

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3666	Date: November 23, 2016
	Change Request 9797

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This change request 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 40 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

EFFECTIVE DATE: January 1, 2017

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

IMPLEMENTATION DATE: January 3, 2017

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	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

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SUBJECT: New Waived Tests

EFFECTIVE DATE: January 1, 2017

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IMPLEMENTATION DATE: January 3, 2017

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:

- G0477QW, February 12, 2016, Greenbrier International, Inc. Assured THC One Step Marijuana Test Cassette;
- G0477QW, February 12, 2016, Greenbrier International, Inc. Assured THC One Step Marijuana Test Strip;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Amphetamine Cassette;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Amphetamine Cup;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Amphetamine DipCard;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Cocaine Cassette;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Cocaine;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Cocaine DipCard;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Marijuana Cassette;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Marijuana Cup;
- G0477QW, March 18, 2016, Safecare Biotech Urine Test Marijuana DipCard;

- 83986QW, May 13, 2016, Teco Diagnostics OBGYN-VpH Vaginal pH Screening Kit;
- G0477QW, June 9, 2016, Native Diagnostics International DrugSmart Multi-Panel Drug Screen Cup Tests;
- G0477QW, June 9, 2016, Native Diagnostics International DrugSmart Multi-Panel Drug Screen Cup with OPI 2000 Tests;
- G0477QW, June 9, 2016, Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card Tests;
- G0477QW, June 9, 2016, On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Cup Tests;
- G0477QW, June 9, 2016, On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Cup with OPI 2000 Tests;
- G0477QW, June 9, 2016, On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Dip Card Tests;
- G0477QW, June 9, 2016, On-Site Testing Specialists, Inc. On-Site Testing Specialists Multi-Panel Drug Screen Dip Card with OPI 2000 Tests;
- G0477QW, June 9, 2016, Alfa Scientific Designs, Inc. Instant-View Multi-Drug Urine Test Cup;
- G0477QW, June 9, 2016, Alfa Scientific Designs, Inc. Instant-View Multi-Drug Urine Test Panel;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Marijuana Dip Card Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Marijuana Quick Cup Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Marijuana Strip Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Marijuana Turn-Key Split Cup Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Methamphetamine Dip Card;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Methamphetamine Quick Cup Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Methamphetamine Strip Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Methamphetamine Turn-Key Split Cup Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Phencyclidine Dip Card Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Phencyclidine Quick Cup Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Phencyclidine Strip Test;
- G0477QW, July 18, 2016, Assure Tech. Co., Ltd. AssureTech Phencyclidine Turn-Key Split Cup Test;

- 87631QW, July 25, 2016 Roche Molecular, cobas Liat System cobas Liat Influenza A/B & RSV Assay;
- G0477QW, July 28, 2016, Germaine Laboratories, Inc., AimScreen Multi-Drug Urine Test DipDevice;
- G0477QW, July 28, 2016, Germaine Laboratories, Inc., SafeCup II Multi-Drug Urine Test Cup;
- G0477QW, July 29, 2016, NexScreen LLC, NEXSCREEN Multi-Drug Urine Test Cup;
- G0477QW, July 29, 2016, NexScreen LLC, NEXSCREEN Multi-Drug Urine Test Dip Card;
- 86308QW, August 4, 2016, McKesson Consult Mononucleosis Test Cassette {whole blood}; and
- 87880QW, September 4, 2016, Princeton BioMeditech StatusFirst Strep A.

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								Other
		A/B MAC		D M E M A C	Shared- System Maintainers					
		A	B		H H H	F I S S	M C S	V M S	C W F	
9797.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X							
9797.2	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							
9797.3	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 A N	C O N T R A C T O R
		A	B	H H H		
9797.4	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:

"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