



# Provider Inquiry Assistance

## New Waived Tests – JA6906

Related CR Release Date: May 28, 2010

Date Job Aid Revised: June 11, 2010

Effective Date: July 1, 2010

Implementation Date: July 6, 2010

**Key Words** MM6906, CR6906, 1968CP, Waived, Tests

**Contractors Affected**

- Part A/B Medicare Administrative Contractors (A/B MACs)
- Medicare Carriers

**Provider Types Affected** Clinical diagnostic laboratories, billing Medicare Carriers or A/B MACs for laboratory tests, are impacted by this change.



Change Request (CR) 6906 alerts providers that the Centers for Medicare & Medicaid Services (CMS) has listed the latest tests approved by the Food and Drug Administration (FDA) as waived tests under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

**Provider Needs to Know...**

- Listed below are the latest tests approved by the FDA as waived tests under CLIA.
- The tests are valid as soon as they are approved.
- The Current Procedural Terminology (CPT) codes for the following new tests **MUST have the modifier QW** to be recognized as a waived test.

CPT Code	Effective Date	Description
82465QW, 83718QW, 84478QW, 80061QW, 82947QW, 82950QW, 82951QW, 82952QW	December 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system
82465QW, 83718QW, 84478QW, 80061QW	December 2, 2009	Infopia USA LipidPro lipid profile and glucose measuring system (LipidPro Lipid Profile test strips)
G0430QW	January 1, 2010	American Screening Corporation One Screen Drug Test Cards
G0430QW	January 1, 2010	American Screening Corporation One Screen Drug Test Cups
G0430QW	January 1, 2010	Express Diagnostics International Inc. DrugCheck Waive Drug Test Cards
G0430QW	January 1, 2010	UCP Biosciences, Inc., UCP Home Drug Screening Test Cards
G0431QW	January 1, 2010	Phamatech QuickScreen One Step Amphetamine Test
G0431QW	January 1, 2010	Phamatech QuickScreen One Step THC Screening Test
86308QW	January 4, 2010	Acceava Mono Cassette {For whole blood}
81003QW, 82044QW, 82570QW, 84703QW	January 4, 2010	Siemens, Clinitek Status+ Analyzer
81003QW, 82044QW, 82570QW, 84703QW	January 4, 2010	Siemens, Clinitek Status Connect System
82274QW, G0328QW	January 26, 2010	Care Diagnostics Clarity IFOB Test

- The following CPT codes do not require a QW modifier to be recognized as a waived test: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651.

#### Important Items to Remember From CR6852

- CR6852 [Clinical Laboratory Fee Schedule (CLFS) - Special Instructions for Specific Test Codes (CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, and G0431QW)] provided special instructions

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for the proper use of CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW, G0431, and G0431QW as of April 1, 2010.

- The MLN Matters® article related to CR6852 is available at <http://www.cms.gov/MLN MattersArticles/downloads/MM6852.pdf> on the CMS website.

**CR6852 also stated the following:**

- If a laboratory with a CLIA certificate of waiver performs a qualitative drug screening test for multiple drug classes, using a non-chromatographic method, then the test code G0430QW would be the appropriate code to bill;
  - The test code G0431 is a direct replacement for CPT Code 80101;
  - Clinical laboratories with a CLIA certificate of waiver should utilize new test code G0431QW; and
  - Effective July 1, 2010, CPT Code 80101 will no longer be covered by Medicare, and CPT Code 80101QW was deleted on April 1, 2010.
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**Background**

- CLIA regulations require a laboratory facility to be appropriately certified for each test it performs.
  - 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.
  - CMS identifies waived tests by providing an updated list of waived tests to Medicare contractors on a quarterly basis via a Recurring Update Notification.
  - To be recognized as a waived test, some CLIA waived tests have unique Healthcare Common Procedure Coding System (HCPCS) procedure codes and some must have a QW modifier (CLIA Waived Test) included with the HCPCS code.
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**Operational Impact**

Medicare Carriers and A/B MACs will not search their files to adjust claims affected by this change, but processed prior to the implementation of CR6906. However, they will adjust such claims that providers bring to their attention.

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**Reference Materials**

The related MLN Matters® article can be found at <http://www.cms.gov/MLN MattersArticles/downloads/MM6906.pdf> on the CMS website.

The official instruction (CR6906) regarding this change may be viewed at <http://www.cms.gov/Transmittals/downloads/R1968CP.pdf> on the CMS website.

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