



## New Waived Tests

MLN Matters Number: MM12996

Related Change Request (CR) Number: 12996

Related CR Release Date: November 23, 2022 Effective Date: April 1, 2023

Related CR Transmittal Number: R11717CP Implementation Date: April 3, 2023

Related CR Title: New Waived Tests

### Provider Types Affected

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This MLN Matters Article is for providers billing Medicare Administrative Contractors (MACs) for Clinical Laboratory Improvement Amendments (CLIA) waived laboratory tests they provide to Medicare patients.

### Provider Action Needed

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Make sure your billing staff knows about:

- 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.

Since these tests are marketed immediately after approval, we tell the MACs of the new tests so they process claims accurately. There are 7 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:

- 82010QW, 82962, May 27, 2022, AmVentureX Inc. BioCoach Blood Glucose and Ketone Monitoring System
- 80305QW, June 07, 2022, Micro Distributing STATDIP One Step Drug Test;
- 80305QW, June 07, 2022, Micro Distributing STATCup II One Step Drug Test Cup
- 87880QW, June 09, 2022, Clarity Diagnostics LLC Clarity Strep A Rapid Test Strip
- 87880QW, June 09, 2022, Independent Medical Co-op Inc. IMCO Strep A Rapid Test Strip

- 80305QW, August 31, 2022, Instant Technologies Inc. iSCREEN Urine Test Dx Drug Screen Square Cup
- 80305QW, August 31, 2022, Verséa Holdings Inc. Verséa THC One Step Marijuana Test Strip
- 86386QW, September 06, 2022, Abbott Diagnostics Scarborough Inc. NMP22 BladderChek Test (Prescription Home Use) and (Professional Use)

The tests on the first page of the list attached to [CR 12996](#) (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 12996. They'll adjust claims you bring to their attention.

## Information

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We issued CR 12996 to your MAC as the official instruction for this change.

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

## Document History

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Date of Change	Description
November 23, 2022	Initial article released.

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