

MLN Matters Number: MM4136

Related Change Request (CR) #: 4136

Related CR Release Date: December 16, 2005

Effective Date: January 1, 2006

Related CR Transmittal #: 779

Implementation Date: January 3, 2006

## New Waived Tests

**Note:** This article was revised to contain web addresses that conform to the new CMS website and to show they are now MLN Matters articles. All other information remains the same.

## Provider Types Affected

Suppliers and providers billing Medicare carriers for laboratory tests

## Provider Action Needed



### STOP – Impact to You

This article is based on Change Request (CR) 4136, which includes new waived tests approved by the Food and Drug Administration (FDA) under Clinical Laboratory Improvement Amendments (CLIA) of 1988.



### CAUTION – What You Need to Know

The following are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under the CLIA: Clearview Ultra FOB Test; Clarity Hemosure One-Step Immunological Fecal Occult Blood Test; Branam Medical Corporation ToxCup Drug Screen Cup; ReliaLAB Inc. InstaRead Lithium System (fingerstick or venipuncture whole blood); Roche Diagnostics AccuChek Instant Plus Dual Testing System; Acon Laboratories, Inc. FSH One Step Menopause Test Strip (Professional Use); Acon Laboratories, Inc. FSH One Step Menopause Test Device (Professional Use); Biosite Triage Meter (Whole Blood); Biosite Triage Meter Plus (Whole Blood); Acon Mononucleosis Rapid Test Strip (Whole Blood); Acon Mononucleosis Rapid Test Device (Whole Blood); iCassette Multi-Drug, Multi-Line Screen Test Device; accutest Multi-Drug, Multi-Line Screen Test Device; and RediScreen Multi-Drug; Multi-Line Screen Test Device.

### Disclaimer

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### GO – What You Need to Do

See the *Background* section of this article for further details regarding the effective dates and CPT codes for these approved waived tests.

## Background

The regulations of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 require a facility to be appropriately certified for each test performed. To ensure that the Centers for Medicare & Medicaid Services (CMS) pays only 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.

### *Waived Tests Requiring QW Modifier*

The descriptions, Current Procedural Terminology (CPT) codes, and effective dates of the latest tests approved by the Food and Drug Administration (FDA) as waived tests under the CLIA are listed below.

Waived Test Requiring QW Modifier	CPT Code/Modifier	Effective Date
1. Clearview Ultra FOB Test	82274QW, G0328QW	August 18, 2004
2. Clarity Hemosure One-Step Immunological Fecal Occult Blood Test	82274QW, G0328QW	March 16, 2005
3. Branan Medical Corporation ToxCup Drug Screen Cup	80101QW	July 19, 2005
4 ReliaLab Inc. InstaRead Lithium System (fingerstick or venipuncture whole blood)	80178QW	April 22, 2005
5. Roche Diagnostics AccuChek Instant Plus Dual Testing System	82962 and 82465QW	August 24, 2005
6. Acon Laboratories, Inc. FSH One Step Menopause Test Strip (Professional Use)	83001QW	August 24, 2005
7. Acon Laboratories, Inc. FSH One Step Menopause Test Device (Professional Use)	83001QW	August 24, 2005
8. Biosite Triage Meter (Whole Blood)	83880QW	August 26, 2005
9. Biosite Triage Meter Plus (Whole Blood)	83880QW	August 26, 2005
10. Acon Mononucleosis Rapid Test Strip (Whole Blood)	86308QW	September 1, 2005
11. Acon Mononucleosis Rapid Test Device (Whole Blood)	86308QW	September 1, 2005
12. iCassette Multi-Drug, Multi-Line Screen Test Device	80101QW	July 8, 2005

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13. accutest Multi-Drug, Multi-Line Screen Test Device	80101QW	September 1, 2005
14. RediScreen Multi-Drug, Multi-Line Screen Test Device	80101QW	September 1, 2005

To be recognized as a waived test, the CPT codes for these new waived tests must have the modifier QW.

### *Tests That Do Not Required QW Modifier*

However, the tests listed in the following table (also included on the first page of the list attached to CR4136) do not require a QW modifier to be recognized as a waived test:

Waived Tests Not Requiring QW Modifier	CPT Codes Not Requiring Modifier QW
Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	81002
Urine pregnancy tests by visual color comparison	81025
Fecal occult blood	82270, 82272 G0107 (Contact your Medicare carrier for claims instructions.)
Blood glucose by glucose monitoring devices cleared by the FDA for home use	82962
Hemoglobin by copper sulfate – non-automated	83026
Ovulation tests by visual color comparison for human luteinizing hormone	84830
Blood count; spun microhematocrit	85013
Erythrocyte sedimentation rate – non-automated	85651

### *HCPCS Codes 83880QW, 82271, 83037, 83037QW*

The new waived CPT/Healthcare Common Procedure Coding System (HCPCS) code, **83880QW**, has been assigned for the B-type natriuretic peptide (BNP) test performed using the Biosite Triage Meter (Whole Blood) and the Biosite Triage Meter Plus (Whole Blood).

The new waived code, 80178QW, has been assigned for the lithium test performed using the ReliaLAB Inc. InstaRead Lithium System (fingerstick or venipuncture whole blood).

For 2006, the new CPT/HCPCS code **82271** replaced the CPT code 82273 and is for tests for blood, occult, by peroxidase activity (e.g., guaiac), qualitative; other

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sources. The CPT/HCPCS code 82271QW is effective January 1, 2006, and replaces the CPT/HCPCS code 82273QW for the following test systems:

- Aerscher Hemaprompt FG;
- SmithKline Gastrocult; and
- Beckman Coulter Primary Care Diagnostics Gastrocult.

For 2006, the new CPT/HCPCS code 82272 was developed to cover blood, occult, by peroxidase activity (e.g., guaiac), feces, single specimen, (e.g., from digital rectal exam) testing. This code has been added to the existing codes for fecal occult blood tests with an effective date of January 1, 2006.

For 2006, the new CPT/HCPCS code **83037** was developed to cover the testing for hemoglobin; glycosylated (A1c) by a device cleared by the FDA for home use.

The following previously listed tests have been assigned the CPT/HCPCS code **83037QW** with an Effective Date of January 1, 2006:

- Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test;
- Cholestech GDX A1C Test (Prescription Home Use);
- Metrika A1c Now for Prescription Home Use (K020234);
- Provalis Diagnostics Glycosal™ HbA1c Test; and
- Provalis Diagnostics In2it In-Office Analyzer (II) A1C Prescription Home Use Test System.

**Note:** See the attachment to CR4136 for a complete listing of tests granted waived status under CLIA.

## Implementation

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The implementation date for the instruction is January 3, 2006.

## Additional Information

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For complete details, please see the official instruction issued to your carrier regarding this change. That instruction (CR4136) may be viewed at <http://www.cms.hhs.gov/transmittals/downloads/R779CP.pdf> on the CMS website.

If you have any questions, please contact your carrier at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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