



New Waived Tests

Related CR Release Date: March 7, 2024

MLN Matters Number: MM13546

Effective Date: April 1, 2024

Related Change Request (CR) Number: [CR 13546](#)

Implementation Date: April 1, 2024

Related CR Transmittal Number: R12534CP

Affected Providers

- Hospitals
- Physicians
- Suppliers

Action Needed

Make sure your billing staff knows about:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New CLIA-waived tests approved by the FDA
- Use of modifier QW for CLIA-waived tests

Background

CLIA regulations require a facility to be appropriately certified for each test they do. CMS edits laboratory claims at the CLIA certificate level to make sure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate.

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The HCPCS codes for the following new tests must have the modifier QW to be recognized as a waived test.

The HCPCS codes, effective date, and description for the latest tests the FDA approved as waived tests under CLIA are:

- 0352UQW, October 19, 2023, Cepheid GeneXpert Xpress System {Xpert Xpress MVP} Under Proprietary Laboratory Analyses
- 82274QW, G0328QW, November 13, 2023, Rodimedi & Associates Inc. RedTunica iFOB One Step Rapid Test
- 80305QW, November 16, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET/mAMP) Urine Test Panel
- 80305QW, November 17, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methadone (MTD) Urine Test Panel

- 80305QW, November 30, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methylenedioxyamphetamine (MDMA) Urine Test Panel
- 82274QW, G0328QW, November 30, 2023, Diacarta INC. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test (See analysis tab)
- 82274QW, G0328QW, November 30, 2023, DiaCarta Inc. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 82274QW, G0328QW, December 01, 2023, DiaCarta Inc iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 80305QW, December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW, December 05, 2023, American Screening Corp Discover Fentanyl Rapid Test Cassette
- 80305QW, December 05, 2023, Verify Diagnostics Inc. VeriCheck Drug Test Cup (Urine)
- 80305QW, December 06 ,2023, CLIAWaived Inc. Test Yourself At Home Home Rapid Test Cup (Urine)
- 80305QW, December 06, 2023, CLIAwaived Inc. Rapid Drug Test Device "RDTD" for Fentanyl in Urine
- 80305QW, December 06, 2023, Instant Technologies Inc. iCassette Fentanyl Urine Test Cassette
- 80305QW, December 06, 2023, Healgen Scientific LLC Healgen Drug of Abuse Urine Quick Split Cup
- 80305QW, December 07, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET500/mAMP500) Urine Test Panel
- 80305QW, December 14, 2023, Wondfo USA Co. Ltd SAFElife Cannabinoids (THC) Urine Test
- 87400QW, December 14, 2023, Becton Dickinson and Company BD Veritor Plus Analyzer {BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit} (For use with nasal swabs only)
- 80305QW, December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Panel
- 80305QW, December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Cup
- 80305QW, December 18, 2023, Wondfo USA Co Ltd. SAFElife T-Dip Propoxyphene (PPX) Urine Test Panel
- 80305QW, December 18, 2023, Preferred Med Supply #1 Best Multi-Panel Drug Test Cup
- 80305QW, December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW, December 22, 2023, Guangzhou Decheng Biotechnology Co. Ltd. Docheck Multi-Drug Urine Test Cup
- 80305QW, December 27, 2023, Medical Distribution Group Inc. Identify Diagnostics Fentanyl Urine Cassette

Find FDA approval information about these tests and their use by:

- Using the [FDA search feature](#)
- Referring to the FDA Review Decision Summary documentation about the tests

MACs won't search their files to either take back payment or retroactively pay claims affected by CR 13546. They'll adjust claims you bring to their attention.

More Information

We issued CR 13546 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
March 7, 2024	Initial article released.

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