CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1905	**Date: February 5, 2010**
	Change Request 6800

SUBJECT: New Waived Tests

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

New / Revised Material
Effective Date: April 1, 2010
Implementation Date: April 5, 2010

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

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

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1905	Date: February 5, 2010	Change Request: 6800

SUBJECT: New Waived Tests

Effective Date: April 1, 2010

Implementation Date: April 5, 2010

I. GENERAL INFORMATION

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

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

CPT Code	Effective Date	Description
80101QW, G0430QW	July 1, 2009 for 80101QW, January 1, 2010 for G0430QW	Inverness Medical Innovations Signify ER Drug Screen
82274QW, G0328QW	September 9, 2009	Germaine Laboratories AimStep Immunological Fecal Occult Blood Test (iFOBT)
81003QW, 82044QW, 82570QW	September 14, 2009	Siemens Clinitek 50 Urine Chemistry Analyzer
87880QW	September 15, 2009	CLIA waived inc Rapid Strep A Test
82044QW	October 26, 2009	Genzyme Diagnostics OSOM ImmunoDip Urinary Albumin Test

We have been informed by Bayer Healthcare that the following tests are no longer manufactured or distributed:

- Bayer Mulitstick Pro 7G Reagent Strips,
- Bayer Mulitstick Pro 10LS Reagent Strips,
- Bayer Mulitstick Pro 11 Reagent Strips,
- Bayer Clinitek 50 Urine Chemistry Analyzer,
- Bayer Clinitek Status Urine Chemistry Analyzer,
- Bayer Clinitek 50 Urine Chemistry Analyzer - for microalbumin, creatinine,
- Bayer Diagnostics/ Microalbustix Reagent Strip, and
- Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine.

Hence, these tests were removed from the attachment.

Based on a concern received from the laboratory industry on correct coding, the CPT code assigned to the following test systems has been changed from 83518QW to 82044QW with an effective date of April 1, 2010:

- Beckman Coulter ICON Microalb,
- Boehringer Mannheim Chemstrip Micral,
- Diagnostic Chemicals ImmunoDip™ Urinary Albumin Test,
- Diagnostic Chemicals ImmunoDip™ Urinary Albumin Screen (Urine Dipstick), and
- Roche Diagnostics Chemstrip Micral (urine dipstick).

For 2010, the Healthcare Common Procedure Coding System (HCPCS) included the following new codes:

- G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure, and

- G0431 – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class.

Therefore, the HCPCS code G0430QW was added to the following test systems since they are qualitative drug screening tests for multiple drug classes using a non-chromatographic method:

- Abbott Diagnostics Signify ER Drug Screen Test,
- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC) and Cocaine (COC),
- Accu-Stat Drugs of Abuse Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamines, Opiates and Phencyclidine,
- accutest Multi-Drug, Multi-Line Screen Test Device,
- Acon One Step Multi-Drug, Multi-Line Screen Test Device (Professional Use),
- ADC CLIA Waived Marijuana (THC) and Cocaine Test,
- ADC CLIA Waived Multiple Drug Test Card,
- Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test,
- Advantage Diagnostics Corporation ADC Multiple Drug Test Card,
- Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test,
- Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test,
- Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Cup Test,
- Amedica Biotech Amedica Drug Screen Test Cup,
- American Bio Medica Rapid TOX,
- Aventir Biotech LLC Home Check Multiple Drug Test Cup,
- Aventir Biotech LLC Home Check Multiple Drug Cup Test {Professional version},
- Biotechnostix Rapid Response Multi-Drug, Multi-Line Screen Test Card with Integrated Cup,
- Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device,
- Branan Medical Corporation Fastect II Drug Screen Dipstick Test,
- Branan Medical Corporation, FasTox Multiple Drug Dipcard,
- Branan Medical Corporation, QuickTox Drug Screen Dipcard,
- Branan Medical Corporation ToxCup Drug Screen Cup,
- BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine),
- BTNX Inc. Rapid Response Multi-Drug One Step Screen Test Panel (Urine),
- Drug Detection Devices Ltd. Multi-Drug Multi-Line Screeners Dip Drug Test With the Integrated Screeners AutoSplit KO Test Cup,
- First Check Diagnostics First Check Multi Drug Cup,
- First Check Diagnostics First Check 12 Drug Test,

- Forefront Diagnostics Drugfree@Home THC/COC Test Kit,
- iCassette Multi-Drug, Multi-Line Screen Test Device,
- Innovacon Integrated E-Z Split Key Cup II {Professional Use},
- Innovacon Multi-Clin Drug Screen Test Device,
- Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device,
- 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II,
- Phamatech At Home Drug Test (Model 9150T),
- Quest Diagnostics Incorporated, Express Results Integrated Multi-Drug Screen Cup {professional use},
- RediScreen Multi-Drug, Multi-Line Screen Test Device,
- Redwood Toxicology Laboratory Reditest 6 Cassette substance abuse screening device {Professional Use},
- Syntron Bioresearch Quikscreen Multiple Drug Cup Test {Professional version},
- Twin Spirit, Inc. DrugSmart Cup,
- Wolfe Drug Testing RealityCheck Integrated Specimen Cup,
- Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC), and
- Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET).

In addition, the HCPCS code G0431QW was added to the following test systems since they are qualitative drug screening tests using a single drug class method:

- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC),
- ADC CLIA Waived Marijuana (THC) Test,
- DyanGen NicCheck II Test Strips,
- First Check Diagnostics LLC, First Check Home Drug Test Marijuana,
- Mossman Associates, Inc. NicCheck I Test Strips,
- Phamatech At Home Drug Test (Model 9068),
- Phamatech At Home Drug Test (Model 9073),
- Phamatech At Home Drug Test (Model 9073T),
- Phamatech At Home Drug Test (Model 9078),
- Phamatech At Home Drug Test (Model 9078T),
- Phamatech At Home Drug Test (Model 9083),
- Phamatech At Home Drug Test (Model 9133),
- Phamatech QuickScreen One Step Cocaine Screening Test,
- Phamatech QuickScreen One Step Methamphetamine Test,
- Phamatech QuickScreen One Step Opiate Screening Test,
- Phamatech QuickScreen One Step PCP Screening Test, and
- Worldwide Medical Corporation, First Check® Home Drug Test (THC).

This RUN can be found in Chapter 16, §70.8.

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

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6800.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.	X			X						
6800.2	The Medicare contractor shall permit the use of codes G0430QW and G0431QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after January 1, 2010.	X			X					X	
6800.3	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X			X						
6800.4	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.	X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6800.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

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

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

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

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

ATTACHMENT – TESTS GRANTED WAIVED STATUS UNDER CLIA