
CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 102

Date: FEBRUARY 20, 2004

CHANGE REQUEST 3061

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.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 24, 2003

***IMPLEMENTATION DATE: April 5, 2004**

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

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	16/70.8 Certificate of Waiver

III. FUNDING: *Medicare contractors only:

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
X	Recurring Update Notification

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 102	Date: February 20, 2004	Change Request 3061
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Subject: New Waived Tests – April 1, 2004

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 these new tests must have the modifier QW to be recognized as a waived test.

CPT Code/Modifier	Effective Date	Description
87899QW	8-21-2003	Binax NOW RSV Test
87899QW	8-29-2003	Integrated Biotechnology Quick Lab RSV Test
86701QW	09-30-2003	OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood
82274QW G0328QW	10-16-2003	Enterix InSure Fecal Immunochemical Test
87880QW	10-21-2003	Germaine Laboratories Strep AIM Tower

The new waived code, 87899QW, has been assigned for the Binax NOW RSV test and the Integrated Biotechnology Quick Lab RSV Test. The new code G0328QW has been added for the Enterix InSure Fecal Immunochemical Test and the Enterix InSure™ Fecal Occult Blood 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 #	Requirements	Responsibility
3061.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	All Contractors
3061.2	The Medicare contractor shall permit the use of the new codes 87899QW for claims submitted by facilities with a valid CLIA certificate of waiver with dates of service on or after August 21, 2003.	All Contractors
3061.3	The Medicare contractor shall permit the use of the new codes G0328QW for claims submitted by facilities with a valid CLIA certificate of waiver with dates of service on or after January 1, 2004.	All Contractors
3061.4	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.	All Contractors

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

Effective Date: December 24, 2003 Implementation Date: April 5, 2004 Pre-Implementation Contact(s): Kathy Todd (410) 786-3385 Post-Implementation Contact(s): Kathy Todd (410) 786-3385	These instructions should be implemented within your current operating budget.
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[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 through 12/24/2003

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. ADC CLIA Waived Marijuana (THC) Test	Advantage Diagnostics Corporation (ADC)	Screening test for the presence/detection of cannabinoids (THC) in urine
	2. Phamatech At Home Drug Test (Model 9078)	Phamatech	
	3. Phamatech At Home Drug Test (Model 9078T)	Phamatech	
	4. 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	

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* 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	

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<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. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	ADC	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
	2. ADC CLIA Waived Marijuana (THC) and Cocaine Test	ADC	
	3. Forefront Diagnostics <u>Drugfree@Home</u> THC/COC Test Kit	Forefront Diagnostics, Inc.	
	4. 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.)	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
	Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test	Advantage Diagnostics Corporation, Ltd.	
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
	Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET)	Worldwide Medical Corporation	
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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002, 82570QW	1. Bayer Multistick Pro 7G Reagent Strips	Bayer 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 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 Diagnostics	
	3. Bayer Multistick Pro 11 Reagent Strips	Bayer Diagnostics	
81003QW	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
	2. Chemstrip Mini UA – qualitative dipstick for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes – automated	Boehringer Mannheim Corporation	
	3. Hypoguard Diascreen® Urine Chemistry Analyzer	Hypoguard USA, Inc.	
	4. Roche Diagnostics/Boehringer Mannheim Chemstrip 101 Urine Analyzer	Roche Diagnostics/Boehringer Mannheim Corporation	
	5. Teco Diagnostics URITEK TC-101 Urine Strip Reader	Teco Diagnostics	
	6. ThermoBiostar™ PocketChem™ UA	ThermoBiostar™	
81007QW	Diatech Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
82010QW	PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	Measures ketones in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82010QW, 82962	Abbott Laboratories, Medisense Products Precision™ Xtra™ Advanced Diabetes Management System	Abbott Laboratories, Inc.	Monitoring of blood glucose levels and measures ketones in whole blood
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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW G0328QW	1. Enterix InSure™ Fecal Occult Blood Test	Enterix, Inc.	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
	2. 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.	
	5. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU)	ActiMed Laboratories, Inc.	
	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	Polymer Technology Systems CardioChek PA Analyzer {PTS Panels Lipid Panel Test Strips}	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW, 80061QW, 82523QW	Cholestech LDX	Cholestech	Measures total cholesterol, HDL cholesterol, triglycerides, and glucose levels in whole blood
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	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
82947QW, 82950QW, 82951QW, 82952QW	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	HemoCue B-Glucose Photometer	HemoCue	Measures glucose levels in whole blood
82947QW, 82950QW, 82951QW, 82952QW	HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	Measures glucose levels 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, 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

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82962, 82985QW (cont.)	2. LXN IN CHARGE Diabetes Control 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
83001QW	1. Applied Biotech, Inc. RU25 Plus FSH Menopause Test	Applied Biotech, Inc..	Detects follicle stimulating hormone in urine
83036QW	2. Genua Menopause Monitor Test	Genua 1944 Inc	
	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.	
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	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83518QW (cont.)	4. Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick)	Diagnostic Chemicals Limited (USA)	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
	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
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)
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 Hemoglobin System	HemoCue	Measures hemoglobin level in whole blood
	2. HemoCue Donor Hemoglobin Checker System	HemoCue	
	3. GDS Diagnostics HemoSite Meter - for hemoglobin	GDS Technology, Inc.	
	4. GDS Technology STAT-Site MHgb Test System	GDS Technology	
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.	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
85610QW(cont.) (Contact your Medicare carrier for claims instructions.)	3. CoaguChek PST for Prothrombin Time	Boehringer Mannheim 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	
	4. ITC Protime Microcoagulation System for Prothrombin Time	International Technidyne Corporation (ITC)		
	5. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Prescription Home Use	International Technidyne Corporation		
	6. International Technidyne ProTime Microcoagulation System (ProTime 3 Cuvette) Professional Use	International Technidyne Corporation		
	7. Lifescan Harmony™ INR Monitoring System -- Prescription Home Use and Professional Use	Lifescan, Inc.		
	8. Roche/Boehringer Mannheim CoaguChek System for Professional Use	Roche Diagnostics/ Boehringer Mannheim Corporation		
	9. Roche Diagnostics Coaguchek PST	Roche Diagnostics		
	10. Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time)	Roche Diagnostics Corporation		
	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	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
86308QW (cont.)	2. BioStar Aceeva Mono Test (whole blood)	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
	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.	
	15. Wyntek Signify Mono Test	Wyntek Diagnostics, Inc.	
	86318QW	1. Abbott FlexPak HP Test for whole blood	
2. Abbott TestPack Plus H. pylori (for whole blood)		Abbott Laboratories	
3. Applied Biotech SureStep H. pylori WB Test (whole blood)		Applied Biotech, Inc.	

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TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>	
86318QW (cont.)	4. 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	
	5. Becton Dickinson Link 2 <i>H. pylori</i> Rapid Test (for whole blood)	Cortecs Diagnostics Limited		
	6. JANT Pharmacal Corp. H. pylori WBTest	Applied Biotech, Inc.		
	7. LifeSign Status H.pylori (for whole blood)	Princeton BioMeditech		
	8. Meridian BioScience ImmunoCard STAT! <i>H.pylori</i> Whole Blood Test	Applied Biotech, Inc.		
	9. Polymedco, Inc. Poly stat H.pylori	Applied Biotech, Inc.		
	10. QuickVue One-Step H. Pylori Test for Whole Blood	Quidel		
	11. Quidel QuickVue One-Step H.pylori II Test.	Quidel Corporation		
	12. Remel RIM® A.R.C. H.pylori Test	Remel		
	13. SmithKline Diagnostics FlexSure HP Test for IgG Antibodies to H. pylori in Whole Blood	SmithKline Diagnostics, Inc.		
	14. Trinity Uni-Gold™ H.pylori	Trinity BioTech		
	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	OraSure Technologies OraQuick Rapid HIV-1 Antibody Test	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in fingerstick whole blood specimens
		OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood*	OraSure Technologies, Inc.	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in fingerstick 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)	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87077QW (cont.)	2. Delta West CLOtest	Delta West Tri-Med Specialties	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
	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 <i>H. pylori</i>	Medical Instruments Corporation	
	6. Serim Pyloritek Test Kit	Serim	
	87210QW	1. Stesans Maybe?Mom Mini Ovulation Microscope	
	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	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
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 Strip Test	Acon Laboratories, Inc.	
	4. Applied Biotech SureStep Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	5. Beckman Coulter Primary Care Diagnostics ICON DS Strep A	Acon Laboratories, Inc.	

This list includes updates through 12/24/2003

* 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.)	6. Beckman Coulter ICON SC Strep A Test	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
	7. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter	
	8. Becton Dickinson LINK 2 Strep A Rapid Test (direct from throat swab)	Applied Biotech, Inc.	
	9. Binax NOW Strep A Test	Binax	
	10. BioStar Aceava Strep A Test (direct specimen only)	Wyntek Diagnostics, Inc.	
	11. DE Healthcare Products, TruView Strep A Test	DE Healthcare Products	
	12. Fisher HealthCare Sure-Vue Strep A (direct from throat swab)	Applied Biotech, Inc.	
	13. Genzyme Contrast Strep A (direct from throat swab)	Genzyme Diagnostics	
	14. Genzyme OSOM® Strep A Ultra Test – 25 Test Kit Size	Genzyme Corporation	
	15. Germaine Strep AIM Tower*	Germaine Laboratories, Inc.	
	16. Henry Schein Inc, One Step+ Strep A Test	Henry Schein	
	17. Immunostics Immuno/Strep A Detector	Acon Laboratories, Inc	
	18. Instant Technologies iStrep Strep A	Acon Laboratories, Inc	
	19. Jant Pharmacal AccuStrip Strep A (II) (direct from throat swab)	Applied Biotech, Inc.	
	20. LifeSign LLC Status Strep A	Princeton BioMeditech	
	21. Mainline Confirms Strep A Dots Test (direct from throat swab)	Applied Biotech, Inc.	

This list includes updates through 12/24/2003

* 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.)	22. Meridian Diagnostics ImmunoCard STAT Strep A (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
	23. Polymedco, Inc. Poly stat A (II)	Applied Biotech, Inc.	
	24. QuickVue In-Line One-Step Strep A Test (K934484)	Quidel Corporation	
	25. QuickVue® Dipstick Strep A	Quidel Corporation	
	26. Quidel QuickVue® In-Line Strep A	Quidel Corporation	
	27. Remel RIM® A.R.C. Strep A Test	Applied Biotech, Inc.	
	28. SmithKline ICON Fx Strep A Test (from throat swab only)	Binax	
	29. Stanbio QuStick Strep A	Stanbio Laboratory	
	30. Wyntek Diagnostics OSOM Strep A Test	Wyntek Diagnostics, Inc	
	31. Wyntek OSOM® Ultra Strep A Test	Wyntek Diagnostics, Inc.	
	87899QW	1. Binax NOW RSV Test*	Binax
2. Integrated Biotechnology Quick Lab RSV Test*		Integrated Biotechnology Corp.	
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

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* Newly added waived test system

70.8 - Certificate of Waiver

(Rev. 102, 02-20-04)

A3-3628.2

Effective September 1, 1992, all laboratory testing sites (except as provided in [42 CFR 493.3\(b\)](#)) must have either a CLIA certificate of waiver, *certificate for provider-performed microscopy procedures*, certificate of registration, *certificate of compliance*, or *certificate of accreditation* to legally perform clinical laboratory testing *on specimens from individuals in the United States*.

The Food and Drug Administration approves CLIA waived tests on a flow basis. The CMS identifies CLIA waived tests by providing an updated list of waived tests to the Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

For a list of specific HCPCS codes subject to CLIA see <http://www.cms.hhs.gov/clia/waivetbl.pdf>