

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 4137</b>	<b>Date: September 21, 2018</b>
	<b>Change Request 10958</b>

**SUBJECT: New Waived Tests**

**I. SUMMARY OF CHANGES:** This Change Request (CR) will inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. 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 the contractors can accurately process claims. There are 16 newly added waived complexity tests. The initial release of this Recurring Update Notification applies to Chapter 16, section 70.8 of the IOM.

**EFFECTIVE DATE: January 1, 2019**

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

**IMPLEMENTATION DATE: January 7, 2019**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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

Pub. 100-04	Transmittal: 4137	Date: September 21, 2018	Change Request: 10958
-------------	-------------------	--------------------------	-----------------------

**SUBJECT: New Waived Tests**

**EFFECTIVE DATE: January 1, 2019**

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

**IMPLEMENTATION DATE: January 7, 2019**

## 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:

- 80305QW, March 8, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Cups;
- 80305QW, March 8, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test DipCards;
- 87651QW, May 2, 2018, Alere i Instrument (Alere i Strep A 2);
- 82274QW, G0328QW, May 4, 2018, McKesson Consult Immunochemical Fecal Occult Blood Test;
- 80305QW, May 15, 2018, MyDrugTestCups.com, MyDrugTest Multi-Drug Urine Test Cup;
- 80305QW, May 15, 2018, MyDrugTestCups.com, MyDrugTest Multi-Drug Urine Test Dip Card;
- 80305QW, May 16, 2018, Confirm BioSciences, Smart Choice Multi Panel DOA Test Cup;
- 80305QW, May 16, 2018, Confirm BioSciences, Smart Choice Multi Panel DOA Test Dip Card;
- 82044QW, 82570QW, June 14, 2018, BTNX, Inc., Rapid Response U120S Urine Analyzer Test System (BTNX, Inc. Rapid Response Urinalysis Reagent Strips (Microalbumin/Creatinine));
- 80305QW, July 16, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Cups;
- 80305QW, July 16, 2018, Express Diagnostics International DrugCheck Multi Panel Drug Test Dip Card;
- 81003QW, July 27, 2018, BTNX, Inc., Rapid Response U120 Urine Analyzer Test System;
- 80305QW, July 30, 2018, Hangzhou Clongene Biotech Co., Ltd. Clungene Multi-Drug Test Easy Cup;
- 80305QW, July 30, 2018, Hangzhou Clongene Biotech Co., Ltd. Clungene Multi-Drug Test Dip Card;
- 87502QW, August 10, 2018, Mesa Biotech Accula (Accula Flu A/Flu B test); and
- 87502QW, August 10, 2018, Sekisui Inc., Silaris Dock (Silaris Influenza A&B 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 in a facility with a valid, current CLIA certificate, 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		
10958.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X								
10958.2	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								
10958.3	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 M A C	C E D I		
		A	B	H H H				
10958.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get		X					

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
	article release notifications, or review them in the MLN Connects weekly newsletter.					

**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**