

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



News Flash –

REVISED product from the Medicare Learning Network® (MLN)

[“Power Mobility Devices \(PMDs\): Complying with Documentation & Coverage Requirements,” Fact Sheet, ICN 905063, Downloadable](#)

MLN Matters® Number: MM7694

Related Change Request (CR) #: 7694

Related CR Release Date: February 3, 2012

Effective Date: April 1, 2012

Related CR Transmittal #: R2408CP

Implementation Date: April 2, 2012

## New Waived Tests

### Provider Types Affected

This MLN Matters® Article is intended for clinical laboratories and providers who submit claims to Medicare contractors (carriers and Medicare Administrative Contractors (MACs)) for laboratory test services provided to Medicare beneficiaries are affected.

### Provider Action Needed



#### STOP – Impact to You

There are eleven newly waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

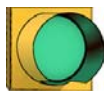


#### CAUTION – What You Need to Know

Change Request (CR) 7694 from which this article is taken announces that (effective April 2, 2012,) the Food and Drug Administration (FDA) has approved new waived tests under CLIA. The codes for these tests are in a table in the Background section.

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2011 American Medical Association.



## GO – What You Need to Do

You should ensure that your billing staffs are aware of these new waived tests.

## Background

CLIA regulations require a facility to be appropriately certified for each test that 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.

CR7694, from which this article is taken, announces the latest 11 tests approved by the FDA as waived tests under CLIA (effective April 2, 2012). The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW, defined as CLIA waived test, to be recognized as a waived test. However, the tests displayed at the beginning of the following table (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.

**TESTS GRANTED WAIVED STATUS UNDER CLIA**

CPT Code	Effective Date	Description
82274QW G0328QW	September 8, 2004	Hemosure One-Step Fecal Occult Blood Test
81003QW	October 28, 2009	Acon Mission U120 Urine Analyzer
G0434QW	May 5, 2011	Premier Integrity Solutions P/Tox Drug Screen Cup {OTC}
81003QW	June 2, 2011	BTNX Rapid Response U120 Urine Analyzer
G0434QW	July 7, 2011	Instant Technologies, Inc. iCassette DX Drug Screen Test
G0434QW	July 19, 2011	Express Diagnostic Int'l Inc DrugCheck Waive RT (Model 9308z)
80061QW, 82465QW, 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW	August 16, 2011	Alere Cholestech LDX {Whole Blood}
82055QW	September 13, 2011	Acon Laboratories Inc. Mission Saliva Alcohol Test Strip
G0434QW	September 13, 2011	Amedica Biotech Instant Test Cup

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CPT Code	Effective Date	Description
81003QW	September 26, 2011	Immunostics Inc., Detector Uristrip+ Analyzer
82055QW	October 4, 2011	Teco Diagnostics Saliva Alcohol Test
86386QW	January 1, 2012	Alere NMP22 BladderChek Test (Prescription Home Use)
86386QW	January 1, 2012	Alere NMP22 BladderChek Test (Professional Use)

For 2012, the new CPT code 86386 was developed for the Nuclear Matrix Protein 22 (NMP22), qualitative test. Therefore, the CPT code assigned to the Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use is changed to 86386QW with an effective date of January 1, 2012.

Please note that your carrier or A/B MAC will not search their files to either retract payment or retroactively pay claims; however, should adjust claims you bring to their attention.

### Additional Information

The official instruction, CR7694, issued to your carrier and A/B MAC regarding this change may be viewed <http://www.cms.gov/transmittals/downloads/R2408CP.pdf> on the Centers for Medicare & Medicaid Services (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.

**News Flash:** It's Not too Late to Give and Get the Flu Vaccine. Take advantage of each office visit and protect your patients against the seasonal flu. Medicare will continue to pay for the seasonal flu vaccine and its administration for all Medicare beneficiaries through the entire flu season. The Centers for Disease Control and Prevention (CDC) also recommends that patients, healthcare workers and caregivers be vaccinated against the seasonal flu. Protect your patients. Protect your family. Protect yourself. Get the Flu Vaccine—Not the Flu. Remember: The flu vaccine plus its administration are covered Part B benefits. The flu vaccine is NOT a Part D-covered drug. For more information on coverage and billing of the flu vaccine and its administration, and related provider resources, visit [2011-2012 Provider Seasonal Flu Resources and Immunizations](#). For the 2011-2012 seasonal flu vaccine payment limits, visit [http://www.CMS.gov/McrPartBDrugAvgSalesPrice/10\\_VaccinesPricing.asp](http://www.CMS.gov/McrPartBDrugAvgSalesPrice/10_VaccinesPricing.asp) on the Centers for Medicare & Medicaid Services (CMS) website.

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