



New Waived Tests

MLN Matters Number: MM12204

Related Change Request (CR) Number: 12204

Related CR Release Date: April 27, 2021

Effective Date: July 1, 2021

Related CR Transmittal Number: R10721CP

Implementation Date: July 6, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services they provide to Medicare patients

PROVIDER ACTION NEEDED

This article tells you of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests the FDA has approved. Since these tests are marketed upon approval, CMS must tell the MACs of the new tests so that they can accurately process claims. Make sure your billing staffs are aware of these tests.

BACKGROUND

The CLIA regulations require a facility to be appropriately certified for each test it performs. 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.

The CPT codes for the new tests we list below 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 12204 (for example, CPT 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 CPT code, effective date, and description for the latest tests FDA-approved waived tests under CLIA are:

- 80305QW, August 25, 2020, Verify Diagnostics Inc. VeriCheck Drug Test Cup
- 80305QW, August 25, 2020, Verify Diagnostics Inc. VeriCheck Drug Test Dip
- 80305QW, September 23, 2020, Axiom BioResearchInc.DrugExam Multi Drug Screen Test
- 80305QW, October 9, 2020, American Screening LLC Discover Panel Dip Card Tests MOR 300

- 80305QW, October 9, 2020, American Screening LLC Discover Quick Cup Tests MOR 300
- 80305QW, October 9, 2020, American Screening LLC Discover Quick Cup Tests MOR 2000
- 80305QW, October 9, 2020, American Screening LLC Discover Plus Panel Dip Card Tests MOR 300
- 80305QW, October 9, 2020, American Screening LLC Discover Plus Panel Dip Card Tests MOR 2000
- 80305QW, October 9, 2020, American Screening LLC Discover Plus Quick Cup Tests MOR 300
- 80305QW, October 9, 2020, American Screening LLC Discover Plus Quick Cup Tests MOR 2000
- 80305QW, October 9, 2020, American Screening LLC OneScreen Plus Quick Cup Tests MOR300
- 80305QW, October 9, 2020, American Screening LLC OneScreen Plus Quick Cup Tests MOR2000
- 80305QW, October 9, 2020, American Screening LLC Reveal Panel Dip Card Tests MOR2000
- 80305QW, October 9, 2020, American Screening LLC Reveal Quick Cup Tests MOR300
- 80305QW, October 9, 2020, American Screening LLC Reveal Quick Cup Tests MOR2000

Also, CR 12204 gives the following HSPCS code description changes, effective October 6, 2020:

- HCPCS code 87400 description changed to “Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Influenza, A or B, each”. HCPCS code 87400QW describes the waived testing performed by the Quidel Sofia 2 (Sofia Influenza A+B FIA) and the BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}.
- HCPCS code 87420 description changed to “Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; respiratory syncytial virus”. HCPCS code 87420QW describes the waived testing performed by the Quidel Sofia 2 (Sofia RSV FIA) and by the BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens) {Includes a reader}.
- HCPCS code 87430 changed to “Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Streptococcus, group A”. HCPCS code 87430QW describes the waived

testing performed by the Quidel Sofia 2 {Sofia Strep A+ FIA} (from throat swab only) and the BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab).

ADDITIONAL INFORMATION

Note: MACs won't search their files to adjust payment for impacted claims they processed before implementing CR 12204. However, they will adjust such claims that you bring to their attention.

We issued [CR 12204](#) to your MAC as the official instruction for this change.

For more information, contact your [MAC](#).

DOCUMENT HISTORY

Date of Change	Description
April 27, 2021	Initial article released.

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