



## New Waived Tests

MLN Matters Number: MM10055

Related Change Request (CR) Number: 10055

Related CR Release Date: May 12, 2017

Effective Date: January 1, 2017

Related CR Transmittal Number: R3771CP

Implementation Date: July 3, 2017

### PROVIDER TYPE AFFECTED

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

### PROVIDER ACTION NEEDED

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Change Request (CR) 10055 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify MACs of the new tests so that they can accurately process claims. Make sure that your billing staffs are aware of these CLIA-related changes.

### BACKGROUND

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The 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 CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

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 attached list (that is, 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.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

- 82465QW, 83718QW, 82947QW, 82950QW, 82951QW, 82952QW, December 22, 2016, Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL+Glu test strips)
- 82465QW, 83718QW, December 22, 2016, Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL test strips)

- 82465QW, 82947QW, 82950QW, 82951QW, 82952QW, December 22, 2016, Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+Glu test strips)
- 82465QW, 83718QW, 82947QW, 82950QW, 82951QW, 82952QW, December 22, 2016, Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL+Glu test strips)
- 82465QW, 83718QW, December 22, 2016, Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL test strips)
- 82465QW, 82947QW, 82950QW, 82951QW, 82952QW December 22, 2016, Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+Glu test strips)
- 81003QW, January 23, 2017, Germaine Laboratories, Inc. AimStrip Urine Analyzer 2 System (AimStrip Urine Reagent Strips)
- 81003QW, January 23, 2017, Germaine Laboratories, Inc. AimStrip Urine Analyzer 2 System (Fisherbrand Urine Reagent Strips)
- 87804QW, January 23, 2017, LifeSign LLC, Status Flu A+B {Nasal and Nasopharyngeal Swabs}
- 87804QW, January 23, 2017, Sekisui Diagnostics LLC, OSOM Ultra Flu A&B Test {Nasal and Nasopharyngeal Swabs}
- 80305QW, February 2, 2017, Advin Biotech, Inc. ATTEST
- 87801QW, March 6, 2017, Alere i System Respiratory Syncytial Virus

The new waived complexity code G0475 [HIV antigen/antibody, combination assay, screening] describes the testing assigned to the waived CPT 87806QW when it is performed for screening purposes. Effective January 1, 2017, the use of G0475QW will be permitted for claims submitted by facilities with a valid, current CLIA certificate of waiver.

The new waived complexity code, 87801QW [Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique] is assigned to the testing performed by the Alere i System Respiratory Syncytial Virus test.

The attachment to CR1005 contains the test name, manufacturer, and use for each above listed CPT codes. You should be aware that MACs will not search their files to either retract payment or retroactively pay claims; however, they should adjust claims that you bring to their attention.

## ADDITIONAL INFORMATION

The official instruction, CR10055, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3771CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

## DOCUMENT HISTORY

Date of Change	Description
May 15, 2017	Initial article released.

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