



## New Waived Tests

Related CR Release Date: November 1, 2024	MLN Matters Number: MM13858
Effective Date: January 1, 2025	Related Change Request (CR) Number: CR 13858
Implementation Date: January 6, 2025	Related CR Transmittal Number: <a href="#">R129335CP</a>

Related CR Title: New Waived Tests

### Affected Providers

- Hospitals
- Physicians
- Suppliers

### Action Needed

Make sure your billing staff knows about these updates:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- The new waived test approved by the FDA
- The HCPCS code, effective date, and description for latest waived test

### Background

CLIA regulations require facilities to be appropriately certified for tests they do. We edit laboratory claims at the CLIA certificate level to ensure Medicare & Medicaid only pay for laboratory tests categorized as waived under CLIA in facilities with a CLIA certificate of waiver.

The FDA has approved 1 new waived test under CLIA. HCPCS code 81515 must have the QW modifier for us to recognize it as a waived test.

The HCPCS code, effective date, and description for this waived test are below:

Code	Effective Date	Test/Manufacturer
81515QW System {XPert Xpress MVP}	January 1, 2025	Cepheid GeneXpert Xpress

For more information on this test and its use:

- Use the [FDA search feature](#)
- Refer to the FDA Review Decision Summary documentation about this test

**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

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We issued [CR 13858](#) 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 6, 2024	Initial article released.

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