



QIAGEN heading the fight against Coronavirus

Despite containment efforts, the COVID-19 coronavirus outbreak caused by the SARS-CoV-2 virus, is rapidly spreading across the globe with new cases showing up daily in Asia Pacific, Europe, the US, and South America. Declared a Public Health Emergency and raised to pandemic status by the World Health Organization on March 11th, it is becoming critical to identify and isolate new patients and those who have come into contact with them. As more people are exposed, the global need for rapid diagnostics during the ongoing coronavirus outbreak will play a crucial role in containing the spread.

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 the public health system to help treat patients and 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 research at the beginning all the way to screening, 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 prep 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. Since January **we have increased our output of viral RNA extraction kits from 400,000 tests per month to 3.3 million per month in March, with a goal to produce 20 million per month by October.**

Our suite of solutions include:

QIAstat-Dx Respiratory 2019-nCoV 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 test for multiple 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 point-of-care testing in situations where a result is needed quickly (for example in airports, at borders 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). The panel is also CE-IVD marked which means it is authorized for diagnostic use in Europe.

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



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. QIAGEN is working on enabling customers to use this system for lab developed RT-PCR tests. **The QIASymphony is ideal for use in hospitals or central testing labs which receive large numbers of patient samples.**



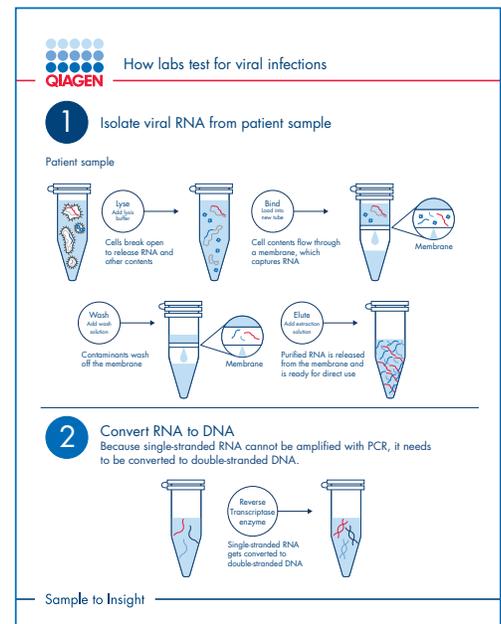
The EZ1 Advanced instrument which automates the critical RNA extraction step of the COVID-19 test

Other products and testing components

QIAGEN also offers a range of solutions used for research into SARS-CoV-2, such as bioinformatics with our QIAGEN Digital Insights Portfolio and QIAseq NGS solutions that are being used to investigate potential drug and vaccine candidates. Finally, QIAGEN's development pipeline includes additional diagnostic solutions such as RT-PCR and serology assays.

How a 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

"Syndromic testing is useful in airports, on borders, on cruise ships-location in which it becomes critical to isolate the patient and those who have come into contact with them."

– 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 January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a "public health emergency of international concern."
- Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats and bats.
- As of April 27th over three million cases of coronavirus had been diagnosed worldwide with 207,262 deaths recorded.
- As of April 27th cases of coronavirus had been detected in 210 countries, areas or 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

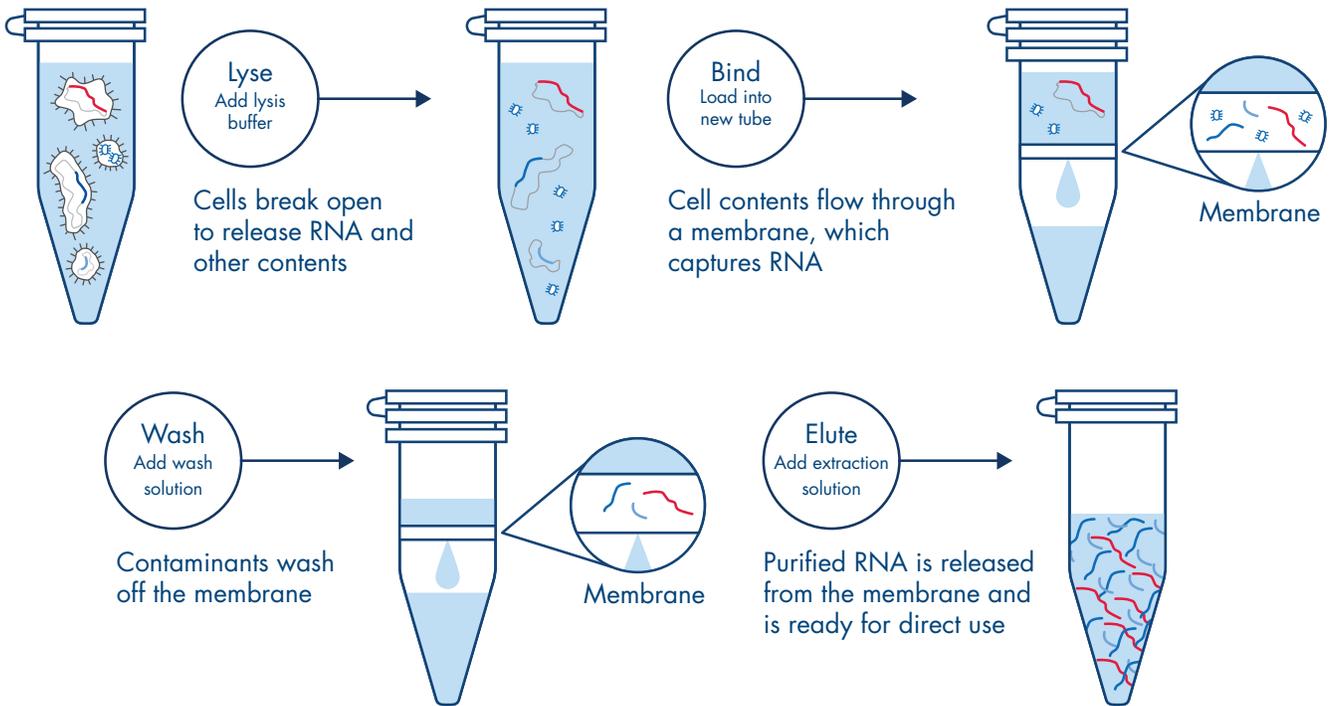
corporate.qiagen.com/newsroom/press-releases/2020/20200226_coronavirus/

Coronavirus statistics, facts and figures

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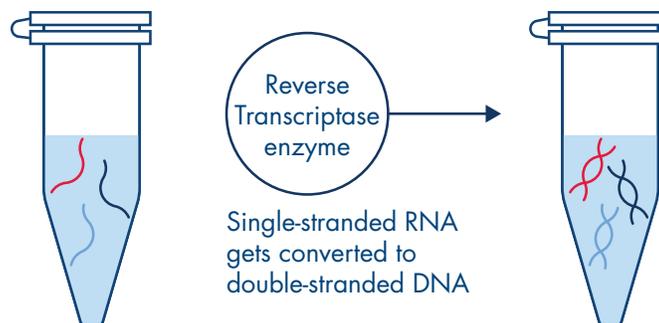
1 Isolate viral RNA from patient sample

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.



3

Generate large amounts of viral DNA for detection

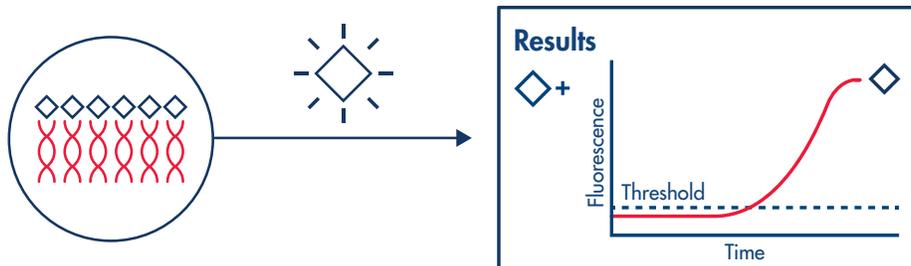


The viral DNA exponentially amplifies in a PCR reaction that is specific to the pathogen. A fluorescent probe gets added to the amplified DNA to enable downstream detection.

4

Virus detection

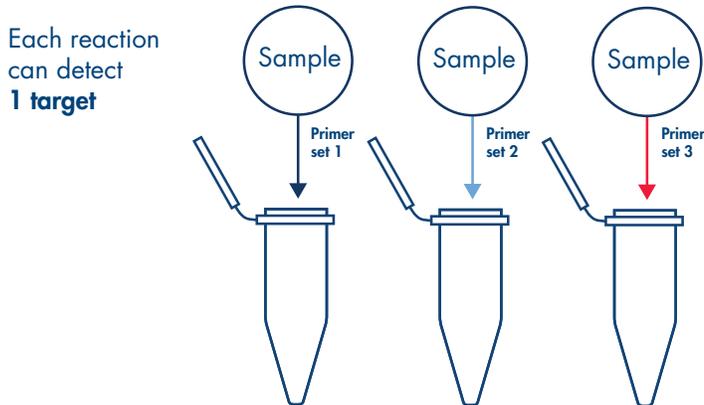
The fluorescent signal of the probe is measured over time and relates to the amount of DNA present in the sample.



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

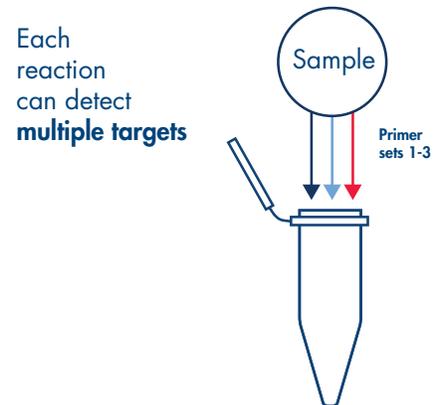
The difference between singleplex PCR and multiplex PCR

Singleplex PCR:
single reaction in one tube



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

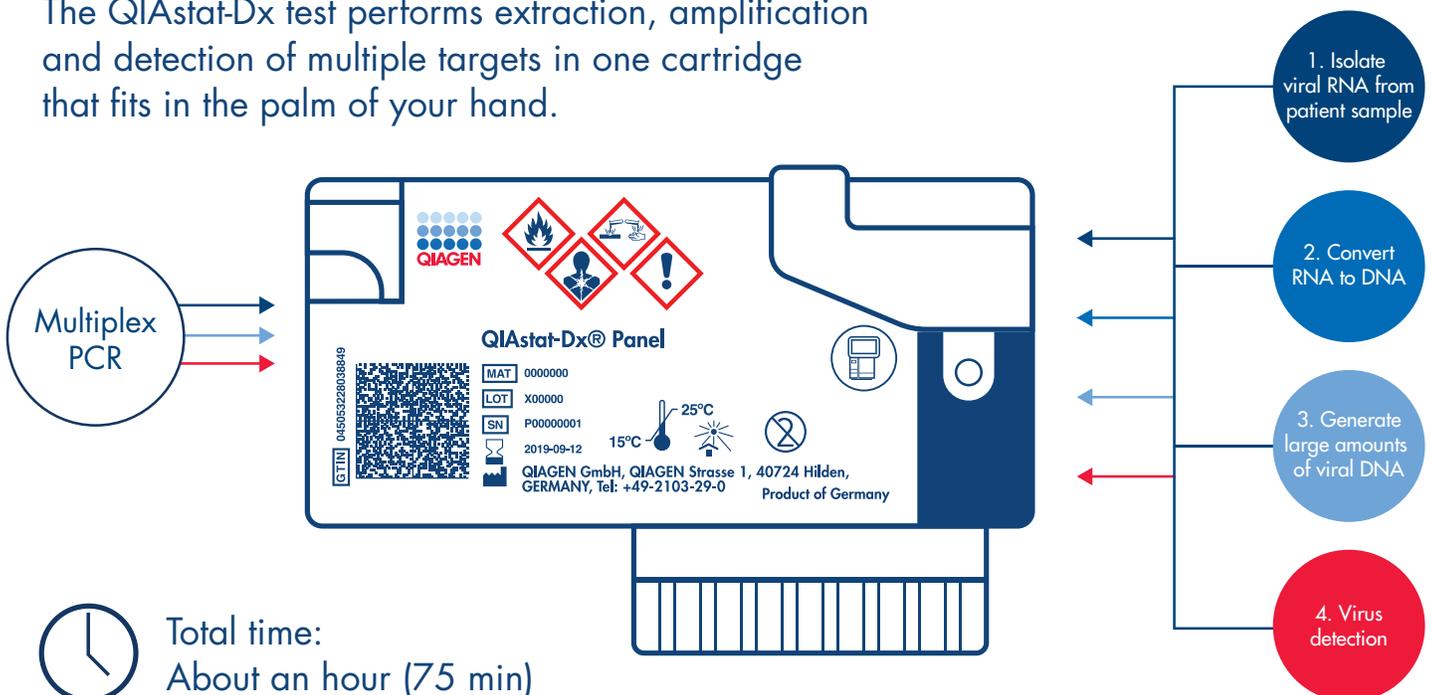
Multiplex PCR:
multiple reactions in one tube



- 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.



Interpreting results on the QIAstat-Dx

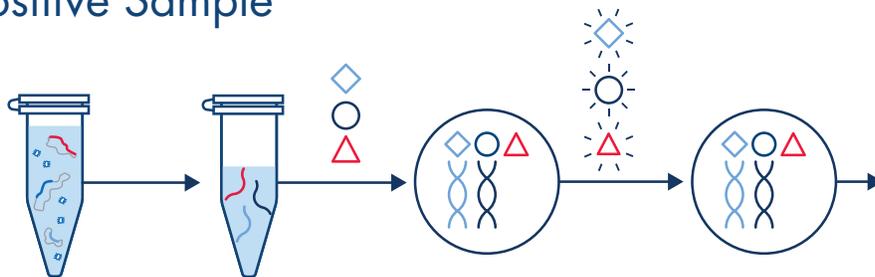
1. Isolate viral RNA from patient sample

2. Convert RNA to DNA

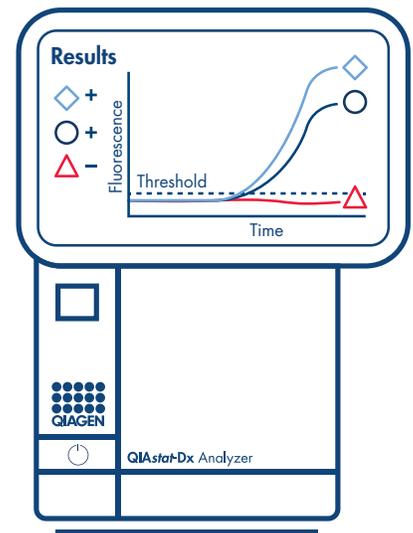
3. Generate large amounts of viral DNA

4. Virus detection

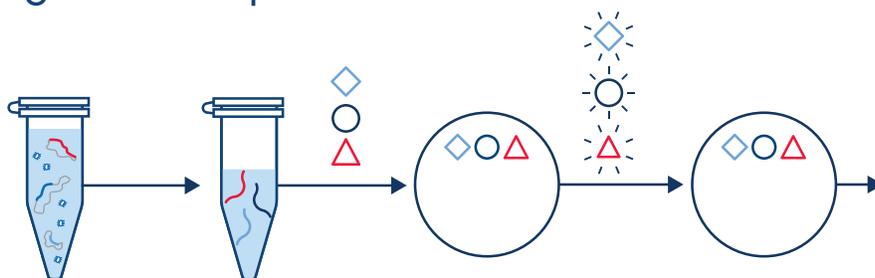
Positive Sample



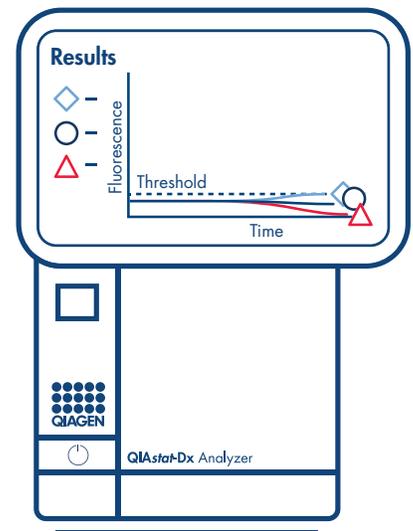
Amplification **occurred for 2 targets**, while there was no amplification for the third target. Thus, there are **2 positive results and 1 negative result**.



Negative Sample



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



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