

Q: Will LabCorp Patient Service Centers collect specimens?

A: • Beginning Monday, April 27, 2020, physicians will be able to direct asymptomatic patients for IgG antibody specimen collection to LabCorp's network of Patient Service Centers, including more than 100 LabCorp at Walgreens locations. Specimen collection for all other COVID-19 testing including IgA and IgM antibodies, and the novel coronavirus (COVID-19) NAA tests, are not being offered for collection at LabCorp's Patient Service Center locations. All COVID-19 serology test options offered by LabCorp can be drawn by phlebotomists that are located in physician offices and healthcare facilities.

• Serology testing is not intended as a diagnostic test for patients who are exhibiting symptoms consistent with COVID-19. Serology testing should be used only for patients who were diagnosed with COVID-19 or had symptoms consistent with COVID-19, and have been confirmed by a physician to have recovered. It may also be used in instances when an individual thinks they might have had COVID-19 in the past and needs confirmation. In either case, the serology tests are only for people who are no longer symptomatic.

Test Availability

- LabCorp is now performing three qualitative COVID-19 serology tests: SARS-CoV-2 Antibody, IgG; SARS-CoV-2 Antibody, IgA; SARS-CoV-2 Antibody, IgM.
- **The SARS-CoV-2 Antibody, IgG** test is broadly available for client ordering as of Monday, April 27, 2020.
- **The SARS-CoV-2 Antibody, IgA and SARS-CoV-2 Antibody, IgM** tests are not currently available for offering outside of the hospital and health systems network.
- LabCorp is preparing to make the tests more broadly available over the coming weeks for ordering by hospitals and health systems, organizations, and physicians.

Test Overview

- **Serology testing is not intended as a primary diagnostic test for COVID-19.** The RT-PCR diagnostic test for COVID-19 detects the **SARS-CoV-2** virus [test # 139900], and is available for ordering by physicians and healthcare providers across the U.S.

- The serology testing provides evidence that a patient has likely been exposed to the SARS-CoV-2 virus.
- These three serologic assays, IgG, IgA and IgM, are qualitative and are reported as positive, negative or equivocal. These tests do not provide an antibody titer (i.e., quantitative assessment of the amount of antibodies present).
- SARS-CoV-2 Antibody IgG, IgA and IgM are not offered as a panel or profile.
- Serology testing should not be used as the sole basis for a diagnosis nor assurance of immunity.

Use Case Overview

- The antibody response to SARS-CoV-2 is not typical as there does not appear to be an early IgM response. Early published literature suggests that an antibody response may be detected in about 30% at 4 days after onset of symptoms, 75% by 8-10 days.
- The most likely use of this test is to investigate whether the person has been exposed to the virus in the past and has developed antibodies.
- Clinical understanding of the utility of SARS-CoV-2 serology testing is evolving rapidly. At this time, the potential clinical utility of the assay(s) include:
 - Investigating who has been in contact with the virus,
 - Exposure studies for a population,
 - Helping assess if an individual with recent symptoms suggesting COVID-19, but who did not undergo molecular diagnostic testing for SARS-CoV-2 or who was tested but whose results were negative, likely had COVID-19, and
 - Helping assess those who suffer COVID-19 symptoms, yet test negative for SARS-CoV-2 NAA and negative for other respiratory pathogens.

Q: What is the FDA authorization/approval status of the serological tests?

A: • These assays were released for diagnostic use under the Food and Drug Administration (FDA) guidance "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers and Food and Drug Administration Staff" originally issued on February 29, 2020, and updated on March 16, 2020, with additional guidance on serological tests.

- The FDA guidance describes a policy regarding the use of serologic testing without an emergency use authorization (EUA). The following information is provided pursuant to that guidance:
 - These tests have not been reviewed by the FDA.
 - Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
 - Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
 - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- These tests have not been reviewed by the FDA, but are being offered by the company in accordance with the public health emergency guidance issued by the FDA on March 16.

Q: What does a positive/negative result mean?

A:

- A positive serologic result indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus.
- A negative serologic result suggests that an individual has not developed detectable antibodies at the time of testing.
- While contingent on a variety of factors, a negative result could be due to testing too early in the course of infection, the absence of exposure to the virus, or the lack of an adequate immune response, which can be due to conditions or treatments that suppress immune function.
- Confirmation of infection with SARS-CoV-2 must be made through a combination of clinical evaluation and other applicable tests.

- Decisions about ongoing monitoring, treatment or return to normal activities for patients being treated for suspected infection with SARS-CoV-2 should also be made in accordance with guidance from public health authorities.

Q: What is LabCorp doing for the patient?

A:

- Online patient appointment scheduling
- Dedicated PSC hours for vulnerable patients
- “Wait Where You’re Comfortable” Program
- Online/mobile patient portal for results
- Increased frequency of deep cleaning and sanitization at our locations
- No COVID-19 specimens for molecular testing are collected at patient service centers

Q: What is the price and CPT for the SARS-CoV-2 antibody tests?

A:

- The AMA CPT Editorial Panel approved a specific CPT code for antibody testing effective April 10, 2020.
 - 86769 Antibody: severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(Coronavirus disease COVID-19)
- Reimbursement and pricing for the tests are not yet determined.
- However, for clients who are authorized, the tests can be ordered pending determination of the reimbursement and pricing.
- Patients will be not required to make any up-front out-of-pocket payment for the antibody testing.

Q: What is the sample type and expected turnaround time for serology testing?

A: See the table below:

	IgG	IgM	IgA
Test Number	164055	164034	164072
Test Name	SARS-CoV-2 Antibody, IgG	SARS-CoV-2 Antibody, IgM	SARS-CoV-2 Antibody, IgA
Specimen Requirements	Serum from venous blood draw in serum gel tube or a red top tube. Sample volume is 0.5 mL (min 0.4 mL) for each assay. Ship at room temperature.		
Expected Turnaround Time	1-3 days from the time the specimen is picked up, assuming adequate testing supplies		