ARUP LABORATORIES

HOTLINE: COVID-19 Test Offerings

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	3002723	COVID-19 IgG by ELISA											x	
2	3002776	COVID-19 IgG, Qualitative by CIA											x	
3	3002638	SARS-CoV-2 (COVID-19) by NAA				x		x						

3002723 COVID-19 IgG by ELISA COVID19IGG

Methodology: Enzyme-Linked Immunosorbent Assay
Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Collect: Serum separator tube (SST).
Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.1 mL)
Storage/Transport Temperature: Refrigerated.
Remarks: Required: Submit specimen in ARUP Standard Transport Tube (ARUP Item # 15824) only.
Do not submit sample in original SST collection tube.
Unacceptable Conditions: Grossly hemolyzed, grossly icteric, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: Negative

0.7 Index or less	Negative
0.8-1.0 Index	Indeterminate
1.1 Index or greater	Positive

Interpretive Data: This test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). In compliance with this authorization, please visit https://www.aruplab.com/infectious-disease/coronavirus/testing for more information and to access the applicable fact sheets. 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.

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.

3002638 **SARS-CoV-2 (COVID-19) by NAA** **COVID19NAA**

Changes Effective 9/9/2020

Patient Demographics Form for Public Health Reporting

Specimen Collection and Handling

Additional Technical Information

Methodology: Qualitative Nucleic Acid Amplification
Performed: Daily
Reported: 1-4 days

Specimen Required: Collect: Nasopharyngeal swab. Also acceptable: Oropharyngeal swab, nasal swab. Saliva.
Refer to the "COVID-19 Specimen Collection Guide" at https://www.aruplab.com/infectious-disease/coronavirus/testing
Specimen Preparation: **Nasopharyngeal swab:** Place in viral transport media (ARUP supply #12884) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787, Liquid Amies, or saline (minimum volume 1.2mL). Place each specimen in an individually sealed bag.
Oropharyngeal or nasal swab: Place in viral transport media (ARUP supply #12884) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787, Liquid Amies, or saline (minimum volume 1.2mL). Or collect using the Aptima Multitest Swab Collection Kit. Place each specimen in an individually sealed bag.
Saliva: Transport in COVID-19 ARUP Transport Media (ATM) Saliva Collection Tube (ARUP supply #56257) available online through eSupply using ARUP Connect or contact ARUP Client Services at (800) 522-2787.
Storage/Transport Temperature: Frozen
Remarks: Specimen source required. If submitting media that is not listed in the "COVID-19 Specimen Collection Guide," send the package insert or ingredient list to COVID-19Requests@aruplab.com so it can be reviewed for compatibility with ARUP testing platforms.
Unacceptable Conditions: Undiluted saliva. Saliva submitted in anything other than the ARUP Saliva Collection Tube. Swabs not in media. Wood swabs, calcium alginate swabs. Media with guanidine-containing materials, 'molecular media' that indicates inactivation of pathogens and preservation of RNA/DNA, charcoal media. Specimens sent in tubes with pop-top lids/caps. Specimens in glass tubes.
Stability (collection to initiation of testing): **Swabs:** Ambient: Unacceptable; Refrigerated: 2 days; Frozen: 1 month
Saliva: Ambient: 5 days; Refrigerated: 5 days; Frozen: 5 days

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 Coronavirus SARS-CoV-2 (COVID-19) by nucleic acid amplification 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.

Not Detected results do not rule out the presence of PCR inhibitors in the patient specimen or assay-specific nucleic acid in concentrations below the level of detection by the assay.

Detected results are indicative of the presence of SARS-CoV-2 RNA. Due to the complexity of nucleic acid amplification methodologies, there may be a risk of false-positive results. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Reliable results are dependent on adequate specimen collection, transport, storage, and handling.

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

New York DOH Approved.

HOTLINE NOTE 9/9/2020: Changes to specimen requirements, interpretive data.	Saliva introduced as acceptable specimen; clarifications in interpretation.
HOTLINE NOTE 6/17/2020: There is an increase in the minimum transport volume.	Increase minimum transport volume to 1.2 mL.
HOTLINE NOTE 5/18/2020: There is a clinically significant charting name change.	Change the charting name for component 3002640, to SARS-CoV-2 by NAA.