

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:

- 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.
- 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.
- The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
- Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
- Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
- 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# | TestNumber | 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 | <u>3002638</u> | SARS-CoV-2 (COVID-19) by NAA | X | X | | X | | X | | | | X | | |



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New Test 3002723 COVID-19 IgG by ELISA COVID19IGG

Available Now

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.

New Test 3002776 COVID-19 IgG, Qualitative by CIA COV19QUALG

Available Now

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.

<u>Unacceptable Conditions:</u> 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.



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

COVID19NAA

Changes Effective 6/17/2020



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 or Nasal swab.

Refer to https://ltd.aruplab.com/api/ltd/pdf/479?_ga=2.1847542.611705577.1589487387-1588029776.1584652665

Specimen Preparation: Nasopharyngeal swab: Place in viral transport media, Liquid Amies, or saline (minimum volume 1.2 mL).

Place each specimen in an individually sealed bag.

Oropharyngeal or nasal swab: Place in viral transport media, Liquid Amies, or saline (minimum volume 1.2 mL). Or collect using

the Aptima Multitest Swab Collection Kit. Place each specimen in an individually sealed bag. Also acceptable: Media that is equivalent to viral transport media or universal transport media.

<u>Storage/Transport Temperature:</u> Frozen Remarks: Specimen source required.

<u>Unacceptable Conditions:</u> 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 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.

If the result is Not Detected, this does 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.

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

New York DOH Approved.

| HOTLINE NOTE 6/17/2020: There is an increase in the minimum transport volume. | Increase minimum transport volume to 1.2 mL. |
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| 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. |