
	14. InSure Quik Fecal Immunochemical Test (F.I.T.)	Enterix, Inc.	
	15. Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT)	New Bay Bioresearch Co. Ltd.	
	16. OcculTech Fecal Occult Blood Rapid Test	YD Diagnositcs Corp.	
	17. Teco Rapid Fecal Occult Blood (FOB) Card Test	Teco Diagnostics	
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc.	
	2. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}	Abaxis, Inc	
82435QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Abbott i-STAT 6+ Cartridge {Whole Blood}	i-Stat Corporation	Measures chloride, glucose, potassium, sodium, urea nitrogen, and hematocrit in whole blood

**This list includes updates from Change Request 6685**  
 \* 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.)	1. Advanced Care	Johnson & Johnson	Cholesterol monitoring
	2. Boehringer Mannheim Accu-Chek InstantPlus Cholesterol	Boehringer Mannheim	
	3. ChemTrak AccuMeter	ChemTrak	
	4. ENA.C.T Total Cholesterol Test	ActiMed Laboratories, Inc.	
	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	
	6. Lifestream Technologies Cholesterol Monitor	Lifestream Technologies, Inc.	
	7. Lifestream Technologies Personal Cholesterol Monitor	Lifestream Technologies, Inc.	
	8. Polymer Technology Systems (PTS) MTM Bioscanner 1000 (for OTC use) for cholesterol	Polymer Technology Systems, Inc.	
	9. PTS Bioscanner Test Strips Cholesterol	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
	2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL Panel Test Strips)	Polymer Technology Systems, Inc.	

**This list includes updates from Change Request 6685**

\* 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.), 82962	<ol style="list-style-type: none"> <li>1. Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)</li> <li>2. Roche Diagnostics AccuChek Instant Plus Dual Testing System</li> </ol>	Polymer Technology Systems, Inc.	Measures total cholesterol and monitors blood glucose levels
82465QW(Contact your Medicare carrier for claims instructions.), 83718QW	Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol and HDL cholesterol in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	<ol style="list-style-type: none"> <li>1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)</li> <li>2. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)</li> </ol>	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW	Cholestech LDX	Cholestech Corp.	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood

**This list includes updates from Change Request 6685**

\* 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.), 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 6685**

\* 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, 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.	
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.	

**This list includes updates from Change Request 6685**  
 \* 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>
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)	Unipath Limited	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception
82947QW, 82950QW, 82951QW, 82952QW	1. HemoCue B-Glucose Photometer	HemoCue, Inc.	Measures glucose levels in whole blood
	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
	3. Abbott i-STAT G Cartridge {Whole Blood}	i-Stat Corporation	
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW	Abbott i-STAT EC4+ Cartridge {Whole Blood}	i-Stat Corporation	Measures glucose, potassium, sodium, and hematocrit in whole blood
82985QW	LXN Fructosamine Test System	LXN Corporation	Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)
82962, 82465QW(Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol

**This list includes updates from Change Request 6685**  
 \* 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>
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. Siemens Medical Diagnostics DCA Vantage Analyzer	Siemens Healthcare Diagnostics, Inc.	
	3. Siemens DCA 2000 Analyzer	Siemens Healthcare Diagnostics, Inc.	
	4. Siemens DCA 2000+ Analyzer	Siemens Healthcare Diagnostics, Inc.	

**This list includes updates from Change Request 6685**  
 \* 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>
83037QW	1. Bayer A1CNow+ {For professional use}	Bayer Corp.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use
	2. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories	
	3. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	
	4. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	5. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	
83518QW	1. Beckman Coulter ICON Microalb	Beckman Coulter, Inc.	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
	2. Boehringer Mannheim Chemstrip Micral	Boehringer Mannheim	
	3. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test	Diagnostic Chemicals Limited	
	4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)	Diagnostic Chemicals Limited (USA)	
	5. Roche Diagnostics Chemstrip Micral (urine dipstick)	Roche Diagnostics Corporation	
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	ESA Biosciences, Inc.	Quantitative measurement of blood lead in whole blood
83718QW	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood

**This list includes updates from Change Request 6685**

\* 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>
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
83880QW	1. Biosite Triage Meter {Whole Blood} 2. Biosite Triage Meter Plus {Whole Blood}	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
83986QW	All qualitative color comparison pH testing - body fluids (other than blood)	Various	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates
83986QW	1. FemTek pHEM-ALERT® 2. Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test 3. Common Sense Ltd. VA-Sense Kit 4. Lil' Drug Store Products Inc. Vagi- Screen Vaginal Health Test	FemTek, LLC Common Sense Ltd. Common Sense, Ltd. Lil' Drug Store Products Inc.	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	1. CLIAwaived Inc. Thyroid Test Rapid TSH Cassette {Whole Blood}* 2. ThyroTec, Inc. ThyroTest Whole Blood TSH Test 3. Jant Pharmacal Accutest TSH {Whole Blood} 4. Qualigen, Inc. FastChek TSH {Whole blood}	Screening Devices Canada Inc. ThyroTes, Inc. 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 6685**

\* 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>
84520QW, 84450QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84478QW	PTS, Inc. Bioscanner 2000 for Triglycerides	Polymer Technology Systems, Inc.	Measures triglycerides in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp.	Diagnosis of pregnancy
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	<ol style="list-style-type: none"> <li>1. Biosafe Laboratories, Inc., Anemiapro Self Screener</li> <li>2. HemoCue Donor Hemoglobin Checker System HemoCue</li> <li>3. HemoCue Hemoglobin System</li> <li>4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood)</li> <li>5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System</li> <li>6. HemoCue Hb 301 System</li> <li>7. GDS Diagnostics HemoSite Meter - for hemoglobin</li> <li>8. GDS Technology STAT-Site MHgb Test System</li> </ol>	<p>Biosafe Laboratories, Inc.</p> <p>HemoCue, Inc.</p> <p>HemoCue, Inc.</p> <p>HemoCue, Inc.</p> <p>HemoCue, Inc.</p> <p>HemoCue, Inc.</p> <p>GDS Technology, Inc.</p> <p>GDS Technology</p>	Measures hemoglobin level in whole blood
85576QW	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation

**This list includes updates from Change Request 6685**  
 \* 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 (Contact your Medicare carrier for claims instructions.)	1. AvoSure PT System (prescription home use)	Avocet Medical, Inc.	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency
	2. AvoSure Pro (professional use)	Avocet Medical, Inc.	
	3. CoaguChek PST for Prothrombin Time	Boehringer Mannheim Corporation	
	4. HemoSense INRatio System	HemoSense, Inc.	
	5. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)	
	6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	
	7. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation	
	8. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.	
	9. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation	
	10. Roche Diagnostics Coaguchek PST	Roche Diagnostics	
	11. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics	
	12. Roche Diagnostics CoaguChek XS	Roche Diagnostics	

**This list includes updates from Change Request 6685**  
 \* 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>
86294QW	1. Bion Diagnostic Sciences BTA stat Test (for home use)	Bion Diagnostic Sciences, Inc.	Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients
	2. Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use	Maritech, Inc.	
86308QW	1. 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. Acon Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	
	3. Acon Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	4. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, Inc.	
	5. BioStar Acceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	6. Cardinal Health SP Brand Rapid Test Mono {Whole Blood}	Cardinal Health	
	7. Clearview MONO Whole Blood, K042272/A013	Inverness Medical Professional Diagnostics	
	8. Clearview MONO Whole Blood, K042272/A016	Innovacon, Inc.	
	9. Clearview Mono-plus II	Applied Biotech, Inc.	
	10. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	11. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	12. Icon Mono	Beckman Coulter, Inc.	
	13. Immuno Detector Mono {Whole Blood}	Princeton BioMeditech Corp.	

**This list includes updates from Change Request 6685**

\* 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.)	14. Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
	15. Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood}	ACON Laboratories, Inc.	
	16. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	17. Jant Pharmacal Accutest Value + Mononucleosis Rapid Test {Whole Blood}	Innovacon, Inc.	
	18. LifeSign Status Mono {for whole blood}	Princeton BioMeditech Corp.	
	19. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	20. McKesson Medi-lab Performance Infectious Mononucleosis Test	Applied Biotech, Inc.	
	21. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
	22. PerMaxim RediScreen Mononucleosis {Whole Blood}	ACON Laboratories, Inc.	
	23. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	24. Poly Stat Mono Test {Whole Blood}	Innovacon, Inc.	
	25. ProAdvantage by NDC Infectious Mononucleosis Test Device (Whole Blood Only)*	Biosite Inc.	
	26. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	
	27. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation	

**This list includes updates from Change Request 6685**

\* 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>
86308QW (cont.)	28. RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}	ACON Laboratories, Inc.	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
	29. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	
	30. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	
	31. Signify Mono Cassette {Whole Blood}	Innovacon, Inc.	
	32. Signify Mono Whole Blood	Inverness Medical Professional Diagnostics	
	33. Stanbio Rely Mono Rapid Test{Whole Blood}	Innovacon, Inc.	
	34. Wampole Mono-Plus WB	Wampole Laboratories	
	35. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	36. Wyntek Signify Mono Test	Wyntek Diagnostics, Inc.	
	86318QW	1. Abbott FlexPak HP Test for whole blood	
2. Abbott Laboratories Signify H. Pylori Cassette {Whole Blood}		Innovacon, Inc.	
3. Abbott TestPack Plus H. pylori (for whole blood)		Abbott Laboratories	
4. Acon® H. pylori Test Device		ACON Laboratories, Inc.	
5. Alfa Scientific Designs Instant View H. Pylori Whole Blood Rapid Test		Alfa Scientific Designs, Inc.	
6. Applied Biotech SureStep H. pylori WB Test (whole blood)		Applied Biotech, Inc.	
7. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood		Beckman Coulter, Inc.	

**This list includes updates from Change Request 6685**  
 \* 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.)	8. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)	Cortecs Diagnostics Limited	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
	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.	
	19. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	
	20. Inverness Medical Signify H. Pylori Whole Blood	Innovacon, Inc.	
	21. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	22. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	

**This list includes updates from Change Request 6685**

\* 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.)	23. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood		
	24. Polymedco Poly Stat H. Pylori Test (Whole Blood)	Innovacon, Inc.			
	25. Pro-Advantage by NDC H. pylori Device (Whole Blood)*	Innovacon, Inc.			
	26. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel Corporation			
	27. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation			
	28. Remel RIM® A.R.C. H.pylori Test	Remel			
	29. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.			
	30. Trinity Uni-Gold™ H.pylori	Trinity Biotech			
	31. Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}	Applied Biotech , Inc.			
	86618QW	Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay		Wampole Laboratories	Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood
	86701QW	1. OraSure Technologies OraQuick Rapid HIV-1 Antibody Test		OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)
2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood		OraSure Technologies, Inc.			
3. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)		Trinity Biotech			

**This list includes updates from Change Request 6685**

\* 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>
86703QW	1. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood and venipuncture whole blood specimens
	2. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	
87077QW	1. Ballard Medical Products CLOtest	Ballard Medical Products	Presumptive identification of <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. Quidel Quickvue Influenza A+B Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
	2. BinaxNow Influenza A & B Test, K092223*	Binax, Inc	

**This list includes updates from Change Request 6685**

\* 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.)	3. 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
	4. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}, K053126	Binax, Inc.	
	5. BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens and Nasal Specimens (NS)}	Binax, Inc.	
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. EarlyDetect Pro Influenza A Test	SA Scientific, Inc	
	3. 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. EarlyDetect Pro Influenza B Test	SA Scientific, Inc	
	3. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	
87807QW	1. Binax NOW RSV Test (K021687)	Binax, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. Binax NOW RSV Test (K032166/A005)	Binax, Inc.	
	3. Fisher Scientific Sure-View RSV Test	SA Scientific, Inc.	
	4. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
	5. Quidel Quick View RSV Test	Quidel Corporation	
	6. SA Scientific SAS RSV Alert	SA Scientific, Inc.	
87808QW	Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs

**This list includes updates from Change Request 6685**

\* 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>
87809QW	Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	Immunochemical test for the qualitative detection of adenoviral antigens from eye fluid
87880QW	1. Abbott Signify Strep A Test (from throat swab only)	Wyntek Diagnostics, Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	2. Abbott Laboratories Signify Strep A Dipstick	Innovacon, 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.	
	8. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	ACON Laboratories, Inc.	
	9. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter, 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 Aceava Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	14. Biotechnostix Rapid Response Strep A Rapid Test Device	Acon Laboratories Co.	
	15. Biotechnostix Rapid Response Strep A Rapid Test Strip	Acon Laboratories Co.	

**This list includes updates from Change Request 6685**

\* 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.)	16. Cardinal Health SP Brand Rapid Test Strep A Dipstick(K033855)	Applied Biotech Inc.	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
	17. Cardinal Health SP Brand Rapid Test Strep A Dipstick (K010582/A028)	Innovacon, Inc.	
	18. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	19. DE Healthcare Products TruView Strep A Cassette Test	ACON Laboratories, Inc.	
	20. Diagnostic Test Group Clarity Strep A Rapid Test Strips	Princeton BioMeditech Corp.	
	21. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	22. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	23. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	24. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	25. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	26. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	27. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	28. Henry Schein Inc, One Step+ Strep A Dipstick Test	Henry Schein	
	29. Immunostics Detector Strep A Direct	ACON Laboratories, Inc.	
	30. Immunostics Immuno/Strep A Detector	ACON Laboratories, Inc.	

**This list includes updates from Change Request 6685**

\* 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>
87880QW (cont.)	31. Instant Technologies iStrep 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
	32. Inverness Medical BioStar Aceava Strep A Test	Innovacon, Inc.	
	33. Inverness Medical BioStar Aceava Strep A Twist	Innovacon, Inc.	
	34. Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations)	Innovacon, Inc.	
	35. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	36. Jant Pharmacal Accustrip Strep A Value+ Test Strip	Innovacon, Inc.	
	37. Jant Pharmacal Accutest Integrated Strep A Rapid Test Device	Innovacon, Inc.	
	38. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	39. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	40. LifeSign LLC Status Strep A	Princeton BioMeditech	
	41. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	42. McKesson Medi-Lab Performance Strep A Test Dipstick	Applied Biotech, Inc.	
	43. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	44. Moore Medical The Supply Experts Strep A Rapid Test – Dipstick	Innovacon, Inc.	
	45. PSS World Medical Select Diagnostics Strep A Dipstick	Innovacon, Inc.	

**This list includes updates from Change Request 6685**  
 \* 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.)	46. PSS World Medical Select Diagnostics Strep A Twist	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
	47. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	48. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc	
	49. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	50. QuickVue® Dipstick Strep A	Quidel Corporation	
	51. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	52. Quidel QuickVue In-Line Strep A {direct from throat swab}(K934484/A013)	Quidel Corporation	
	53. RAC Medical Clarity Strep A Rapid Test Strips	Acon Laboratories Co.	
	54. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	55. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax, Inc.	
	56. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	
	57. Stanbio QuStick Strep A	Stanbio Laboratory	
	58. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	59. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
87905QW	1. Gryphus Diagnostics BVBlue	Gryphus Diagnostics, LLC	Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.
	2. Genzyme Diagnostics OSOM BVBlue Test	Gryphus Diagnostics, LLC	

**This list includes updates from Change Request 6685**

\* 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>
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens
89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	1. Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility	Embryotech Laboratories, Inc.	Screening test to measure sperm concentration
	2. SpermCheck Vasectomy	Princeton BioMeditech Corp.	Detects sperm in semen following a vasectomy
89321QW	Fertell Male Fertility Test	Genosis Ltd.	Determines whether the concentration of motile sperm is above a cut-off level of 10 million motile sperm cells per ml