

## IMPORTANT NEW COVID LAB INFORMATION

### NO WRITTEN LAB ORDER NEEDED FOR SOME TESTS

COVID-19: Modified Ordering Requirements for Laboratory Billing

Interim Rule:

During the COVID-19 Public Health Emergency, CMS is relaxing billing requirements for laboratory tests (PDF) required for a COVID-19 diagnosis. Any health care professional authorized under state law may order tests. **Medicare will pay for tests without a written order from the treating physician or other practitioner:**

***If an order is not written, an ordering or referring National Provider Identifier (NPI) is not required on the claim***

***If an order is written, include the NPI of the ordering or referring professional, consistent with current billing guidelines***

***The Interim Final Rule can be found here.***

***<https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-09608.pdf>***

***In part, it states this:***

***Given the critical importance of expanding COVID-19 testing to combat the pandemic and the heightened risk that the disease presents to Medicare beneficiaries, we are amending our regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law. Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, we are also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which we are removing the ordering requirements publicly available.***

A List of the test which do NOT required a written order can be found here:

***<https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>***

Use the link above to view all tests and all codes. Examples of test on the list include:

**COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE**

*Updated April 30, 2020*

CPT/HCPCS Code	Laboratory Code Long Descriptor	Code Category
<b>COVID-19 Related Codes</b>		
U0001	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	COVID-19
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC)	COVID-19
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), 2 amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	COVID-19
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	COVID-19
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	COVID-19
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	COVID-19
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	COVID-19
<b>Influenza/RSV Related Codes</b>		
87275	Infectious agent antigen detection by immunofluorescent technique; influenza B virus	Influenza/RSV
87276	Infectious agent antigen detection by immunofluorescent technique; influenza A virus	Influenza/RSV
87279	Infectious agent antigen detection by immunofluorescent technique; Parainfluenza virus, each type	Influenza/RSV

**CLIA WAIVED Point of Care Testing for COVID and QW Modifier**

MLN 11765 : <https://www.cms.gov/files/document/mm11765.pdf>

*This article informs you about the addition of the QW modifier to HCPCS code U0002 (2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC) and 87635 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique]. Medicare will permit the use of codes U0002QW and 87635QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020. Make sure your billing staffs are aware of these changes.*

Three Test Kits Appear on the Waived List:

"W" denotes that the kit is approved for clinics with Waived Certificates. All approved kits and equipment including those only approved for H-complex labs and M-moderately complex labs can be found at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

#### Test Kit Manufacturers and Commercial Laboratories Table:

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Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s) <sup>1</sup>	Authorization Documents <sup>2</sup>	Other Documents/
03/20/2020	Cepheid	Xpert Xpress SARS-CoV-2 test	Molecular	H, M, W	HCP, Patients, IFU for Labs, IFU for Point-of-Care	Letter Granting EUA Amendment(s) (April 28, 2020)
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Molecular	H, M, W	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 21, 2020)
03/23/2020	Mesa Biotech Inc.	Accula SARS-CoV-2 Test	Molecular	H, M, W	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 30, 2020)