

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3563	Date: July 15, 2016
	Change Request 9687

Transmittal 3550, dated June 24, 2016, is being rescinded and replaced by Transmittal 3563 dated July 15, 2016 to correct 3 items in the attachment to the Recurring Update Notification. The items corrected were the second bullet on page 5 for the Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card was changed to Assure Tech Co., Ltd. AssureTech Amphetamine Quick Cup; the fourth bullet on page 12 for the Assure Tech Co., Ltd. AssureTech Morphine Strip was changed to the Assure Tech Co., Ltd. AssureTech Morphine Turn-Key Split Cup; and the CPT code for the Meridian Bioscience Immunocard STAT! HpSA (Stool) was changed to 87338QW. All other information remains the same.

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This change will inform contractors of new CLIA waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 29 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

EFFECTIVE DATE: October 1, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 3, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3563	Date: July 15, 2016	Change Request: 9687
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SUBJECT: New Waived Tests

EFFECTIVE DATE: October 1, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 3, 2016

I. GENERAL INFORMATION

A. 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 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 (i.e., 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:

- G0434QW [from August 21, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Healgen Scientific LLC, Healgen Multi-Drug Urine Test Dip Card;
- G0477QW, March 8, 2016, Tanner Scientific Multi-Panel Drug Test Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Cassette;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Marijuana Test Dip Card;

- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Cassette;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Metamphetamine Test Dip Card;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Easy Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Split Key Cup;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Cassette;
- G0477QW, March 18, 2016, Hangzhou Clongene Biotech Co., Ltd. Clungene Morphine Test Dip Card;
- 87338QW, March 22, 2016, Meridian Bioscience Immunocard STAT! HpSA (Stool);
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Amphetamine Turn-Key Split Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Cocaine Turn-Key Split Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Dip Card;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Quick Cup;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Strip;
- G0477QW, March 31, 2016, Assure Tech Co., Ltd. AssureTech Morphine Turn-Key Split Cup;
- G0477QW, April 21, 2016, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup Tests; and
- G0477QW, April 21, 2016, Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Cup with OPI 2000 Tests.

The new waived complexity code 87338QW [Qualitative or semiquantitative detection test for helicobacter pylori in stool, multiple-step method] was assigned for the detection of Helicobacter pylori antigens in stool performed using the Meridian Bioscience Immunocard STAT! HpSA (Stool) test.

This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

B. Policy: The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and 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.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C	Shared- System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
9687.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X									
9687.2	The Medicare contractor shall permit the use of code 87338QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 22, 2016.		X								X	
9687.3	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.		X									
9687.4	Contractors shall not use the explanatory information under the "Use" column in the attachment as the reason for rejecting a claim.		X									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
9687.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

