



New Waived Tests

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Related Change Request (CR) Number: 11982

Related CR Release Date: October 2, 2020

Effective Date: January 1, 2021

Related CR Transmittal Number: R10381CP

Implementation Date: January 4, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article tells you of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify the MACs of the new tests so that they can accurately process claims. There are five newly added waived complexity tests listed in the table below.

BACKGROUND

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR 11982 (for example, CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test. (See the Official Instruction for CR11982 in the *Additional Information* section for the 26 page list of *Tests Granted Waived Status Under CLIA*)

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

CPT Code	Effective Date	Description
86308QW	March 5, 2020	Henry Schein One Step + Ultra MonoTest Kit (Whole Blood)

CPT Code	Effective Date	Description
87804QW	April 21, 2020	Henry Schein One Step + Ultra Flu Test Kit (Sekisui Diagnostics)
87804QW	July 15, 2020	Fisher Healthcare, Sure-View Signature Influenza A & B Test
80305QW	July 22, 2020	Medline Industries, Inc. Medline Drug Test Cup
80305QW	August 18, 2020	Micro Distributing II, Ltd., STATTEST Wondfo Home Drug Test

Note: MACs will not search their files to either retract payment or retroactively pay claims, however, MACs should adjust claims if you bring those claims to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 11982, issued to your MAC regarding this change, is available at <https://www.cms.gov/files/document/r10381CP.pdf>. The 26 page list of Tests Granted Waived Status Under CLIA is attached to this CR.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
October 5, 2020	Initial article released.

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