

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



**News Flash –**

**NEW product(s) 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

MLN Matters® Number: MM7566

Related Change Request (CR) #: 7566

Related CR Release Date: October 21, 2011

Effective Date: January 1, 2012

Related CR Transmittal #: R2321CP

Implementation Date: January 3, 2012

## New Waived Tests

### Provider Types Affected

This article is for clinical diagnostic laboratories billing Medicare Carriers or Part A/B Medicare Administrative Contractors (MACs) for laboratory tests.

### Provider Action Needed



#### **STOP – Impact to You**

If you do not have a valid, current, Clinical Laboratory Improvement Amendments of 1998 (CLIA) certificate and submit a claim to your Medicare Carrier or A/B MAC for a Current Procedural Terminology (CPT) code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted.



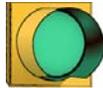
#### **CAUTION – What You Need to Know**

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The CPT codes that the Centers for Medicare & Medicaid Services (CMS)

#### Disclaimer

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considers to be laboratory tests under CLIA (and thus requiring certification) change each year. Change Request (CR) 7566, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits.



### GO – What You Need to Do

Make sure that your billing staffs are aware of these CLIA-related changes for 2012 and that you remain current with certification requirements.

## Background

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The CPT codes in the following table must have the modifier QW to be recognized as a waived test. However, 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
81003QW	February 14, 2011	Germaine Laboratories Inc. AimStrip Urine Analyzer
G0434QW	April 22, 2011	UCP Biosciences, Inc. UCP Drug Screening Test Cups
G0434QW	April 22, 2011	Diagnostic Test Group Clarity Multiple Drug Screen Test Cups
81003QW	March 24, 2011	Mediwatch urinewatch Urine Analyzer
G0434QW	June 17, 2011	Insight Medical Drug of Abuse Urine Cassette Test
G0434QW	June 17, 2011	Insight Medical Drug of Abuse Urine Cup Test
G0434QW	June 17, 2011	Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Instant Technologies, Inc. iScreen Drug of Abuse Urine (Cup) Test
G0434QW	June 17, 2011	Jant Pharmacal Accutest Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Jant Pharmacal Accutest Drug of Abuse Urine (Cup) Test

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CPT Code	Effective Date	Description
G0434QW	June 17, 2011	Total Diagnostic Solutions Drug of Abuse Urine (Cassette) Test
G0434QW	June 17, 2011	Total Diagnostic Solutions Drug of Abuse Urine (Cup) Test
G0434QW	June 30, 2011	Diagnostic Test Group Clarity Simple Drug Screening Cups
G0434QW	June 30, 2011	Diagnostic Test Group Clarity Multi-Drug Test Cards
81003QW	July 14, 2011	Stanbio Uri-Trak 120 Urine Analyzer
G0434QW	July 21, 2011	UCP Biosciences, Inc. U-Checker Drug Screening Test Cups

### Additional Information

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The official instruction, CR7566 issued to your carrier and A/B MAC regarding this change may be viewed at

<http://www.cms.gov/Transmittals/downloads/R2321CP.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/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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