

New Waived Tests

Related CR Release Date: November 14, 2025	MLN Matters Number: MM14273
Effective Date: January 1, 2026	Related Change Request (CR) Number: <u>CR 14273</u>
Implementation Date: January 5, 2026	Related CR Transmittal Number: R13465CP

Affected Providers

- Hospitals
- Physicians
- Suppliers

Action Needed

Make sure your billing staff knows about these updates effective January 1, 2026:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- 2 new FDA-approved waived tests: codes, effective dates, and descriptions

Background

Facilities must have appropriate certification to perform tests per CLIA regulations. We edit laboratory claims at the CLIA certificate level to ensure Medicare only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver.

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MLN Matters: MM14273 Related CR 14273

Key Updates

FDA has approved 2 new waived tests under CLIA. Include the QW modifier to make sure we recognize these CPT codes as waived tests.

See the table below for the codes, effective dates, and descriptions.

Code	Effective Date	Description
87494QW	January 1, 2026	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique
87812QW	January 1, 2026	Infectious agent antigen detection by Immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza types A and B

Learn more about these tests and their use by:

- Using the FDA search feature
- Referring to the FDA Review Decision Summary documentation about these tests

Note: Medicare Administrative Contractors (MACs) won't search their files to either retract payment or retroactively pay claims. However, MACs will adjust claims if you bring them to their attention.

More Information

We issued CR 14273 to your MAC as the official instruction for this change. For more information, find your MAC's website.

Document History

Date of Change	Description
November 14, 2025	Initial article released.

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