



New Waived Tests

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Related Change Request (CR) Number: 12581

Related CR Release Date: January 14, 2022

Effective Date: April 1, 2022

Related CR Transmittal Number: R11188CP

Implementation Date: April 4, 2022

Provider Types Affected

This MLN Matters Article is for physicians, other providers, and suppliers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

In this Article, you'll learn about:

- The latest tests approved by the FDA as waived tests under CLIA
- Laboratory claim edits
- Facility certification requirements

Make sure your billing staff knows about these changes.

Background

CR 12581 informs MACs of new FDA-approved [Clinical Laboratory Improvement Amendments of 1988 \(CLIA\)](#) waived tests. CMS notifies MACs of the new tests so that they can accurately process claims.

CLIA regulations require a facility to be appropriately certified for each test they perform. To make sure Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, we edit laboratory claims at the CLIA certificate level.

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 show as a waived test.

However, the tests mentioned on the first page of the list attached to [CR 12581](#) (for example: 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.

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

September 23, 2021

- 81003QW, Teco Diagnostics Inc. Uritek TC-201 Urine Chemistry Test System

October 7, 2021

- 87880QW, Cardinal Health Strep A Dipstick - Rapid Test

October 20, 2021

- 80048QW, Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Basic Metabolic Panel Reagent Disc} (Whole Blood)
- 80053QW, Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel Reagent Disc} (Whole Blood)
- 80051QW, Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Electrolyte Panel Reagent Disc} (Whole Blood)
- 82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW and 84520QW, Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)
- 80069QW, Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)
- 80048QW, Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Basic Metabolic Panel Reagent Disc} (Whole Blood)
- 80053QW, Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel Reagent Disc} (Whole Blood)
- 80051QW, Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Electrolyte Panel Reagent Disc} (Whole Blood)
- 82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW and 84520QW, Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)
- 80069QW, Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)

November 10, 2021

- 87880QW, Cardinal Health H. Pylori Rapid Test - Whole Blood/Serum Cassette (Whole Blood).

MACs won't search their files to either retract payment or retroactively pay previously processed claims. They will adjust such claims that you bring to their attention.

More Information

We issued [CR 12581](#) to your MAC as the official instruction for this change.

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

Document History

Date of Change	Description
January 18, 2022	Initial article released.

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