

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



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- [“Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians”](#)
Web-based Training (WBT)

MLN Matters® Number: MM9072

Related Change Request (CR) #: CR 9072

Related CR Release Date: February 27, 2015

Effective Date: April 1, 2015

Related CR Transmittal #: R3207CP

Implementation Date: April 6, 2015

New Waived Tests

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9072 informs MACs about the changes in the 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, Centers for Medicare & Medicaid Services (CMS) must notify its MACs of the new tests to allow MACs to accurately process claims.

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The CPT codes that CMS considers to be laboratory tests under CLIA (and thus requiring certification) change each year. Make sure your billing staffs are aware of these changes.

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Background

The Clinical Laboratory Improvement Amendments of 1988 (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.

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

- G0434QW, September 18, 2014, CLIAwaived Inc. Rapid Drug Test Cup {Cassette Dip Card format};
- 86308QW, September 23, 2014, AimStep Mono {Whole Blood};
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Marijuana Panel Dip;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Marijuana Quick Cup;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Marijuana Strip;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Marijuana Turn-Key Split Cup;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Methamphetamine Panel Dip;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Methamphetamine Quick Cup;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Methamphetamine Strip;
- G0434QW, September 26, 2014, Polymed Therapeutics FaStep Methamphetamine Turn-Key Split Cup;
- G0434QW, October 9, 2014, Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests;

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- G0434QW, October 9, 2014, Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests;
- G0434QW, October 9, 2014, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card Tests;
- G0434QW, October 9, 2014, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card with OPI 2000 Test;
- G0434QW, October 17, 2014, Healgen Oxazepam Test Strip;
- G0434 QW, October 17, 2014, Healgen Oxazepam Test Dip Card;
- G0434QW, October 17, 2014, Healgen Oxazepam Test Cup;
- G0434QW, October 17, 2014, Healgen Oxazepam Test Cassette;
- G0434QW, October 17, 2014, Healgen Morphine Test Strip;
- G0434QW, October 17, 2014, Healgen Morphine Test Dip Card;
- G0434QW, October 17, 2014, Healgen Morphine Test Cup;
- G0434QW, October 17, 2014, Healgen Morphine Test Cassette;
- G0433QW, October 29, 2014, Chembio Diagnostic Systems, Inc. DPP HIV 1/2 Assay {Oral Fluid}; and
- 87389QW [from December 5, 2014 to December 31, 2014], Oregenis, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}; and
- 87806QW [on and after January 1, 2015] , Oregenis, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood};
- G0434QW, December 10, 2014, Transmetron Invitro Pro Drug Test Cups;
- G0434QW, December 10, 2014, Coastline Medical Management Coastline Explorer Cup {Cassette Dip Card Format};
- 86780QW, December 15, 2014, Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood};

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- G0434QW, December 19, 2014, On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card Tests;
- G0434QW, December 19, 2014, On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card with OPI 2000 Tests; and
- 87502QW, January 5, 2015, Alere i Influenza A & B Test {Direct Nasal swab only}..

From December 5, 2014, to December 31, 2014, the CPT code 87389QW has been assigned for the detection of antigen to HIV-1, and antibodies to HIV-1 and HIV-2 performed using the Orogenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}. On and after January 1, 2015, the CPT code assigned to Orogenics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood} will be 87806QW.

The new CPT code 86780QW has been assigned for the immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in whole blood performed using the Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood}.

The new CPT code 87502QW has been assigned for the differential and qualitative detection of influenza A and influenza B viral nucleic acids using isothermal nucleic acid amplification technology performed using the Alere i Influenza A & B Test {Direct Nasal swab only}.

Additional Information

The official instruction, CR9072 issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3207CP.pdf> on the CMS website.

If you have questions, please contact your MAC at their toll-free number. The number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work?

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