



## New Waived Tests

Related CR Release Date: November 24, 2023    MLN Matters Number: MM13455

Effective Date: January 1, 2024

Related Change Request (CR) Number: [CR 13455](#)

Implementation Date: January 2, 2024

Related CR Transmittal Number: R13281CP

Related CR Title: New Waived Tests

### Affected Providers

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- Hospitals
- Physicians
- Suppliers

### Action Needed

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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

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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 code, effective date, and description for the latest tests approved by the FDA as waived tests under CLIA are:

- 83036QW September 27, 2023, Abbott Diagnostics Technologies AS Afinion 2 analyzer {Afinion HbA1c}
- 83036QW September 27, 2023, Abbott Diagnostics Technologies AS AS100 Analyzer {Afinion HbA1c}
- 87633QW August 10, 2023, Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)
- 80061QW, 82465QW, 82962, 83718QW, 84478QW September 20, 2023, Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)

- 80305QW May 15, 2023, American Screening Corporation Discover Plus Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation G-Card Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation G-Cup Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Onescreen Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Precision DX Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision DX Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Multi-Panel Drug Test Cup
- 85610QW July 27, 2023, ARKRAY USA Assure PT Care Prothrombin Time PT/INR Monitoring System Professional Use
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M2000
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M300
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test
- 87633QW May 5, 2023, Biofire Diagnostics SPOTFIRE Respiratory Panel Mini
- 80305QW August 23, 2023, BTNX Inc. Rapid Response Multi-Drug One Step Cup
- 80305QW July 11, 2023, BTNX Inc. L-Cup Home Rapid Test (Urine)
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Marijuana test kit (THC urine test)
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Cup
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Panel
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Cup (Urine)
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Panel (Urine)
- 80305QW August 24, 2023, Clarity Diagnostics LLC. Clarity Multi-Drug Urine Test Cup (Urine)
- 87633QW June 20, 2023, Cue Health Inc. Cue Health Monitoring System (For use with Anterior Nasal Swabs)
- 80305QW October 2, 2023, Docheck USA Inc. Amazewell Multi-Drug Urine Test Cup
- 80305QW August 2, 2023, Easy Healthcare Corporation Easy@Home Single Drug Screen Test (Cocaine Urine Test)
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit For Cannabis
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Five (5) Drugs
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Twelve (12) Drugs
- 82120QW, 83986QW September 22, 2023, Genabio Diagnostics Inc. GenaCheck Vaginal Health pH Screening Test

- 87420QW June 29, 2023, Healgen Scientific LLC Rapid Check RSV Antigen Test (Nasopharyngeal swabs)
- 80305QW August 24, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Compact Round Cup
- 80305QW August 24, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Round Cup
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN CLICK CUP
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN FLAT CUP
- 80305QW August 3, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card
- 80305QW July 11, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Buprenorphine (BUP))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Methamphetamine (MET))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Methylenedioxymethamphetamine (MDMA))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Morphine (MOP))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Oxycodone (OXY))
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREENING CLICK CUP
- 80305QW May 25, 2023, Medical Distribution Group Bicycle Health CLIA WAIVED DRUG TEST
- 80305QW May 25, 2023, Neopharma Technologies Sdn. NEOTEST Drug Test Dip Card
- 80305QW May 25, 2023, Neopharma Technologies Sdn. NEOTEST Drug Test Multi Panel Cup (Urine)
- 80305QW June 22, 2023, Pregmate LLC ez level DRUG TEST
- 80305QW June 22, 2023, Pregmate LLC ez level MARIJUANA THC DRUG TEST
- 87633QW September 20, 2023, Quidel Sofia 2
- 87633QW July 27, 2023, Roche Molecular cobas Liat System {Cobas SARS-CoV-2 & Influenza A/B}
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Cup
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Dip Card
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine Cassette
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine DipCard
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine Cassette

- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine DipCard
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana Cassette
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana DipCard
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW THC Urine Strip Test
- 85018QW October 2, 2023, Sanguina Inc. AnemoCheck Home
- 80305QW August 14, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi Panel Drug Urine Test Cup
- 80305QW May 31, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Cup
- 80305QW May 31, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Dip Card
- 80305QW August 14, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO THC One Step Marijuana Test Dip Card
- 83036QW September 29, 2023, Siemens Healthcare Diagnostics Inc. DCA Vantage Analyzer {Siemens DCA Systems Hemoglobin A1c Reagent Kit}
- 80305QW August 15, 2023, Smartox SMARTEST Drug of Abuse Urine Test Cup
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Cup
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Cup LC
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card LC
- 87420QW August 21, 2023, VersÃ©a Diagnostics LLC Versea Easy Lab PRO Rapid RSV Test
- 80305QW September 8, 2023, Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Panel 50
- 80305QW September 8, 2023, Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Strip 50
- 80305QW June 23, 2023, VivaChek Diagnostics Inc. BioSieve Multi-Drug Urine Test Cup
- 80305QW June 26, 2023, Walgreen Co. Walgreens Multi Panel Urine Test Cup
- 80305QW June 5, 2023, Wal-Mart Stores Inc. Equate Multi Panel Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife C-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife T-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Multi-Drug Urine Test Panel

The tests on the first page of the list attached to CR 13455 (in other words, HCPCS codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) don't require a QW modifier to be recognized as a waived test.

MACs won't search their files to either take back payment or retroactively pay claims affected by CR 13455. They'll adjust claims you bring to their attention.

## More Information

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We issued CR 13455 to your MAC as the official instruction for this change.

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

## Document History

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Date of Change	Description
November 27, 2023	Initial article released.

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