



Related MLN Matters Article #: MM3984

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Related Change Request #: CR3984

### *New Waived Tests Approved by the Food and Drug Administration (FDA) Under Clinical Laboratory Improvement Amendments (CLIA) of 1988*

#### Keywords

Tests, CLIA, Laboratory, MM3984, CR3984, R642CP, CPT, Modifier, QW, 83721QW, 87799QW, Waiver, FDA, Certificate

#### Provider Types Affected

Providers/suppliers billing services to Medicare carriers

#### Key Points

- The effective date of instruction is October 1, 2005.
- The implementation date is October 3, 2005.
- MLN Matters article MM3984 informs Medicare carriers of new tests granted waived status under CLIA by the FDA.
- The latest test approved by the FDA as waived tests under the CLIA are listed in the table on page 2 of MM3984.
- The Current Procedural Terminology (CPT) codes for the new tests in the table must have the modifier QW to be recognized as a waived test.
- CPT codes **81002**, **81025**, **82270**, **G0107**, **82962**, **83026**, **84830**, **85013**, and **85651** do not require a QW modifier to be recognized as a waived test.
- New waived code **83721QW** has been assigned for LDL cholesterol testing performed using the Polymer Technology Systems Cardiochek PA Analyzer as of March 25, 2005.
- New waived code **87899QW** has been assigned for Trichomonas testing performed using the Genzyme OSOM Trichomonas Rapid Test as of March 16, 2005.

#### Important Links

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3984.pdf>

<http://www.cms.hhs.gov/Transmittals/downloads/R642CP.pdf>