



# MLN Matters



Information for Medicare Fee-for-Service Health Care Professionals

MLN Matters Number: MM6287 **Revised**

Related Change Request (CR) #: 6287

Related CR Release Date: December 19, 2008

Effective Date: January 1, 2009

Related CR Transmittal #: R1652CP

Implementation Date: January 5, 2009

## New Waived Tests

**Note: This article was revised on April 11, 2018, to update Web addresses. All other information remains the same.**

## Provider Types Affected

Clinical laboratories and providers that submit claims to Medicare carriers and/or Medicare Administrative Contractors (MACs) for laboratory test services provided to Medicare beneficiaries.

## Provider Action Needed

This article is based on Change Request (CR) 6287 and alerts providers that the Centers for Medicare & Medicaid Services (CMS) has listed the latest tests approved by the Food and Drug Administration as waived tests under Clinical Laboratory Improvement Amendments of 1988 (CLIA). The tests newly added to the waived tests are in the table on page 2 of this article. Be sure your billing staffs are aware of these changes.

## Background

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & 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 CLIA waived tests by providing an updated list of waived tests to the Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique HCPCS procedure codes and some must have a QW modifier included with the HCPCS code.

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For a list of specific HCPCS codes subject to CLIA, see <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf>.

## Key Points of CR6287

- Listed below are the latest tests approved by the Food and Drug Administration 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 at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf> (i.e., CPT codes: 81002, 81025, 82270, 82272, G0394, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

CPT Code	Effective Date	Description
83036QW	October 11, 2007	Siemens Medical Diagnostics DCA Vantage Analyzer
81003QW	May 28, 2008	Henry Schein OneStepPlus Urine Analyzer
82274QW G0328QW	July 1, 2008	Germaine Laboratories Compliance Gold iFOB (immunological fecal occult blood) Test
82274QW G0328QW	July 1, 2008	Beckman Coulter Hemoccult ICT (K080812)
82274QW G0328QW	July 22, 2008	BTNX Inc. Rapid Response Immunolgal Fecal Occult Blood Test (IFOBT)
80101QW	July 31, 2008	Aventir Biotech LLC Home Check Multiple Drug Cup Test
80101QW	August 18, 2008	American Bio Medica Rapid TOX
83986QW	September 18, 2008	Common Sense Ltd. VA-SENSE Kit

- For 2009, the new CPT code 87905 was developed for infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid) testing. Therefore, the CPT code assigned to the Gryphus Diagnostics BVBlue test and the Genzyme Diagnostics OSOM BVBlue Test is changed to 87905QW with an effective date of January 1, 2009.

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- Providers please note that your contractor will not search their files to either retract payment or retroactively pay claims processed before CR6287 is implemented. However, they will adjust such claims if you bring them to your contractor's attention.

## Additional Information

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If you have questions, please contact your Medicare contractor 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>.

The official instruction (CR6287) issued to your Medicare A/B MAC, or carrier is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1652CP.pdf>.

## Document History

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- December 20, 2008 – Initial article released.
- April 11, 2018 – The article is revised to update Web addresses. All other information remains the same.

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