

MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

Visit ARUP's [COVID-19 Testing page](#) for more information about these tests and ARUP's response to COVID-19.

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
2	3002638	2019 Novel Coronavirus SARS-CoV-2 by PCR											x	
2	3002776	COVID-19 IgG, Qualitative by CIA											x	

HOTLINE: Effective April 2020

New Test
Available Now

3002638

2019 Novel Coronavirus SARS-CoV-2 by PCR

COVID19PCR



Patient Demographics Form for Public Health Reporting



Specimen Collection and Handling

Methodology: Qualitative Polymerase Chain Reaction
Performed: Daily
Reported: 1-4 days

Specimen Required: Collect: Nasopharyngeal swab.

Also acceptable: Nasopharyngeal swab AND Oropharyngeal swab. **Place both swabs in one collection tube.**

Refer to the "COVID-19 Specimen Collection Guide" at <https://www.aruplab.com/infectious-disease/coronavirus/testing>

Specimen Preparation: Place in viral transport media or saline (minimum volume 1mL). Place each specimen in an individually sealed bag.

Also acceptable: Media that is equivalent to viral transport media or universal transport media.

Storage/Transport Temperature: Frozen

Remarks: Specimen source required. **Submit only one collection tube per patient.**

Unacceptable Conditions: Wood swabs, calcium alginate swabs.

Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 1 month

Interpretive Data: This test should be ordered for the detection of the 2019 novel coronavirus SARS-CoV-2 in individuals who meet SARS-CoV-2 clinical and/or epidemiological criteria.

The 2019 Novel Coronavirus SARS-CoV-2 by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA) for US laboratories certified under CLIA to perform high complexity tests. This test has not been FDA cleared or approved. In compliance with this authorization, please visit <https://www.aruplab.com/infectious-disease/coronavirus> for more information and to access the applicable information sheets.

CPT Code(s): U0003; (Alt code: 87635)

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.

New Test
Available Now

3002776

COVID-19 IgG, Qualitative by CIA

COV19QUALG

Methodology: Qualitative Chemiluminescent Immunoassay
Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Collect: Serum separator tube (SST) or EDTA plasma.

Specimen Preparation: Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 0.5mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.25 mL)

Storage/Transport Temperature: Refrigerated.

Remarks: Required: ARUP Standard Transport Tube for specimen submission (ARUP Item# 15824). Do not submit sample in original collection tube.

Unacceptable Conditions: Grossly hemolyzed, grossly icteric, or severely lipemic specimens.

Stability (collection to initiation of testing): Refrigerated: 1 week; Frozen: 1 month

Reference Interval: Negative

Interpretive Data: This test was developed and its performance characteristics determined by ARUP Laboratories. Testing was conducted in a CLIA certified laboratory. It has not been reviewed by the FDA. This test should not be used for screening of donated blood.

CPT Code(s): 86769

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.