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 continue to be crucial as countries face a second wave of infection and struggle to deal with the approaching flu season.

A need for timely testing

Quick action is needed to determine a timely diagnosis and contain the coronavirus pandemic sometimes even on location. As the northern hemisphere readies itself for the flu season, tests that can differentiate between SARS-CoV-2 and influenza will play an increasingly critical role in ensuring patients receive appropriate treatment. Even with the first promising vaccines appearing on the horizon, diagnostic tests will continue to play an important role over the months to come: initially in tracking, tracing and containing infection as COVID-19 vaccination programs are established and the vaccine gradually distributed, and later to monitor the immune response in the vaccinated population. Different diagnostic tools are needed to meet these various needs.

QIAGEN's COVID-19 molecular testing solutions

QIAGEN has an industry leading track record in providing molecular tests that have been widely used in previous viral outbreaks such as SARS (also a form of coronavirus), Avian and Swine flu. Our long-standing relationships with the WHO, and CDC mean that we are well placed to act fast in emergency outbreak situations.

From the earliest 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 a comprehensive portfolio of COVID-19 testing solutions, covering the needs of clinical and research customers.**

Our suite of COVID-19 tests for clinical and research applications include tests for both current and past infections. This infographic gives an overview of these different tests and their uses.

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

Tests for current COVID-19 infection

PCR tests

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.

QIAstat-Dx Respiratory SARS-CoV-2 Panel

This multiplex PCR test can differentiate SARS-CoV-2 from 21 other pathogens implicated in serious respiratory syndromes. The panel runs on QIAGEN's QIAstat-Dx instrument and can **deliver a result in about one hour with minimal hands-on time**. This test has the advantage of guiding patient diagnosis whether a person turns out to be positive for the COVID-19 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.

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.

NeuMoDx

The NeuMoDx 96 and 288 systems offer a rapid, high throughput and fully automated PCR test for COVID-19 that can deliver a result within an hour. Two tests are currently available on the instruments:

- The single-plex NeuMoDx SARS-CoV-2 diagnostic test for use with nasopharyngeal swabs has been granted emergency use authorization by the FDA and CE-IVD status. **In November 2020, CE-IVD approval was also obtained for use with saliva samples**. The saliva claim extension is currently in review with the FDA.
- The multiplex NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage test, which **can detect COVID-19, influenza and respiratory syncytial virus (RSV)**, received CE-IVD registration in November 2020, and has been submitted to the FDA for EUA consideration.

TThe NeuMoDx 96 and 288 systems offer a fully automated, rapid COVID-19 PCR test.

The NeuMoDx is ideal for use in hospitals or central testing labs which receive large numbers of patient samples.

Kits and instruments supporting laboratory developed tests (LDTs)

QIAGEN's sample preparation kits and lab automation instruments are used by labs around the world as an integral part of LDTs. They also feature in the CDC's recommended protocol for COVID-19 testing.

Products used in COVID-19 applications include the EZ1 DSP Virus kits which run on EZ1 Advanced workstations; QIAamp DSP Viral RNA Mini kits, which can be automated on QIAcube instruments; and the QIAsymphony instrument which provides complete automation of sample preparation and PCR analysis.

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

QIAprep&amp Viral RNA UM Kit

QIAGEN's QIAprep&amp Viral RNA UM Kit integrates a two-minute liquid-based sample preparation step with a real-time PCR detection step. From start to finish it takes less than one hour to deliver a result. Because this is a consolidated test, it requires only two pipette tips vs the ten usually needed for a typical PCR test, thereby reducing the impact of resource bottlenecks. The test is automatable with standard lab equipment and can be scaled to handle up to 2,600 samples per thermo cycler per eight-hour shift.

The kit can be used to detect targets from any RNA virus, including COVID-19, making it highly flexible.

The test is available for research applications. An EUA submission and a CE-IVD registration is expected as early as by the end of the year.

Antigen tests

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.

QIAreach SARS-CoV-2 Antigen Test

This rapid, portable test detects the SARS-CoV-2 nucleocapsid protein on nasopharyngeal swabs from people with active COVID-19 infection. Up to eight patient samples can be analyzed in parallel on the digital eHub detection instrument, or up to 30 per hour. An unambiguous, qualitative result is delivered in 2–15 minutes. Testing of clinical samples has shown the test to have a sensitivity of 90% and a specificity of 100%.

The same eHub can also be used to simultaneously run the QIAread Anit-SARS-COV-2 Antibody Test.

The QIAreach SARS-CoV-2 Antigen Test is being marketed and distributed in the US after applying for FDA emergency use authorization (EUA) for symptomatic patients. CE-IVD registration for the EU and other markets is expected by the end of the year

The new QIAreach SARS-CoV-2 Antigen test.

Tests for previous COVID-19 infection

Antibody tests

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.

QIAreach Anti-SARS-CoV-2 Total Test

This serology test detects markers of the adaptive immune response (total immunoglobulin – IgA, IGM and IgG) in people who have had a recent or prior SARS-CoV-2 infection.

The new serological test runs on an easy-to-use and portable digital device (eHub) 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.

Other products and testing components

QIAGEN 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. We also supply reagents to other companies for use in their own COVID-19 tests.

"Our products have widespread real-world impact, and this crisis amplifies this for us. When a customer in Minnesota tells us how extremely grateful he is for a rapid and accurate negative COVID-19 result, because it cleared a dying patient to be visited by his family, we know our work is making a difference."

– 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 November 16th, nearly 60 million cases of COVID-19 had been diagnosed worldwide with over 1.3 million recorded deaths.
- It is estimated the the US alone is currently testing at a rate of 1.5 million COVID-19 tests per day.

Further Information about QIAGEN's coronavirus testing solution

www.qiagen.com/customer-stories/latest-news-on-the-fight-against-coronavirus

www.qiagen.com/customer-stories/suppliers-behind-the-front-lines-of-covid-19

Coronavirus statistics, facts and figures

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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.

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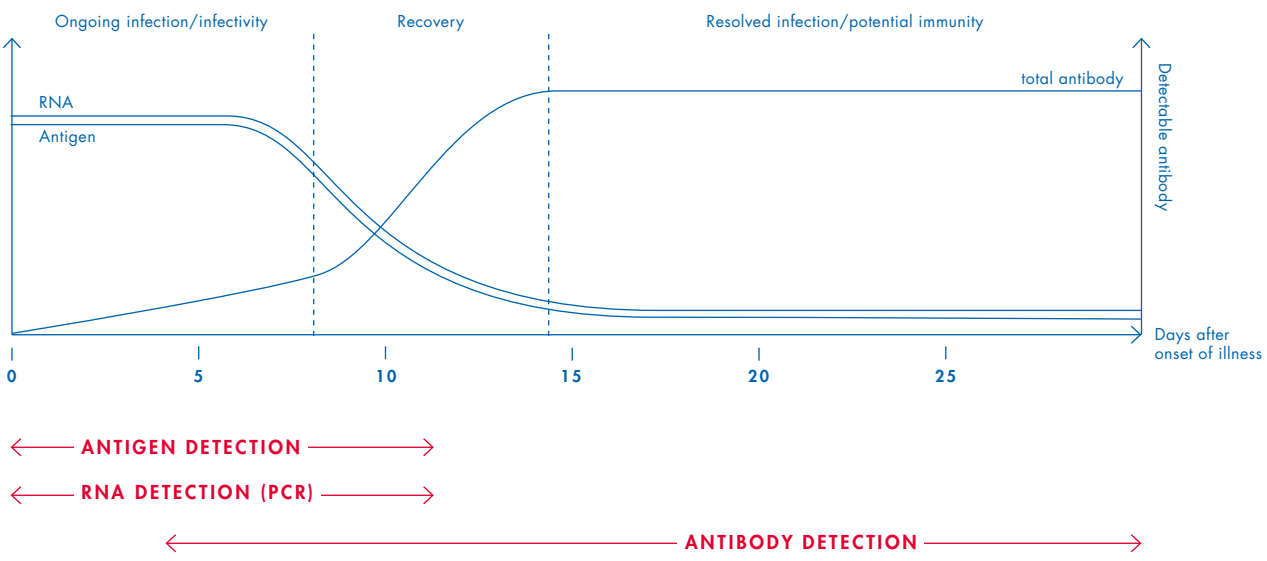

A COVID-19 test for multiple situations

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.