

---

# CMS Manual System

## Pub. 100-04 Medicare Claims Processing

---

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal 469

Date: FEBRUARY 4, 2005

---

CHANGE REQUEST 3650

**SUBJECT: New Waived Tests – April 1, 2005**

**I. SUMMARY OF CHANGES:** This instruction informs contractors of new waived tests approved by the Food and Drug Administration under the 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.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: April 1, 2005**

**\*IMPLEMENTATION DATE: April 4, 2005**

**II. CHANGES IN MANUAL INSTRUCTIONS: (N\A if manual not updated.)**  
**(R = REVISED, N = NEW, D = DELETED)**

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

**III. FUNDING: \*Medicare contractors only:**

**These instructions shall be implemented within your current operating budget.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
<b>X</b>	<b>Recurring Update Notification</b>

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

## Attachment - Recurring Update Notification

<b>Pub. 100-04</b>	<b>Transmittal: 469</b>	<b>Date: February 4, 2005</b>	<b>Change Request 3650</b>
--------------------	-------------------------	-------------------------------	----------------------------

**SUBJECT: New Waived Tests – April 1, 2005**

### 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 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.

Listed below are the latest tests approved by the Food and Drug Administration as waived tests under the 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, G0107, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

CPT Code/Modifier	Effective Date	Description
86703QW	6-25-2004	OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {Oral Fluid, Fingerstick Whole Blood and Venipuncture Whole Blood}
84443QW	8-18-2004	ThyroTec, Inc. ThryoTest Whole Blood TSH Test
87880QW	10-29-2004	Beckman Coulter ICON DS Strep A Test
87880QW	10-29-2004	Laboratory Supply Company (LSC) PEP Strep A Cassette Test
87880QW	10-29-2004	Laboratory Supply Company (LSC) PEP Strep A Dipstick Test
87880QW	10-29-2004	Stanbio Laboratory EZ-Well Strep A Rapid Device Test
83036QW	11-9-2004	Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System

The new waived code, 86703QW, has been assigned for the HIV-1 and HIV-2 antibody test performed using the OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {Oral Fluid, Fingerstick Whole Blood and Venipuncture Whole Blood}.

The new waived code, 84443QW, has been assigned for the thyroid stimulating hormone (TSH) test performed using the ThyroTec, Inc. ThyroTest Whole Blood TSH Test.

The CPT code 87807 is a new code for 2005 that is for infectious agent antigen detection by immunoassay with direct optical observation: respiratory syncytial virus. Hence, the CPT code 87807QW replaces the CPT code 87899QW for the Binx NOW RSV Test and the Integrated Biotechnology Quick Lab RSV 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.

**C. Provider Education:** None.

**II. BUSINESS REQUIREMENTS**

*"Shall" denotes a mandatory requirement*

*"Should" denotes an optional requirement*

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3650.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.			X						
3650.2	The Medicare contractor shall permit the use of the code 86703QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of services on or after June 25, 2004.			X					X	
3650.3	The Medicare contractor shall permit the use of the code 84443QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of services on or after August 18, 2004.			X					X	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3650.4	The Medicare contractor shall permit the use of the code 87807QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of services on or after January 1, 2005.			X					X	
3650.5	The Medicare contractor shall deny the use of the code 87899QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of services on or after April 1, 2005.			X					X	
3650.6	Contractors need 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						

### III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

#### A. Other Instructions:

The attachment contains the complete list of waived tests, including the new waived tests listed previously. In the attachment, the information in the "Use" column explains the purpose of the waived test. If denial is appropriate, this explanation is unacceptable to use as the reason for the denial of a claim. Use the appropriate remittance advice message that describes why the test was denied.

X-Ref Requirement #	Instructions

#### B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

#### C. Interfaces: N/A

#### D. Contractor Financial Reporting /Workload Impact: N/A

**E. Dependencies: N/A**

**F. Testing Considerations: N/A**

**IV. SCHEDULE, CONTACTS, AND FUNDING**

<b>Effective Date:</b> April 1, 2005 <b>Implementation Date:</b> April 4, 2005 <b>Pre-Implementation Contact(s):</b> Kathy Todd (410) 786-3385 <b>Post-Implementation Contact(s):</b> Kathy Todd (410) 786-3385	<b>Medicare contractors shall implement these instructions within their current operating budgets.</b>
--	--

Attachment

## 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 G0107 (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 #**

## 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. Phamatech At Home Drug Test (Model 9063)	Phamatech	Screening test for the presence/detection of amphetamine in urine
	2. Phamatech QuickScreen One Step Amphetamine 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)	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. Phamatech At Home Drug Test (Model 9078)	Phamatech	
	4. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	5. Worldwide Medical Corporation, First Check® Home Drug Test (THC)	Worldwide Medical Corporation	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9073)	Phamatech	Screening test for the presence/detection of cocaine metabolites in urine
	2. Phamatech At Home Drug Test (Model 9073T)	Phamatech	
	3. Phamatech QuickScreen One Step Cocaine Screening Test	Phamatech	

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

\* 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 (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	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	DynaGen NicCheck I Test Strips	Dynagen, Inc.	Detects nicotine and/or its metabolites in urine, which is used as an aid in indicating the smoking status of an individual and as an aid in the identification of a smoker as a low or high nicotine consumer
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9083)	Phamatech	Screening test for the presence/detection of opiates in urine
	2. Phamatech QuickScreen One Step Opiate Screening Test	Phamatech	
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. Phamatech At Home Drug Test (Model 9133)	Phamatech	Screening test for the presence/detection of phencyclidine in urine
	2. Phamatech QuickScreen One Step PCP Screening Test	Phamatech	

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

\* 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. Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC)	Accu-Stat Diagnostics, Inc.	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	
	3. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	
	4. Forefront Diagnostics Drugfree@Home THC/COC Test Kit	Forefront Diagnostics, Inc.	
	5. Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC)	Worldwide Medical Corporation	
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 phencyclidine (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.)	Phamatech At Home Drug Test (Model 9150T)	Phamatech	Screening test for the presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine

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

\* 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 cannabinoids (THC), cocaine metabolites, opiates and methamphetamines in urine
81002, 82570QW	<ol style="list-style-type: none"> <li>1. Bayer Multistick Pro 7G Reagent Strips</li> <li>2. Bayer Multistick Pro 10LS Reagent Strips</li> <li>3. Bayer Multistick Pro 11 Reagent Strips</li> </ol>	<p>Bayer Diagnostics</p> <p>Bayer Diagnostics</p> <p>Bayer Diagnostics</p>	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	<ol style="list-style-type: none"> <li>1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes - automated</li> <li>2. Biosys Laboratories Optima Urine Analyzer</li> <li>3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated</li> <li>4. Hypoguard Diascreen® Urine Chemistry Analyzer</li> <li>5. Roche Diagnostics Urisys 1100 Urine Analyzer</li> <li>6. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer</li> </ol>	<p>Bayer</p> <p>Biosys Laboratories</p> <p>Boehringer Mannheim Corporation</p> <p>Hypoguard USA, Inc.</p> <p>Roche Diagnostics Corp.</p> <p>Roche Diagnostics/Boehringer Mannheim Corporation</p>	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections

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

\* 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.)	7. Teco Diagnostics URITEK TC-101 Urine Strip Reader	Teco 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
	8. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
81007QW	Diatch Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood
82010QW, 82962	1. Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System (K983504)	Abbott Laboratories, Inc.	Monitoring of blood glucose levels and measures ketones in whole blood
	2. Abbott Medisense Precision Xtra Advanced Diabetes Management System (K040814)	Abbott Laboratories, Inc	
82044QW, 82570QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine	Bayer Corp.	Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage
	2. Bayer Diagnostics/MICROALBUSTIX™ Reagent Strip	Bayer Inc.	
82055QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	1. OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test	OraSure Technologies, Inc.	Quantitative determination of alcohol (ethanol) in saliva
	2. OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	OraSure Technologies, Inc.	

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

\* 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.)	3. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test	STC Technologies Inc.	Quantitative determination of alcohol (ethanol) in saliva
	4. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test	STC Technologies Inc.	
82120QW, 83986QW	1. Litmus Concepts FemExam TestCard (from vaginal swab)	Litmus Concepts, Inc.	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
	2. Quidel QuickVue Advance pH and Amines Test	Quidel Corporation	
82273QW	1. Aerscher Hemaprompt FG	Aerscher Diagnostics	Rapid screening test to detect the presence of gastric occult blood
	2. SmithKline Gastrocult	SmithKline	
82273QW, 83986QW	Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates
82274QW G0328QW	1. Beckman Coulter Hemocult ICT	Beckman Coulter, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	2. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	
	3. Enterix InSure Fecal Immunochemical Test	Enterix, Inc.	
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.	

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

\* 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 (cont.) (Contact your Medicare carrier for claims instructions.)	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	Cholesterol monitoring
	6. Lifestream Technologies Cholesterol Monitor	Lifestream Technologies	
	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, 84478QW, 80061QW	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. Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW	Cholestech LDX	Cholestech	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels in whole blood

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

\* 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>
82523QW	Ostex International Osteomark NTX Point of Care Prescription Home Use	Ostex International Inc.	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)	Unipath Limited	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception
82947QW, 82950QW, 82951QW, 82952QW	1. HemoCue B-Glucose Photometer	HemoCue	Measures glucose levels in whole blood
	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
82985QW	LXN Fructosamine Test System	LXN Corporation	Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)
82962, 82985QW	1. LXN Duet Glucose Control Monitoring System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period
	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	
83001QW	1. Acon Laboratories, Inc. FSH Menopause Predictor Test	Acon Laboratories, Inc.	Detects follicle stimulating hormone in urine
	2. Applied Biotech, Inc. RU25 Plus FSH Menopause Test	Applied Biotech, Inc.	
	3. Genua Menopause Monitor Test	Genua 1944 Inc	
	4. Synova Healthcare MenocheckPro (Professional Use)	Applied Biotech, Inc.	
83036QW	1. Bayer DCA 2000 – glycosylated hemoglobin (Hgb A1c)	Bayer	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes

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

\* 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.)	2. Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c)	Bayer Corp.	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
	3. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test	Bio-Rad Laboratories	
	4. Cholestech GDX A1C Test (Prescription Home Use)	Cholestech Corporation	
	5. Metrika A1c Now™ - Professional Use (K000887)	Metrika, Inc.	
	6. Metrika A1c Now for Prescription Home Use (K020234)	Metrika, Inc.	
	7. Metrika A1c Now for Professional Use (K020235)	Metrika, Inc.	
	8. Metrika DRx® HbA1c (Professional Use Test System)	Metrika, Inc.	
	9. Provalis Diagnostics Glycosal™ HbA1c Test	Provalis Diagnostics Ltd.	
	10. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System*	Provalis Diagnostics Ltd	
	83518QW	1. Beckman Coulter ICON Microalb	
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	

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

\* 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>
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83718QW	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood
83986QW	All qualitative color comparison pH testing - body fluids (other than blood)	Various	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates
83986QW	FemTek pHEM-ALERT®	FemTek, LLC	Vaginal pH detection (acid-base balance)
84443QW	ThyroTec, Inc. ThyroTest Whole Blood TSH Test*	ThyroTes, Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84478QW	PTS, Inc. Bioscanner 2000 for Triglycerides	Polymer Technology Systems, Inc.	Measures triglycerides in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp	Diagnosis of pregnancy
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	1. HemoCue Donor Hemoglobin Checker System HemoCue 2. HemoCue Hemoglobin System 3. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood) 4. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System 5. GDS Diagnostics HemoSite Meter - for hemoglobin	HemoCue HemoCue HemoCue HemoCue GDS Technology, Inc.	Measures hemoglobin level in whole blood

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

\* 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.)	6. GDS Technology STAT-Site MHgb Test System	GDS Technology	Measures hemoglobin level in whole blood
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 Corporation	

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

\* 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. Applied Biotech SureStep Mono Test (whole blood)	Applied Biotech, 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. BioStar Aceava Mono Test (whole blood)	Wyntek Diagnostics, Inc.	
	3. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	
	4. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.	
	5. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.	
	6. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.	
	7. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.	
	8. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.	
	9. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation	
	10. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation	
	11. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.	
	12. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics	
	13. Wampole Mono-Plus WB	Wampole Laboratories	
	14. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.	

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

\* 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.)	15. Wyntek Signify Mono Test	Wyntek Diagnostics, 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
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 TestPack Plus H. pylori (for whole blood)	Abbott Laboratories	
	3. Acon® H. pylori Test Device	ACON Laboratories, Inc.	
	4. Applied Biotech SureStep H. pylori WB Test (whole blood)	Applied Biotech, Inc.	
	5. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood	Beckman Coulter, Inc.	
	6. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)	Cortecs Diagnostics Limited	
	7. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.	
	8. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech	
	9. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.	
	10. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.	
	11. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel	
	12. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation	
	13. Remel RIM® A.R.C. H.pylori Test	Remel	
	14. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.	

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

\* 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.)	15. Trinity Uni-Gold™ H.pylori	Trinity BioTech	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
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 2. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood	OraSure Technologies, Inc. OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in fingerstick whole blood specimens
86703QW	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
87077QW	1. Ballard Medical Products CLOtest 2. Delta West CLOtest 3. GI Supply HP-FAST 4. GI Supply, Div. Chek-Med Systems HP One 5. Medical Instruments Corporation Pronto Dry H. pylori 6. Serim Pyloritek Test Kit	Ballard Medical Products Delta West Tri-Med Specialties Mycoscience Labs, Inc. GI Supply Medical Instruments Corporation Serim	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
87210QW	1. Stesans Maybe?Mom Mini Ovulation Microscope 2. O2 Unlimited Donna Ovulation Tester	LEC Associates O2 Unlimited Corp.	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)
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	1. 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

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

\* 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.)	2. Quidel Quickvue Influenza A+B Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens that does differentiate between influenza types A and B
87804QW	Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasal wash and nasopharyngeal swab specimens
87804QW	Binax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasal wash and nasopharyngeal swab specimens
87807QW	1. Binax NOW RSV Test	Binax	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. Integrated Biotechnology Quick Lab RSV Test	Integrated Biotechnology Corp.	
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. Acon® Strep A Rapid Strip Test	Acon Laboratories, Inc.	
	3. Acon® Strep A Twist Rapid Test	Acon Laboratories, Inc.	
	4. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	5. Beckman Coulter ICON DS Strep A Test*	Princeton BioMeditech Corp.	
	6. Beckman Coulter ICON SC Strep A Test	Acon Laboratories, Inc	
	7. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	Acon Laboratories, Inc.	
	8. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter	
	9. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	10. Binax NOW Strep A Test	Binax	

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

\* 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.)	11. BioStar Aceava Strep A Test (direct specimen 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
	12. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	13. DE Healthcare Products TruView Strep A Cassette Test	Acon Laboratories, Inc.	
	14. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	15. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	16. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	17. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	18. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	19. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	20. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	21. Immunostics Detector Strep A Direct	Acon Laboratories, Inc	
	22. Immunostics Immuno/Strep A Detector	Acon Laboratories, Inc	
	23. Instant Technologies iStrep Strep A	Acon Laboratories, Inc	
	24. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	25. Laboratory Supply Company (LSC) PEP Strep A Cassette Test*	Acon Laboratories Co.	
	26. LSC PEP Strep A Dipstick Test*	Acon Laboratories Co.	

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

\* 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.)	27. LifeSign LLC Status Strep A	Princeton BioMeditech	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
	28. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	29. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	30. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	31. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc.	
	32. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	33. QuickVue® Dipstick Strep A	Quidel Corporation	
	34. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	35. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	36. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax	
	37. Stanbio Laboratory E-Z Well Strep A Rapid Device Test*	Acon Laboratories Co.	
	38. Stanbio QuStick Strep A	Stanbio Laboratory	
	39. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc.	
	40. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
89300QW(This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility	Embryotech Laboratories, Inc.	Screening test to measure sperm concentration

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

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

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

\* Newly added waived test system