

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services



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**MLN Matters® Number: MM9416**

**Related Change Request (CR) #: CR 9416**

**Related CR Release Date: November 13, 2015**

**Effective Date: January 1, 2016**

**Related CR Transmittal #: R3406CP**

**Implementation Date: January 4, 2016**

## New Waived Tests

### Provider Types 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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This article is based on Change Request (CR) 9416 which informs your 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 its contractors of the new tests so that MACs can accurately process claims. CR 9416 informs MACs of the newly added waived complexity tests. See the Background and Additional Information Sections of this article for further details, and make sure that your billing staff is aware of these changes.

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## Background

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that CMS only pays 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.

**Note:** CR 8871 mentioned that effective for services performed on or after June 2, 2014, the HCPCS G0472, HCV screening, will be recognized as a covered service. The HCPCS code G0472QW describes the hepatitis C antibody test performed using the OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference. The OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference test was mentioned as a new waived test in CR 8054. The related MLN Matters® articles for CR8871 and CR 8054 may be viewed at [MM8871](#) and [MM8054](#).

## CR9416 Updates

The latest tests approved by the FDA as waived tests under CLIA are listed in the tables that follows. The Current Procedural Terminology (CPT) codes for these new tests in Table 1 must have the modifier ‘QW’ to be recognized as a waived test.

**Table 1: TESTS GRANTED WAIVED STATUS UNDER CLIA  
(Requires QW Modifier)**

CPT Code(s)	Effective Date	Description
<b>86308QW</b>	January 21, 2015	Medline Mono Test Cassette {Whole Blood}
<b>G0434QW</b>	June 5, 2015	AssureTech Co. LTD, AssureTech Oxycodone Strip {OTC}
<b>G0434QW</b>	June 5, 2015,	AssureTech Co. Ltd, AssureTech Secobarbital Strip {OTC};
<b>G0434QW</b>	June 5, 2015	AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Panel Dip {OTC}
<b>G0434QW</b>	June 5, 2015	AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Quick Cup {OTC}
<b>G0434QW</b>	June 5, 2015	AssureTech Co. Ltd, AssureTech Secobarbital/Oxycodone Turn Key-Split Cup {OTC}
<b>82274QW, G0328QW</b>	June 26, 2015	Medline iFOB Test

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<b>CPT Code(s)</b>	<b>Effective Date</b>	<b>Description</b>
<b>G0434QW</b>	July 16, 2015	Noble Medical Inc. Noble 1 Step + Cup
<b>82274QW, G0328QW</b>	July 28, 2015	Sekisui Diagnostics, LLC OSOM iFOB Test
<b>86318QW</b>	August 19, 2015	Alere Clearview H. pylori Whole Blood Only {Whole Blood};
<b>86318QW</b>	August 19, 2015	Alere Signify H. pylori Whole Blood Only {Whole Blood}
<b>87880QW</b>	August 21, 2015	LABSCO Advantage Strep A
<b>G0434QW</b>	August 31, 2015	UCP Biosciences, Inc. UCP Drug Test Mini Cups
<b>G0434QW</b>	Sept. 22, 2015	American Screening Corporation, Reveal Mini Drug Test Cups
<b>G0434QW</b>	October 13, 2015	,Assure Tech Co., Ltd AssureTech Buprenorphine Strip;
<b>G0434QW</b>	October 13, 2015	Assure Tech Co., Ltd AssureTech Methadone Strip;
<b>G0434QW</b>	October 13, 2015	Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Panel Dip;
<b>G0434QW</b>	October 13, 2015	Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Quick Cup; and
<b>G0434QW</b>	October 13, 2015	Assure Tech Co., Ltd AssureTech Buprenorphine/Methadone Turn Key-Split Cup.

However, the tests referenced in the attachment of CR9416 titled, “*TESTS GRANTED WAIVED STATUS UNDER CLIA*”, do not require a ‘QW’ modifier to be recognized as a waived test. These tests have been extracted from that document and are listed in Table 2.

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**Table 2: TESTS GRANTED WAIVED STATUS UNDER CLIA  
(Do not require QW Modifier)**

CPT Code(s)	Test Name	Use
<b>81002</b>	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
<b>81025</b>	Urine pregnancy tests by visual color comparison	Diagnosis of pregnancy
<b>82270, 82272</b> Contact your Medicare carrier for claims instructions	Fecal occult blood	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
<b>82962</b>	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Monitoring of blood glucose levels
<b>83026</b>	Hemoglobin by copper sulfate – non-automated	Monitors hemoglobin level in blood
<b>84830</b>	Ovulation tests by visual color comparison for human luteinizing hormone	Detection of ovulation (optimal for conception)
<b>85013</b>	Blood count; spun microhematocrit	Screen for anemia
<b>85651</b>	Erythrocyte sedimentation rate – non-automated	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

**Note:** MACs will not search their files to either retract payment or retroactively pay claims processed prior to the implementation of CR 9416. However, your MAC should adjust claims if you bring such claims to their attention.

### Additional Information

The official instruction, CR 9416, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3406CP.pdf> on the CMS website.

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