

# New Waived Tests

Source: NAHC, March 18, 2024

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA (Clinical Laboratory Improvement Amendments of 1988).

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are as follows (most are drug tests):

- 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 Methylenedioxymethamphetamine (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 80
- 305QW 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. Dochek Multi-Drug Urine Test Cup
- 80305QW December 27, 2023, Medical Distribution Group Inc. Identify Diagnostics Fentanyl Urine Cassette

Some home health and hospice agencies perform tests that are considered waived under the CLIA which requires the home health agency or hospice to have a CLIA Certificate of Waiver. Waived tests a home health or hospice agency may perform include, but are not limited to:

- Blood glucose by glucose monitoring devices cleared by the FDA for home use
- Prothrombin time home tests (PT/INR)
- Dipstick or tablet reagent urinalysis
- Flu test
- Drug test

Performing these types of tests, and any included in the [Tests Granted Waived Status Under CLIA](#) table, requires the agency to have a current CLIA certificate of waiver. An agency that obtains a sample and takes it to a laboratory for testing is not required to hold a CLIA certificate of waiver for that particular test, i.e. PT/INR where the agency's personnel obtain a blood sample from the patient and take that sample to a laboratory for testing.