



New Waived Tests

Related CR Release Date: April 5, 2023

MLN Matters Number: MM13162

Effective Date: July 1, 2023

Related Change Request (CR) Number: [CR 13162](#)

Implementation Date: July 3, 2023

Related CR Transmittal Number: R11943CP

Related CR Title: New Waived Tests

Affected Providers

- Physicians
- Providers
- 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.

Since these tests are marketed immediately after approval, we tell the Medicare Administrative Contractors (MACs) of the new tests so they process claims accurately. There are 6 newly added waived complexity tests. These new tests must have the modifier QW to be recognized as a waived test. The HCPCS code, effective date, and description for these latest tests are:

- 80305QW, September 16, 2022, Healstone Biotech Inc., Healstone Accurate Drug of Abuse Urine Test Cup
- 89321QW, December 20, 2022, Medtox Diagnostics Inc., Labcorp OnDemand Men's Rapid Fertility Test
- 80305QW, January 4, 2023, Virant Diagnostics Inc., U-Now Drug Test Cup

- 80305QW, January 13, 2023, Sakar International Inc., Vivitar Laboratories The Solution Home Rapid Test Kit/Test Dip Card Multi Drug
- 80305QW, January 13, 2023, Sakar International Inc., Vivitar Laboratories The Solution Home Rapid Test Kit/Multi Test Cup
- 86780QW, G0433QW, February 23, 2023, Chembio Diagnostic Systems, Inc., DPP HIV-Syphilis (Fingerstick whole blood)

The tests on the first page of the list attached to CR 13162 — 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 13162. They'll adjust claims you bring to their attention.

More Information

We issued CR 13162 to your MAC as the official instruction for this change.

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

Document History

Date of Change	Description
April 6, 2023	Initial article released.

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