

RESOURCE GUIDE

COVID-19 Antibody Testing in a Pandemic

California State University San Marcos

Masters In Public Health Program Summer Internship Program 2020

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'There is no human endeavor that is outside the realm of public health'

-William Foege, MD, MPH, Director Centers for Disease Control and Prevention 1977-1983



This project was created and directed by Dr. Deborah Morton as an internship opportunity for graduate students in the Masters of Public Health (MPH) program at California State University-San Marcos. What we have developed is an objective resource guide containing detailed information about the status, logistics, and significance of COVID-19 antibody testing, which is up to date as of the time of publishing. Each team member has received an antibody test at various locations in order to present our first-hand experiences about the process, including accuracy and disclosure by test providers.



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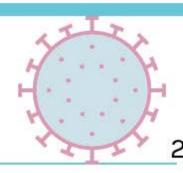
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DEFINITION

- Antibody testing (serologic testing) is a way to test if an individual has developed antibodies for a certain virus (in this case SARS-CoV-2) during the later stages of recovery or post-recovery.
- Unlike molecular tests (used to diagnose active infection) which require saliva or mucus swab, antibody testing requires a blood withdrawal for the lab sample.
- It is not known for certain to what extent one has immunity or if one has immunity at all from testing positive for antibodies, because research is still being conducted about the nature of SARS-CoV-2 antibodies and how long they will remain in one's system.
- The potential for herd immunity and convalescent plasma therapy are two hopeful outcomes of antibody testing research. Furthermore, positive results from antibody testing can contribute to government data accuracy including adjusted mortality and recovery rates.
- Due to the severity of the COVID-19 pandemic, the FDA has authorized some manufacturers to distribute antibody tests for clinical use under the Emergency Use Authorization

(EUA). However, it is important to note that FDA authorization is not equivalent to FDA approval and is only valid for the duration of the EUA.

What is Antibody Testing?



EMERGENCY USE AUTHORIZATION (EUA)

FDA approval can take years for in vitro diagnostic or IVD processes like PCR or antibody tests. The <u>Emergency Use Authorization</u> or EUA is a special authorization designated for emergencies like the Coronavirus Pandemic.

- The EUA is the fastest program the Food and Drug Administration can use to encourage new products to be developed.
- The FDA also has EUAs for treatments and vaccines as well.
- The EUA for IVD was established on February 4th, 2020 in conjunction with a request from CDC Director Robert Redfield.
 Due to errors in one of the components, revised guidance was added to the EUA on February 29th.
- This guidance allowed for diagnostic tests to acquire data, and test people, while only having applied for the EUA, rather than waiting for approval.
- This led to hundreds of unscrupulous tests being produced and given to the public against the FDA's wishes.
- On May 4th, May 11th, and June 16th, the FDA updated the guidance and corrected the EUA allowing them to revoke approval from tests which do not meet their standards and discouraging public use without approval.

What is Antibody Testing?

BENEFITS OF GETTING AN ANTIBODY TEST DONE



First, the antibody test can tell a person if they've been exposed to COVID-19, which should encourage them to get a PCR test to see if they currently still have COVID-19. The window for optimal testing is between 2 weeks from symptom onset and 4 months.



Second, the antibody test can inform public health agencies to help map out where COVID-19 has been and is going, and can help in understanding prevalence, or the current number of persons who would test positive for COVID-19



Third, the antibody test, if positive, can help a person in donating convalescent plasma. Convalescent plasma comes from the blood of a person who has been exposed to COVID-19 and has antibodies. Donating this blood can help others fighting COVID-19, as well as potentially the donor, should they contract COVID-19 again, as if immunity does occur is likely only temporary.

What is Antibody Testing?

COST

- While there are free PCR tests given by the county, there are no free antibody tests available in this same way.
- There is a no-cost option available when donating blood at RedCross and/or local bloodbanks.
- The CARES act outlines rules for pricing transparency and providers must list the cash price of the testing on their website.
- Without insurance, the test can range in cost from \$99-\$200 depending on where and how it is purchased.
- With insurance, the price varies on co-pay based on the insurance and can range between \$10-\$50.



AT HOME TESTING

There is currently <u>no</u> at-home antibody test that has been given authorization from the FDA.

WHAT IS CONVALESCENT PLASMA?

- Immune (i.e. "convalescent")
 plasma refers to plasma that is
 collected from individuals, following
 resolution of infection and
 the development of antibodies.
- It is used to treat COVID-19 patients who are experiencing severe symptoms of the disease and for those who have been infected and have certain pre-existing medical conditions that might make them vulnerable to serious illness.
- Convalescent plasma therapy is still in the experimental stages for COVID-19, but the preliminary results have been showing a positive trend toward successful treatment.

Healthlabs.com



Healthlabs.com is an online lab where individuals can purchase health and wellness testing. HealthLabs.com offers an expansive collection of lab test categories and test types at discounted rates. Tests can range from STD and allergy testing to the newly FDA-authorized COVID-19 antibody test. The purchase of the test and payment occur online as well as the selection of a lab near or within a zip-code of choice.

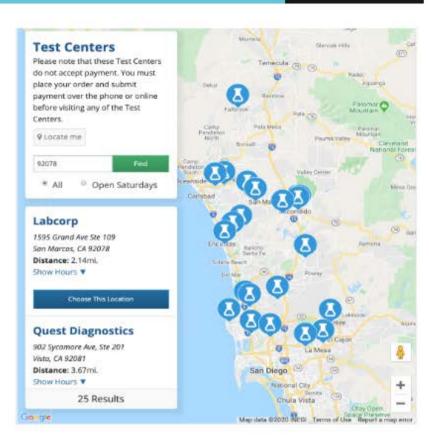
Finding a Lab: Healthlabs.com



San Diego County

When I typed the zip code of San Marcos, CA (92078), 25 results for laboratory collection sites appeared. I will list them below:

- · Labcorp: 1595 Grand Ave. Ste 109 San Marcos, CA
 - · Hours: M-F 8:00am-4:30pm (closed for lunch 12:00pm-1:00pm)
- · Quest Diagnostics: 902 Sycamore Ave. Ste 201 Vista,
 - Hours: M-F 7:30am-11:30am
- Labcorp: 1955 Citracado Pkwy. Suite 103 Escondido, CA
 - Hours: M-F 7:30am-4:00pm (closed for lunch 12:00pm-1:00pm)
- Quest Diagnostics: 3257 Camino De Los Coches Ste 201 Carlsbad, CA 92009
 - Hours: M-F 7:00am-1:30pm (closed for lunch 11:00am-12:00pm)
- 477 N FI Camino Real Ste Quest Diagnostics: B201 Encinitas, CA 92024
 - Hours: M-F 7:30am-4:30pm (closed for lunch 12:00pm-1:00pm)
- Labcorp: 499 N. El Camino Real, Ste 101 Encinitas, CA 92024
 - Hours: M-F 7:30 am-4:30 pm, Saturday 8:00am-12:00pm
- Labcorp: 225 E 2nd Ave Ste 201 Escondido, CA 92025
 - · Hours: M-f 7:00am-4:00pm (closed for lunch 12:00pm-1:00pm), Satudays 8:00am-11:00am
- . Quest Diagnostics: 488 E Valley Pkwy Suite 314 Escondido,
 - Hours: M-F 7:00am-4:00pm (closed for lunch) 12:00pm-1:00pm)
- <u>Labcorp:</u> 629 East Grand Ave Escondido, CA 92025
 - · Hours: M-F 7:00am-4:00pm (closed for lunch 11:00am-12:00pm)
- Labcorp: 735 E Ohio St #101 Escondido, CA 920255
 - Hours: M-F 8:00am-4:30pm (closed for lunch 12:00pm-1:00pm)
- Labcorp: 2067 West Vista Way, Suite 275 Vista, CA 92083
 - Hours: M-F 6:30am-4:30pm
- Labcorp: 351 Santa Fe Dr Ste 210 Encinitas, CA 92024
 - Hours: M-F 8:00am-4:30pm (closed for lucnh) 12:00pm-1:00pm)
- Quest Diagnostics: 3601 Vista Way, Ste 104 Oceanside. CA
 - Hours: M-F 7:00am-4:00pm



- Quest Diagnostics: 15725 Pomerado Rd Ste 208 Poway, CA 92064
 - Hours: M-F 7:30am-4:00pm (closed for lunch 12:00pm-1:00pm)
- Labcorp: 8901 Activity Rd. Suite 201 San Diego, CA 92126
 - Hours: M-F 8:00am-5:00pm
- Labcorp: 9850 Genesee Ave Ste 120 La Jolla, CA 92037
 - Hours: M-F 7:00am-5:00
- Quest Diagnostics: 9333 Genesee Ave Ste 180 San Diego, CA 92121
 - Hours: M-F 7:00am-3:00pm (closed for lunch 11:00am-12:00pm)
- Labcorp: 587 E. Elder Street Fallbrook, CA 92028
- Hours: M-F 7:00am-4:00pm
- Quest Diagnostics: 521 E Elder St Ste 201 Fallbrook, CA 92028
 - Hours: M-F 7:30am-4:30pm (closed 11:30am-12:30pm) Labcorp: 7300 Girard Ave Ste 105 La Jolla, CA 92037
- - Hours: M-F 8:00am-4:00pm (closed for lunch 12:00pm-1:00pm)
- Labcorp: 3737 Moraga Ave. Suite A102 San Diego, CA 92117
- Hours: M-F 7:30am-3:30pm (closed 12:00pm-1:00pm)
- Quest Diagnostics: 7910 Frost St Ste 180 San Diego, CA 92123 Hours: M-F 7:00am-4:00pm (closed 11:30am-12:30pm)
- Quest Diagnostics: 9643 Mission Gorge Rd Santee, CA 92071
- Hours: 7:00am-4:00pm (closed for lunch 11:30am-12:30pm)
- Labcorp: 5555 Reservoir Dr. Ste 101 San Diego, CA 92120
- Hours: M-F 8;00am-5:00pm (closed for lunch 12:00pm-1:00pm)
- Quest Diagnostics: 8881 Fletcher Pkwy, Ste 285 La Mesa, CA 91942
 - Hours: M-F 7:30am-4:00pm

** This is not an entirely comprehensive list of every single lab in the area. It is merely the first 25 results when a zip code is entered into www. healthlabs/find-a-lab.com

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Finding a Lab: Healthlabs.com



State of Hawai'i

When I typed the zip code of Waikoloa Village, HI (96738), 25 results for laboratory collection sites appeared. I will list them below:

- Clinical Laboratories of Hawai'i: 68-1845 Waikoloa Rd, Suite 207 Waikoloa HJ 96738
 - Hours: M-F 8:00am-3:30pm (closed for lunch 12:30pm-1:00pm)
- <u>Diagnostic Laboratory Services</u>: 65-1267 Kawaihae Rd. Kamuela, HI 96743
 - Hours: M-F 7:00am-4:00pm (closed for lunch 12:30pm-1:30pm)
- Clinical Laboratories of Hawai'i: 5-1158 Mamalahoa Hwy, Suite 27B Kamuela, HI 96743
- Hours: M-F 6:00am-5:00pm, Saturdays 9:00am-11:00am)
- Clinical Laboratories of Hawai'i: 54-383 Hospital Rd Kapaau, HI 96755
 - Hours: M-F 7:30am-4:00pm, Saturdays 8:00am-11:00am (closed for lunch 12:00pm-1:00pm)
- Clinical Laboratories of Hawai'i: 45-547 Plumeria St Honokaa, HI 96727
 - Hours: M-F 7:30am-3:30pm (closed for lunch 12:00pm-1:00pm)
- <u>Diagnostic Laboratory Services</u>: 75-170 Hualalai Road Suite B200-201 Kailua-Kona, HI 96740
 - Hours: Monday & Friday 7:00am-4:00pm
- Clinical Laboratories of Hawai'i: 75-5905 Walua Rd Kailua-Kona, HI 96740
 - Hours: M-F 6:00am-5:00pm, Saturday 7:00am-11:00am
- Clinical Laboratories of Hawai'i: 79-1019 Haukapila St Kealakekua, HI 96750
 - Hours: M-F 7:30am-5:00pm
- Clinical Laboratories of Hawai'i: 81-980 Hale Kii St Kealakekua, HI 96750
 - Hours: M-F 6:00am-3:00pm
- Clinical Laboratories of Hawai'i: 1190 Waianuenue Ave Hilo, HI 96720
 - Hours: M-F 7:30am-4:30pm, Saturday 8:00am-1:00pm
- Clinical Laboratories of Hawai'i: 82 Puuhonu Place, Suite 204 Hilo. HI 96720
 - Hours: M-F 7:30am-4:30pm (closed for lunch 12:30pm-1:30pm)
- Clinical Laboratories of Hawai'i: 670 Ponahawai St, Suite 114 Hilo, HI 96720
 - Hours: M-F 5:30am-5:00pm, Saturday 6:00am-12:00pm)





- <u>Diagnostic Laboratory Services</u>: 670 Ponahawai St. Suite 122 Hilo, HI 96720
 - Hours: M-F 6:00am-5:00pm, Saturday 6:00am-10:00am
- <u>Diagnostic Laboratory Services</u>: 1248 Kinoole St. Suite 102 Hilo, HI 96720
- Hours: M-F 6:00am-5:00pm, Saturday 6:00am-10:00am
- Clinical Laboratories of Hawai'i: 33 Lanihuli St Hilo, HI 96720
- Hours: M-F 6:00am-5:30pm, Saturday 6:00am-12:00pm
- Clinical Laboratories of Hawai'i: 1 Kamani St Pahala, HI 96777
- Hours: M-F 8:00am-4:00pm (closed for lunch 12:00pm-1:00pm)
- Clinical Laboratories of Hawai'i: 15-2662 Pahoa Village Rd Pahoa, HI 96778
- Hours: M-F 7:00am-3:00pm (closed for lunch 12:00pm-1:00pm)
- Clinical Laboratories of Hawai'i: 100 Keokea Place Kula, HI 96790
 - Hours: M-F 8:00am-3:00pm
- Clinical Laboratories of Hawai'i: 221 Piïkea Ave, Suite C Kihei, HI 96753
 - Hours: M-F 6:30am-5:00pm, Saturday 7:30am-11:30am
- <u>Diagnostic Laboratory Services:</u> 81 Makawao Ave. Suite 104 Pukalani, HI 96768
 - Hours: M-F 6:30am-12:30pm
- Clinical Laboratories of Hawai'i: 55 Pukalani St Pukalani, HI 96768
 - Hours: M-F 6:30am-4:30pm, Saturday 6:30am-12:00pm
- Clinical Laboratories of Hawai'i: 80 Pakana St Wailuku, HI 96793
 - Hours: M-F 6:30am-4:30pm
- <u>Diagnostic Laboratory Services</u>: 200 Kalepa Pl. Suite 202 Kahului, HI 96732
 - Hours: M-F 7:00am-4:30pm, Saturday 7:00am-11:00am
- Clinical Laboratories of Hawai'i: 95 Lono Ave, Suite 101 Kahului, HI 96732
- Hours: M-F 6:30am-2:30pm, Saturday 6:30am-10:30am
- Clinical Laboratories of Hawai'i: 110 Kaahumanu Ave, Suite 108 Kahului, HI 96732
 - Hours: M-F 6:30am-4:30pm

** This is not an entirely comprehensive list of every single lab in the area. It is merely the first 25 results when a zip code is entered into www. healthlabs/find-a-lab.com

Finding a Lab: ArcGIS-San Diego

An ArcGIS map database is available and displays some lab locations to get tested for COVID-19 and what type of tests they are conducting at each lab location. The three main tests being conducted in San Diego county are Molecular testing, antibody testing, and a combination of both molecular and antibody testing.



Molecular testing:

Molecular diagnostics usually require samples from the patient from nasopharyngeal swabs or sputum (phlegm expelled through coughing) samples.

Antibody testing:

Antibody (serology)
tests are blood-based
tests that can be used to
identify whether people
have been exposed to a
particular pathogen by
looking at their immune
response.

Molecular & Antibody testing:

Testing using both techniques from molecular as well as serology testing to determine active infection and/or presence of antibodies.

Finding a Lab: ArcGIS-Bay Area

https://covid-19-giscorps.hub.arcgis.com/pages/contribute-covid-19-testing-sites-data



Molecular testing:

Molecular diagnostics usually require samples from the patient from nasopharyngeal swabs or sputum (phlegm expelled through coughing) samples.

Antibody testing:

Antibody (serology)
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Molecular &

Antibody testing:

Testing using both techniques from molecular as well as serology testing to determine active infection and/or presence of antibodies.

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Labcorp operates one of the largest clinical laboratory networks in the world, with a United States network of 36 primary laboratories. You can get information about their services and testing available on their website at https://www.labcorp.com/antibody-testing or reach their customer service line at (800) 845-6167.

Accessibility & Protocol:

The COVID-19 antibody test can be obtained through labcorp.com as well as through a healthcare provider. To make an appointment or get detailed lab information there is a search engine available on LabCorp's website displaying all LabCorp locations near any zip code typed in. Walk-ins are also welcome at all lab locations. Please note that not all lab locations offer all services.

Testing specifications:

This test is only available to individuals who are not currently showing any symptoms of COVID-19. Only IgG antibody testing is currently being used. Test results can be sent automatically through the Labcorp patient portal. An account will need to be made at the same time as the request for a test is sent out.

Insurance and cost:

LabCorp will bill the cost of the COVID-19 IgG antibody test directly to your insurance carrier, or if uninsured, to the appropriate government program. The cost of the test is based on rates established by the Centers for Medicare & Medicaid Services (CMS). Although the test itself does not have any upfront out-of-pocket costs, according to Labcorp, there is a nonrefundable \$10 charge for the physician order through PWNHealth when using Labcorps physician option rather than going through your normal health care provider.

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Quest Diagnostics is a CLIA licensed American clinical laboratory offering their products and services in over 130 countries. They have approximatley 2,000 patient service centers across the U.S. You can get information about their services on https://www.questdiagnostics.com or reach their customer service line at (866) 697-8378.

Accessibility & Protocol:

Appointments can be made at any Quest patient service center. Anyone can get tested with a doctor's order or by purchasing the test online through QuestDirect, but it is required that no symptoms of COVID-19 have been experienced in the past 10 days. A mask or face covering is required to be worn inside the testing site. Fasting is not required before the blood withdrawal.

Testing specifications:

Quest Diagnostics uses three FDA authorized commercial manufacturers: Abbott Laboratories, EuroImmun, and Ortho-Clinical Diagnostics. Only IgG antibody testing is currently being used. Test results can be sent automatically through the MyQuest online portal and are typically available within 3 days.

Insurance and cost:

According to its website, Quest Diagnostics is partnered with several health insurance networks including UnitedHealthcare ®, Aetna ®, Humana ®, Cigna®, and accepts most Anthem ®, and BlueCross BlueShield ® plans. You can check on the Quest Diagnostics website to see if your insurance is accepted. Straight up out-of-pocket cost for the antibody test is \$119.



KAISER PERMANENTE®

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Kaiser Permanente is one of the leading health care providers/hospital networks in California with divisions in several other states including Hawaii. You can get information about their COVID-19 testing services at https://kp.org.

Accessibility & Protocol:

Unlike LabCorps and Quest Diagnostics, which are available to the general public (if meeting specified conditions), Kaiser is currently offering antibody testing for members only. It should also be noted that while Kaiser is offering the antibody tests, they are more careful about promoting the tests since they are not operating as a commercial laboratory, and accuracy of antibody tests are still in the process of improvement and evaluation. Your primary care provider may offer some guidance about this matter.

<u>Testing specifications:</u>

Kaiser is currently testing members who:

- Have no current COVID-19 symptoms (COVID-19 symptoms may include fever, cough, shortness of breath, chills, headache, loss of smell or taste, vomiting, and diarrhea); and
- Had symptoms but don't anymore. It needs to have been more than 14 days since the onset of COVID-19 symptoms or a positive PCR (diagnostic) test; and
- Have not had an antibody test in the last 30 days (unless an additional antibody test has been approved by an infectious disease physician).

Insurance and cost:

Antibody testing is offered free by Kaiser for their members (not including any co-pay costs). If the test is done outside of Kaiser Permanente you may be responsible for any charges. Individuals can file a claim form for reimbursement. If you paid for an antibody test from a licensed provider after March 1, you can file a claim form for reimbursement which can be found at https://kp.org

Research Reflections



Being involved in a project directly relevant to a current event, let alone a pandemic, is something I have never done before. Creating this resource guide has been interesting updates FDA, due to from the in government policies, and advances in scientific research, the content and direction has evolved throughout the timespan of our work. Furthermore, meeting as a group via Zoom once a week over the course of two months was not the traditional style of a graduate school internship, but it allowed us to work independently while collaborating as a group at the same time. As a team, we had to be adaptable, thoughtful, and creative. Each team member brought something unique to the table, and I am so grateful for the connections I was able to make through this internship. I have been living abroad since the beginning of the outbreak, so working on this particular project was the perfect way for me to stay connected and informed about COVID-19 related news in California and the U.S. I truly hope that our resource guide will serve to educate you about COVID-19 antibody testing and will help you in making the best decisions for yourself as we all navigate life in a pandemic.



Leila

Being a part of this project was not something I initially planned on, but I am grateful for the way it has benefitted me during such a time of chaos. Due to the restraints set because of the pandemic, everything was conducted virtually through Zoom. This project became something I looked forward to every week while in quarantine. Being located in Hawai'i during this process has been somewhat eye-opening and has allowed me to fully understand the importance of this guide and how much it is truly needed. Although Hawai'i is a smaller state, there are still strict precautions in place to prevent infection of COVId-19. Participating project has allowed me to learn more about COVID-19, and its implications on the world. It also allowed me to participate in educational discussions with my colleagues, which have only amplified my interest in the field of Public Health. I truly believe this resource guide will provide ample information to those who seek to know more about this pandemic. As we continued to gain new information on this virus our information became more organized and reliable. I hope this resource guide will benefit everyone who reads it in the same way that creating it has benefitted me.

Research Reflections



Rick

COVID19 presented all of us with a unique opportunity as public health students. Being able to dive deep into understanding the strangely complicated situation that is COVID19 Antibody testing. Having been a patient advocate for years for Hep C, I was familiar with the purpose of antibody testing vs PCR testing. What was discovered during this project, however, was unfortunately enlightening. Finding out that the window for testing was only a few months, and that most of the tests that have been used were potentially unreliable, alongside the strange FDA decisions, it was all rather alarming. But to see that there is hope in treatment like convalescent plasma. To see that there is purpose in doing antibody testing, for people to be able to donate an add to a potential treatment, was promising. To know that we as people can simply donate blood and not only find out if we have been exposed but to help literally in the fight against a pandemic, it is an opportunity which can help so many. In this project, working together we condensed a rather bizarre array of information into an opportunity to empower our community with what we hope is a helpful guide for you.



Dr. Morton

Faculty in academic public health departments can always offer internship opportunities to MPH students and may employ students in their own research, a process that I had never previously conducted. Due to COVID-19 pandemic restrictions at CSUSM, MPH students do not have their usual community-based internship prospects available since all internships in any discipline must temporarily be conducted online with faculty involved projects. Being an epidemiologist, what better could MPH students there be than pandemic happening in real-time, disrupting, and threatening our very own lives! The purpose of the COVID-19 Antibody Testing Project was to create a resource guide for the public to understand antibody testing, its purpose, accuracy, availability, time frame, locations, and cost. Three MPH students have spent eight weeks in Summer, 2020, working diligently and have a produced an accurate, informative, easily accessed, understandable and useful guide to why, where, when and how the public can access COVID-19 antibody testing sites, what the results identify and what it means for those who test positive for COVID-19 antibodies. In addition, our weekly internship meetings were lively and stimulating conversations about the chaos of the pandemic, current scientific research on COVID-19, and exchange of breaking related news concerning the disruption and breakdown of all connections of all human systems during a pandemic. Our MPH student's concern and caring for the general public is a hallmark and an extremely admirable trait of all our MPH students, but particularly the three with whom I worked during this internship. Each brought their strengths, unique mindsets, knowledge, perspectives, and skills to the final product, our resource guide to COVID-19 antibody testing. It was a true pleasure and a rewarding process to work with these MPH students and I am quite proud of their final product! Excellent work by all!

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Due to currently living in Hungary, I have not had access to the testing providers discussed in this guide. However, I had asked my aunt who lives in San Francisco if she could get tested at Kaiser to offer some feedback on my behalf about the testing process. Ultimately she did not take the test because her primary care provider advised against it unless she had already tested positive via molecular test or had experienced COVID-19 symptoms. I thought this was interesting information to provide since it seems to be a different approach from LabCorp and Quest Diagnostics. Ultimately her PCP's reasoning was that Kaiser does not want to over-promote antibody testing due to concerns over whether or not specificity and sensitivity claimed by testing manufacturers is valid. Therefore I am curious whether or not this is standard advice by Kaiser personnel or if it is an issue of personal opinion.



Although antibody testing is something that has been used to diagnose illnesses like HIV and fungal infections, I did not hear about it until now. I had never undergone any type of blood testing before, let alone one that tests if my immune system has a defense against a novel coronavirus. The experience definitely surreal, as everyone precautions considering how infectious COVID-19 is. I got my test done at a lab run by Quest Diagnostics. I used healthlabs.com to purchase my test and find a lab that was close to my location. As I walked through lobby there were multiple hand dispensers and I remember being relieved they were taking it seriously. As I got off the elevator there was a table with someone working and signs stating all OBGYN visits and pregnancy patients needed to get their temperature checked. I did not have to, which I thought was odd since I was there to check for COVID-19 antibodies. For the blood draw itself, it was quick and nearly painless. I was able to get my results within 2 days. The overall experience took about 25 minutes.

On the door was a sign indicting covid19 testing outside located a slight distance from the clinic itself. This sign was for PCR screening, not Antibody testing.



Walking into the clinic, the waiting room was filled with reminders to follow interventions and a sign with a box split the well and sick sides. A box for mask dispensing was located next to a sign by the door for those without masks

After a brief wait, my vitals were checked; then, he led me to a smaller patient room where my blood would be drawn. The blood draw itself was quick, and nothing out of the ordinary. My elbow wrapped with coband, and they informed me it would be one to two days for results. Without insurance, the Antibody test cost \$168.00. This cost is essential because the CARES act only covers people WITH insurance. But it does require all healthcare providers to list the price of the test on their website. Which neither the clinic I went to, nor many other clinics do. The receipt was emailed to me, also delivered to the same email address was the result of my test.

The result came back within the day and was unsurprisingly negative. I say this because I am on immunosuppressant drugs, so had the test come back positive, the test would have produced a false positive as

I do not produce antibodies.

Useful Documents & Links



All information in this resource guide was compiled from these listed websites. It is recommended to check them for updates in the information.

- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqstesting
 - sars-cov-2#ivcnote find out information directly from the FDA about regulations, status
 - of test development, laboratories and manufacturers, etc.
- https://www.cdph.ca.gov/Programs/OSPHLD/Pages/Home.aspx# find updated information specifically regarding California for COVID-19 data, resources for residents,
 - health policies, etc.
- https://testing.covid19.ca.gov information about COVID-19 testing in California,
 plus
 - access to arcgis search for testing locations
- https://www.arcgis.com/apps/Nearby/index.html?
 appid=43118dc0d5d348d8ab20a81967
 a15401&distance=20&find=San%2520Francisco%252C%2520CA%252C%2520USA direct link to arcgis search most results show detailed information including test
 - types offered, active/not active, exact locations, if insurance is accepted, etc., however you cannot filter results based on antibody testing.
- https://covid-19-giscorps.hub.arcgis.com/pages/contribute-covid-19-testing-sitesdata - An ArcGIS map database displaying some lab locations to get tested for COVID-19 and what type of tests they are conducting at each lab location.
- https://www.centerforhealthsecurity.org/resources/COVID-19/serology/Serology-based-tests-for-COVID-19.html#sec1 Information on different serology testing techniques and what they can tell us. Refer to table ____ in appendix.
- https://nchmd.org/docs/default-source/coronavirus-(covid-19)/antibody-factsheet.pdf?sfvrsn=40a6f061_2

Antibody:

a blood protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood.

<u>Antigen:</u>

A toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies.

Convalescent Plasma:

Liquid (plasma) that is collected from people who have recovered from a disease, whose blood is presumed to have antibodies for that disease. These antibodies are what helped the person fight off the initial infection.

EUA:

Emergency use authorization in the United States is an authority granted to the Food and Drug Administration under sections of the Federal Food, Drug, and Cosmetic Act as added to and amended by various Acts of Congress, including by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

FDA:

The U.S Food & Drug Administration is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, food, & more.

Herd Immunity:

The resistance to the spread of a contagious disease within a population that results if a sufficiently high proportion of individuals are immune to the disease, especially through vaccination.

IgG:

Short for immunoglobulin G, the most common type of antibody found in the human bloodstream.

<u>lgM:</u>

Short for Immunoglobulin M, it is the largest antibody, and it is the first antibody to appear in the response to initial exposure to an antigen.

Immunity:

The ability of an organism to resist a particular infection or toxin by the action of specific antibodies or sensitized white blood cells.

In-vitro diagnostic (IVD):

Tests done on samples such as blood or tissue that have been taken from the human body to detect diseases or other conditions.

Molecular Testing:

Usually require samples from the patient from nasopharyngeal swabs or sputum (phlegm expelled through coughing) samples.

PCR:

Polymerase chain reaction, or PCR, is a laboratory technique used to make multiple copies of a segment of DNA. PCR is very precise and can be used to amplify, or copy, a specific DNA target from a mixture of DNA molecules.

SARS-CoV-2:

The scientific name of the new strain of coronavirus is SARS-CoV-2. In people, the disease caused by the virus is called Coronavirus Disease 2019, or COVID-19.

Serology Assays:

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19.

Serologic Testing:

The test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself.

Interpreting COVID-19 Test Results





GUIDANCE ON

INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION	
VIRAL TESTING: (testing for current infection)	Positive	Most likely* you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. "If you are a healthcare or critical infrastructure worker, notify your work of your test result.	
	Negative	Most likely" you DO NOT <u>currently</u> have an active COVID-19 infection.	If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don't have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.	
ANTIBODY TESTING: (testing for past infection with the virus)	Positive	You likely* have HAD a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. Take steps to protect yourself and others.	
	Negative	You likely" NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. Take steps to protect yourself and others.	
BOTH (antibody and viral testing)	Viral Positive, Antibody Positive	Most likely* you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.	
	Viral Positive, Antibody Negative	Most likely* you DO currently have an active COVID-19 infection and can give the virus to others.	Stay home* and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.	
	Viral Negative , Antibody Positive	You likely* have HAD and RECOVERED FROM a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.	
	Viral Negative, Antibody Negative	You likely* have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.	

No test is ever perfect. All tests occasionally result in false positive results fould be negative because you DO NOT have COVID-19 but comes back positive) or false negative results it the test result should be positive because you DO nove COVID-19, but comes back negative). Sometimes the results are not definitive (the result is unclear, and you don't know if it is positive ar negative). For this and other reasons, results should always be reviewed by a healthcape negless love!

-Viral tests are typically performed on respiratory specimens such as nosal swabs or throat swabs. They test for the presence of the virus, usually by testing for the virus's RNA or sametimes by testing for the virus's RNA. If your antigen test is negative, please ask your healthcare provider if additional testing with an RNA test is needed and how long you should stay home.

Antibody testing, also called "servingic testing" or "servingy", is typically performed on a bload sample, ideally, the results show whether you have ever been infected with the virus in the past or may be currently infected. Antibody tests on the past of the pas

Guide to Serology Based Tests

Type of test Time result		What it tells us	What it cannot tell us	Figure
Rapid diagnostic test (RDT)	10-30 minutes	The presence or absence (qualitative) of antibodies against the virus present in patient serum.	The amount of antibodies in the patient serum, or if these antibodies are able to inhibit virus growth	RDT figure
Enzyme linked 2-5 immunosorbent hours assay (ELISA)		The presence or absence (quantitative) of antibodies against the virus present in patient serum.	If the antibodies are able to inhibit virus growth.	ELISA figure
Neutralization 3-5 assay days		The presence of active antibodies in patient serum that are able to inhibit virus growth ex vivo, in a cell culture system.	It may miss antibodies to viral proteins that are not involved in replication.	PRNT figure
Chemiluminescent 1-2 hours		The presence or absence (quantitative) of antibodies against the virus present in the patient serum.	If the antibodies are able to inhibit virus growth.	CLIA figure

Virus & Development of Antibody Timeline

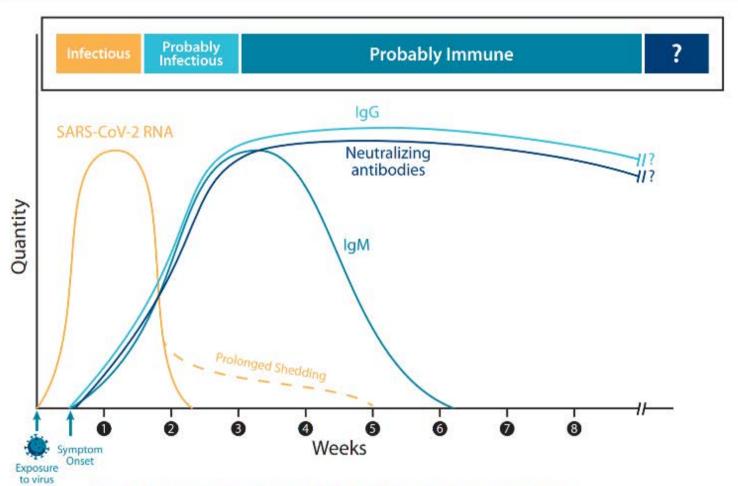


Figure 1. Kinetics of viral replication and the humoral immune response.



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Mask Infographic

