

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



News Flash -

REVISED product from the Medicare Learning Network® (MLN)

[“Contractor Entities At A Glance: Who May Contact You About Specific Centers for Medicare & Medicaid Services \(CMS\) Activities,”](#) Educational Tool, ICN 906983, Downloadable only.

MLN Matters® Number: MM8146

Related Change Request (CR) #: CR 8146

Related CR Release Date: December 21, 2012

Effective Date: April 1, 2013

Related CR Transmittal #: R2619CP

Implementation Date: April 1, 2013

## New Waived Tests

### Provider Types Affected

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This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare contractors (carriers and Part B Medicare Administrative Contractors (MACs)) for laboratory services.

### Provider Action Needed

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This article, based on Change Request (CR) 8146, informs Medicare contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its contractors of the new tests so that they can accurately process claims. There are 24 newly added waived tests. Be sure your billing staffs are aware of these changes.

#### Disclaimer

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## Background

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that the Medicare and Medicaid Programs 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 (FDA) 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 list attached to CR8146 (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
82274QW	April 19, 2012	Medline iFOB One-Step Immunological Fecal Occult Blood Test
G0434QW	May 9, 2012	Wondfo Multi-Drug Urine Test Cup (Cup format);
G0434QW	May 9, 2012	Wondfo Multi-Drug Urine Test Panel (Dip card format)
83037QW	May 30, 2012	Bayer A1C Now SelfCheck
G0434QW	July 3, 2012	CLIAwaived Inc. Single Drug Dipstick Test
G0434QW	July 3, 2012	CLIAwaived Inc. Rapid Dip Drug Test
G0434QW	July 27, 2012	Wondfo Cannabinoids Urine Test (Cup Format)
G0434QW	July 27, 2012	Wondfo Cannabinoids Urine Test (Dip card Format)
G0434QW	August 2, 2012	Wondfo Amphetamine Urine Test (Cup Format)
G0434QW	August 2, 2012	Wondfo Amphetamine Urine Test (Dip card Format)
G0434QW	August 2, 2012	Wondfo Oxazepam Urine Test (Cup Format)
G0434QW	August 2, 2012	Wondfo Oxazepam Urine Test (Dip card Format)
G0434QW	August 2, 2012	Wondfo Secobarbital Urine Test (Cup Format)
G0434QW	August 2, 2012	Wondfo Secobarbital Urine Test (Dip card Format)
82055QW	August 16, 2012	CLIAwaived Inc. Rapid Saliva Alcohol Test
G0434QW	August 24, 2012	Brannan Medical Corporation Fastect II Drug Screen Dipstick Test;
G0434QW	August 24, 2012	Brannan Medical Corporation QuickTox Drug Screen Dipcard
G0434QW	August 27, 2012	CLIAwaived Inc. Instant Nicotine Detection Test

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CPT Code	Effective Date	Description
87807QW	September 13, 2012	Alere BinaxNOW RSV Card
87804QW	September 13, 2012	Alere BinaxNow Influenza A & B Card (Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens)
82055QW	September 13, 2012	Chematics Inc. Alco-Screen 02 Saliva Alcohol Test
85610QW	September 18, 2012	Roche Diagnostics CoaguChek XS Plus System
81003QW	September 26, 2012,	Acon Laboratories, Inc. Insight U120 Urine Analyzer
G0434QW	October 5, 2012	Medimpex United Inc. MedimpexQ Test Multi X Drug Cup Test

Medicare contractors will not search files to either retract payment or retroactively pay claims based on the changes in CR8146; however, claims should be adjusted if you bring them to your contractor's attention.

### Additional Information

The official instruction, CR8146, issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2619CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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