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SPECIAL EDITION: August Update

Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Laboratory Testing

There is precedence for the American Medical Association (AMA) Current Procedural Terminology (CPT[®]) Editorial Panel immediately releasing CPT codes when an emergent issue arises. Due to the coronavirus disease (COVID-19) pandemic, this mechanism was used in the spring of 2020 to approve,

revise, and release several CPT Category I codes. In addition, new proprietary laboratory analyses (PLA) codes were approved in May 2020 and June 2020. The following table outlines the changes that were published on the AMA's website, and effective immediately following final approval by the CPT Editorial Panel.

COVID-19-Related CPT Category I Code Approvals through June 2020		
Code	Long Code Descriptor	Effective Date
●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	March 13, 2020
▲86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single-step method (eg, reagent strip);	April 10, 2020
#●86328	severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) ▶(For severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease {COVID-19}] antibody testing using multiple-step method, use 86769)◀	April 10, 2020

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COVID-19-Related CPT Category I Code Approvals through June 2020		
Code	Long Code Descriptor	Effective Date
	<p>►The following codes (86602-86804) are qualitative or semiquantitative immunoassays performed by multiple-step methods for the detection of antibodies to infectious agents. For immunoassays by single-step method (eg, reagent strips), see codes 86318, 86328. Procedures for the identification of antibodies should be coded as precisely as possible. For example, an antibody to a virus could be coded with increasing specificity for virus, family, genus, species, or type. In some cases, further precision may be added to codes by specifying the class of immunoglobulin being detected. When multiple tests are done to detect antibodies to organisms classified more precisely than the specificity allowed by available codes, it is appropriate to code each as a separate service. For example, a test for antibody to an enterovirus is coded as 86658. Coxsackie viruses are enteroviruses, but there are no codes for the individual species of enterovirus. If assays are performed for antibodies to coxsackie A and B species, each assay should be separately coded. Similarly, if multiple assays are performed for antibodies of different immunoglobulin classes, each assay should be coded separately. When a coding option exists for reporting IgM specific antibodies (eg, 86632), the corresponding nonspecific code (eg, 86631) may be reported for performance of either an antibody analysis not specific for a particular immunoglobulin class or for an IgG analysis.◀</p> <p>►(For the detection of antibodies other than those to infectious agents, see specific antibody [eg, 86021-86023, 86376, 86800, 86850-86870] or specific method [eg, 83516, 86255, 86256]).◀</p> <p>►(For infectious agent/antigen detection, see 87260-87899)◀</p>	<p>Revised Guidelines Effective Date April 10, 2020</p>
86635	<p>Antibody; Coccidioides</p> <p>►(For severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease {COVID-19}] antibody testing, see 86328, 86769)◀</p>	<p>Parenthetical Note Effective Date April 10, 2020</p>
●86769	<p>Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</p> <p>►(For severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease {COVID-19}] antibody testing using single-step method, use 86328)◀</p>	April 10, 2020
<p>*Note: Code 87426 below is a child code under parent code 87301. It is presented here in its entirety, ie, the long descriptor, which includes the language from its parent code 87301.</p>		
●87426	<p>Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])</p>	June 25, 2020

continued

COVID-19-Related CPT PLA Code Approvals through June 2020			
Proprietary Name and Clinical Laboratory or Manufacturer	Code	Long Code Descriptor	Effective Date
BioFire® Respiratory Panel 2.1 (RP2.1), BioFire® Diagnostics, BioFire® Diagnostics, LLC	✕●0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected ▶(For additional PLA code with identical clinical descriptor, see 0223U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)◀	May 20, 2020
QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH	✕●0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected ▶(For additional PLA code with identical clinical descriptor, see 0202U. See Appendix O or the most current listing on the AMA CPT website to determine appropriate code assignment)◀	June 25, 2020
COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory	●0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed ▶(Do not report 0224U in conjunction with 86769)◀	June 25, 2020

As science moves from determining who is currently infected to who has had the infection (antibody testing), the next step during the COVID-19 pandemic is to determine who has mounted neutralizing antibodies against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus.

The CPT Editorial Panel convened a special meeting to approve additional codes specific to laboratory testing for COVID-19. To address the ongoing clinical need to report testing, the CPT Editorial Panel expedited the publication to the AMA website and approved two new Category I codes and two new PLA codes on Monday, August 10, 2020, at <https://www.ama-assn.org/delivering-care/public-health/covid-19-2019-novel-coronavirus-resource-center-physicians>. These codes are **effective immediately** for use in reporting these laboratory tests.

Immunology

#●86408 Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen

#●86409 titer

Code 86408 was established for reporting SARS-CoV-2 neutralizing antibody screen and code 86409 for reporting SARS-CoV-2 neutralizing antibody titer. Currently, no existing CPT codes are specifically for tests that measure a patient's SARS-CoV-2 neutralizing antibodies. There also are not codes related to utilizing a cellular reporter system to measure live virus infection of cells in culture.

A cellular response to infection is measured through the use of a cellular reporter system as a measure of infection. These tests determine if antibodies present in a patient specimen can directly block infection of cells expressing the viral entry receptor on their surface.

Proprietary Laboratory Analyses

- **0225U** Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
- **0226U** Surrogate viral neutralization test (sVNT), severe acute respiratory

syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum

New code 0225U describes infectious agent detection by nucleic acid (DNA and RNA) by amplified probe technique through polymerase chain reaction and electrochemical detection that generates a result of detected or not detected for each of the analytes. Code 0226U describes a high-throughput quantitative blocking ELISA assay to assess the patient's viral neutralization capacity to SARS-CoV-2.

In addition to listing codes 0225U and 0226U in the Pathology and Laboratory section, these new PLA codes will also be included with the procedure's proprietary name in Appendix O in the CPT code set.

To report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the proprietary name listed in Appendix O. Codes 0225U and 0226U will be listed in Appendix O as follows:

Proprietary Name and Clinical Laboratory or Manufacturer	Alpha-Numeric Code	Code Descriptor
►ePlex® Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc◄	● 0225U	►Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected◄
►Tru-Immune™, Ethos Laboratories, GenScript® USA Inc◄	● 0226U	►Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum◄

The following clinical examples and procedural descriptions reflect typical clinical scenarios when it would be appropriate to report these new codes.

Due to the early utilization stage for these tests, clinical indications are subject to further refinement as knowledge of the novel coronavirus evolves. The CPT Editorial Panel will continue to review and may clarify these indications as more information becomes available.

Clinical Example (86408)

A 56-year-old female was discharged from the hospital after a lengthy stay with severe COVID-19, which was confirmed with molecular testing for

SARS-CoV-2. Two weeks after her recovery, she presents at a blood donation center for testing to determine eligibility for convalescent plasma donation.

Description of Procedure (86408)

Combine the patient's serum, diluent, and pseudovirus expressing the SARS-CoV-2 spike protein with cultured cells in a multi-well plate. Following incubation period, add substrate, which will luminesce in the presence of viral infection. Measure the signal on a multi-well plate reader. Compare the specimen measurements to the control specimen to generate a qualitative result.

Clinical Example (86409)

A 56-year-old female was discharged from the hospital after a lengthy stay with severe COVID-19, which was confirmed with molecular testing for SARS-CoV-2. Two weeks after her recovery, she presents at a blood donation center for testing to determine eligibility for convalescent plasma donation.

Description of Procedure (86409)

Incubate serial dilutions of patient's sera with target cells and pseudovirion expressing the SARS-CoV-2 spike protein. Measure antibody-neutralizing activity using quantitative or semi-quantitative assessment of the changes in the signal activity. Compare the results to the control specimen and interpret and report the results.

Clinical Example (0225U)

A 77-year-old female with hypertension and diabetes presents with worsening fevers, cough, and respiratory distress. A respiratory pathogen panel is ordered to determine possible infectious causes for her findings.

Description of Procedure (0225U)

Load a sample of a nasopharyngeal swab specimen into the ePlex RP2 Panel cartridge and insert into the instrument. Provide a result of detected or not detected for each of 22 pathogens.

Clinical Example (0226U)

A 45-year-old male presents to his physician with flu-like symptoms a few months ago. He did not get a

PCR viral test for SARS-CoV-2 but thinks he had it. He is concerned with future exposure to COVID-19 and wants to know if he has immunity. Plasma is submitted to assess the patient's viral neutralization capacity to SARS-CoV-2.

Description of Procedure (0226U)

Subject plasma to a multistep-blocking ELISA assay. The laboratory professional reads the absorbance, interprets the findings, and sends a report specifying the patient's inhibition capacity to SARS-CoV-2 to the ordering physician.

See the following question and answer regarding the differences between the test represented in codes 86408 and 86409 and code 86328.

Question and Answer

Question: *What is the difference between codes 86408 and 86409 and code 86328, which was approved on April 10, 2020?*

Answer: Code 86328 describes immunoassay for infectious agent antibody(ies). Code 86408 was established for reporting the SARS-CoV-2 neutralizing antibody *screen* and code 86409 SARS-CoV-2 neutralizing antibody *titer*. These tests are used to determine if antibodies present in a patient specimen can directly block infection of cells. An antibody screen produces a present or absent result. Code 86328 describes only the presence of antibodies. In contrast, codes 86408 and 86409 are used to report tests that determine if the antibodies present can block the COVID-19 virus infection.

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The *CPT*[®] *Assistant* Special Edition information is designed to provide accurate, up-to-date coding information. We continue to make every reasonable effort to ensure the accuracy of the material presented. However, this publication does not replace the CPT codebook; it serves only as a guide.

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