

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



MLN Matters® Number: MM8301 **Revised**

Related Change Request (CR) #: CR 8301

Related CR Release Date: July 24, 2013

Effective Date: October 1, 2013

Related CR Transmittal #: R2745CP

Implementation Date: October 7, 2013

## New Waived Tests

**Note:** This article was revised on July 25, 2013, to reflect a new Change Request (CR). That CR corrected the name of the test in row two of the table in the background section from “B Henry Schein OneStep+ Influenza A&B Test” to “Henry Schein OneStep+ Influenza A&B Test”. The transmittal number, CR release date, and link to the CR was also changed. All other information remains the same.

## Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare Claims Administration Contractors (Medicare Contractors) for services to Medicare beneficiaries.

## 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)

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consider to be laboratory tests under CLIA (and thus requiring certification) change each year. Change Request (CR) 8301, 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 2013 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 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 CR8301 (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, and G0328QW	January 3, 2013,	OSOM iFOB Test OSOM iFOBT Contol Kit
87804QW	February 13, 2013	Henry Schein OneStep+ Influenza A&B Test
G0434QW	February 27, 2013	American Screening Corporation Discover Drug Test Cards
G0434QW	February 27, 2013	American Screening Corporation Discover Multi-panel Drug Test Cups
81003QW	March 15, 2013,	Moore Medical, mooremedical Urine Analyzer U120
82055QW	March 25, 2013	Chematics Inc. Alco-Screen Saliva Alcohol Test

## Additional Information

The official instruction, CR8301 issued to your Medicare Contractor regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2745CP.pdf> on the CMS website.

If you have any questions, please contact your Medicare Contractor at their toll-free number, which is available 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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