

COMBAT & CONTAIN

CORONAVIRUS

CRISIS



COVID-19 IgG / IgM

BECAUSE COVID-19 SURVEILLANCE SCREENING MATTERS...

- ...to identify asymptomatic COVID-19 cases.
- ...to complement RT-PCR tests for accurate diagnosis.
- ...to avoid rapidly spreading cases from undetected patients.
- ...to differentiate from common cold, flu and allergies.
- ...to predict who might be immune if the virus comes back.
- ...to establish "Herd Immunity Threshold" to help prevent COVID-19 pandemic.
- ...to identify people with protective immunity for "convalescent plasma therapy".
- ...to show the full scope of the pandemic, not just individual infections.
- ...to conduct Surveillance / Epidemiological studies for effectively control program.

CE

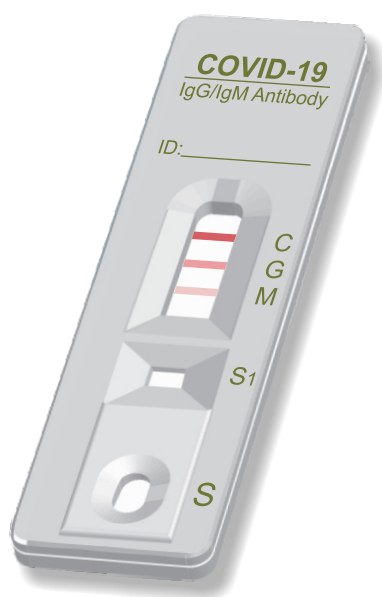
Affimedix
Discovering Health Diagnostics for Life®



Affimedix, Inc., a growing Global Medical Device company with its headquarter in Silicon Valley of California, focuses on R & D, product design, development, manufacturing and marketing of its "Proprietary" Point-Of-Care, ELISA and CLIA Diagnostic Tests.

TestNOW™ - COVID-19 IgG / IgM

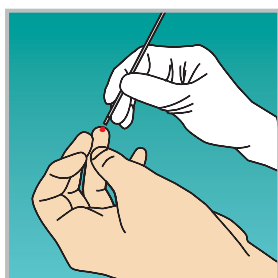
A Rapid Lateral flow assay intended for qualitative detection of IgG and IgM antibodies to the SARS-CoV-2 virus in patients suspected of COVID-19 infection.



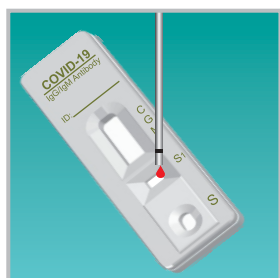
Product Features:

- Point-Of-Care COVID-19 Serological Screening Test
- Identify suspected patients with 2µl Finger prick Blood
- Quick Results in Just 15 Minutes, saving critical time
- Clinical Specificity: 99.0%
- Clinical Sensitivity: 87.5% (vs. RT-PCR- confirmed samples)
- Accuracy: 96.8%
- Complementary to RT-PCR testing
- No special facilities needed; test can be used anywhere
- Results are easy and clear to read
- Can detect "Silent Infections"
- No specialized training required to operate
- No complex extraction procedure required
- Not for diagnosis of active COVID-19 infection

Simple Rapid Testing



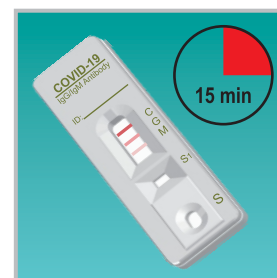
Collect Blood Sample



Add blood sample to S1 well



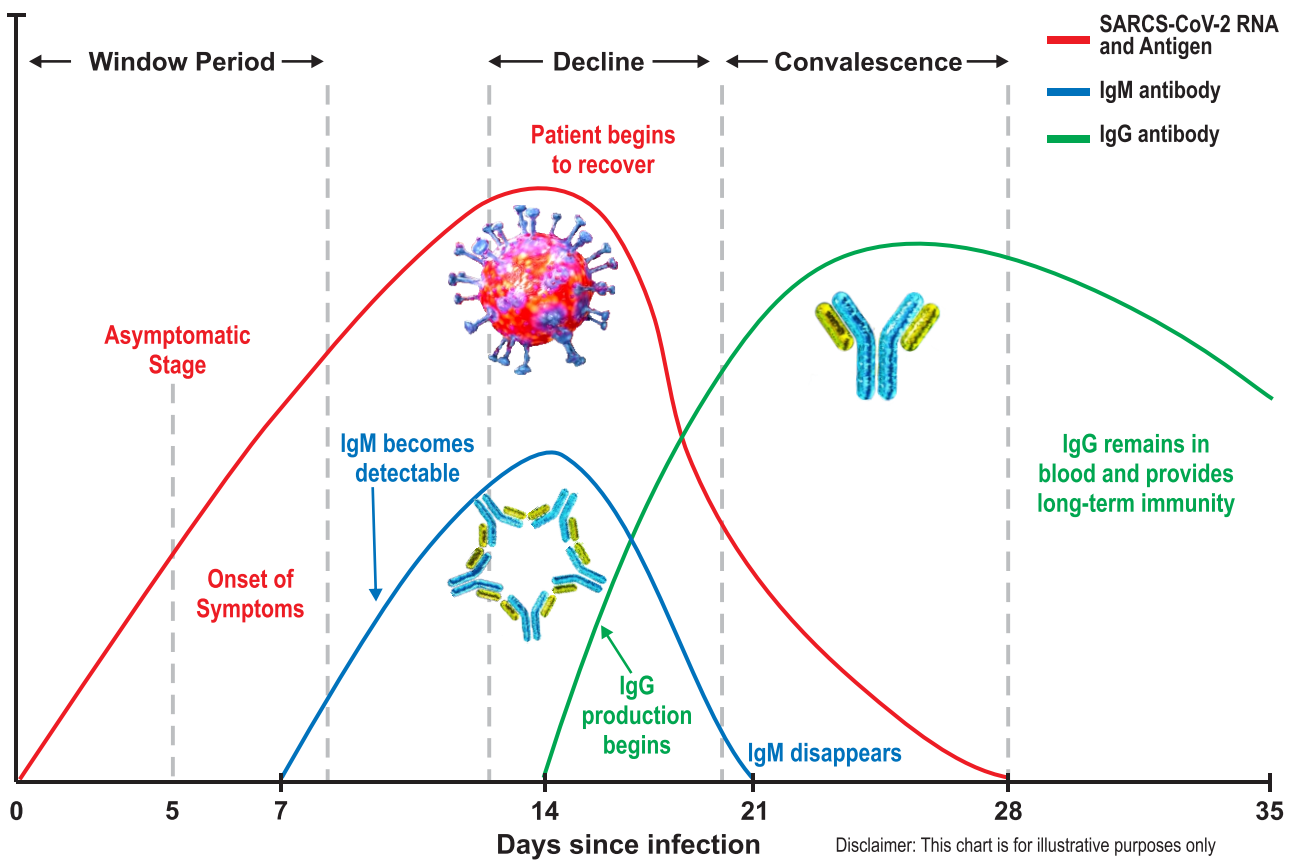
Add 2 drops of Buffer to S well



Read results at 15 minutes

WHY DO WE NEED ANTIBODY TESTS FOR COVID-19?

- RT-PCR (RNA) tests can give high false negative results (~30%) due to improper sampling.
- RT-PCR testing is a major issue when dealing with millions of people in a global pandemic.
- Combining Antibody test with RT-PCR test enabled doctors to detect 98.6% of COVID-19 cases compared to 51.9% with a single RT-PCR test. (Source: *New England Journal of Medicine*, March 31, 2020).
- Supplementing RT-PCR with Antibody test can significantly improve the accuracy of the COVID-19 diagnosis, and these calls are becoming increasing louder.



Variation of the Levels of SARS-CoV-2 RNA and Antigen, IgM and IgG after infection

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	-	-	Patient may be in the window period of infection.
+	+	-	Patient may be in early stage of infection.
+	+	+	Patient is in active phase of infection.
+	-	+	Patient may be in the late or recurrent stage of infection.
-	+	-	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
-	-	+	Patient may have had past infection and has recovered.
-	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

Clinical Significance of an IgM/IgG Serological Test Result

EXPONENTIAL GLOBAL DEMAND FOR COVID-19 "IMMUNITY TEST" TO START "SERO-SURVEYS"

USA Today, April 2, 2020

FDA authorizes first coronavirus blood test, a key step for showing immunity and testing for vaccines

Such tests could identify people who have recovered from COVID-19, a key for knowing who's immune and for developing a vaccine.

The New York Times, April 2, 2020

F.D.A. Approves First Coronavirus Antibody Test in U.S.

The new test, by contrast, looks for protective antibodies in a finger prick of blood. It tells doctors whether a patient has ever been exposed to the virus and now may have some immunity.

Chicago Tribune, April 3, 2020

The next coronavirus test will tell you if you are now immune. And it's fast.

Interestingly, the more people who have had it, the safer everyone is, under the concept of "herd immunity."

MIT Technology Review, April 2, 2020

The Coronavirus test that might exempt you from social distancing – if you pass

It could also give survivors of the infection confirmation that they are now immune, meaning they no longer pose threat to others and could potentially return to work and public life.

Business Insider, April 3, 2020

The UK plans to issue coronavirus 'Immunity Passports' so people can leave the lockdown early

The UK plans to roll out "Immunity Passports" to allow people who have contracted COVID-19 to leave the lockdown early.

BARRON'S, April 3, 2020

A Simple Blood Test May Be the Answer to Getting America Back to Work

It could take many months for new drugs or vaccines to beat back Covid-19. But, rapid tests for viral antibodies that could provide a path to normalcy more quickly.

NBC News, April 4, 2020

An at-home finger prick blood test may help detect your exposure to coronavirus

Americans may soon be able to learn if they've ever been infected with COVID-19 with a prick of their finger and a smartphone—and without having to leave their homes.

VOX, April 2, 2020

How Covid-19 immunity testing can help people get back to work

We need to find out who has the antibodies to the virus. Testing to see who has the Covid-19 coronavirus has become one of the most crucial elements of slowing the global pandemic. And it may also hold the key to a return to normal.

Cleveland.com, April 2, 2020

Antibody Coronavirus Tests could deliver faster results, better understanding of reach

A potential solution to know just how widespread the coronavirus is -- and how many people have had it without developing symptoms - could be antibody testing.

Business Insider, March 30, 2020

Germany could issue thousands of people coronavirus 'Immunity Certificates' so they can leave the lockdown early

Germans could soon be issued "Immunity Certificates" that would allow them to leave the country's coronavirus lockdown earlier than the rest of the population if they test positive for antibodies to the virus.

Business Insider, April 1, 2020

A quick finger-prick blood test can determine whether you've ever had the coronavirus. It could soon become widely available.

Experts are racing to develop tests that can identify who has recovered from COVID-19 and may be immune. Blood from recovered people could also be used to treat critically ill coronavirus patients.



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