CHARTING A COMPLEX WORLD:

TECHATLAS | A DIVISION OF RACAPITAL

COVID-19 (CORONAVIRUS) DIAGNOSTICS

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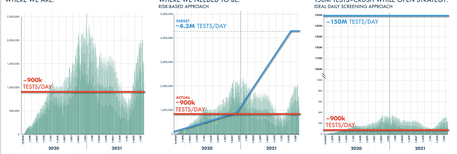
Anything wrong/outdated? Please contact curt@macap.com.
Strategic Overview & Instructions on How to Use This.map

COVID-19 DIAGNOSTICS:

IT'S NOT ABOUT HOW MUCH TESTING WE DO; IT'S ABOUT HOW MUCH TESTING WE NEED



Before the vaccine rollout, the US was piecing together as much capacity as it could, but only recently has testing supply surpassed testing demand. In the scramble to find solutions which could quickly and incrementally scale, many seemed to lose sight of what was needed – testing that was easy enough and scalable enough to crush the pandemic while remaining open. What was needed was an innovative new approach at an entirely different scale – a solution will focus on minimizing infectious days, where the virus can readily spread. Any testing paradigm that ignores the ~40% of patients who are asymptomatic is woefully inadequate. Screening is therefore the needed answer. Ideally we would have had good enough tests that are quick enough and cheap enough to implement a broad daily screening regimen ("Crush while Open Strategy") to crush the pandemic while allowing essential workers to safely return to work and students to go back to school.

COVID-19 DIAGNOSTICS:

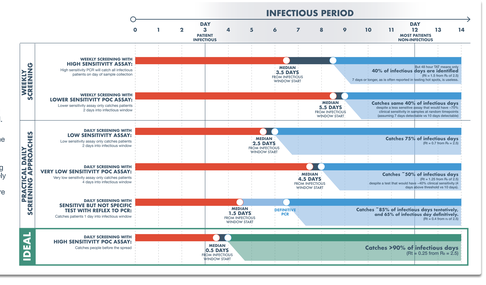
ROUTINE TESTING PARADIGM

INFECTIOUS DAYS IDENTIFIED IS MORE IMPORTANT THAN PURE SENSITIVITY

- Sensitivity at a single timepoint is not the same as sensitivity overall.
- Missing 1 patient completely (10 day infectious window) is the same as catching 10 patients one day earlier in a screening paradigm.
- The real world impact of screening with "low sensitivity assays" is likely to be even higher because more infectious patients likely have more detectable virus.
- It seems that viral titer across symptomatic and asymptomatic patients is comparable, making screening possible.

SOURCE: Chemical analysis of infectious samples of SARS-CoV-2 again suggesting issues with sensitivity of available screens for asymptomatic and symptomatic patients. Curtis Chun, 4/30/2020.

https://www.medrxiv.org/content/10.1101/2020.04.29.068445v1.full.pdf



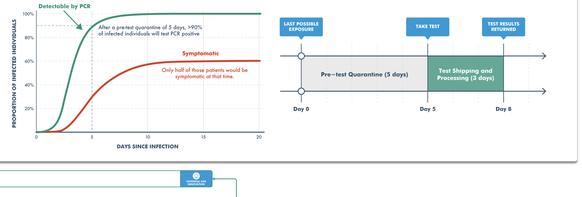
COVID-19 DIAGNOSTICS:

SINGLE-INSTANCE TESTING

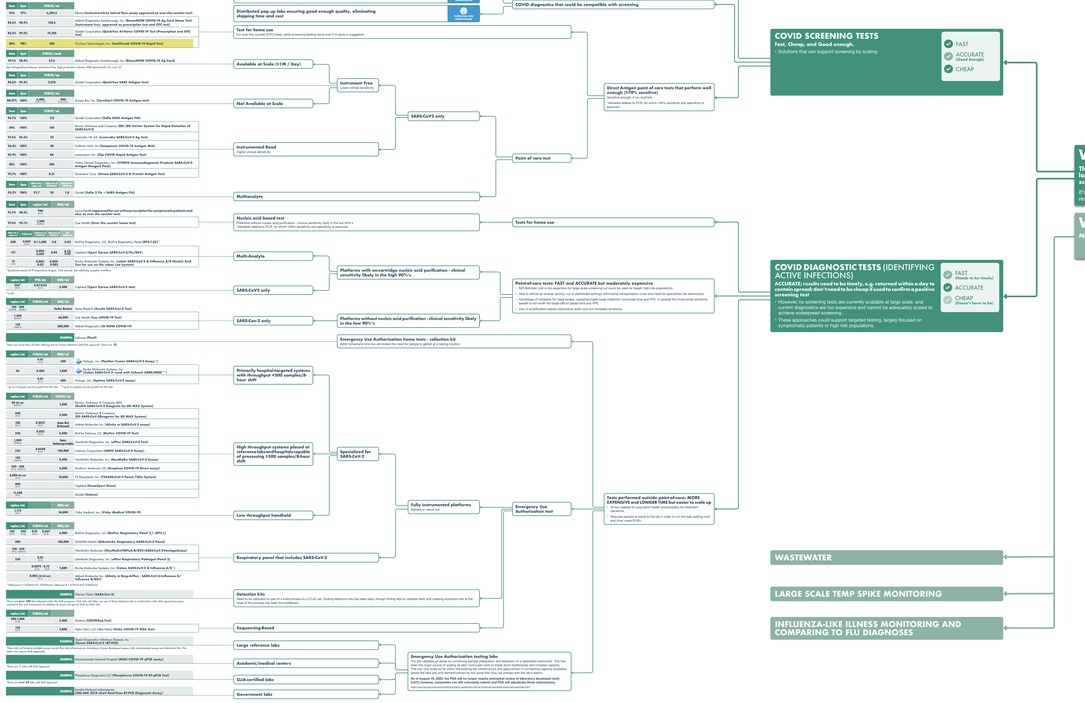
The real world diagnostic performance of COVID-19 tests depends upon how soon after infection the test is taken in addition to the test's inherent sensitivity and specificity. To ensure optimal test performance, a period of quarantine should precede taking the test.

For individuals who want to gather safely in small groups for the holidays or other functions where masks and distancing are not practical, the risk of COVID-19 transmission can be greatly diminished by quarantining for 14 days before the event [1] or by taking an appropriately timed PCR or antigen test. In order for tests to detect the presence of SARS-CoV2, the virus that causes COVID-19, the virus needs time to replicate after the timepoint of initial infection. For a period of time after infection that varies from person to person, the number of viral particles in the body will be too small to detect. For example, if an individual were infected at 9:00 a.m. on a given day, a PCR test taken at noon the same day would almost certainly be negative because the virus would not have had enough time to replicate to the level of detectability. In contrast, if a person were to self-quarantine for 5 days before taking the test, and that test were to produce a negative result, high confidence can be placed in the accuracy of the negative test result indicating true absence of infection (figure 1). A home-collected test (e.g., Pixel by Labcorp), can provide accurate and timely results provided that sufficient shipping and processing time is allowed to receive the results (varies by region, but 2-3 days is typical). The timeline in figure 2 illustrates what this testing paradigm looks like and how it saves 6 days relative to a full 14-day quarantine. Point of care PCR tests, where available, reduce this even further by eliminating the three day shipping and wait time. Point of care antigen tests have been shown to be less sensitive, so an additional day+ of pre-test quarantine is warranted.

Time Course of Covid-19 Detectability and Symptom Presentation



[1] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-ltc.html

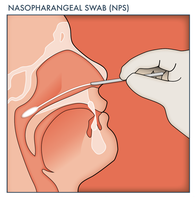


COVID-19 DIAGNOSTICS

SELF-COLLECTED SALIVA AND NASAL SWAB OPTIONS ARE ADEQUATE FOR SCREENING

Initial testing focused on nasopharangeal swabs, collection of these swabs involves a healthcare worker donning personal protective equipment to collect a sample—slowing the collection through this painful process. This consumes precious healthcare worker time and incremental PPE.

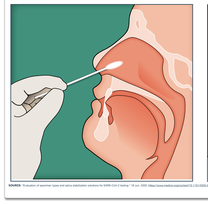
NASOPHARANGEAL SWAB (NPS)



BOTTLENECK BREAKERS

While NPS swabs are the gold standard for upper respiratory infections such as SARS-CoV-2, nasal and saliva samples have shown 85% or better sensitivity in comparison. This greatly speeds, simplifies, and enables distributed sample collection (i.e. no specialized training and PPE).

NASAL SWAB



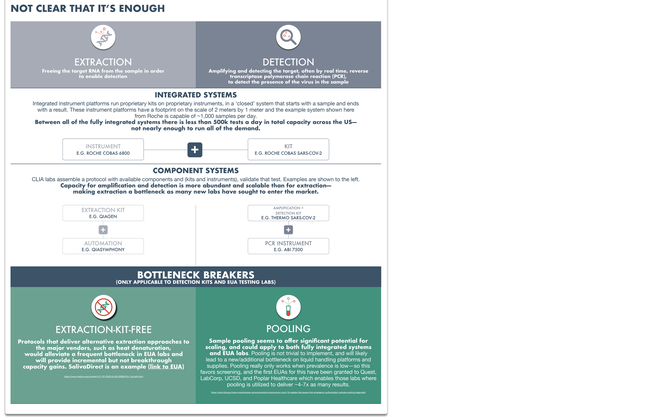
SALIVA COLLECTION

SOURCE: "Evaluation of upper-lower types and extra-nasal extraction solutions for SARS-CoV-2 testing." 31 Jun. 2020. https://www.medrxiv.org/content/10.1101/2020.06.30.20142911

COVID-19 DIAGNOSTICS:

SAMPLE POOLING HOLDS THE MOST POTENTIAL OF EXISTING EFFORTS TO SCALE UP

NOT CLEAR THAT IT'S ENOUGH



COVID-19 TESTING

To save lives, we need vaccines to prevent infection and drugs to treat people who become infected. Fortunately, many of both are in development, though we don't yet know what works. The first vaccines are likely to become available towards the end of 2020 for front-line workers and for masses in 1H21.

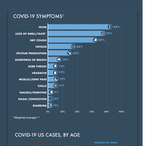
Drugs to treat infections may already be available if existing ones we have for other diseases turn out to work for COVID-19 (e.g. remdesivir, Actemra, but if we do need new ones (as we likely will), then those probably won't be available until September 2020 or later (need to run tests and manufacture).

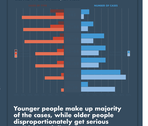
COVID-19

DISEASE OVERVIEW

SYMPTOMS:

Fever, dry cough, fatigue, and shortness of breath are the major symptoms associated with COVID-19. The CDC also includes loss of taste or smell, chills, muscle pain, headache, and sore throat as symptoms to watch for. While these symptoms have been reported, they occur much less frequently.





DISEASE PROGRESSION:

PRE-INFECTION

COVID-19 can be prevented through the use of basic precautions and (in the future) an effective vaccine.

POST-EXPOSURE

After exposure to SARS-CoV-2, it takes several days for symptoms to develop. During this incubation period, the infected person is able to transmit the virus despite being unaware of their illness. This is why "social distancing", quarantine, contact tracing, testing, hand washing, and mask wearing are critical. Most people develop symptoms between 2-14 days post-infection, with the majority developing symptoms by 5 days[1].

If we had a therapy that was safe, efficacious, and easy to administer, it would be great to provide it to people who are exposed (e.g., healthcare workers as caretakers or hospital workers) to try to prevent these from becoming infected. This kind of treatment is called post-exposure prophylaxis, and while there are currently no drugs approved for COVID-19, there are some promising candidates in the RDEA pipeline. Those who believe they have been exposed to the virus should self-quarantine for 14 days to prevent spreading it to others.

MILD

Most patients who develop COVID-19 have a mild disease course and are able to manage their symptoms at home using over-the-counter medications that relieve pain and/or reduce fever (e.g., Tylenol/acetaminophen or Advil/ibuprofen). If you are diagnosed with COVID-19, please follow the advice of your healthcare professional.

Some "asymptomatic" patients with COVID-19 may not develop any noticeable symptoms and may not realize they have been infected. Because these individuals can still spread the virus, everyone should employ basic protective measures like social distancing, hand washing, and mask wearing (obviously none of those are necessary if you live by yourself and never see anyone else, though washing hands is still a habit).

HOSPITALIZATION

Some patients who develop COVID-19 symptoms become seriously ill (1 out of every 6 diagnosed), but a lower rate amongst all, including undiagnosed, who are infected). Develop difficulty breathing, and must be admitted to the hospital to manage these symptoms. Older people (65 years old) and those with other medical issues are more at risk of developing serious illness. Serious medical issues include cardiovascular disease (CVD), diabetes, high blood pressure (hypertension), chronic lung disease (CLD), cancer, and cerebrovascular disease (CVD). The most common symptoms are difficulty breathing and decreased levels of oxygen in their blood, requiring administration of supplemental oxygen[2].

Acute respiratory distress syndrome (ARDS) is a serious complication in patients with severe disease and is associated with a high risk of respiratory failure. These patients must be carefully managed in the intensive care unit, often with the use of mechanical ventilation, and have the highest rate of death from COVID-19[3]. ARDS is common for hospitalized patients with COVID-19 (20-42%) and results in a significant percentage of deaths (~50%). Those who do survive ARDS may be left with long-term PTSD. ARDS is also associated with kidney, liver, and heart complications, which can also increase the risk of mortality[3, 4].

[1] Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). February 2020. https://www.who.int/docs/default-source/coronaviruse/coronavirus-disease-2019-report.pdf
[2] Management of Patients with Liver Disease during the COVID-19 Pandemic. Fan, Rahmani, Zhang. March 2020. https://www.sciencedirect.com/science/article/pii/S2468-1253(20)30077-7?via%3Dihub
[3] Management of Patients with Frailty in Intensive Care during the Coronavirus Disease Pandemic. Flaatten, Beil, Guidet, Cecconi, Sprung, Szabo. April 2020. https://link.springer.com/article/10.1007/s00134-020-06062-x
[4] Management of Patients with Frailty in Intensive Care during the Coronavirus Disease Pandemic. Flaatten, Beil, Guidet, Cecconi, Sprung, Szabo. April 2020. https://link.springer.com/article/10.1007/s00134-020-06062-x

WHO HAS COVID?

There are not yet solutions that adequately scale to address large-scale screening. Given the high asymptomatic prevalence, screening is critical.

It's important to know the answer quickly and isolate patients with positive results.

WHERE IS COVID?

Methods intended to identify hotspots for increased testing.

COVID DIAGNOSTIC TESTS (IDENTIFYING ACTIVE INFECTIONS)

ACCURATE: results need to be timely, e.g. returned within a day to contain spread; don't need to be cheap if used to confirm a positive screening test

- However, no screening tests are currently available at large scale, and current diagnostics are too expensive and cannot be adequately scaled to achieve widespread screening.
- These approaches could support targeted testing, largely focused on symptomatic patients or high-risk populations.

FAST (Needs to be timely)
ACCURATE
CHEAP (Doesn't have to be)

Who is already immune to COVID?

Before a vaccine is developed and protective titers are definitively known, this will simply answer the question "Who had COVID?" by testing for seroconversion.

These assays are simpler to scale and needed less frequently than tests for "Who has COVID?". Accuracy is more important than speed for these tests.

These tests rely upon a blood draw, and migrating to a dried blood spot will make collection simpler.

The early tests released in this category had poor performance and added to confusion about prevalence; they should not have been released.

SARS-COV-2

REPLICATION AND TRANSMISSION

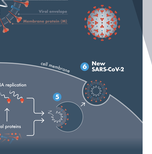
The virus that causes COVID-19 is called SARS-CoV-2. SARS stands for "severe acute respiratory syndrome," which can involve shortness of breath, pneumonia and/or respiratory distress, and the virus is named because it closely resembles the virus (SARS-CoV) that caused the SARS outbreak of 2002/2003. Both viruses belong to the Coronavirus (CoV) family.

SARS-CoV-2 is enclosed by a protective lipid (fatty) membrane containing proteins that give the virus structure and allow for infection. The membrane is a weak point that makes it easy to kill with soap, bleach, or alcohol. Inside the virus there is a single strand of ribonucleic acid, or RNA, that contains the virus's genetic information. The coat of the virus is covered in spike protein molecules, including the spike protein (S), which allows the virus to attach to host cells and gives the virus its distinctive shape.

SARS-CoV-2 enters host cells by binding a specific protein, called "ACE2," on the cell surface; once inside, the virus hijacks the host's cellular machinery to replicate and assemble more viral particles. After the virus binds to the host cell, enzymes produced by the host (TMPRSS2) activate the viral spike protein (S), which allows the virus to enter the cell (see schematic below)[1]. Once inside the cell, the virus rapidly imparts more copies of its genetic material (RNA) as well as the proteins needed to create new viral particles. The RNA is packed into new particles, which are released into the body to infect surrounding cells.

SARS-CoV-2 is thought to first infect the cells of the nose and throat, from where it can spread to the lungs where it can cause significant symptoms until it progresses into the lung. During the first stage of infection, patients are made aware of spread the virus to others by coughing or sneezing, even before they start to show symptoms (referred to as "asymptomatic") or while their symptoms are too mild to distinguish from a harmless cold. Once the virus makes it way into the lungs, more notable symptoms (coughing, fever, and/or shortness of breath) start to become more prevalent. SARS-CoV-2 also uses additional receptors to enter cells, including CD147 and CD26, which are found on the surface of many other cell types in the body, which can infect more people. In contrast, SARS-CoV and MERS-CoV primarily and quickly infect lung cells, which are deeper in the respiratory tract and cause an earlier onset of various symptoms, so patients can be identified and quarantined sooner before they spread the virus, making it easier to stamp out the original SARS and MERS cases before they triggered a pandemic.

- Spike protein on the virus binds to ACE2, a cell-surface protein. TMPRSS2, an enzyme, helps the virus enter
- The virion releases its RNA
- Some RNA is translated into proteins by the cell's machinery
- Some of these proteins form a replication complex with the viral RNA genome to make more copies of the genome, including some that stay in the cell nucleus, although the virus has proofreading proteins that try to correct the mistakes, some slip through
- Proteins and RNA are assembled into a new virion and
- released



TRANSMISSION:

SARS-CoV-2 is spread from person to person mainly through respiratory droplets that are created when a person coughs, sneezes, or talks (similar to how influenza spreads). These droplets are thought to travel no more than six feet. Droplets can also be created when people with COVID-19 breathe, but these droplets are not thought to travel more than six feet. Therefore it feel should be considered a minimum. 10 feet apart is better. Wearing masks in public places can help prevent both the spread of these droplets to others if you are infected and at least partially reduce inhalation of these droplets from others if you are well.

SARS-CoV-2 may also spread by touching an infected surface followed by subsequent contact with the eyes, nose, or mouth. Regular hand washing and disinfection of commonly touched surfaces can help reduce this type of spread.

There is no evidence that SARS-CoV-2 can spread through feed (different from foodborne viruses like norovirus or hepatitis A) or through mosquitoes (different from mosquito-borne viruses like Zika or West Nile). SARS-CoV-2 causes respiratory symptoms that increase its spread to others, unlike foodborne viruses that cause gastrointestinal symptoms and are spread through feces. Mosquitoes need to ingest blood to reproduce and spread to mosquito-borne viruses, the spread of SARS-CoV-2 occurs directly from person to person and not through an animal host.

SARS-CoV-2 could theoretically be transmitted by blood transfusion, but viral transmission has not been linked to blood transfusion for SARS-CoV-2, SARS, or MERS. Viral genomic material has been detected in the blood of ~15% of patients hospitalized with COVID-19[3], but not in patients with milder disease[1]. For COVID-19, we do not yet know whether these patients have infectious viral particles in their blood or only (noninfectious) genomic material. Both SARS and MERS, two other coronaviruses that have caused epidemics in the past, have been detected in the blood of infected patients[4] and were transmitted during infections, particularly SARS (~75% of patients with SARS[4] and ~33% of patients with MERS[4]). Additionally, replicating coronavirus particles have been detected in the blood of mice infected with SARS[5]. We also know that non-human primates can be infected with the virus that causes SARS (SARS-CoV) via blood transfusions and that these animals also develop SARS symptoms[6]. While blood transfusions were a concern during the outbreaks of SARS and MERS, no blood transfusion cases were reported during the outbreaks of SARS and MERS that none of these diseases have been detected in 8,422 SARS cases and 2,229 MERS infections[4] worldwide) and almost no asymptomatic infections (greatly reducing the risk of infected patients donating blood).

[1] Virological Assay for SARS-CoV-2 in Human Nasopharyngeal Swab Specimens. Lisa Pickett, MPH, Jennifer Gardy, PhD, Jennifer Hoang, MD, Mark Tyndall, MD, Kevin Fong, MD. April 2020. https://www.medrxiv.org/content/10.1101/2020.04.17.20067728v1.full.pdf
[2] Transmission of SARS-CoV-2 in Domestic Dogs and Cats. Michael Stout, Nicholas Lederer, Jonathan Lewis, Cynthia Chandler, Stephen Dewey, Gregory Gray. April 2020. https://www.medrxiv.org/content/10.1101/2020.04.15.20067223v1.full.pdf
[3] Clinical Characteristics and Imaging Manifestations of the 2019 Novel Coronavirus Disease (COVID-19): A Meta Analysis. Rodriguez-Morales, Cardona-Ospina, Gutierrez-Ocampo, Catalina Villamizar, Jeffrey Tejeda, Kevin Marquez, Luis Cramsen, Rafael Vitek, Mario Pacheco, Yadanar Fanny, Chen, Wilson Lagos, Paola Arteaga, Alejandro Morris, Sarah Paniz-Mondolfi, Alfonso J Rabaan, Ricardo Gray, Reinaldo Hurtado, Ricardo Franco, Osmel Villamil, Juan Montoya, Nicolas Gallagher, Oscar Ollarza, Yamarelis Martinez, Abdallat, Yousef Al Mahmoud, Jorge Quiroz, Guillermo Perouzel, Esteban Cawcutt, Matthew Butera, Aldo Rolando, Karina Williams, Eric Gerardo. March 2020. https://www.medrxiv.org/content/10.1101/2020.03.26.20044610v1.full.pdf
[4] Transmission of Coronaviruses in Blood Products. Simon Devine, Cameron Cohen, Mazzulli, Walker, Gyenes, Yu, Preiksaitis, Chris Mazzulli, Tilley, Gregory Devine, Gregory Gubbay, Jason. April 2020. https://onlinelibrary.wiley.com/doi/pdf/10.1111/trf.15828
[5] Transmission of mouse SARS-coronavirus in mice. Yoichiro Kamata, Junki Fujiyama, Toshiki Taira, Hiroshi Hasegawa, Ichiro Kurane, Ikuo Tsunetsugu. June 2006. https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1348-0421.2006.00857.x
[6] Transmission of Human SARS Coronavirus in Cynomolgus Macaques. Fumihiro Kaneko, Tsuyoshi Sekizuka, Hirofumi Katano, Masato Tamura, Yoshiko Komatsu, Naoko Sato, Masuko Sato, Junzo Matsuishi, Hideki Hasegawa, Masato Kuroda. April 2004. https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1348-0421.2006.00857.x

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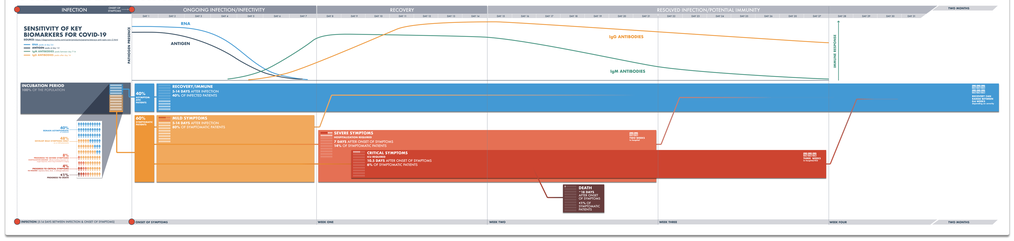
DISEASE SEVERITY AND

PROGRESSION TIMELINE



QUANTITATIVE PLATFORMS that can update thresholds when correlates of protection are determined

Proven high performance serology (>99% specificity)

This performance has only been demonstrated for an immunoprevalence available in the lab. These assays are ready to go for epidemiology studies and will be ready to go for correlate of protection studies with specificity. If, now that these assays have been validated on blood draws, data are validating dried blood spots as a more convenient sample.

Company	Assay	Specimen	Sensitivity	Specificity
Roche Diagnostics	Elecsys Anti-SARS-CoV-2	S	98.8%	99.8%
Diasorin	Liaison SARS-CoV-2 Total antibody assay (CLIA)	S	99.4%	99.6%
Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	88.7%	98.4%
Abbott Laboratories	ARCHITECT SARS-CoV-2 IgG Reagent	RBD	100%	99.4%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 Total Reagent Pack	S	99.6%	99.8%
Abbott Laboratories	Anti-SARS-CoV-2 IgG assay	N	100%	99.8%
Siemens Healthineers	SARS-CoV-2 Total	RBD	100%	99.8%
Beckman Coulter, Inc.	Access SARS-CoV-2 IgG	RBD	99.5%	99.8%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 IgG Reagent Pack	S	100%	99.8%
Abbott Laboratories	Anti-SARS-CoV-2 IgG assay	N	100%	99.8%
Roche Diagnostics	Elecsys Anti-SARS-CoV-2 S	RBD	100%	99.8%
Immunodiagnostic Systems Ltd	EDI SARS-CoV-2 IgG on DiaSorin Assay	RBD	100%	99.8%
Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	100%	99.8%
Diasorin	Liaison SARS-CoV-2 S1/S2 IgG	S	99.4%	99.8%
Siemens Healthineers	SARS-CoV-2 IgG	S	100%	99.8%
Beckman Coulter	Access SARS-CoV-2 IgG	S	99.4%	99.8%
Roche Diagnostics	Elecsys Anti-SARS-CoV-2	N	99.5%	99.8%
Diasorin	Liaison SARS-CoV-2 S1/S2 IgG	S	99.4%	99.8%
Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	99.4%	99.8%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 IgG	S	99.6%	99.8%
Beckman Coulter	Access SARS-CoV-2 IgG	N	99.5%	99.8%
Abbott Laboratories	Anti-SARS-CoV-2 IgG assay	S	99.4%	99.8%
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Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	99.4%	99.8%
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Siemens Healthineers	SARS-CoV-2 IgG	S	100%	99.8%
Beckman Coulter	Access SARS-CoV-2 IgG	S	99.4%	99.8%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 IgG Reagent Pack	S	99.6%	99.8%
Abbott Laboratories	Anti-SARS-CoV-2 IgG assay	N	100%	99.8%
Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	99.4%	99.8%
Diasorin	Liaison SARS-CoV-2 S1/S2 IgG	S	99.4%	99.8%
Euroimmun	Anti-SARS-CoV-2 ELISA (IgG)	S	99.4%	99.8%

Immunoanalyzer

Equipment should be capable of high throughput.

Company	Assay	Specimen	Sensitivity	Specificity
Lumiras Corporation	LUMIRA® SARS-CoV-2 Multi-Antigen IgG Assay	S	99.4%	99.8%
Quidel Corp.	Lyra® SARS-CoV-2 Antibody Reagents	RBD	100%	99.8%
Siemens Healthineers	Atellica IM SARS-CoV-2 Total Ab assay	RBD	100%	99.8%
Thermo Fisher Scientific	QuantiVerse® COVID-19 Total Antibody ELISA Kit	RBD	100%	99.8%
COVID-Gerulin, Kantaro Semiconductor	Gerulin-COVID-19 IgG Antibody Test	S	100%	99.8%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 Total Ab assay	RBD	100%	99.8%
ZEUS Scientific, Inc.	ZEUS ELISA SARS-CoV-2 IgG Test System	S	99.4%	99.8%
GenBody USA Inc.	Infinia SARS-CoV-2 Neutralization Antibody Detection Kit	RBD	100%	99.8%
AdCitomedix US Inc.	AdviSARS-CoV-2 ELISA (IgG)	S	99.4%	99.8%

ELISA assay (automated or semi-high performance)

Company	Assay	Specimen	Sensitivity	Specificity
Wadsworth Center, New York State Department of Health	Plexus Test SARS-CoV-2	RBD	100%	99.8%
Ortho Clinical Diagnostics	VITROS Anti-SARS-CoV-2 IgG	S	99.6%	99.8%
Primerdesign Ltd	Genesig® Coronavirus COVID-19 ELISA pan-pro Antibody Test	S	100%	99.8%
Bioheen Biotechnology, Inc.	Bioheen Diagnostics eC-19ab	RBD	100%	99.8%
Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test	RBD	100%	99.8%

Solid-that have developed a high-flow, high performance

| Company | Assay