QIAGEN heading the fight against Coronavirus

Despite containment efforts, COVID-19 caused by the SARS-CoV-2 virus has spread across the globe with cases in every inhabited territory. Declared a global pandemic by the World Health Organization on March 11th the challenge now is to identify and isolate new patients and those who have come into contact with them to prevent further spread of the disease. Rapid molecular diagnostics will play an increasingly crucial role in maintaining cases at manageable levels as countries make steps to come out of lockdown.

A need for timely testing

Quick action is needed to determine a timely diagnosis and contain the coronavirus pandemic sometimes even on location. There are currently no vaccines or treatments for the COVID-19 virus, making testing the only measure available to public health systems in their efforts to contain the virus. Another major challenge is that tests do not provide a one-size-fits-all solution. Different types of tests are necessary depending on the specific stage and circumstances of the outbreak: from fundamental research to better understand the virus, to screening for active infection and surveillance of previous infections, appropriate testing according to each unique situation is extremely critical. QIAGEN provides differentiated diagnostic tools which can meet these needs and be implemented at all the stages of the viral outbreak to contain its spread and help treat patients.

QIAGEN's COVID-19 molecular testing solutions

QIAGEN has an industry leading track record in providing molecular testing solutions that have been widely used in previous viral outbreak situations such as SARS (also a form of coronavirus), Avian and Swine flu. These solutions included QIAGEN components such as sample preparation and PCR reagents, instrumentation, and complete workflows. Our long-standing relationships with the WHO, and CDC mean that we are well placed to act fast in emergency outbreak situations.

From the very first days of the novel coronavirus outbreak, QIAGEN's dedicated global teams have been working around the clock to ensure availability of existing testing solutions and to develop new, dedicated COVID-19 tests to address international testing needs. We have dramatically scaled up production, moving to 24 hour, seven-day-a week operations at our manufacturing sites, and are investing in additional equipment capacity. **Today, we offer the most comprehensive portfolio of COVID-19 testing solutions on the market, covering the needs of clinical and research customers, from manual to automated sample processing, low to high throughput, single-plex to multi-plex, and from active infection testing to detection of previous viral exposure.**

Our suite of COVID-19 solutions for clinical and research applications include:

The new QIAreach Anti-SARS-CoV-2 Total test.

QIAreach Anti-SARS-CoV-2 Total Test

Serology testing may help to determine if a person has been previously infected with the SARS-CoV-2 virus, even if they have never shown any symptoms.

The QIAreach Anti-SARS-CoV-2 Total test is a new serology test intended to identify individuals who may have had a recent or prior infection with the SARS-CoV-2 virus. The test does this by detecting markers of the adaptive immune response (total immunoglobulin (IgA, IgM and IgG) raised in response to a SARS-CoV-2 infection.

The new serological test is an easy-to-use and portable digital device that provides reliable results in 10 minutes. Each eHub handles up to eight patient samples simultaneously and performs up to 32 total tests per hour. The nanoparticle fluorescent detection technology uses serum or plasma from patient samples. The test has a sensitivity of 100% (CI 88.43–100.00%) and specificity of 100% (CI 95.20–100.00%).

The QIAreach Anti-SARS-CoV-2 Total Test was submitted for US FDA Emergency Use Authorization (EUA) in August 2020.

COMING SOON! QIAreach Anti-SARS-CoV-2 Antigen Test

QIAGEN has announced plans to launch a rapid portable test that can detect SARS-CoV-2 antigens in people with active infections that can deliver a result in less than 15 minutes and process on average, around 30 nasal swab samples per hour. This test, which is expected to become available in the fourth quarter of 2020 is designed for use in environments that require a high volume of fast and accurate test results. The portable test offers a new combination of speed and scale that marks an important step towards decentralized mass testing that health authorities all over the world have been urgently seeking.

Two versions of the Antigen Test are scheduled for US launch – one for labs and one for point-of-care (POC) use. QIAGEN will apply for FDA Emergency Use Authorization and seek CE-IVD registration in Europe. A CLIA Waiver in the US would allow the POC version to be used in settings like airports or stadiums.

The QIAreach Anti-SARS-CoV-2 Antigen Test uses the same QIAGEN eHub system as the recently announced QIAreach Anti-SARS-CoV-2 Total Test, making it possible to run the two tests simultaneously on different ports of the same eHub.

QIAstat-Dx Respiratory SARS-CoV-2 Panel

For use with the QIAstat-Dx instrument, the QIAstat-Dx Respiratory-SARS-CoV-2 Panel can differentiate the novel coronavirus from 21 other pathogens implicated in serious respiratory syndromes. The highly sensitive test works by targeting two genes, ORF1b and the E gene of the SARS-CoV-2 virus, and can deliver a result in about one hour with minimal hands-on time. This so-called syndromic test has the advantage over other RT-PCR-based tests of being able to detect several respiratory diseases at once, allowing

diagnosis and treatment of the patient whether they turn out to be positive for the novel coronavirus or a different respiratory infection.

The speed and ease-of-use of the test make it perfect for testing in situations where a result is needed quickly (for example in airports, at boarders and on cruise ships).

The QIAstat-Dx Respiratory-SARS-CoV-2 Panel was the first syndromic solution integrating detection of SARS-CoV-2 coronavirus to receive FDA emergency use authorization (EUA). A version of the panel is also CE-IVD marked which means it is authorized for diagnostic use in Europe.

The new QIAstat-Dx Respiratory-SARS-CoV-2 panel.

Kits and instruments supporting laboratory developed tests (LDTs)

In February 2019, the U.S. Centers for Disease Control (CDC) released a recommended protocol for a real-time PCR (RT-PCR) test for detection of SARS-CoV-2. Listed in these recommendations are **a number of QIAGEN products for sample preparation and PCR, including QIAGEN's EZ1 DSP Virus kits which run on EZ1 Advanced workstations, and QIAamp DSP Viral RNA Mini kits, which can be automated on QIAcube instruments**. Many labs have adopted this CDC guideline, and multiple other protocols from around the globe also include QIAGEN testing products.

The EZ1 Advanced instrument which automates the critical RNA extraction step of the COVID-19 test.

High-throughput automation tests

QIAGEN provides instruments for the automation of molecular biology applications, offering greater standardization, minimizing hands-on-time and enabling customers to process samples in larger numbers. **The QIAsymphony modular system** provides complete automation of sample preparation and PCR analysis, while **the NeuMoDx 96 and 288 systems** offer a rapid and fully automated PCR test for COVID-19 that can deliver a result within an hour. **A new multiplex test for influenza, respiratory syncytial virus (RSV) and the SARS-CoV-2 virus is scheduled for launch in the fourth quarter of this year.** These solutions are ideal for use in hospitals or central testing labs which receive large numbers of patient samples.

TThe NeuMoDx 96 and 288 systems offer a fully automated, rapid COVID-19 PCR test. The test has been granted FDA Emergency Use Authorization for the US market.

COMING SOON! QIAprep&amp Viral RNA UM Kit

QIAGEN's novel and innovative QIAprep&amp Viral RNA UM Kit integrates a two-minute liquid-based sample preparation step with real-time PCR detection steps of a COVID-19 test into a single, streamlined process which takes less than one hour to deliver a result. ▷

The kit uses a nasopharyngeal, oropharyngeal or nasal swab suspended in a common transport media, such as Universal Transport Media (UTMTM), as starting material. This is added to an optimized buffer which allows preparation of the sample in under two minutes, before being combined with an RT-qPCR reaction mix for rapid amplification on any thermocycler using any assay. The test is automatable with standard lab equipment and can be scaled to handle up to 2600 samples per eight-hour shift per cycler.

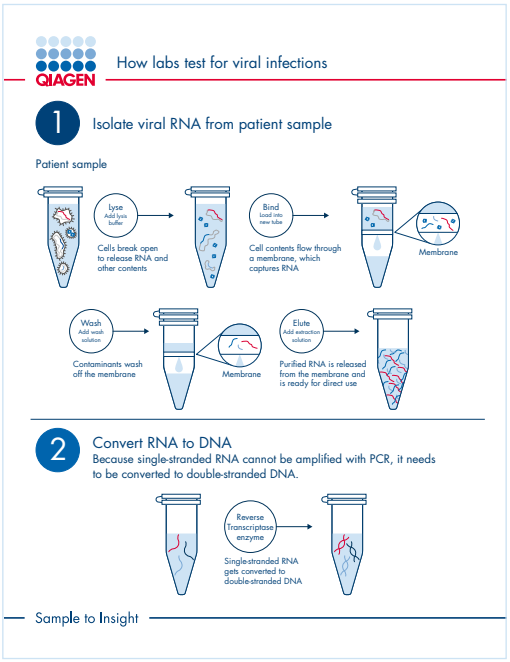
The test will be available for research applications from October 15.

Other products and testing components

QIAGEN also offers a range of solutions used for research into SARS-CoV-2, such as the QIAseq-SARS-CoV-2 Primer Panel which converts viral RNA samples into libraries ready for next-generation sequencing (NGS), and bioinformatics solutions to support COVID-19 drug, vaccine and epidemiology research.

How an RT-PCR diagnostic test for COVID-19 works

Most of coronavirus tests work on the same basic principle, since viruses like SARS-CoV-2 have genomes made of single-stranded RNA molecules. First the viral RNA must be extracted from the sample using a process of lysis (to release RNA from inside the virus), binding (RNA is bound to either silica membrane in QIAGEN's QIAamp Kits, or magnetic beads as in our EZ1 kits), washing (buffers are washed over the bound nucleic acids to remove impurities) and elution (the RNA is recovered from the substrate to give pure RNA). Then in a process called reverse transcription the RNA is converted to DNA. The sections that differentiate the virus are then copied many times using probes or primers that are specific to the viral sequence using a PCR machine. The new copies of the sequence contain fluorescent dyes which can be detected by an instrument called a fluorometer. A fluorescent signal indicates a patient is coronavirus positive, while an absence of fluorescent signal means a patient does not have the disease. This process is called real-time PCR (RT-PCR).



An infographic of this process and how the QIAGEN QIAstat-Dx solution differs can be found at the end of this document.

"Our dedicated task force has moved very fast to develop and make available the QIAstat-Dx respiratory panel with SARS-CoV-2 detection. We are partnering closely with authorities and customers around the world to bring rapid, accurate diagnosis to the fight against the deadly infectious disease. As we have in past health crises such as SARS and the swine flu, QIAGEN is working hard to deliver better, faster testing solutions for hospitals and public health institutions to aid in the effort to monitor and bring the outbreak under control. Our employees' extraordinary response embodies QIAGEN's core mission to make improvements in life possible."

– Thierry Bernard CEO of QIAGEN and Senior Vice President, Head of the Molecular Diagnostics Business Area

"Increased testing is the only way to gain visibility on the magnitude of the pandemic, which will ultimately lead to helping control it. QIAGEN's Access Anti-SARS-CoV-2 is a smart solution for antibody testing that provides results with confidence."

– Davide Manissero, Chief Medical Officer, Infection and Immune Diagnostics

"We have teams in China, Germany, the US and Spain working around the clock to ensure instruments and kits will be available to customers worldwide."

– Alex Boada, Head of Manufacturing, QIAGEN Barcelona

Coronavirus statistics, facts and figures

- The virus has been named "SARS-CoV-2" and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19").
- On March 11, 2020 the World Health Organization raised the COVID-19 outbreak to pandemic status.
- Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats and bats.
- As of September 23th, over 31 million cases of COVID-19 had been diagnosed worldwide with over 970,000 recorded deaths.
- As of September 23th, cases of COVID-19 had been detected in 213 countries, areas and territories.

Further Information about QIAGEN's coronavirus testing solution

www.qiagen.com/gb/insights-magazine/qiagen-supports-healthcare-workers-around-the-world-in-the-fight-against-coronavirus
www.qiagen.com/us/insights-magazine/a-rapid-response-to-covid-19
corporate.qiagen.com/newsroom/press-releases/2020/20200226_coronavirus/

Coronavirus statistics, facts and figures

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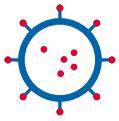
COVID-19 tests explained

	PCR TEST	ANTIGEN TEST	ANTIBODY TEST
			
INFECTION STAGE	**Viral RNA** **Current infection**	**Protein from the viral surface (antigen)** **Current infection**	**Antibody produced by the human body in response to SARS-CoV-2 infection** **Past infection**
TEST SOLUTIONS	PCR tests measure viral RNA which can be live, dead or viral fragments. These are currently considered the gold-standard test for SARS-CoV-2 detection. **TARGETED** Targeted tests detect a specific section of RNA from the SARS-CoV-2 genome, and can determine if a patient is carrying the virus. **SYNDROMIC** Syndromic tests detect not only SARS-CoV-2 RNA, but also nucleic acids from a variety of respiratory pathogens causing acute respiratory illness with nearly indistinguishable signs and symptoms.	SARS-CoV-2 antigen tests detect viral antigens (proteins produced by the virus) that are present during an active infection, from a nasal swab sample	Antibody tests detect markers of the immune response (immunoglobulin, or Ig) specific to the SARS-CoV-2 virus, from blood samples. These markers remain in the blood even after recovery from the disease, and can even be present following asymptomatic infection.
TURN AROUND TIME	Up to 24h[1] From 1h	<15 minutes	<15 minutes

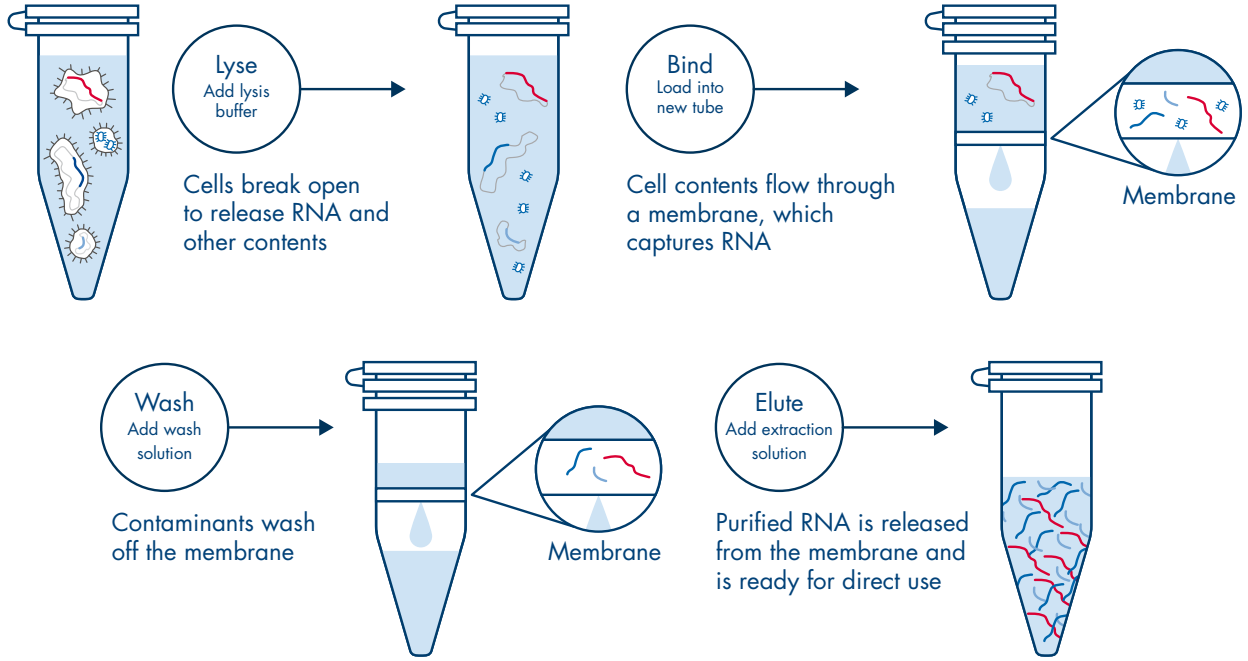
[1] Includes sample collection and delivery time to central lab.

Click here to view full infographic.

How labs test for viral infections

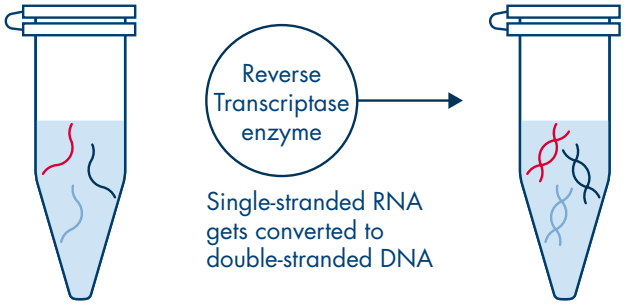
1 Isolate viral RNA from patient sample

Patient sample



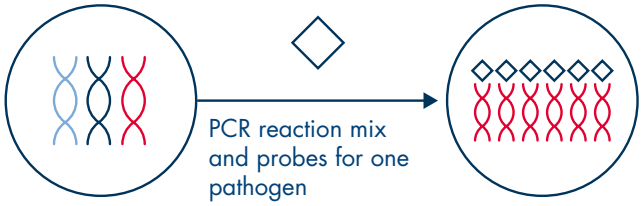
2 Convert RNA to DNA

Because single-stranded RNA cannot be amplified with PCR, it needs to be converted to double-stranded DNA.



How labs test for viral infections

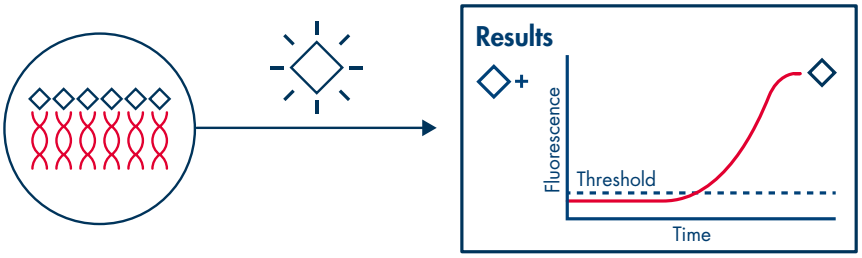
3 Generate large amounts of viral DNA for detection



The viral DNA exponentially amplifies in a PCR reaction that is specific to the pathogen. A fluorescent probe gets added to the amplified DNA to enable downstream detection.

4 Virus detection

The fluorescent signal of the probe is measured over time and relates to the amount of DNA present in the sample.

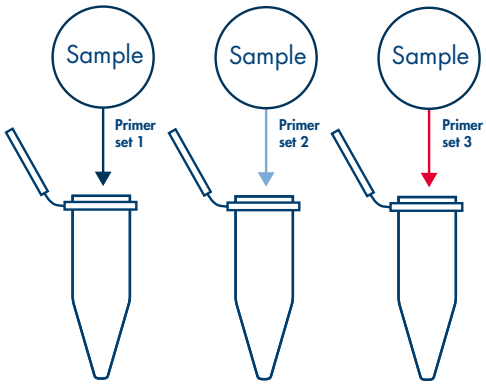


A result is positive for a specific virus when the fluorescence is greater than a defined threshold.

The difference between singleplex PCR and multiplex PCR

Singleplex PCR: single reaction in one tube

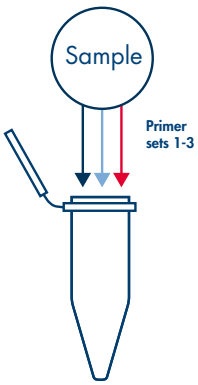
Each reaction can detect **1 target**



- Cumbersome
- Get answer for 1 target
- More risk for error and contamination

Multiplex PCR: multiple reactions in one tube

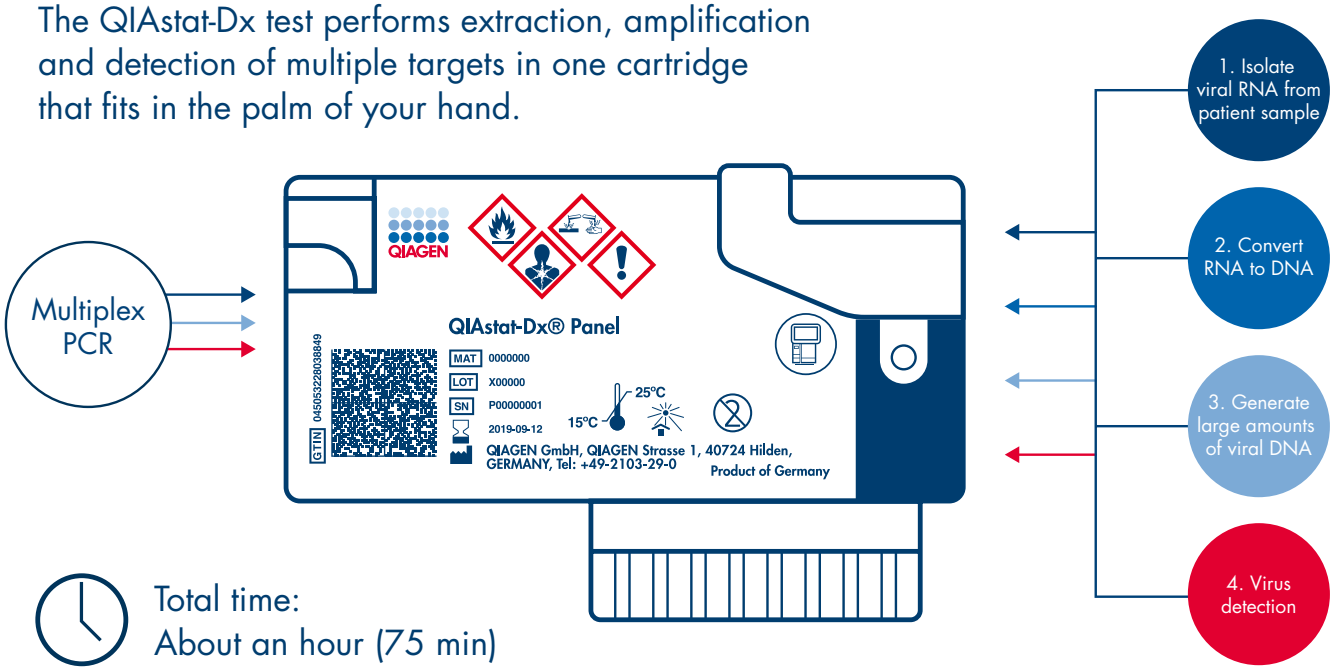
Each reaction can detect **multiple targets**



- Save time and resources
- Get answers for multiple targets
- Faster diagnosis

How the QIAstat-Dx test does it all

The QIAstat-Dx test performs extraction, amplification and detection of multiple targets in one cartridge that fits in the palm of your hand.

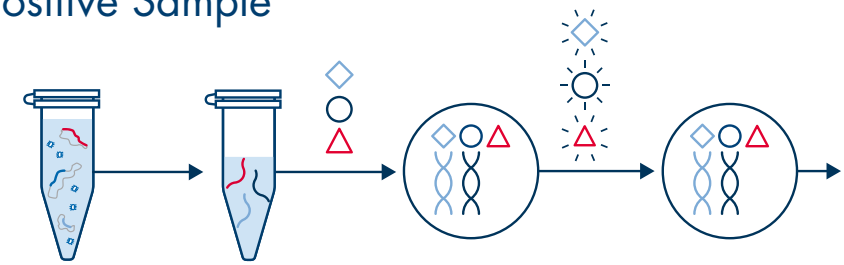


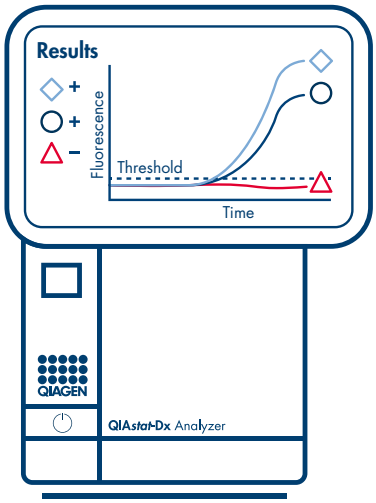
Total time:
About an hour (75 min)

Interpreting results on the QIAstat-Dx

1. Isolate viral RNA from patient sample
2. Convert RNA to DNA
3. Generate large amounts of viral DNA
4. Virus detection

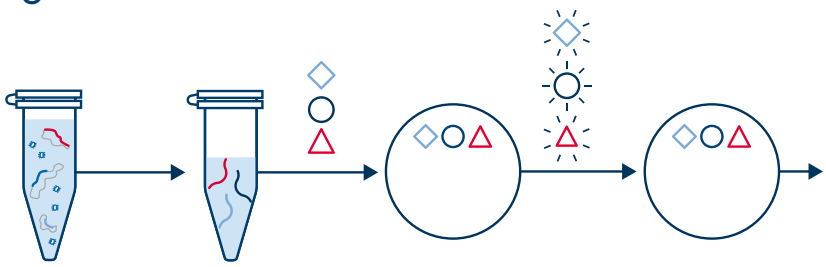
Positive Sample

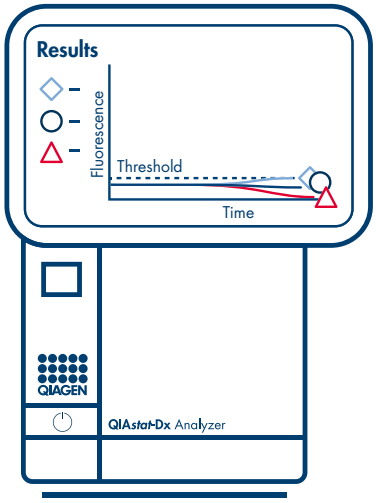




Amplification **occurred for 2 targets**, while there was no amplification for the third target. Thus, there are **2 positive results and 1 negative result**.

Negative





Amplification **did not occur** for any targets, leading to no change in fluorescence. Thus, there are **3 negative results**.

COVID-19 tests explained

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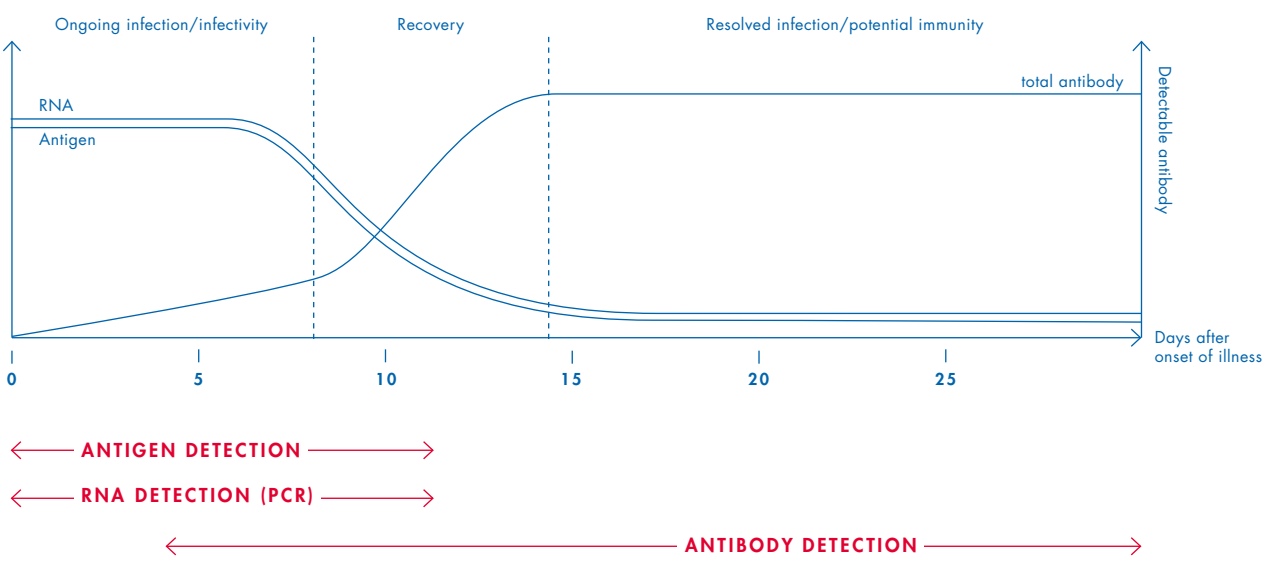
	PCR TEST	ANTIGEN TEST	ANTIBODY TEST
INFECTION STAGE	**Viral RNA** **Current infection**	**Protein from the viral surface (antigen)** **Current infection**	**Antibody produced by the human body in response to SARS-CoV-2 infection** **Past infection**
TEST SOLUTIONS	PCR tests measure viral RNA which can be live, dead or viral fragments. These are currently considered the gold-standard test for SARS-CoV-2 detection. **TARGETED** Targeted tests detect a specific section of RNA from the SARS-CoV-2 genome, and can determine if a patient is carrying the virus. **SYNDROMIC** Syndromic tests detect not only SARS-CoV-2 RNA, but also nucleic acids from a variety of respiratory pathogens causing acute respiratory illness with nearly indistinguishable signs and symptoms.	SARS-CoV-2 antigen tests detect viral antigens (proteins produced by the virus) that are present during an active infection, from a nasal swab sample	Antibody tests detect markers of the immune response (immunoglobulin, or Ig) specific to the SARS-CoV-2 virus, from blood samples. These markers remain in the blood even after recovery from the disease, and can even be present following asymptomatic infection.
TURN AROUND TIME	Up to 24h[1]	From 1h	<15 minutes	<15 minutes
USAGE	For testing symptomatic patients and screening of asymptomatic patients, including pre-operative patients. Typically run in a core lab or large hospital lab.	For testing patients exhibiting severe respiratory symptoms, needed for differential diagnosis to guide clinical management decisions such as treatment.	For high volume screening of people with or without symptoms at the point-of-care (e.g. airports, schools, cruise ships, stadiums, doctors offices).	This is useful in understanding the spread of the disease, and will be important to monitor the success of new vaccines against the virus.
QIAGEN'S SOLUTION	**The NeuMoDx System[2]** A high-throughout, automated SARS-CoV-2 PCR testing solution, able to provide a result in one hour. Currently available with a targeted SARS-CoV-2 test. A syndromic test on this device for influenza, RSV and the SARS-CoV-2 virus is coming soon.	**The QIAstat-Dx Syndromic Testing System[3]** A rapid multiplex testing device, able to differentiate SARS-CoV-2 from 20+ other respiratory pathogens, including viruses and bacteria, in around one hour. The QIAstat-Dx provides a qualitative result. Ct values and amplification curves are provided.	**QIAreach SARS-CoV-2 Antigen Test[4]** Coming soon A rapid portable test that can detect SARS-CoV-2 antigens in less than 15 minutes and process around 30 swab samples per hour using a small digital detection system.	**QIAreach Anti-SARS-CoV-2-Total Test[5]** Not available in all markets An easy-to-use digital test run on a portable device, that detects antibodies from blood samples of people potentially exposed to the SARS-CoV-2 virus and provides a result within 10 minutes.

[1] Includes sample collection and delivery time to central lab.

TIMECOURSE



A COVID-19 test for multiple situations

QIAGEN is building the most comprehensive portfolio of COVID-19 testing solutions for research and diagnostics. In addition to the solutions shown, we also offer viral RNA extraction kits, sample automation solutions (QIAsymphony, QIAcube and EZ1) and PCR reagents for use in lab developed tests, plus dedicated NGS panels and bioinformatics tools for use in COVID-19 research.

Find out more about QIAGEN's complete COVID-19 testing portfolio at *www.qiagen.com/coronavirus*.

[2] The NeuMoDx™ SARS-CoV-2 Test Strips are intended for in vitro diagnostic use.
For the US version:
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

[3] The QIAstat-Dx Respiratory SARS-CoV-2 Panels are intended for in vitro diagnostic use.
For the US version:
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity and moderate complexity tests.
- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

[4] The QIAreach™ SARS-CoV-2 Antigen Test is currently under development and

[5] The QIAreach™ Anti-SARS-CoV-2 Total Test product availability may vary by country specific regulatory requirements and approvals. Contact your country representative for further details.
- This test has not been reviewed by the FDA.
- 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.
- 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.
- 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.

Product availability may vary by country specific regulatory requirements and approvals. Contact your country representative or visit *www.qiagen.com* and *www.neumodx.com* for further details.