



New Waived Tests

MLN Matters Number: MM10198

Related Change Request (CR) Number: 10198

Related CR Release Date: July 27, 2017

Effective Date: October 1, 2017

Related CR Transmittal Number: R3812CP

Implementation Date: October 2, 2017

PROVIDER TYPE AFFECTED

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

Change Request (CR) 10198 informs 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 following approval, the Centers for Medicare & Medicaid Services (CMS) must notify the MACs of the new tests so that they can accurately process claims. CR10198 lists 17 newly added waived complexity tests.

BACKGROUND

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 or waiver, laboratory claims are currently edited at the CLIA certificate level.

This article includes the latest tests approved by the 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 (that is, 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 include:

- 87880QW, December 8, 2016, Quidel Sofia Strep A+ FIA (from throat swab only);
- 80305QW, April 28, 2017, Alere Toxicology Services Alere iCup Rx Multi-Drug Urine Test Cup;

- 82044QW, and 82570QW, May 10, 2017, Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine));
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Amphetamine Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Oxazepam Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Cocaine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Marijuana Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methamphetamine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Morphine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Oxycodone Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Barbiturates Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Buprenorphine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methylenedioxymethamphetamine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Phencyclidine Panel Dip;
- 80305QW, May 16, 2017, Assure Tech. Co., Ltd. AssureTech Methadone Panel Dip;
- 87804QW, May 30, 2017, Quidel Sofia 2 {Sofia Influenza A+B FIA}; and
- 82274QW, G0328QW, June 5, 2017, Jant Pharmacal Coporation Accutest ValuPak Immunochemical Fecal Occult Blood Test.

Note: MACs will not search their files to either retract payment or retroactively pay claims; however, MACs should adjust claims if they are brought to their attention.

ADDITIONAL INFORMATION

The official instruction, CR10198, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3812CP.pdf>. If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>

DOCUMENT HISTORY

Date of Change	Description
July 28, 2017	Initial article released.

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