



**News Flash** - Flu Season is upon us! Begin now to take advantage of each office visit as an opportunity to talk with your patients about the flu virus and their risks for complications associated with the flu. Encourage them to get their flu shot. It's their best defense against combating the flu this season. *(Medicare provides coverage of the flu vaccine without any out-of-pocket costs to the Medicare patient. No deductible or copayment/coinsurance applies.)* And don't forget, health care professionals need to protect themselves also. **Get Your Flu Shot. – Not the Flu.** Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For information about Medicare's coverage of flu vaccine and its administration as well as related educational resources for health care professions, please go to [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/flu\\_products.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/flu_products.pdf) on the CMS website.

MLN Matters Number: MM5715

Related Change Request (CR) #: 5715

Related CR Release Date: September 28, 2007

Effective Date: October 1, 2007

Related CR Transmittal #: R1346CP

Implementation Date: October 1, 2007

**Note:** This article was updated on September 20, 2012, to reflect current Web addresses. All other information remains the same.

## New Waived Tests

### Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare carriers and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries

### Provider Action Needed

This article is based on Change Request (CR) 5715 which informs carriers and A/B MACS of new waived tests approved by the Food and Drug Administration (FDA) under Clinical Laboratory Improvement Amendments of 1988 (CLIA).

### Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test they perform. Laboratory claims are currently edited at the CLIA certificate level in order to ensure that the Centers for Medicare & Medicaid Services (CMS) only pays for laboratory tests

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categorized as waived complexity under CLIA (for facilities with a CLIA certificate of waiver).

New waived tests are approved by the FDA on a flow basis, and the tests are valid as soon as they are approved. The new waived tests announced by CR5715 are in the following table:

CPT Codes	Effective Date	Description
83001QW	October 21, 2003	Genosis Fertell Female Fertility Test
84443QW	April 2, 2007	Jant Pharmacal Accutest TSH {Whole Blood}
86308QW	April 12, 2007	Signify Mono Whole Blood
86308QW	April 12, 2007	Clearview MONO Whole Blood
82465QW, 83718QW, 84460QW, 80061QW, 84478QW	May 16, 2007	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}
86318QW	May 16, 2007	Immunostics Detector H. Pylori WB (H. pylori Antibody Test) {Whole Blood}
86308QW	May 17, 2007	Immuno Detector Mono {Whole Blood}
80101QW	May 24, 2007	Innovacon Multi-Clin Drug Screen Test Device
80101QW	May 24, 2007	Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device
87880QW	May 24, 2007	Cardinal Health SP Brand Rapid Test Strep A Dipstick(K010582/A028)
86318QW	May 24, 2007	Cardinal Health SP Brand Rapid Test H. pylori {Whole Blood}(K024350/A15)
82042QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	May 31, 2007	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 1) { Whole Blood}
86308QW	May 31, 2007	Cardinal Health SP Brand Rapid Test Mono {Whole Blood}
82247QW, 84075QW, 84157QW, 84450QW, 84460QW	May 31, 2007	Arkay SPOTCHEM EZ Chemistry Analyer (Spotchem II Basicpanel 2) { Whole Blood}
86318QW	June 11, 2007	Fisher Healthcare Sure-View H. pylori Test {Whole Blood}
89321QW	June 18, 2007	Fertell Male Fertility Test

**Note: The Current Procedural Terminology (CPT) codes for these new waived tests must have the modifier QW to be recognized as a waived test.**

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Also, the new waived CPT/HCPCS code, 82310QW, has been assigned for the total calcium test performed using the Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) { Whole Blood}. The new waived CPT/HCPCS code, 82565QW, has been assigned for the creatinine test performed using the Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) { Whole Blood}. The new waived CPT/HCPCS code, 89321QW, has been assigned for the semen motility test performed using the Fertell Male Fertility Test.

Your Medicare carrier or MAC will not automatically adjust claims processed prior to the implementation of these changes. However, they will adjust such claims that you bring to their attention.

## Additional Information

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For complete details, please see the official instruction, CR5715, issued to your carrier or A/B MAC regarding this change. That instruction may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1346CP.pdf> on the CMS website. The attachment to CR 5715 includes the list of tests granted waived status under CLIA, and the tests mentioned on the first page of the attachment (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.

If you have questions, please contact your Medicare 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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