

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11082	Date: October 28, 2021
	Change Request 12504

SUBJECT: New Waived Tests

I. SUMMARY OF CHANGES: This Change Request (CR) will inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its contractors of the new tests so that the contractors can accurately process claims. There are 3 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the Internet Only Manual (IOM).

EFFECTIVE DATE: January 1, 2022

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 3, 2022

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Medicare Carriers Manual Section 5220 Overpayments

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