

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 642

Department of Health
&
Human Services

Centers for Medicare
&
Medicaid Services

Date: August 5, 2005

Change Request
3984

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 & Medicaid Services must notify its contractors of the new tests so that the contractors can accurately process claims.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : October 01, 2005

IMPLEMENTATION DATE : October 03, 2005

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) N/A

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

R/N/D	Chapter / Section / SubSection / Title
-------	--

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Recurring Notification Form

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 642	Date: August 5, 2005	Change Request 3984
--------------------	-------------------------	-----------------------------	----------------------------

SUBJECT: New Waived Tests

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 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
86318QW	December 9, 2004	Germaine Laboratories, Aimstep H. pylori {whole blood}
87807QW	January 28, 2005	Binax Now RSV Test (K032166/A005)
81003QW	February 18, 2005	Physician Sales & Service, Inc. PSS Select Urine Analyzer
87880QW	March 8, 2005	McKesson Medi-Lab Performance Strep A Test Dipstick
86308QW	March 8, 2005	Clearview Mono-Plus II
86318QW	March 8, 2005	Wampole Laboratories Clearview H. pylori II {finger stick or whole blood}
87899QW	March 16, 2005	Genzyme OSOM Trichomonas Rapid Test
86308QW	March 16, 2005	McKesson Medi-lab Performance Infectious Mononucleosis Test
83721QW	March 25, 2005	Polymer Technology Systems Cardiochek PA Analyzer
87880QW	April 21, 2005	Biotechnostix Rapid Response Strep A Rapid Test Strip
87880QW	April 21, 2005	Biotechnostix Rapid Response Strep A Rapid Test Device
87880QW	April 21, 2005	RAC Medical Clarity Strep A Rapid Test Strips

80101QW	June 3, 2005	Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)
---------	--------------	--

The new waived code, 83721QW, has been assigned for LDL cholesterol testing performed using the Polymer Technology Systems Cardiochek PA Analyzer.

The new waived code, 87899QW, has been assigned for Trichomonas testing performed using the Genzyme OSOM Trichomonas Rapid Test.

B. Policy:

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

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

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	
3984.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.			X						
3984.2	The Medicare contractor shall permit 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 March 16, 2005.			X					X	
3984.3	The Medicare contractor shall permit the use of the code 83721QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of services on or after March 25, 2005.			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			
F I S S	M C S					V M S	C W F		
3984.4	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. PROVIDER EDUCATION

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			
F I S S	M C S					V M S	C W F		
3984.5	A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.			X					

IV. 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

Effective Date*: October 1, 2005 Implementation Date: October 3, 2005 Pre-Implementation Contact(s): Kathy Todd (410) 786-3385 Post-Implementation Contact(s): Kathy Todd (410) 786-3385	No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.
---	---

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

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 3984

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 3984

* 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. 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 3984

* 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 3984

* 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
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	<ol style="list-style-type: none"> 1. Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine 2. Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use)* 	<p>Accu-Stat Diagnostics, Inc.</p> <p>Acon Laboratories, Inc.</p>	Screening test for the presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, opiates, and phencyclidine in urine
80101QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Branan Medical Corporation Fastect II Drug Screen Dipstick Test	Branan Medical Corporation	Screening test for the presence/detection of amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites, methadone, methamphetamines, methylenedioxymethamphetamine, opiates, oxycodone, phencyclidine and tricyclic antidepressants in urine
81002, 82570QW	<ol style="list-style-type: none"> 1. Bayer Multistick Pro 7G Reagent Strips 2. Bayer Multistick Pro 10LS Reagent Strips 3. Bayer Multistick Pro 11 Reagent Strips 	<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"> 1. Bayer Clinitek 50 Urine Chemistry Analyzer – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes - automated 	Bayer	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 3984

* 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.)	2. Biosys Laboratories Optima Urine Analyzer	Biosys Laboratories	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infect
	3. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Boehringer Mannheim Corporation	
	4. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	5. Physician Sales & Service, Inc. PSS Select Urine Analyzer*	Biosys Laboratories, Inc.	
	6. Roche Diagnostics Urisys 1100 Urine Analyzer	Roche Diagnostics Corp.	
	7. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer Mannheim Corporation	
	8. Teco Diagnostics URITEK TC-101 Urine Strip Reader	Teco Diagnostics	
	9. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
	81007QW	Diotech Diagnostics Uriscreen (for OTC use)	
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	

This list includes updates from Change Request 3984

* 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>
82044QW, 82570QW	1. Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine 2. Bayer Diagnostics/ MICROALBUSTIX™ Reagent Strip	Bayer Corp. Bayer Inc.	Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage
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
82120QW, 83986QW	1. Litmus Concepts FemExam TestCard (from vaginal swab) 2. Quidel QuickVue Advance pH and Amines Test	Litmus Concepts, Inc. Quidel Corporation	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82273QW	1. Aerscher Hemaprompt FG 2. SmithKline Gastrocult	Aerscher Diagnostics SmithKline	Rapid screening test to detect the presence of gastric occult blood
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 2. Enterix InSure™ Fecal Occult Blood Test 3. Enterix InSure Fecal Immunochemical Test	Beckman Coulter, Inc. Enterix, Inc. Enterix, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay

This list includes updates from Change Request 3984

* 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, 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.	

This list includes updates from Change Request 3984

* 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	Polymer Technology Systems Cardiochek PA Analyzer (PTS Panels Chol + Glu Test Panel)	Polymer Technology Systems, Inc.	Measures total cholesterol and monitors blood glucose levels
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
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)

This list includes updates from Change Request 3984

* 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. 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
	2. Bayer DCA 2000+ - glycosylated hemoglobin (Hgb A1c)	Bayer Corp.	
	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.	

This list includes updates from Change Request 3984

* 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.)	10. Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System	Provalis Diagnostics Ltd	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes
83518QW	1. Beckman Coulter ICON Microalb	Beckman Coulter	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
83718QW	PTS Bioscanner (for OTC use) - for HDL cholesterol	Polymer Technology Systems, Inc.	Measures HDL cholesterol in whole blood
83721QW	Polymer Technology Systems Cardiochek PA Analyzer*	Polymer Technology Systems, Inc.	Measures LDL 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

This list includes updates from Change Request 3984

* 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>
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"> 1. Biosafe Laboratories, Inc., Anemiapro Self Screener 2. HemoCue Donor Hemoglobin Checker System HemoCue 3. HemoCue Hemoglobin System 4. HemoCue Hemoglobin 201+ (Capillary, Venous, Arterial Whole Blood) 5. HemoCue Hemoglobin 201+/HemoCue Hemoglobin Microcuvette System 6. GDS Diagnostics HemoSite Meter - for hemoglobin 7. GDS Technology STAT-Site MHgb Test System 	<p>Biosafe Laboratories, Inc.</p> <p>HemoCue</p> <p>HemoCue</p> <p>HemoCue</p> <p>HemoCue</p> <p>GDS Technology, Inc.</p> <p>GDS Technology</p>	Measures hemoglobin level in whole blood
85610QW (Contact your Medicare carrier for claims instructions.)	<ol style="list-style-type: none"> 1. AvoSure PT System (prescription home use) 2. AvoSure Pro (professional use) 3. CoaguChek PST for Prothrombin Time 4. HemoSense INRatio System 5. ITC Protime Microcoagulation System for Prothrombin Time 	<p>Avocet Medical, Inc.</p> <p>Avocet Medical, Inc.</p> <p>Boehringer Mannheim Corporation</p> <p>HemoSense, Inc.</p> <p>International Technidyne Corporation (ITC)</p>	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

This list includes updates from Change Request 3984

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
85610QW (cont.) (Contact your Medicare carrier for claims instructions.)	6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation	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
	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	
85576QW	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation
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	Matritech, 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. Clearview Mono-plus II*	Applied Biotech, Inc.	

This list includes updates from Change Request 3984

* 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.)	4. Genzyme Contrast Mono (whole blood)	Genzyme Diagnostics	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis		
	5. Genzyme OSOM Mono Test	Wyntek Diagnostics, Inc.			
	6. Jant Accutest Infectious Mononucleosis Test (whole blood)	Applied Biotech, Inc.			
	7. LifeSign UniStep Mono Test (whole blood)	Princeton BioMeditech Corp.			
	8. McKesson Medi-lab Performance Infectious Mononucleosis Test*	Applied Biotech, Inc.			
	9. Meridian ImmunoCard STAT Mono (for whole blood)	Applied Biotech, Inc.			
	10. Polymedco, Inc. Poly stat Mono	Applied Biotech, Inc.			
	11. Quidel Cards O.S. Mono (for whole blood)	Quidel Corporation			
	12. Quidel QuickVue+ Infectious Mononucleosis (Whole Blood)	Quidel Corporation			
	13. Remel RIM® A.R.C. Mono Test	Applied Biotech, Inc.			
	14. Seradyn Color Q Mono (whole blood)	Genzyme Diagnostics			
	15. Wampole Mono-Plus WB	Wampole Laboratories			
	16. Wyntek Diagnostics OSOM Mono Test (whole blood)	Wyntek Diagnostics, Inc.			
	17. Wyntek Signify Mono Test	Wyntek Diagnostics, Inc.			
	86318QW	1. Abbott FlexPak HP Test for whole blood		SmithKline Diagnostics, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
		2. Abbott 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.			

This list includes updates from Change Request 3984

* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
86318QW (cont.)	5. Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood	Beckman Coulter, Inc.	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood	
	6. Becton Dickinson Link 2 H. pylori Rapid Test (for whole blood)	Cortecs Diagnostics Limited		
	7. Cardinal Health SP Brand Rapid Test H. pylori	Applied Biotech Inc.		
	8. Germaine Laboratories, Aimstep H. pylori {whole blood}*	Acon Laboratories, Inc.		
	9. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.		
	10. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech		
	11. Meridian BioScience ImmunoCard STAT! H.pylori Whole Blood Test	Applied Biotech, Inc.		
	12. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.		
	13. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel		
	14. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation		
	15. Remel RIM® A.R.C. H.pylori Test	Remel		
	16. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.		
	17. Trinity Uni-Gold™ H.pylori	Trinity BioTech		
	18. 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

This list includes updates from Change Request 3984

* 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>
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	
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	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

This list includes updates from Change Request 3984

* 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	1. 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
	2. BinaxNOW® Influenza A & B Test in nasopharyngeal (NP) swab and nasal wash/aspirate specimens	Binax, Inc.	
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 (K021687)	Binax, Inc.	Rapid immunoassay for the qualitative detection of respiratory syncytial virus antigen
	2. Binax NOW RSV Test (K032166/A005)*	Binax, Inc.	
	3. 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	

This list includes updates from Change Request 3984

* 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.)	9. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	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
	10. Binax NOW Strep A Test	Binax	
	11. BioStar Aceava Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	12. Biotechnostix Rapid Response Strep A Rapid Test Device*	Acon Laboratories Co.	
	13. Biotechnostix Rapid Response Strep A Rapid Test Strip*	Acon Laboratories Co.	
	14. Cardinal Health SP Brand Rapid Test Strep A Dipstick	Applied Biotech Inc.	
	15. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	16. DE Healthcare Products TruView Strep A Cassette Test	Acon Laboratories, Inc.	
	17. Fisher HealthCare Sure-View Strep A (direct from throat swab)	Applied Biotech, Inc.	
	18. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	19. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	20. Genzyme OSOM Ultra Strep A Test	Genzyme General	
	21. Germaine Laboratories StrepAim Rapid Dipstick Test	Germaine Laboratories, Inc.	
	22. Germaine Laboratories Strep AIM Tower	Germaine Laboratories, Inc.	
	23. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	24. Immunostics Detector Strep A Direct	Acon Laboratories, Inc	

This list includes updates from Change Request 3984

* 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.)	25. Immunostics Immuno/Strep A Detector	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
	26. Instant Technologies iStrep Strep A	Acon Laboratories, Inc	
	27. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	28. Laboratory Supply Company (LSC) PEP Strep A Cassette Test	Acon Laboratories Co.	
	29. LSC PEP Strep A Dipstick Test	Acon Laboratories Co.	
	30. LifeSign LLC Status Strep A	Princeton BioMeditech	
	31. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	
	32. McKesson Medi-Lab Performance Strep A Test Dipstick*	Applied Biotech, Inc.	
	33. Meridian Diagnostics ImmunoCard STAT Strep A (direct from throat swab)	Applied Biotech, Inc.	
	34. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	35. Polymedco Poly Stat Strep A Liquid Test	Applied Biotech, Inc	
	36. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	37. QuickVue® Dipstick Strep A	Quidel Corporation	
	38. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	39. RAC Medical Clarity Strep A Rapid Test Strips*	Acon Laboratories Co.	
	40. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	41. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax	

This list includes updates from Change Request 3984

* 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.)	42. Stanbio Laboratory E-Z Well Strep A Rapid Device Test	Acon Laboratories Co.	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
	43. Stanbio QuStick Strep A	Stanbio Laboratory	
	44. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	45. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
87899QW	Genzyme OSOM Trichomonas Rapid Test*	Genzyme Corp.	Qualitative detection of <i>Trichomonas vaginalis</i> from vaginal swabs
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 3984

* Newly added waived test system