### INSIGHTS MAGAZINE 2021















### THE PANDEMIC



Sample to Insight is our strategic framework that puts the needs and challenges of our customers front and center.

We identify the key challenges holding customers back and deliver solutions so they can achieve greater success, ultimately helping them exceed their own expectations and gain the insights critical for their work.

Beyond the Pandemic. Celebrating a goal or a home run in a packed stadium. Taking to the dance floor at a family wedding. Meeting friends for a drink or chatting with colleagues over lunch. The pleasures and freedoms we took for granted have been put on hold by a rampant virus that crossed all borders and brought normal life to a halt. And it reminded us of our mortality, our vulnerability.

Like the rest of the world, QIAGEN had to quickly adjust. We also reacted with agility and urgency to join the fight against the pandemic. We developed new tests in record time, and then produced them in mass quantities. We strove to help large numbers of people return to work safely and a semblance of normal life.

Internally, we adopted new ways to work and communicate. Externally, we had to stabilize our supply chains. Yet while we are COVID-relevant, we are not COVID-dependent.

As vaccination rates rise, a post-pandemic era is coming into view. And if another pandemic were to strike in the future, we have all learned valuable lessons and will be fully prepared. Times remain uncertain, but innovations are pointing ahead. Sometime soon, we'll all be heading back out on to the dance floor, to the beach, on a long-distance journey – and to a life beyond the pandemic.

### OUR CULTURE OF EMPOWERMENT

We foster a culture of empowerment, driven by a focus on achieving targets.



Decentralized decision making



Setting ambitious targets



Creating a culture

### OUR PEOPLE

The greatest strength of QIAGEN is our people.

Their diversity, energy, expertise
and creativity are critical to our success.

>5,600

employees worldwide

> 70

25

4

countries with direct
QIAGEN operations

### OUR FIVE PILLARS OF GROWTH

Sample technologies



Addressing the complete spectrum of biological samples

QuantiFERON



Immune response assays to help fight critical diseases



QIAstat-Dx

Rapid multiplex syndromic testing with a menu of assays

NeuMoD



Bringing the simplicity of clinical chemistry to integrated PCR testing

QIAcuity



Disruptive nanoplate-based digital PCR system

D E V E L O P

V E N T U R E S O M E

DISCIPLINE

LONG-TERM

GROWTH

EMPATHY

TRUST

Beyond the Pandemic. Celebrating a goal or a home run in a packed stadium. Taking to the dance floor at a family wedding. Meeting friends for a drink or chatting with colleagues over lunch. The pleasures and freedoms we took for granted have been put on hold by a rampant virus that crossed all borders and brought normal life to a halt. And it reminded us of our mortality, our vulnerability.

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Our company culture is strongly driven by our business mindset, but culture is a driver in itself. A strong, shared and inspiring culture EMPOWERS each and every QIAGENer to take ownership in our success.



### Jear Friends of GLAGEN,

The last year was one of extraordinary challenges – for people around the world as well as for QIAGEN. Amid a global health crisis and the decision for our company to remain independent, QIAGEN's teams stepped up with passion – and compassion – to help save lives and ensure our future success as a top global provider of molecular testing solutions.

As the COVID-19 pandemic unfolded, we demonstrated to our customers, our shareholders and ourselves the value of our commitment to making improvements in life possible. We are proud of the tireless efforts of QIAGENers across the company in making lifesaving contributions to science and healthcare at this difficult time.

As a critical supplier during the pandemic, our teams worked around the clock to develop new solutions and ramp up manufacturing of key products. Our field service associates continued to meet with customers in hospitals and laboratories with the ambition to leave no one behind. And in our offices around the world, dedicated staff and COVID-testing volunteers have worked steadfastly to make our work environment safe. I would like to pay special tribute to the many QIAGENers affected personally by the virus but who made every effort to return to work as soon as possible and play their part in this tremendous effort to tackle the pandemic. Today, we continue to foster this agility, innovation and empowering spirit with solutions that are paving the way for our long-term growth – now and beyond the pandemic.

Indeed, QIAGEN is COVID-relevant but not COVID-dependent. This pandemic has proven the crucial importance of molecular testing in the research and healthcare value chains. And this has put QIAGEN more than ever before at the center of the revolution in understanding the building blocks of life – DNA, RNA and proteins – leading the way to new benefits and better outcomes for patients and clinicians in the years to come.

To that end, we are training our focus purposefully on the five Pillars of Growth – our largest and most attractive growth opportunities. These include sample technologies, our new digital PCR portfolio, syndromic testing, our multiplex PCR diagnostics platform, and solutions for immune

response monitoring. These are, of course, supported by our continued core business to provide the full range of Sample to Insight solutions.

"As the COVID-19 pandemic unfolded, we demonstrated to our customers, our shareholders and ourselves the value of our commitment to making improvements in life possible."

Equally as important as our commercial success, I value the past year as a medical success. Our focus is on the real heroes – our customers – many of whom have been working on the front lines of the pandemic. We listened to their needs and pulled out all the stops to ensure our products helped them do their jobs successfully. We are truly grateful for their confidence in us and for the privilege to serve them, now and in the future.

At QIAGEN, we are also transforming our corporate culture to instill a business mindset in every QIAGENer, regardless of their role. Through our EMPOWER initiative, we are sparking untapped energies and

developing our associates with knowledge, skills and tools to make decisions, be accountable for their actions and execute efficiently. Changing a culture is a journey that goes hand in hand with investments in our QIAGENers and in growth-driving products for the future.

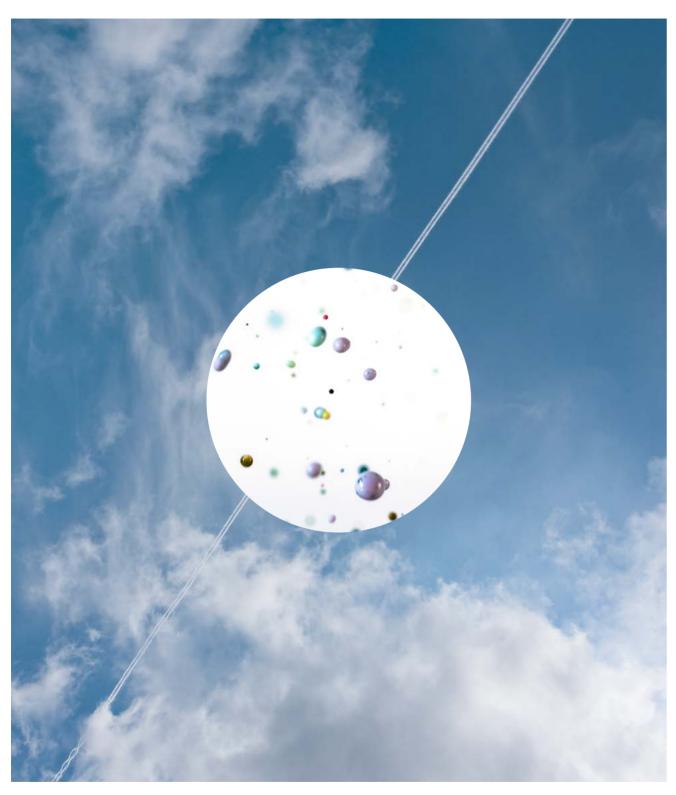
Just as 2020 was a year of stepping up to meet changes and challenges, 2021 and beyond will be a time of accelerating opportunities through an unwavering focus on our five Pillars of Growth. As a strong, independent, sharply focused company, our roadmap sets specific goals to serve our customers and markets while creating long-term value for our stakeholders, including our shareholders and employees.

My colleagues in the Executive Committee and I look forward to hearing from and interacting with you – our stakeholders – as we move forward in this exciting time of dynamic development and growth. As we look beyond the pandemic, this is the time for us to seize the opportunities ahead and prove our value – and to do so with passion and unrelenting focus.

As we all hope to begin emerging from these difficult times around the world, I would like to wish you and those close to you all the very best, particularly in terms of health.

With kindest regards,

Thierry Bernard
Chief Executive Officer



### Weightlessness research

Gravity, a constant force throughout the evolution of life on Earth, influences the architecture and function of cells, as well as entire organisms. In experiments performed on microgravity platforms, like parabolic flights with an Airbus A310 Zero G, scientists in Zurich are studying the impact of the Earth's gravity on chromatin and gene expression regulation in immune cells. Their goal is to determine which molecules switch certain genes on or off under hypergravity and microgravity conditions, and if this reaction is encoded by the genes' geometric position. These insights could tell us if humans are suited to living permanently in weightlessness, or under the different gravitational forces of other planets.



### Warming the cold

Tundra soil of the northern hemisphere's permafrost regions accounts for a mere 15% of the total global land mass, but contains roughly half of all carbon stored in our planet's soil. Norwegian scientists have noted that warming over just 18 months stimulates rapid, microbe-mediated carbon decomposition, while experimental winter warming over five years fundamentally restructures microbial communities. This matters – alarmingly so – because it demonstrates that carbon loss in soil is unlikely to subside as a result of such changes in microbial community composition.



### From stray dogs to space travel

Stray dogs in Chernobyl may offer a unique opportunity to reveal the secrets to success for interstellar travel. Biologists at the University of South Carolina, US, together with the Clean Futures Fund, are studying packs of dogs roaming the former site of the catastrophic 1986 nuclear reactor. The area remains contaminated with gamma radiation similar to that which astronauts would encounter in deep space. Examining changes in the animals' genetics and microbiome, the study aims to uncover biological mechanisms that create tolerance to radiation effects, and which one day might help protect human space travelers.



### Similar or identical?

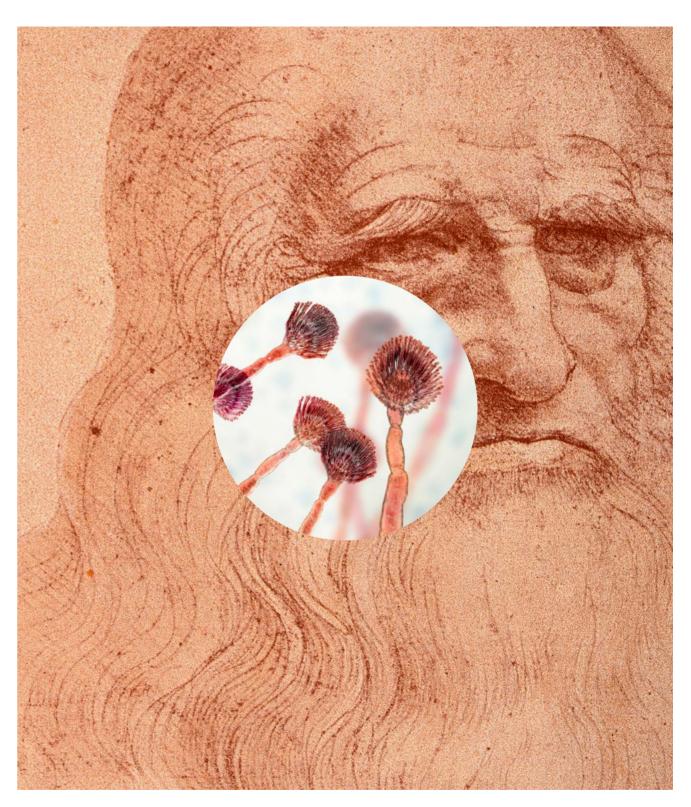
Identical twins develop from a single fertilized egg and possess exactly the same DNA sequences, but they are not as identical as previously assumed. According to researchers at the Iceland-based company deCODE, monozygotic twins accumulate genetic variation beginning at the earliest stages of development, meaning that one twin harbors variants that aren't present in the other. The mutations occur as or before the inner cell mass in the uterine wall splits to form two separately developing embryos. The study suggests using the term "similar twins," instead of identical twins.

### THE FASCINATING WORLD OF MOLECULAR SCIENCE



### Mozart in a musical molecule

Scientists at the ETH University, Zurich, stored the 52 pages of sheet music from Mozart's string quartet "The Hunt" – more than 100 kilobytes of data – in 16,383 DNA sequences. Exploring the storage of data in synthetic DNA is a global trend: a tiny smear could hold 10,000 Gigabytes of data. But using the magic molecule to store data isn't practical yet, because the process of synthesizing DNA in a lab, encoding it, and retrieving the data is expensive. The scientists in Zurich have developed what they call a "massively paralleled," and thus cheaper, method to produce DNA strands at scale.



### What is art?

In the case of Leonardo da Vinci's self-portrait, one answer is the cellulose of the canvas support material, the ground layer of animal glue and gypsum, and the linseed oil layer. These compounds provide not just pleasure for the viewer but nutrients for microorganisms on a painting's surface. Scientists at Vienna University studied the bacteria and fungi colonizing on a canvas with visible signs of biodeterioration, finding bacterial strains like Firmicutes and Proteobacteria, and fungi like Penicillium and Saccharomycetales. While art may nourish the soul, these microorganisms literally thrive on it, creating a microbiome as unique as the work of art itself.

























### DNA EXTRACTION Save the corals

Marine biologist Bry Wilson from Oxford University takes us on a voyage to discover the role sampling and sequencing can play in saving the world's rarest corals.

### **50**

### YOUNG SCIENTISTS

### Scientists of Instagram

Two young scientists tell us about their research and why they are turning to social media platforms to connect with the science community.



### Scientists and health practitioners around the world are working to eliminate TB. Leading the way in the fight is the Harvard University-led

38

TESTING

COVID-19 lab

STREAMLINED

Airport lounge turned

Epidemiologist Rome

how in-airport testing

Buathong explains

could be the pass-

port to reactivating

Thailand's tourism

TUBERCULOSIS

Zero TB Initiative

Zero TB Initiative.

industry.

**52** 

### **58** MULTI-PLEX PCR

Travel health activism Richard Dawood of London's Fleet Street Clinic describes how his passion for travel set him on the path to testing tropical diseases, and now COVID-19.



### DIGITAL PCR

The answers are in the sewage Scientists from opposite ends of the world tell us why digital PCR is creating ripples in the disease monitoring community.







Read our stories and our 2020 Annual Report at financialreport.qiagen.com

### of growth" Business area heads

12

INTERVIEW

"We are ruthlessly

focused on five pillars

Thomas Schweins. Jonathan Sheldon discuss an eventful 2020 and give a glimpse of what is to come in the year ahead.

Jean-Pascal Viola and

20

The pandemic year A virus brought nations to their knees, but also led to unprecedented acceleration in biotechnological

are turning the tide

on COVID-19.

### CHRONOLOGY OF GLOBAL A PANDEMIC RESPONSE

developments. Explore the discoveries that

### Leaving no one behind

26

QIAGEN's global teams of employees and supply chain network stepped up to the challenges set by COVID-19. These are their stories.

### 28

### SYNDROMIC **TESTING**

### From crime scene to COVID-19

When COVID-19 struck, Michelle Volk, CEO of Great Lakes forensics labs, wanted to make a difference. She describes her journey from crime scene investigation to COVID-19 testing with QIAstat-Dx.

### **32**

### EXPERT OPINION

### **Turning expertise** to a new challenge

Two experts in the fields of tuberculosis management and cancer immunology explain how their specialist knowledge has provided insights into the COVID-19 problem, and where they see the future of testing.



C U S

**Thomas Schweins** Senior Vice President, Head of Life Sciences



QIAGEN excelled at handling the unique challenges of the global crisis and is poised for growth in 2021



Jean-Pascal Viola Senior Vice President, Head of Molecular Diagnostics and Corporate Development

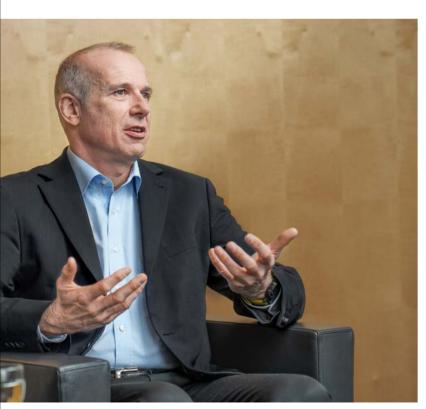
Jonathan Sheldon
Senior Vice President,
Head of QIAGEN
Digital Insights

PILLARS

We gathered the heads of QIAGEN's three business areas, Thomas Schweins (Life Sciences), Jean-Pascal Viola (Molecular Diagnostics) and Jonathan Sheldon (Digital Insights) for a chat about tackling the pandemic, developing tools in areas such as TB and Lyme disease, and hot topics such as diversity and sustainability. We kicked off the discussion with...

"In life sciences, sample technologies have been an essential foundation of fighting the pandemic."

Thomas Schweins



...the pivotal and challenging year 2020...

THOMAS SCHWEINS QIAGEN shifted gears to play a crucial role in tackling COVID, and we showed how swiftly we can react when faced with sudden market demands. In life sciences, sample technologies have been an essential foundation of fighting the pandemic. We offered our customers COVID products for quick Sample to Insight results, and placed instruments where we expect longer-term demand.

JEAN-PASCAL VIOLA That's right. COVID has made molecular testing more relevant than ever. In 2020, several products played a significant role in testing for respiratory illness. Take QIAstat-Dx, which can perform multiple assays at once. So now we're even seeing it in non-hospital settings like airports or on cruise ships. By the end of 2020, we achieved the goal of 2,000 cumulative placements.

...what's ahead in 2021 and the focus on growth...

TS COVID-19 will stay with us for some time, but in 2021 we'll develop both our COVID and non-COVID portfolios. On the COVID side, we have a forthcoming product which makes RNA sequencing much easier, much faster and much cheaper. This will make genomic surveillance more accessible to labs around the world.

JONATHAN SHELDON Let me mention here the new bioinformatics cloud software that enables labs to upload virus sequences and track the emergence of variants. That whole project took literally six weeks from idea to deployment and is a great example of the synergies between Digital Insights and life sciences. As a COVID surveillance system, it will be a valuable tool in fighting the pandemic.

TS Yes, these tools complement each other very well.

In our life sciences non-COVID portfolio we have global responsibility for two out of five pillars of growth – sample technologies and our digital PCR platform, QIAcuity. This year we'll launch a new sample tech system, the EZ2 Connect, replacing the highly successful EZ1 instrument, and will also address the needs of our academic customers. We're also innovating in applications like liquid biopsy and microbial research, where we'll be cross-working with JP's teams.

INSIGHTS BEYOND THE PANDEMIC

The QIAcuity launch turned out to be one of the most successful in our history. We'll build on that success in 2021, focusing on both the dPCR niche and the \$3 billion qPCR market. We're developing an entire ecosystem – instruments, enzymes, plates, tests, content and connectivity – to conduct research. The MDx and Life Sciences teams are joining forces to develop a diagnostic version of this portfolio, and the market here is at least as big as in life sciences.

J-P V On top of that, in Molecular Diagnostics we are focused on our growth pillars. One is our immune response portfolio, where QuantiFERON leads the market in latent TB testing. Upcoming launches include QIA-reach-TB, a test based on QFT for use in low-resource regions, and the QuantiFERON lyme disease test.

We're also expanding our infectious disease business through QIAstat-Dx and NeuMoDx menus, which our customers quickly adopted for COVID-19 testing. Then we expect to add a meningitis panel in Europe and a gastrointestinal panel in the US for 2021. Post-COVID, the company's well placed to address influenza-like illnesses and other respiratory syndromes – especially for at-risk groups, like the immunocompromised.

JS In QDI we have five key initiatives for bioinformatics growth. One, we're building on our foundation of best-in-class applications. Two, growing our online and downloadable databases. Three, new ways to license and deliver content for data scientists. Four, Sample to Insight projects, including the RNA sequencing analysis that's integrating with our GeneGlobe knowledge tool. Last of all, we're building out our partnerships.

...how they're changing QIAGEN culture with the new EMPOWER initiative...

J-P V We want to equip our QIAGENers to make the right decisions, and this means knowing your customer better so you can get a deal done. Efficiency and answers – this is what we are doing with EMPOWER. Our new training tools, like Finance for Non-Financial Managers and Biology for Non-Biologists, are getting everybody on the same page, understanding the basics and driving our business.

TS EMPOWER means clear responsibilities and standardization within a framework that allows decisive action. That is important in fast-moving markets, where quick decisions are vital. That's been our successful philosophy in life sciences now for some time.



INTERVIEW

"COVID has made molecular testing more relevant than ever."

Jean-Pascal Viola



"We're building on our foundation of best-in-class bioinformatics applications."

Jonathan Sheldon

J-P V That's a good point – we are more agile; we're faster. Our goal is the end game, where people truly understand where they fit in the puzzle, and how they can make a difference. Then they're more aware why it's important to cut delays and be on time, on spec, or even ahead of schedule.

JS For me, it's about leading by example – actually walking the walk. I guess it comes down to self-awareness. This may not mean instant, pivotal change, but working day to day to change the company's culture.

### ...how QIAGEN is addressing diversity...

- JS It's critical that the whole organization engages on this. For that to happen, people also have to feel safe in expressing their opinions and views – respectfully and thoughtfully.
- TS Absolutely. Diversity makes us stronger, it makes us better, and it really is a foundation to any society or group of people. This isn't just about gender diversity, but about bringing people together from completely different backgrounds: educational backgrounds, social backgrounds, from various countries and cultures. A diverse team can also produce a fusion of completely new ideas.
- J-P V Yes, when we talk about diversity, we're talking about a lot of things but especially unconscious bias. It's not going to change overnight, but once you are more aware of unconscious bias, you can work on it.

### ...and sustainability...

- TS Sustainability is incredibly important and should be integrated across the board. We need to think about our  $CO_2$  footprint, our waste, and also how we take back certain parts of our value chain and reuse them. We can also learn from the coronavirus crisis. Online meetings like this one used to cost us a lot of  $CO_2$ , because we thought we had to travel to make it work. We can all adjust in all areas: reducing usage, using public transportation. We've increased the number of charging stations here in our parking lots for electric cars, and we've initiatied cutbacks in our plastic packaging.
- J-P V Indeed, we're moving to boxes that don't use styrofoam, and we have clear targets to reduce electricity consumption. Reducing our footprint is more efficient for our business, but it's also our responsibility.

QIAGEN's whole organization is aligned to support our five Pillars of Growth.



Stephany Foster Senior Vice President Human Resources

"We are adapting our HR structures to support our changing strategic focus. Dedicated HR business partners are working directly with sales and service teams within our business areas, which will help streamline processes and bring decision making closer to customers."





Roland Sackers Chief Financial Officer



Barthold Piening Senior Vice President, Head of Global Operations

"In Global Operations, we are making significant changes and initiating projects designed to support our strategy even more effectively. These will provide greater flexibility to our supply systems to support the five Pillars of Growth beyond the pandemic."

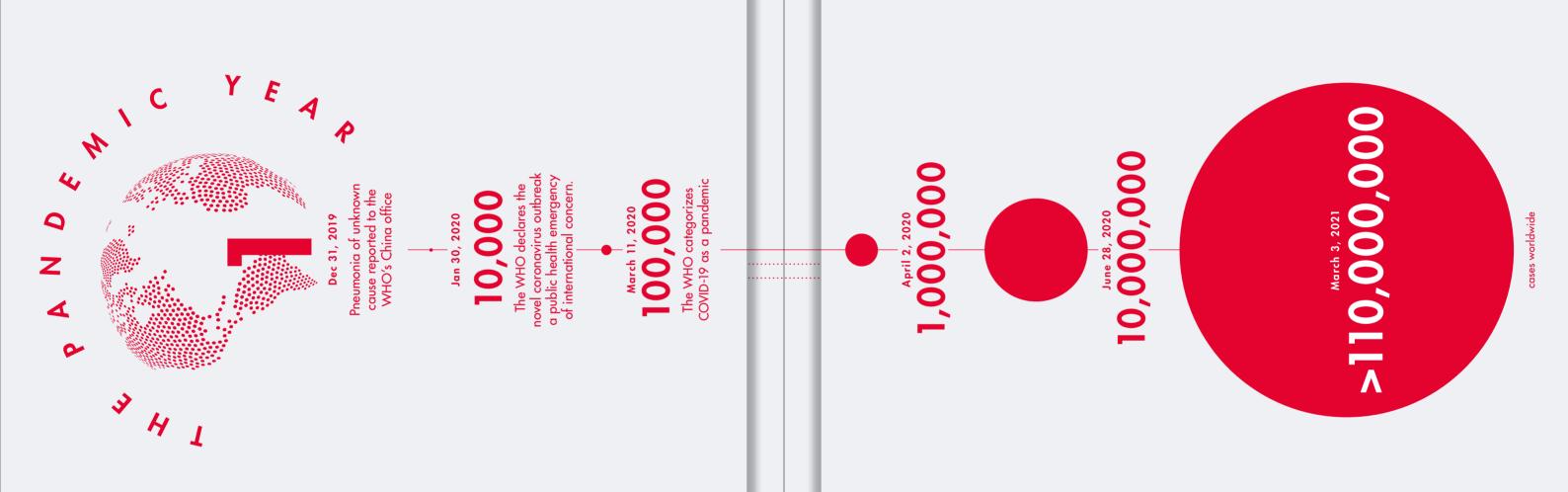
### BEYOND THE



For most of us, COVID-19 began as a seemingly minor disease in a distant part of the world. It was a story too far down the headlines to worry about. Then seemingly overnight, the unknown virus morphed into a pandemic with a deadly global reach. By the time it was taken seriously, it had begun to affect the lives of every human on Earth.

While governments were slow to react, scientists were already at work. As infections soared, QIAGEN developed fast and reliable molecular tests. By ramping up production we made those tests available quickly, and in huge numbers.

Our aim was to stall infection paths with accurate tests that would improve daily lives, and catalyze the return to work, travel and social normality. In short, our aim was to knock COVID-19 back down the headlines.





Jan 9 2020 China reports first death from a new coronavirus – 61-year-old male resident in Wuhan.

Jan 12 First genome sequence of the novel coronavirus is shared by China. QIAGEN starts work developing a test to detect the new virus, based on the QIAstat-Dx Respiratory Panel.

Jan 13 The first case of the novel coronavirus is identified outside of China, in Thailand.

Mid-Jan The German company BioNTech initiates the project "Lightspeed" to develop a vaccine for COVID-19.

2

Immunity tracking

era

2

Genomic surveillance

Jan 20 China declares the outbreak an emergency.

Jan 21 The US Centers for Disease Control and Prevention (CDC) confirms first US coronavirus case.

Dec 30 Dr Li Wenliang an ophthalmologist at Wuhan Central Hospital, China – sends a message to fellow doctors warning about the outbreak of a virus. What Dr Li didn't know: it's an entirely new coronavirus.

Dec 31 2019 Pneumonia of unknown cause reported to the WHO's China office.

Feb 3 US declares public health emergency.

Feb 6 Dr Li Wenliang, the doctor who first informed the world about the outbreak of the virus, dies of COVID-19.

Feb 14 Egypt announces first confirmed COVID-19 case in Africa.

Feb 20 A 38-year-old man, who checked himself into a local hospital in the town of Codogno in Lombardy, officially becomes the first recorded patient with the COVID-19 virus in Italy.

Feb 25 First COVID-19 patient on mainland Spain tests positive using QIAGEN's prototype QIAstat-Dx test.

Feb 26 Brazil confirms a case in São Paulo; the COVID-19 pandemic has reached South America.



March 18 QIAGEN launches the QIAstat-Dx Respiratory SARS-CoV-2 Panel, the first syndromic test to detect SARS-CoV-2

March 31 A report in JAMA Ophthalmology creates a stir with the finding that patients can catch the virus through the eye, despite low prevalence of the virus in



March 30 NeuMoDx SARS-CoV-2 assay is launched. This high throughput randomaccess test enables labs to keep pace with increasing demand for COVID-19 tests.

April 23 In Germany, the first participant is dosed with a COVID-19 vaccine candidate in Europe by BioNTech.

June 22 A study in Sci-

ence Translation Medicine suggests that as many as 80% of Americans who sought care for flu-like illnesses in March were actually infected with the virus that causes COVID-19. According to the research, if one-third of these patients sought COVID-19 testing, it might have amounted to 8.7 million



October 5 QIAGEN launches the QIAprep&amp Viral RNA UM Kit. This rapid one-tube test removes the need for separate nucleic acid extraction and PCR reactions

Nov 4 US reports unprecedented 100,000 cases in one day.

November 16 NeuMoDx 4-plex Flu A-B/RSV/SARS-CoV-2 Vantage Assay is launched in Europe and rest of world in time for the northern hemisphere flu season. This highthroughput test allows hospitals to rapidly determine which of the most common seasonal viruses a patient is infected with.

Nov 18 Pfizer and BioN-Tech annouce that their vaccine met all of the study's primary efficacy endpoints.



December 7 Launch of the QuantiFERON SARS-CoV-2 test to measure longerlived, T-cell mediated immunity. This will play an important role in tracking the effectivity of vaccination programs across the globe.

December 8 First vaccination programs are initiated

December 12 A new COVID-19 variant containing 23 mutations is first reported in the UK. The fast-spreading variant quickly becomes the dominant strain in the UK. A second highly virulent variant is reported in South Africa a few days later.

December 30 WHO urges countries to increase surveillance of genomic viral variants.

January 6 Japan reports a new variant of SARS-CoV-2, detected in four people who had traveled from Brazil.

January 9 One-year anniversary of the first death of COVID-19 in Wuhan, China.

January 20 QIAGEN confirms its SARS-CoV-2 PCR tests are able to detect all known variants of

announces it aims to sequence 20,000 SARS-CoV-2 genomes per week by March. February 25 UNICEF

and AstraZeneca sign a long-term agreement to ensure that up to 170 million doses of COVID-19 vaccine are rapidly available in approximately 85 countries globally.

February 3 The UK

March 8 A new study of the UK and South Africa variants of SARS-CoV-2 predicts that current vaccines may be less effective at neutralizing these variants and that the new variants raise the specter that reinfections could be more likely.

March 18 >400 million vaccines have been distributed globally. At the same time, France, Italy and Germany all show indications of 3rd infection wave beginning.



March 22 QIAGEN launches the QIAseq DIRECT SARS-CoV-2 Kit, a sequencing solution for viral variant detection which halves library preparation times and plasticware use.

March 25 QIAGEN's 4-plex NeuMoDx Flu-AB/ RSV/SARS-CoV-2 Vantage Assay gains FDA Emergency Use Authorization.

QIAGEN has made a significant contribution to the global fight against the COVID-19 pandemic. Never before has the company been under as much pressure to develop new products and increase manufacturing capacity at such a pace and scale. How would you summarize the 2020 pandemic year?

Kerstin: At the beginning of 2020 it quickly became clear to us that we had to develop a test as fast as possible and make it available on a worldwide scale. The second step was to massively expand our manufacturing capacity for both new tests and existing products that were recommended in the CDC and WHO testing guidelines by developing optimized workflows, refocusing our efforts on these products, and doubling the number of production employees.

In March 2020, QIAGEN released a new QIAstat-Dx test to detect SARS-CoV-2 in a matter of weeks, soon followed by the NeuMoDx test. How did QIAGEN respond, develop and produce technologies so quickly in the middle of the pandemic and lockdowns?

This rapid response was possible by vigorous focus and much closer and earlier collaboration throughout all areas of our organization. Controlling, for example, had to deviate from the usual planning cycle of one year and swiftly release budgets to start ad hoc projects to meet the market demand. Consequently, we also launched a new version of QIAamp Viral RNA Mini Kit as early as May, following a massive increase in demand in March.

"It was a matter of developing a test



Kerstin Steinert, Vice President and Head of Global Product **Development Life Sciences & Research Services, on the** most unprecedented expansion of production capacity in QIAGEN's history, during the COVID-19 pandemic.

Now that several vaccines are approved and in use worldwide, does that render the tests superfluous?

There is still a high demand. People want to travel again, go to restaurants, get back into the office – in the medium term, this will only be possible with negative COVID-19 test results. And since new and more virulent mutations are appearing all the time, it is no longer just the detection of a COVID-19 infection that is crucial but also the determination of the variant. Sequencing of the virus is becoming more common and here we will need to develop new solutions, like QIAseq and the new SARS-CoV-2 sequencing panel, to increase throughput. And, of course, after the vaccinations have been given, tests like QuantiFERON-SARS-CoV come in to track immunity.

Are there any other solutions that are market

The QIAprep&amp Viral RNA UM Kit to complement the COVID-19 portfolio is a real innovation and triggers genuine enthusiasm among customers with its extremely simplified and sensitive workflow. The time from sample to insight is now only 60 minutes instead of several hours, with a reduced hands-on time and reduction of plastic components.

For up-to-date licensing information and productspecific disclaimers, see the respective QIAGEN/ NeuMoDx kit handbook or user operator manual. These can be found at www.qiagen.com or www.neumodx.com/client-resources.



Pöppelmann GmbH & Co. KG, a leading supplier of plastic components for QIAGEN, massively ramped up production to supply components for QIAGEN kits.

"It goes without saying that we have to give it our all." Sebastian Hannöver, Pöppelmann, Germany



















one behind.







Production staff working around the clock to deliver COVID-19 test cartridges for use with the QIAstat-Dx instrument.

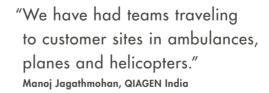
INSIGHTS



PANDEMIC

The manufacturing team in Hilden, Germany, packaging RNA extraction kits used in the CDC COVID-19 test protocol.

In India, special transport was arranged by state governments to allow QIAGEN employees to provide essential onsite support around the country.



"I have never delivered to hospitals before. Now I deliver to a hospital or lab every day." Tony Mazzella, UPS, New York



GLOBAL RESPONSE

Research and development teams at QIAGEN Barcelona developed a QIAstat-Dx COVID-19 test in just five weeks.

"Thanks to the spectacular efforts of teams across the company, we managed to achieve what I had initially believed to be impossible, and with unprecedented speed." Luis Penarrubia, Senior Scientist, QIAGEN Barcelona



27

QIAGEN partnered with UPS throughout the pandemic to ensure delivery of essential COVID tests.

"I'm tired, but I'm also grateful and proud. Our work saves lives and I am honored to be able to contribute."

Je Vai Perry-Bass, Production, QIAGEN Germantown, Maryland, US The manufacturing team at the QIAGEN Germantown site, Maryland, US, switched to 24/7 production to support customer COVID-19 testing needs.







as a forensics laboratory.

INSIGHTS

### "I just kept thinking: What can we do?"

Michelle Volk, CEO and President, Great Lakes Labs

s a third-generation lab enthusiast, Volk has spent her life learning about forensic science and serving coroners as well as local and regional law enforcement agencies in the Indiana suburbs.

Volk learned about forensic science early on from her father and grandfather, and credits them both with steering her career path. In the executive offices at Great Lakes Labs, their portraits hang, facing each other on opposing walls, proudly displayed in their honor. The thought of shifting gears and pivoting her entire lab in response to a pandemic was something she never dreamed of.

"Back in March, it looked pretty grim for our community. It looked pretty grim for our state. It looked grim globally. One day we were actually on our way to do a big collection of DNA at a local county complex and on the drive over, I just kept thinking: What can we do? What can Great Lakes Labs do? We don't do clinical testing. We're a forensic facility. We don't do RNA isolation," says Volk. But inspiration struck shortly thereafter.

How to do her part in overcoming the pandemic was prompted by an event that affected local first responders in Volk's community. As someone coming from a background of first responders, the call for help from a local sheriff resonated with her. The sheriff had a COVID-19 outbreak in his jail and didn't know how to keep his officers safe and healthy in the face of potential spreading, particularly in such close quarters.

Waiting weeks or even days for accurate test results was simply out of the question. After Volk received the call, she consulted with her management team. She decided the best way she could help was to transition from a forensics laboratory to a clinical setting able to provide quick turnaround times for COVID-19 testing.



Growing up with a police detective as a randfather and a forensic toxicologist as a father, Michelle Volk credits these two important figures in her life with steering the direction of her career. Continuing the legacy her dad and arandfather set in motion has been her drive from early on, one that she proudly ntinues by serving through her work in their honor.

### From forensics to clinical

"When I decided to transition the lab from forensic to the COVID-19 testing, it was extremely hectic and stressful, but at the same time very rewarding. We allowed our community the ability to rely on a regional lab for a quick turnaround time and a bevy of information that was going to allow the clinicians to understand exactly why someone was ill and whether they had, or had not, contracted COVID-19," says Volk.

"What we were seeing with the testing across the country and monitoring was that it was taking days, up to weeks, for a result to be returned to the clinician," says Volk. First responders and the frontline workforce were hit hard and often prevented from showing up to work for fear they might have COVID-19, even when they did not. Asymptomatic cases were quite frequent, making testing nearly impossible, even if someone did have the virus.

Volk was moved by helping a young family in which the wife and mother had been exposed to SARS-CoV-2. Since the husband was a first responder, they would need to find outside childcare for their infant and toddler if the wife needed to guarantine. "Receiving her positive test results so quickly meant they were able to make alternate arrangements promptly," she says. "This is the type of community service I wanted Great Lakes Labs to be able to provide, and thanks to QIAGEN, now we can.

"Testing lets our customers know with confidence when it is safe to let their employees return to the workplace." About 40 percent of Great Lakes Labs' COVID-19 testing has been done for healthcare clients and about 10 percent for members of the public.

It's these cases that have struck a special chord with Volk. "It's been wonderful to bring peace of mind to members of the public who want to visit vulnerable

relatives without the fear of introducing the virus," she says, including out-of-town family members who wanted to know if it was safe to visit elderly or immunocompromised parents and relatives.

### Quick response for COVID-19

Having learned about QIAGEN through using the QIAamp DNA Mini Kit as part of Great Lakes Labs' pharmacogenomics expansion in 2018, Volk called QIAGEN to ask for advice. Volk determined that the QIAstat-Dx automated PCR-based testing system would let Great Lakes make the rapid pivot needed.

A lifelong fascination Volk recalls how, at the

age of 10, she and her

sister would help their

father by assembling

for his lab for a nickel

Years later, Volk was

preparing to start law

school when her father

asked her to spend the summer interning at his

crime lab in Gary, Indi-

ana. "I learned early

the power of forensics

communities," she says.

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"The variety of lab disci-

and how it can help

rape collection kits

"We were able to validate the QIAstat-Dx Respiratory SARS-CoV-2 Panels results in less than five days," she says. "It became a very easy decision once we learned how sensitive and specific the QIAstat-Dx is and how easy it is to use."

That ease of use turned out to be an important benefit, given that the COVID-19 pandemic precluded in-person QIAGEN training. "We ended up not needing formal training on the QIAstat-Dx, given our extensive experience," Volk says of her 11 employees, who include her husband, Rick. "What we did instead was to read up on the SARS-CoV-2 virus and a refresher on working with RNA, since our forensics work is DNA-based."

Volk appreciates the QIAstat-Dx system's

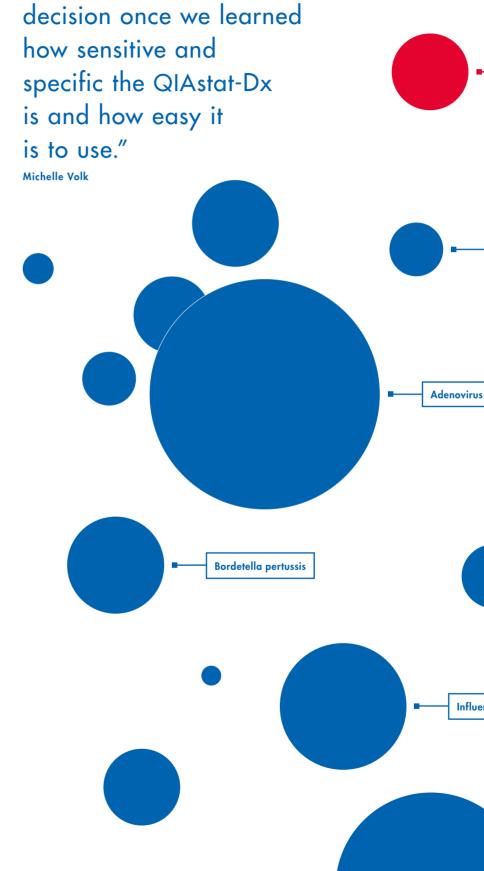
72-minute end-to-end runtime, but it was the amount of information the system provides that convinced her. The QIAstat-Dx Respiratory
SARS-CoV-2 Panel test kit rapidly differentiates the novel coronavirus from 20 other pathogens implicated in respiratory syndromes. "It's hugely beneficial to be able to test for that wide range of pathogens," Volk notes. "Ruling out COVID is helpful, but so is the chance to correctly identify other illnesses so physicians can treat the patients and their symptoms appropriately."







The QIAstat-Dx system is the only sample-to-result syndromic testing platform with bidirectional LIS connectivity and the ability to export Ct and endpoint values.



INSIGHTS

"It was a very easy

SYNDROMIC TESTING

Rhinovirus

SARS-CoV-2

PANDEMIC

### QIAstat-Dx

In about one hour, the QIAstat-Dx Analyzer can screen patient samples for multiple pathogens at one time, eliminating the guesswork in patient diagnosis. Available panels include a respiratory panel that detects over 20 respiratory targets, including SARS-CoV-2 and a gastrointestinal panel that analyzes 24 targets for common pathogens causing GI infections. More panels are under development and include a solution for common meningitis/ encephalitis pathogens.

Product availability may differ from country to country based on regulations and approvals.

### Turning expertise to a new challenge

Over the past year, the COVID-19 pandemic has affected the work of many scientists around the world. Some have seen their projects come to a halt. Others have modified their research focus to new ends. Still others have brought the knowledge of their field to the study of COVID-19, yielding fresh insights into the pandemic. We spoke to two scientists about how their specialist fields can help inform the fight against COVID-19.

### What learnings from TB treatment can we apply to COVID-19?

I am a clinical microbiologist. For the past 25 years, I've focused on tuberculosis (TB) diagnostics – diagnosis of both latent infection and disease – in high-burden settings across Africa and Asia.

I never thought I would do hardcore research on COVID-19 because I am not a virologist. However, I was concerned about the impact COVID-19 might have on TB, so I started investigating this. Based on data from Africa, Asia and Europe, the picture is devastating. Because of the pandemic, people were too frightened to go to hospitals, and as a result, routine work on TB also decreased. In some high-burden countries, TB laboratories were converted into COVID-19 testing laboratories.

We are losing years of progress. TB is like a time bomb. People can develop the disease many years after infection. Because of delay in diagnosis, we will see an increase of transmission, and because of delay in treatment, we'll see a worsening of cases. But it's not just TB. We will pay the toll of the COVID epidemic in many other diseases, from cancer to chronic conditions.

All of this has made me consider how we might apply the lessons of TB diagnostics and management to COVID-19, and the role of testing as vaccinations become more widespread.

Both diseases are transmissible by direct contact and through the air, and both need to be detected as soon

as possible in order to minimize spread. So we need faster tests, ideally running on the same platform, automated if possible, in order to increase and connect testing across a variety of sites.

Surveillance will continue to be crucially important. One of the things we do with our collaborating TB laboratories is support the full genome sequencing of strains that are collected to detect drug resistance, since treatment is the main course of action for TB.

A similar idea should be applied to COVID-19, where more contagious viral mutations have appeared in multiple locations. These mutations may increase even as vaccinations do, because inoculations put pressure on the virus to evolve. And if the time to vaccination is too long, the virus will add more mutations. And yet vaccinating many millions of people in a relatively short period is very difficult, especially during a pandemic. So we're really in a race against time.

If PCR diagnostic tests can be designed to detect variants of the virus – especially if they could be immune escapers – that would be very useful.

Finally, the TB world is a network of laboratories that collaborate. We are all able to exchange information around the world. And this is key to controlling outbreaks and improving treatments. With COVID-19, we are forced to create this network from within the pandemic. But perhaps the networks we build now will prepare us for the next pathogenic outbreak – whether it's bacterial or viral.

INSIGHTS PANDEMIC EXPERT OPINION



Daniella Cirillo, MD, PhD, is Director of the Emerging Bacterial Pathogens Unit at the IRCCS Ospedale San Raffaele, in Milan, Italy, and Director of the WHO Collaborating Centre Milan. Specializing in management of tuberculosis (TB), another disease attacking the respiratory system, Cirillo was struck by the parallels between COVID-19 and TB. Here she talks about the devastating impact the COVID-19 pandemic has had on TB, and how similar approaches might be applied to eradicate the two diseases.

"If PCR diagnostic tests can be designed to detect variants of the virus – especially if they could be immune escapers – that will be very useful."

Dr. Daniella Cirillo

## Adam Brufsky, MD, PhD, is professor of medi-

Adam Brutsky, MD, PhD, is protessor of medicine at the University of Pittsburgh School of Medicine, and principal investigator at the Pittsburgh Breast Cancer Consortium. Since the start of the COVID-19 pandemic, Brufsky has been applying his learnings about breast cancer tumor immunity to understanding the role of the immune system in SARS-CoV-2 infection. Here he talks about how important monitoring immune status could be in defeating COVID-19.

"Viral immunity and anti-tumor immunity are similar in that both involve specific, timed, innate and adaptive responses."

Dr. Adam Brufsky

### How can knowledge from anti-tumor immunity be applied to viral immunity?

As an academic medical oncologist, I am interested in tumor immunity and its role in breast cancer. When the COVID-19 pandemic accelerated nearly one year ago, I, like many researchers around the world, applied my knowledge and training to this important problem. Viral immunity and anti-tumor immunity are similar in that both involve specific, timed, innate and adaptive responses.

Sophisticated testing has provided clues in our understanding of how the immune system influences the development and progression of breast cancer. It is similarly essential to our evolving response to COVID-19. In particular, I believe a tiered testing regime that combines different technologies to determine an individual's current infection and immune status can paint a fuller picture of the pandemic, and help guide decisions about reopening and vaccinations.

Right now, the gold standard is a PCR test using nasal samples or saliva in a 70-minute process to detect viral RNA. However, the turnaround time is variable, because it requires highly complex equipment. Fortunately, there are faster alternatives available, in the form of 2– to 15–minute antigen tests that detect viral proteins. These assays can find acute infection almost as accurately as PCR testing. They are also simpler, faster and can be performed at the point of contact, making them ideal for regular mass screenings in schools, workplaces, transit hubs and other high-traffic public spaces.

But while antigen testing can determine infection, it cannot provide information on whether the individual has protective immunity to SARS-CoV-2. This highlights the need for the second tier, consisting of antibody testing conducted with a blood draw and requiring just 2–10 minutes for results. Antibody testing can determine whether individuals have developed an adaptive immune response to SARS-CoV-2, granting at least temporary immunity. Subsequent antibody tests can determine whether antibodies remain or have faded.

The third tier is the most innovative. T-cell immunity testing measures the T-cell response to SARS-CoV-2 – a critical advance that allows determination of immunity to SARS-CoV-2, even in the face of negative antibody testing. T cells are likely key components of long-term protective immunity. A T-cell SARS-CoV-2 immunity test that is cost effective, easy to use, and scalable would be of great importance in a tiered testing approach. Several are in development and close to clinical application, including one launched in December by QIAGEN.\*

Understanding the T cell response to SARS-CoV-2 could help predict the severity of infection, which may differ from patient to patient and with each new variant strain, and the relative level of protection expected as an individual recovers from infection or is vaccinated.

Such testing is also crucial to vaccinations. Knowledge of an individual's immune status at the time of vaccination is important, because individuals with high titers of anti-SARS-CoV-2 antibodies may not require vaccination. At the same time, antibodies to SARS-CoV-2 may fade or never develop in the first place, suggesting other individuals may require vaccination to avoid reinfection.

Using this tiered testing approach can ensure the correct people are vaccinated, while enabling local, state and national governments to measure their own progress toward community-based immunity. This common metric will be indispensable in negotiations about lifting shutdowns and reopening borders to international travel.

<sup>\*</sup> for research purposes only



### THE PANDEMIC

A pandemic is bound to happen again. But we will be ready for it.

As vaccination programs are rolled out around the world, companies must not only survive the pandemic, but reshape the future too. Beyond the coronavirus, we have to explore new ideas and areas of business.

The pandemic has proven what can be achieved in emergency conditions. Tests and vaccines were developed in record time, and the accrued scientific knowledge will be of long-term benefit to mankind.

Molecular diagnostics has been thrust into the future, but it's a future that QIAGEN is fit to tackle. Just as we helped fight this virus, we will play a vital, active role in the post-pandemic era. Although COVID-19 isn't over yet, that era has already begun.



For the past year, a converted frequent flier lounge in Bangkok's Suvarnabhumi International Airport has been the new field lab of epidemiologist and virus hunter Dr. Rome Buathona, In early January 2020, concerned about reports of an unknown pneumonia-like condition in Wuhan, China, the Thai government activated its Emergency Operations Center and tapped Dr. Rome to establish the country's first international airport screening protocols.

OVID-19 hadn't been identified yet "We only knew it was a pathogen." says Dr. Rome, a national expert on emerging infectious disease investigations and surveillance at the Thai Ministry of Public Health. But Thailand has experience confronting

infectious disease outbreaks, including severe acute respiratory syndrome (SARS) in 2003, H5N1 avian flu in 2004, and Middle East respiratory syndrome (MERS) in 2015. "I imagined something like SARS in 2003, that it would subside in three to six months. But not that it would spread around the world," he says.

Rome knew one likely entry point for the novel pathogen was Suvarnabhumi, as an estimated 80,000 passengers pass through the airport daily. It was also peak travel season, when people from all over the world flock to the tourism-reliant country. Nearly 40 million people visited Suvarnabhumi in 2019 alone.

Rome created a screening protocol that required thermal imaging systems at Thailand's seven international airports. Anyone whose reading was above the threshold would get a core temperature reading. Using this system, Thailand almost immediately identified the first patient outside of China diagnosed with what would later become known as COVID-19. She was a tourist from Wuhan. Thai scientists sequenced the pathogen they had, but Chinese researchers had yet to publish the sequence of the organism they'd discovered. Once they did, Thai health officials compared the two. It was a match: SARS-CoV-2.



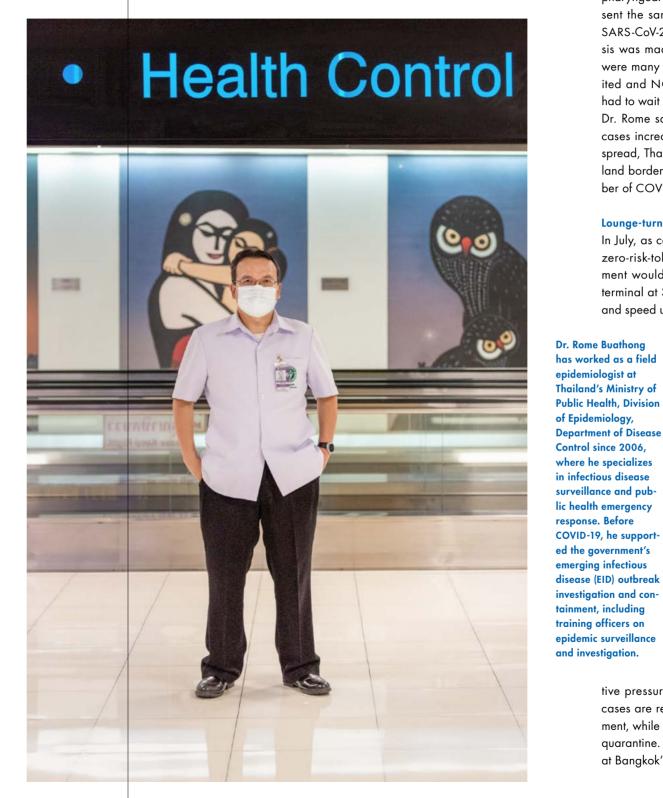
### Suvarnabhumi Airport

Suvarnabhumi International Airport – aka Banakok Airport - is one of the world's busiest transit hubs, with an estimated 80,000 passengers passing through daily. It saw more than 53 million passengers in 2019. It's a regional gateway and connection point for carriers reaching locations both near and far, including Asia, Oceania, Europe, the Middle East and Africa Dr. Rome's lab operates in a converted Emirates lounge, where pipettes and PCR tests have replaced cocktails and hors d'oeuvre.



"There are many layers of testing for us to contain the outbreak." Dr. Rome Buathona

BEYOND



Although Thailand's infection rate remained among the lowest globally, Rome and his team conducted tests, taking both nasopharyngeal and throat swabs for anyone showing fever or respiratory symptoms, and nasopharyngeal swabs only for asymptomatic arrivals. They sent the samples to a reference lab. At the time, no SARS-CoV-2-specific probes were available, so diagnosis was made by whole genome sequencing. "There were many cases to detect, but lab capacity was limited and NGS sequencing was time consuming. We had to wait three to five days to confirm a single case," Dr. Rome says, recalling the chaos as the number of cases increased. By April 2020, to reduce the risk of spread, Thailand's government had closed air, sea and land borders to almost all commercial travel. The number of COVID-19 cases plummeted to near zero.

### Lounge-turned-lab

In July, as cases dropped, the government decided its zero-risk-tolerance approach to pandemic management would include a lab in the main arrivals flight terminal at Suvarnabhumi. The goal was to centralize and speed up testing of the hundreds of short-term-stay

> passengers not required to go into quarantine, who were arriving daily, as well as anyone with COVID-19 symptoms.

They also wanted to control infection spread within the airport itself. RT-PCR testing was essential because of its superior sensitivity to antigen tests, Rome says. Rome's workday starts with the first arriving flight at 6:00am, when he oversees checks of travelers' health documentation, helps conduct health interviews that try to uncover any respiratory symptoms that might evade scans, and administers tests to anyone with symptoms - who are then classified as "persons under investigation" (PUI).

Anyone with a temperature higher than 37.3°C (99.14°F) or COVID-19 symptoms are taken to a UV-disinfected nega-

tive pressure room for rapid RT-PCR testing. Positive cases are referred to hospitals for isolation and treatment, while negative cases proceed to the 14-day state guarantine. To date, there have been 3200 PUIs tested at Bangkok's Suvarnabhumi airport.

INSIGHTS

Within a month, he and his team had transformed the former first-class airline lounge into a lab that conducts tests on arriving passengers, making results available within two hours. Now, Biosafety cabinets, filled with surgical gloves, pipettes and gauze pads, line the walls. A door is marked "PCR room"; a red and yellow sticker on the door warns that it is biosafety level 2. Inside are cyclers that can analyze hundreds of samples at once. The only recognizable sign of its former lounge days is an unstocked bar shaped like a crescent moon.

### Planning for Recovery

Mass testing will be essential to restoring Thailand's tourism sector, which along with manufacturing is a prime economic driver. International passenger arrivals to Thailand have plummeted by some 80 percent since the pandemic began, but Airports of Thailand projects almost 111 million passengers by 2022.

For these situations, he is turning to QIAprep&amp, which integrates steps to prepare a test sample and detect viral RNA into one procedure. QIAprep&amp delivers results in under two hours and can handle up to 2,600 samples per eight-hour shift per cycler.

"That is my challenge – how to screen lots of passengers," says Rome. Even if they don't achieve 100 percent detection at the airport, "We want to detect highly contagious people to get them into the isolation track. QIAprep&amp can test huge volumes."

In addition to QIAprep&amp, the lab is equipped with QIAGEN's QIAstat-Dx instrument. "I want many strategies, not just a single one," says Rome. "There are many layers to testing for us to contain the outbreak."

He also envisions setting up a pilot lab that would test cargo drivers at one of Thailand's border crossings, which could then be replicated at other locations. "The lab should be something really reliable and fast, and test in high volume people who cross the border," Dr. Rome says.

Thailand's pandemic response has earned it accolades worldwide. With a population of 70 million – almost 11 million of whom are packed into Bangkok – Thailand has reported fewer than 27,000 COVID-19 infections and 100 deaths. The WHO has singled out Thailand's "whole-of-government, whole-of-society" containment efforts, and Australia's Lowy Institute

ranked Thailand among the world's top four countries in its COVID-19 performance index. One of the index's criteria is testing per 1,000 people.

But Rome is not willing to rest on his laurels. Any success can be fleeting in the long game of virus control, he says. He's concerned new variants of the virus could sweep the country, potentially rendering vaccines ineffective and setting the clock on Thailand's efforts against COVID-19 back to the beginning. "That is why in 2021, surveillance of the variants is very important," he stresses. "We must survey the variants from the airport, quarantine facility and community to quickly detect new ones."



### QIAprep&amp Viral RNA UM Kit

This kit integrates a two-minute liquid-based sample preparation with a real-time PCR detection. From start to finish it takes less than one hour to deliver a result. 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. It can be used to detect targets from any RNA virus, including COVID-19, making it highly flexible.

The test is currently available for research applications.

Product availability may differ from country to country based on regulations and approvals.



SUSTA Z O Z

### **Plastic Reduction**

BEYOND

The QIAprep&amp kit requires less than 50% of the plastic-ware (pipette tips and tubes) required to run a standard two-step extraction and RT-PCR test. This is just one example of where we are working to reduce, replace and recycle plastic without impacting the reliability of our products.

Additional measures in 2020 included switching from expanded polystyrene foam boxes to environmentally friendly alternatives for cold shipments in the US and Europe, reducing the volume of packaging plastic in our kits, and creating resources to help guide our customers in recycling plastics in our products after use.

"We want to detect highly contagious people to get them into the isolation track.

QIAprep&amp can test huge volumes."

Dr. Rome Buathong



 $\mathbf{12}$ 

1,000 miles across the ocean to bring a species back from the dead



### Save the corals

In April 2019, Bry Wilson stood on the deck of the research vessel, squinting in the sun. Wilson, a marine biologist at the University of Oxford, felt both exhilaration and fear at the thought of the small plastic trunk stowed away on the boat.

t contained small samples of corals that he had recovered from a reef in the remote Chagos Archipelago, located in the Indian Ocean halfway between Madagascar and Indonesia. For the past month, he and his fellow researchers had dived twice a day looking for corals, including the Chagos brain coral (Ctenella chagius), the world's rarest. Found nowhere else, it had been previously thought extinct.



When healthy, the meter-wide brain coral has the same ornate folds as its namesake undulating across its surface. These plush corals were once abundant in the Chagos Archipelago, but Wilson and his colleague had found just a few sickly specimens, pale and fragmented, withered by rising sea temperatures.

But he needed definitive confirmation that they were Ctenella, and only molecular testing could do that. He needed to get the samples to a lab. "I know everyone's samples are precious, but these seemed more precious than it was possible to explain," he says. They could be the last Ctenella corals in the world.

What he didn't know at the time was that he was about to get a \$25,000 research grant from QIAGEN that would not only help him understand exactly what he had in that trunk but would open the door to a new ambitious goal: to save the corals.

Bry Wilson, PhD, is a marine biologist and bioinformatician at the University of Oxford Department of Zoology. He spends much of his time sailing the globe to study the effects of global climate change on tropical coral reefs.

### **Coral Complexities**

The Chagos Archipelago is home to more than 300 species of coral. These animals are at the heart of a complex marine ecosystem that supports a wide variety of reef-dwelling creatures. A coral exists in "this incredibly beautiful symbiosis" with the organisms that live in and around it, Wilson says.

"All these organisms live on and within the coral," he adds, from bacteria, viruses, protists, grazing protozoa, algae and fungi, to crabs, shrimp and fish. "All of those have their own little microbial communities, and they all mix. Corals are immersed in this incredible microbial soup. It's an extraordinarily complex ecosystem. Trying to tease apart what's going on in that crazy chaos is something that really drew me in."

Wilson has always had a passion for science. "When I was five, my father built me a wee lab out of discarded breeze blocks in the back of the garage," he recalls. "I filled it with all manner of trophies from the surrounding fields and forests – discarded bird's eggs, owl pellets, skulls, you name it." In 2005, after reading about the spread of coral diseases, he impulsively packed his bags and flew to the other side of the world to research the impact of disease on the Great Barrier Reef. Sixteen years on, saving the corals has become his life's work.

Wilson has been incorporating molecular testing into his coral research since early in his career. When reports of diseased corals began appearing in scientific literature in 2005, he applied for and received a three-year fellowship to study the impact of the pathogenic bacterium Vibrio coralliilyticus ("coral dissolving" in Greek), on the Great Barrier Reef and in the South Pacific. In the course of that work, he developed a real-time PCR diagnostic assay for checking levels of an enzyme that the bacterium used to break its way into the coral tissues, potentially revealing whether a coral was infected before it showed symptoms.

Since then he's used molecular testing and bioinformatics to try to understand corals' genetic responses to a range of threats, from pathogens to climate change.

### RNA from raft to reef

The research vessel is a former North Sea firefighting ship that has been repurposed as a patrol vessel – and seasonal research platform. To create a cool refuge for RNA and DNA sample processing in the sweltering

INSIGHTS BEYOND DNA EXTRACTION

"The great thing about the QIAGEN kits is that they come with pretty much everything you need."

**Bry Wilson** 





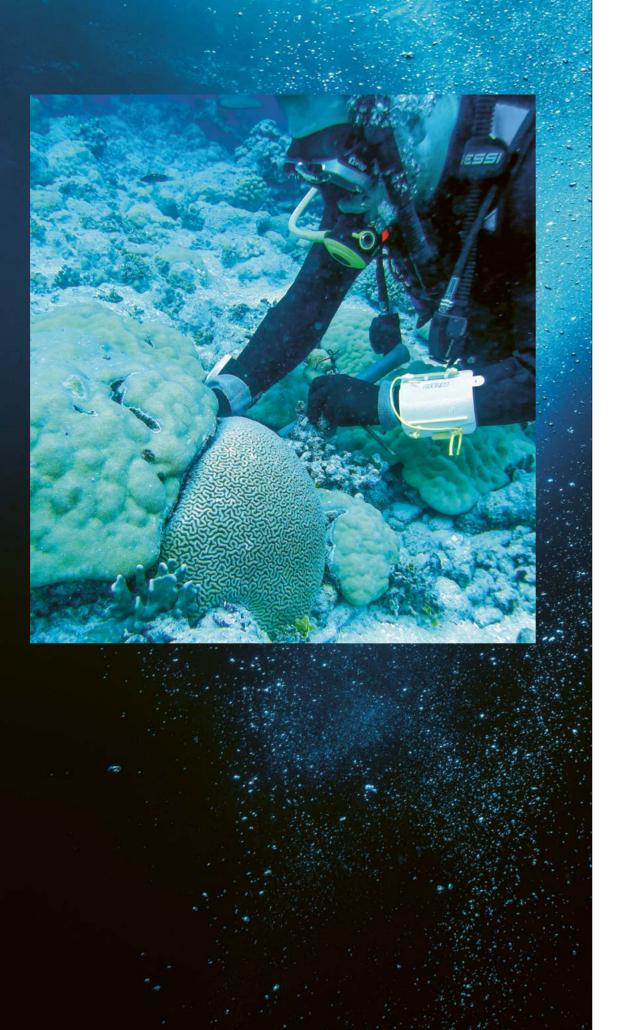
### **Cutting our carbon emissions**

Scientists around the world, like Dr. Wilson, are witnessing first-hand the effects of climate change on the natural environment.

At QIAGEN, we recognize that climate change is one of the most pressing global challenges.

In 2019, we committed to reducing our emissions in line with a 1.5-degree Celsius climate target, as demanded by the 2015 Paris Agreement. In 2020 we achieved reductions of 9.4% and 81.1% in scopes 1 & 2 and scope 3 emissions respectively. These reductions were achieved through implementation of energy efficiency measures, as well as the overall effects of the COVID-19 pandemic.

We plan to build on these successes and will be announcing a new, more ambitious climate target in June 2021.



humidity and heat of the tropics, they built a lab on the deck out of a shipping container. It holds an air conditioning unit, a small freezer stocked with ice packs, a fridge, a worktable and benches. It's equipped with a centrifuge, various lab paraphenalia and molecular testing tools, including QIAGEN DNA extraction kits. "The great thing about the QIAGEN kits is that they come with pretty much everything you need," Wilson says.

He does some sample processing underwater. One approach has been to put coral tissues in an RNA stabilization reagent right there at the reef, because "I'm always trying to find ways to cut down on the amount of time from sampling to processing."

Other times he processes samples while bobbing in one of the inflatable rafts they use to visit reefs the ship can't access. "I'll tell you, pipetting 100 microliters of a compound or chemical when you're in an inflatable boat in a two-meter swell is a challenge."

### From lab to genome

Plastered with permits and airline stickers, the trunk holding the coral samples made it back to the molecular lab at the University of Oxford's John Krebs Field Station, where the samples were stored in a -80°C freezer. Not long after, he got word he'd been awarded a \$25,000 QIAGEN research grant. He used it to fund the sequencing of the genome of the coral in the trunk. The grant came with 16 hours of lab work at QIAGEN's genomics lab in Hilden. So he

shipped the corals to Germany, along with detailed instructions about how to handle the delicate samples.

The results arrived a couple of months later. It was indeed the elusive Chagos Brain coral. "There's almost no data on this coral at all, until now. This is really the first time in the history of the planet that a full genome of this coral has been made available."

It wasn't the only coral he'd extracted DNA from. He'd also analyzed the genomes of the Chagos Archipelago's keystone coral species to better understand the role genetics play in its ability to survive warmer



"Corals are

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chaos is some-

thing that really

waters. "We're looking at certain immune genes to see whether they've got differences in their systems, and whether that's giving them better resilience to heating events," Wilson says. He's also investigating coral holobionts to see how microorganisms may play a role. Understanding these differences and complexities may have applications for coral reef resilience and recovery around the world.

### A field season thwarted by COVID-19

The program researchers headed back to the Chagos Archipelago in February 2020, just as alarming reports of COVID-19 began to emerge from China's Wuhan province. Two days into the expedition, Wilson, along with fellow researchers Margaux Steyaert and Vivian Cumbo, dove a reef in a lagoon in the Three Brothers islands. Gray nurse sharks lurked nearby as they finned along. Nearly an hour in, their dive tanks nearing empty, the trio reluctantly began to return to the surface. As Wilson rose, he looked down into the depths – and suddenly spotted *Ctenella*.

"I just saw this big, beautiful-looking brain," he says.

They quickly swam over.

"There were 10 or 15 of these corals stretching along this reef wall," Wilson recalls. "They were the most beautiful, healthy colonies we'd seen of this coral in well over a decade. My heart was in my throat. I gulped through what little air I had left, like a kid."

Soon after, they had to abort the expedition. While they'd been at sea, largely disconnected from the rest of the world, COVID-19 had become a global pandemic. Countries were closing their borders. Their normal route out of Bahrain was impossible. Eventually they managed to catch one of the last flights out of the Maldives.

### The future of corals

Though the COVID-19 pandemic cut short the 2020 expedition, Wilson has been planning his return ever since. Until he can return to the Chagos Archipelago, he relishes the memory of their discovery. "I think that as a biologist, you just wait and dream that you're going to have this opportunity to find something that nobody else has seen," he says. "It was amazing."

### The Chagos Archipelago

Wilson is a member of the Bertarelli Foundation's marine science program, which draws scientists from around the world to collaborate on research projects in the British Indian Ocean Territory Marine Protected Area.

All fishing and extractive industries are prohibited in this 640,000 sq. km region. Occupying just 60 sq. km of the vast expanse are the Chagos Archipelago's 58 tiny islands and atolls. They're uninhabited except for Diego Garcia atoll, which is home to a US Navy support facility.

The lack of human activity in the region makes it one of the world's best places to study the impact of climate change. "The opportunity to work in this area is like a dream," Wilson says. "It's like an ecosystem from 50–60 years ago."

### SCIENTISTS

In a world in which so many aspects of our lives have moved online, it is a small wonder that scientists are also embracing social media to network and communicate their work. Here we meet two young researchers who have chosen Instagram as their platform of choice.

### Cancer research with samurai spirit

In my research I try to determine novel biological targets of thoracic cancers and introduce molecular profiling-directed therapies into clinical practice. I study aberrant DNA methylation, mRNA and protein expression, using qRT-PCR, bisulfite pyrosequencing and IHC tissue array methods.

Presenting my research results in front of an audience and writing scientific literature on my thesis are the most challenging parts of my work. I have stage fright.

It is a year since I started practicing Japanese iaido, a martial art with a samurai sword. Iaido is about elegance, beauty and strength at the same time. It has a calming effect on me, and teaches discipline and ethics. There is a saying: "A samurai never runs away." That encourages me to deal with the difficult tasks in my life.

QIAGEN products we use: DNA and RNA extraction kits (elute reaction cleanup kits), QIAamp DNA FFPE Tissue Kit, EpiTect Bisulfite Kit, and other bioactive enzymes and solutions.



### F INSTAGRAM



world."

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### Analyzing ancient DNA

My research is focused on the ancient DNA of early human settlers of Sri Lanka. I study two ancient tooth samples, which are 4,000 and 9,000 years old, and were excavated from two cave sites.

The knowledge about early modern human populations in Sri Lanka was limited to archeological evidence that dated back 40,000 years. We attempt to discover their migration routes when they settled in Sri Lanka and compare their genetic constitution with the current tribal population, Veddas, on the island.

Ancient DNA data is not prevalent in the South Asian region due to poor DNA preservation conditions. Therefore, the generation of this data is both locally and internationally very valuable.

QIAGEN products we use: MiniElute PCR purification kit, DNA Investigator Kit and other chemicals and reagents.

51

medical Sciences at Monash University, Australia, and did her MSc in Molecular Life Sciences at the Institute of Biochemistry, Molecular Biology and Biotechnology, University of Colombo, in Sri Lanka.

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tumors.

10 million cases of TB annually

B

4,000 deaths by TB every day, 1.5 million each year

8 countries account for 67% of all TB cases worldwide

INITIATIVE

Throughout much of the first half of the 20th century, mobile tuberculosis (TB) units crisscrossed the US and Europe on the hunt for TB cases. Streetcars, buses, trains, planes and boats equipped with x-ray machines offered free exams. Those with suspicious results were asked to cough up sputum for smear microscopy to identify the pathogen. Family members of people sick with TB were also identified, tested and, if necessary, treated as well.



INSIGHTS BEYOND TUBERCULOSIS



his three-part strategy – search for TB cases, treat the sick, and stop the disease from progressing using preventive treatment – was key to the virtual elimination of TB from wealthy industrialized countries around the world over the past 70 years. The annual TB rate in the United States today is under three cases per 100,000 people. In Canada, it's two per 100,000.

But the numbers are astronomically higher in many poor countries where these same measures were not applied. In Peru, for example, the annual rate is 117 cases per 100,000. That's why, almost every day, two blue vans from Socios En Salud, a branch of the global health organization Partners In Health, find a strategic place to park

in the Carabayllo district of Lima. Its logo designed in consultation with local residents, each van features people holding a hand up in the universal halt! gesture, and the phrase "alto a la TB" – stop TB. Nearby are blue tents they've set up for various screenings. Speakers blast the latest trendy music as well as a jingle about TB screening that was created for this campaign by local artists and regularly plays on local radio.

Like their 20th-century predecessors, these are mobile units searching for TB cases. Now they're equipped with digital x-ray machines, whose results are screened by AI, and vials for collecting sputum to take to a lab for rapid genetic analysis. Another team carries tubes of tuberculin, to conduct skin tests, and the QuantiFERON-TB Gold Plus

"If you're sick with TB, you spread it to the people you love. Grandparents who have TB and don't get treatment can infect a small child. And that child may only get sick 20 or 30 years later. It's a terrible cycle that can be broken if you can get people on preventive treatment."

Mercedes Becerra



Keshavjee (left) and Becerra (right) met while they were studying at Harvard University. The couple are united in their fight to end TB under the umbrella of the Zero TB Initiative

"When you look at the stats, you have to pause and say, 'Four thousand people die every single day from a disease that's been treatable for 70 years? That is outrageous!'" Salmaan Keshavjee

test, and visits persons who have been exposed to tuberculosis to screen them. Socios En Salud even has an x-ray backpack for home visits in areas where the hills are too steep and the roads too rugged for the vans.

Red and white vans are doing the same work thousands of miles away in Pakistan, which has one of the highest TB burdens in the world, with 263 cases per 100,000.

### United under the Zero-TB Initiative

Peru and Pakistan may be on different continents, but their TB programs are united under the umbrella of the Zero TB Initiative, an international coalition of community-based INSIGHTS

health organizations, local and federal governments, the Stop TB Partnership, and NGOs aiming to drastically reduce TB rates across the world. From Karachi to Chennai, Mexicali to Lima, Shenzhen to Ho Chi Minh City, they are working to create TB-free zones in targeted regions – and ultimately everywhere.

The goal is to use the search-treat-prevent strategy that was so successful in the past, refined for local contexts and optimized through the exchange of experiences among regions. The faster and easier it is to accurately test for both TB disease and so-called "latent" TB infection in low-resource areas, the sooner the disease can be eradicated.

"There's knowledge and tools in each of those components that haven't been used to their maximum yield in specific places all at once," says Mercedes Becerra, an epidemiologist and professor of global health and social medicine at Harvard Medical School. "Places that have done that have managed to drop TB rates much faster than the global average of just over 1% per year."

"Tuberculosis is the quintessential disease of poverty," says Salmaan Keshavjee, director of the Harvard Medical School Center for Global Health Delivery, which is a founding partner of the Zero TB Initiative. "When you look at the stats, you have to pause and say, 'Four thousand people die every single day from a disease that's been treatable for 70 years? That is outrageous!"

The husband and wife team are also TB specialists with Advance Access & Delivery and Partners In Health, organizations that support TB programs around the world. They see eliminating TB as a way to right global inequities with deep historical roots. "There's this kind of acceptance that there's one type of strategy or set of tools that we use in the US and Europe that's just not available to the rest of the world," Becerra says. "But it does not have to be this way."

### Righting historical inequities

Becerra and Keshavjee both began to focus on TB while graduate students at Harvard University, where they met. Before shifting to public health, Becerra had studied history and Keshavjee medical anthropology.

"TB serves as a really good marker of historical health inequities and processes that continue to make it difficult

### QuantiFERON-TB Gold Plus (QFT-Plus)

is a simple blood test that aids in the detection of infection with Mycobacterium tuberculosis, the bacteria that causes TB. It is an interferon gamma release assay (IGRA). Unlike the tuberculin skin test (TST), QFT-Plus is a controlled laboratory test that only requires one patient visit and is unaffected by previous Bacille Calmette-Guérin (BCG) vaccination, which frequently causes false-positive TST results.

they're difficult to put on the same graph, she says. "These historical processes have left health systems weaker, unable to provide the services that those populations need – not just for TB but across many diseases."

In the 1990s, both of them went to work with Partners In Health, one of the world's preeminent public health NGOs that supports community health. Becerra went to

for some people to be healthy and have access to health-

care," Becerra says. The gaps in TB case rates between

former colonies and former colonial empires are so vast,

TUBERCULOSIS

multi-drug-resistant TB (MDR-TB).

"If you're sick with TB, you spread it to the people you love," Becerra says. "And even if you get treatment, the people around you may not appear sick, but will end up with the disease later if they go undiagnosed. Grandparents who have TB and don't get treatment can infect a small child. And that child may only get sick 10 or 20 or

30 years later. It's a terrible cycle that can be broken if

you can get people on preventive treatment."

Peru, where she focused on family transmission of TB and

Meanwhile, Keshavjee went to Tomsk, Russia, where a large outbreak of TB was happening in a prison; the death rate was close to 400 per 100,000. Those who did survive, and were eventually released, went on to infect their families. Many had MDR-TB. "The prisons were an epidemiologic pump," he says. "So with our Russian partners, we supported both prison- and community-based treatment programs for TB."

### The Zero TB Initiative is an international

coalition of community-based health organizations, local governments, the Stop TB Partnership, and NGOs that are using a Search-Treat-Prevent strategy to drive down TB rates in specific locales.

TB case rates dropped by 40% in five years. "That was the kernel for the Zero TB Initiative, because it taught us a lot," he says. "And it continues to this day."

That success laid the seeds for the Zero TB Initiative. "The idea was to create a coalition of communities that were committed to creating islands of TB elimination using the comprehensive search-treat-prevent approach," says Keshavjee.

An "island of elimination" is a place where the search, treat, and prevent strategy is implemented with the goal of driving down rates of TB. "At first it may not be the whole population, but it's going to be an island within it," Keshavjee says.

Testing is essential

Testing has played an essential role in the development of these kinds of programs. Timing is key. For TB disease, a chest x-ray returns immediate results. For those determined to be at risk of TB, a rapid molecular test can confirm disease within a few hours. This is a far cry from the days of

exclusive reliance on smear microscopy, a sputum test that is still in use in some places for TB diagnosis, but which misses almost half of sick adults and three-quarters of sick children.

For those who need testing for "latent" TB infection, IGRA tests can be used, and results take about a day. The alternative, a skin test in which tuberculin is injected under the skin of the lower arm, has to be checked by a health professional after two or three days to see whether the site has swelled or hardened.

Skin tests are falling out of favor because they can result in false negatives and require at least two patient visits. And a positive result may indicate exposure to other mycobacteria, a lot of which exists in the environment and is unrelated to TB.

Daniela Puma, a nurse and the coordinator of Socios En Salud's mobile TB unit, says that follow-up visits to check skin test results can be challenging. "We are located in an area of northern Lima where most people work all day. They have one day off, maybe. So they have to take full advantage of that day of consult to have their complete evaluation and get a diagnosis. If we can do everything on one single day, it's better for everyone."

That's why molecular testing, like the QuantiFERON-TB Gold Plus IGRA test, offers an important alternative with advantages over

skin tests wherever health systems have been able to use it to diagnose TB infection. The WHO recommends IGRA tests in its TB guidelines. Done with a simple blood draw, the QuantiFERON IGRA test has a sensitivity of >94% and a specificity of 97%.

"The benefit of the IGRA test is that it's much more specific for tuberculosis, so you end up having to treat fewer people," Keshavjee says. "You don't want to expose people to medicines that they don't need, and you want to make sure that local health delivery capacity is directed at groups at high risk for TB."

The Zero TB Initiative's search-treat-prevent approach has begun to show success in multiple locations. In Karachi, it has reduced TB cases in a dense urban area of two million people by 25–30%. In northern Lima, early results are also promising.



### Access to Healthcare

QIAGEN aims to provide access to cutting-edge molecular technologies to people worldwide, regardless of their economic or social status. This includes diagnostic solutions designed especially for settings where limited medical resources are available.

Our TB portfolio is a good example of this. In 2019, QuantiFERON-TB Gold Plus was added to the diagnostic catalog of the Stop TB Partnership's Global Drug Facility (GDF). The GDF facilitates access and helps match demand for TB diagnostics and drugs with funding from donors, governments and NGOs on a global scale.

QIAreach QuantiFERON-TB, due to launch later this year, builds on this legacy to provide a TB test specifically for use in highburden, resource-limited areas of the world. This public health solution has already gained recognition from the Joint United Nations Program on HIV/AIDS.

### The future of testing

programs.

The use of as much targeted testing as possible, as early as possible, is critical to the future of TB elimination. That's why the Zero TB Initiative co-founder, Advance Access & Delivery, is also evaluating the QIAreach Quantiferon-TB system in Mexicali, Mexico, with local partners. The assay provides ultrasensitive digital detection of latent TB infection using a rugged, portable, battery-operated detection device.

These "islands of elimination" in progress have

inspired community health partners across the

globe to launch their own search-treat-prevent

"It's going to be a leap forward," Keshavjee predicts. "It will allow you to have the device sitting in a clinic, or a doctor's office, or a community health clinic, and you'll be able to just put the blood in and within hours know the results. I think it's going to be a game changer."

COVID-19, however, has set back the fight against TB. It's estimated that 30% of TB cases are missed every year. That number is believed to be much higher now. "When people aren't found, and continue to go untreated, they spread the disease to their families and their communities. The sick go undiagnosed, and the exposed and infected don't receive preventive therapy," Keshavjee says. "So I think, in many ways, the pandemic has been a catastrophe

for the communities struggling against TB. We are going to see the effects for many years."

On the upside, Keshavjee believes that the community health activities advanced by the Zero TB Initiative can also be used to screen, treat and prevent a range of diseases, including cancer, COPD, asthma, diabetes, hepatitis – and COVID-19. "What we're building is a healthcare delivery platform," he says. "We're extending the reach of clinics and laboratories into the communities where people live and work, so it's actually an incredible tool for health-system strengthening."

INSIGHTS BEYOND



### QIAreach-

### QuantiFERON-TB

This new version of the QuantiFERON-TB test is specifically designed to address the needs of low-resource regions of the world with a high TB disease burden. The test, due to launch later this year, will require minimal hands-on time. does not require a laboratory for operation. and is compact and portable. Patients will be able to receive a result from a sinale visit within 24 hours of blood draw.

TUBERCULOSIS

Product availability may differ from country to country based on regulations and approvals.

The opinions and views expressed in this article are those of the individuals named, and not those of any organizations they are affiliated to. They are not intended as a product endorsement

57

BEYOND

FLEET STREET

Dr. Richard Dawood A passionate traveler

who has explored

tries, Richard

from the London

School of Tropical

Dawood is a self-

described "travel

health activist" and

Medicine. Dr.

more than 120 coun-

Dawood got his MD



In pandemic times, interviews at QIAGEN have taken on a new, socially distanced, look.

COVID-19 grounded the journalists, filmmakers, professionals and other frequent travelers who look to London's Fleet Street Clinic for their travel medicine needs. That's when they began to flood into the clinic for COVID-19 tests. Richard Dawood turned to two of QIAGEN's precision instruments to give them fast, accurate PCR results - and get them back to work.

INSIGHTS

leet Street has been the traditional home of British journalism since the 16th century. It's from this storied strip that many journalists have been dispatched by their news agencies to report from countries around the world. That made it a natural place for Dr. Richard Dawood, a travel medicine specialist, and his wife, optometrist

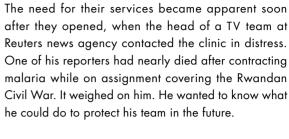
Dr. Gillian Whitby, to launch the Fleet Street Clinic,

Dawood has been fascinated by travel since childhood, traveling around the UK with his parents. But it was a trip he took as a young medical student in the 1970s that set him on a course for travel medicine. One particular event stuck with him, and that was a harrowing stay in a hotel in Kabul, Afghanistan. A group of travelers were stranded there, far too sick with amoebic dysentery to leave the country.

their travel medicine practice, in 1995.

author whose book. "When I approached the rest of my medi-Traveller's Health, cal training, it was slightly through that has been published lens," Dawood says. As he continued to in 10 editions. travel widely throughout Africa and Latin America, "I saw things that were deeply fascinating to me but my medical training left unexplained because they didn't happen in London, Paris or New York. They happened in Ouagadougou or Kabul."

Dawood's experience is what set the trajectory to open a clinic specialized for travelers.



At the time, the standard practice was to send reporters abroad on short notice with little thought as to how the local environment might endanger their health. Dawood knew it wasn't just political instability or war zones that journalists had to be wary of. Bacteria, viruses and parasites could also take a serious or deadly toll.

"To turn this around, we ensured that anyone joining Reuters' TV unit who was eligible to be sent to a highrisk destination was properly prepped and vaccinated, and equipped and educated about travel health issues," says Dawood. To make sure they were ready to travel on a moment's notice, "We did this when they got the job, not when they got the assignment."

That process eventually rolled out across the entire Reuters news agency TV unit. Other media outlets turned to Fleet Street Clinic as well.

### From journalists to COVID-19

Today, most of the newspapers have been replaced by management consultancies and investment firms, so international journalists are just some of the well-traveled patients that Fleet Street Clinic has helped protect during the past 25 years. Some patients live or work nearby, and others seek out the clinic from around the UK. Many travel to dangerous parts of the world, and some have complex travel-related health needs. Musicians and film set crews often tap their expertise. Dawood and members of his staff frequently go on tour with bands across the world or spend weeks on location on film sets, tending to crews that can number in the hundreds.

INSIGHTS BEYOND



MULTI-PLEX PCR



The NeuMoDx system is fully automated and can run up to 288 patient samples at once. It provides accurate and rapid test results in three simple steps that take around an hour. Users can load patient samples as the machine runs, helping to save time and materials used.

Available assays span multiple disease areas such as bloodborne viruses, transplant, sexual & reproductive health, respiratory, and laboratory-developed tests.
CE-IVD assays include SARS-CoV-2, HPV, HIV, Flu A/B/RSV and many more. The SARS-CoV-2 assay is also authorized under FDA Emergency Use Authorization. Several assays are under development and include HSV I/II, VZV, and MG Resistance.

Dawood uses the highthroughput NeuMoDx for large sets of samples – to handle a busy day at the clinic or to test an entire film crew. He reserves the QIAstat-Dx Respiratory SARS-CoV-2 Panel for what he suspects are non-COVID-19 cases, allowing him to quickly pinpoint the infectious microbe – or eliminate the most likely candidates.



"The beauty of having our own equipment means we can actually deliver test results on the same day."

Dr. Richard Dawood





"I think the

world's eyes

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value of fast,

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become clear."

possibilities. The

accurate diagno-

have been

That's when he ordered a NeuMoDx 96. "We like the NeuMoDx because we're not a laboratory. It's doctors and nurses doing the testing. And because it's so selfcontained, it seemed a good choice. Now we're all trained up on its day-to-day use. It was actually fairly straightforward. The beauty of having our own equipment means that we can actually deliver test results on the same day."

MULTI-PLEX PCR

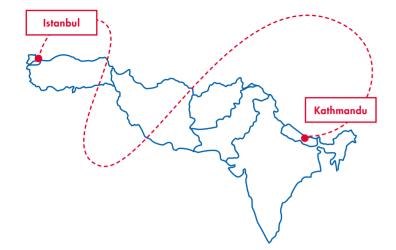
Beyond being capable of handling the testing demand at the clinic, the NeuMoDx system was also essential for allowing some of Fleet Street Clinic's business clients to get back to work as the pandemic ebbed in the warmer months and the UK's lockdown eased.

"The creative industries were very much in the front of the queue to get back to work, and so it was logical that we adapt this molecular testing service to their needs. One of the issues that arises on a film set is that you have many people working together in close proximity. You can't really socially distance people who are appearing in a movie, and you really need a very rapid turnaround of results. And that was where the NeuMoDx really began to help. We could bring samples back, put them on the instrument, and get immediate results – and be able to reassure the people involved in the film production that all was well."

Currently, the clinic is running about 100 COVID-19 tests per day, though that number spiked at over 150 before Christmas and the start of the UK's winter lockdown. With new variants of SARS-CoV-2 emerging around the world, Dawood says a test to detect significant subtypes of the virus is on his wish list for the future.

So far, the clinic has used the NeuMoDx only for COVID-19. "However," Dawood says, "we are very interested in its potential use for other pathogens. I would love to see a much wider menu of tests brought into a point-of-care setting. I'd love to see molecular diagnostics for the full range of intestinal parasites, and for things like Zika."

The pandemic may have ushered in a new era of molecular testing, he says. "I'm hoping that could be one of the longer-term benefits of the massive surge of molecular testing. I think the world's eyes have been opened to the possibilities. The value of fast, accurate diagnosis has really become clear."





It was a trip Dawood took on the Hippie Trail as a university student in the 1970s that set him on a course for travel medicine. A medical kit in his baa, he flew to Istanbul, then set out with friends for Kathmandu, passing through Iran, Afahanistan, India and Pakistan before finally reaching Nepal.

A harrowing stay in a hotel in Kabul, Afahanistan, influenced the trajectory of his career. A group of travelers were stranded there, far too sick with amoebic dysentery to leave the country, which was unstable after a military coup. Luckily, he didn't catch dysentery himself (though he would in the future, along with typhoid, malaria, skin parasites, and other conditions)

"When I approached the rest of my medical training, it was slightly through that lens," Dawood says. As he continued to travel widely throughout Africa and Latin America, "I saw things that were deeply fascinating to me but my medical training left unexplained, because they didn't happen in London, Paris or New York. They happened in Ouagadougou or Kabul."



Product availability may differ from country to country based on regulations and approvals



Dr. Richard Dawood Then, in early January, journalists he knew in China contacted him about a novel pathogen in Wuhan. "They went in to obtain the kind of news footage that everybody saw of the early stages of the pandemic - the affected markets, the hospitals, the response," he says.

Essential to this work are fast and accurate diagnostics, including molecular testing. Fleet Street Clinic is equipped

with two QIAGEN instruments - the NeuMoDx 96 sys-

tem, which offers rapid high-throughput results for 96

samples simultaneously, and the QIAstat-Dx Analyzer,

which together with the QIAstat-Dx Respiratory SARS-

CoV-2 Panel, screens for 20+ targets at once, including

Rapid, comprehensive molecular COVID-19 PCR testing has enabled Fleet Street Clinic's patients to know whether

it's safe for them to leave the country, work in the office,

or sit in the classroom – and whether their symptoms are

caused by COVID-19 or a different pathogen. It's also

enabled some destination-reliant clients, such as film pro-

duction companies, to get back on set.

In fall 2019, Dr. Dawood began using the

QIAstat-Dx Respiratory Panel to rapidly diag-

nose patients. Winter was coming. Some

Londoners were planning their winter holi-

days to warmer climes, and others were

returning from trips abroad. And some of

them were sick, but didn't know what they

were sick with. Getting same-day results

about which pathogen giled them allowed

the clinic to begin targeted treatment almost

**COVID-19** in winter with QIAstat

immediately.

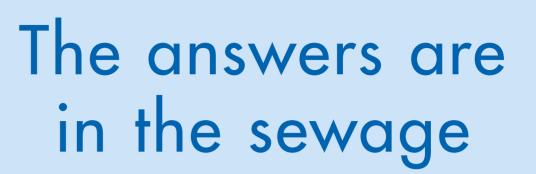
SARS-CoV-2. Both systems return same-day results.

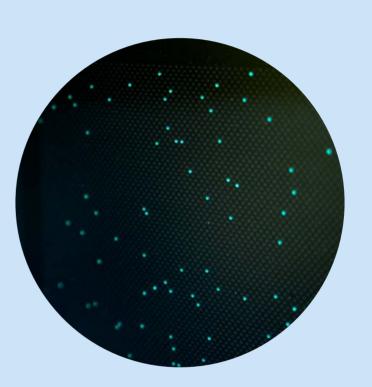
They worried about getting sick. "All of the news gatherers involved in that process needed care, and advice on PPE and protecting their own health," he says. "This was at a point in time when little was known about the virus."

In March, COVID-19 began to tear through Europe. After QIAGEN released the QIAstat-Dx Respiratory SARS-CoV-2 Panel, Dawood used it to test his patients, getting results for up to four people at a time in around an hour.

The demand for PCR tests soon exploded. "We started looking for an instrument that had a much higher throughput, able to cope with perhaps hundreds of tests that might need to be done over a period of time, and for solutions that would allow us to have testing under our own direct control," he says.

COVID-19 in summer with NeuMoDx

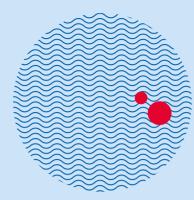




26,000

partitions per well of a digital PCR plate, each equating to an individual PCR reaction to detect SARS-CoV-2.







Wastewater-based epidemiology (WBE) is creating waves around the world. From Australia to Europe. scientists are discovering the value of digital PCR in populationwide disease monitoring.

n March 2020, one of Warish Ahmed's colleagues saw a tweet from a University of Queensland researcher askina if anyone in Brisbane, Australia, could test for SARS-CoV-2 in raw sewage. Researchers in China had just announced they could detect the SARS-CoV-2 virus in the feces of infected people.

But what happened after the waste was flushed away to a wastewater treatment plant, where it mixed with the outflow from hundreds of thousands of toilets, sinks and drains? Were its genetic remnants still detectable? With testing methods for A global project COVID-19 still being developed and distributed around the world, scientists were eager to find new ways to track cases to global response to the understand the scope of the pandemic.

He immediately tagged Ahmed, a senior research scientist at the Commonwealth Scientific and Industrial Research Organization (CSIRO), Australia's national science agency. Ahmed, whose lab specializes in microbial source tracking in water, otherwise known as

Testing sewage for SARS-CoV-2 RNA has become a pandemic. The COVID-19 WBE Collaborative involves over 200 universities, institutions and public health agencies, which monitor more than 1200 sites in 50 countries. The University of California – Merced maintains a dashboard of WBE activities.

MST, had long handled a variety of viral environmental samples from across Queensland. At the first reports of COVID-19 spreading outside of China, he had started work on an analytical method to detect SARS-CoV-2 RNA in wastewater, anticipating the value of an early detection system. The traces were bound to be minuscule when the number of cases was low, but he believed his highly sensitive molecular method could still detect them in raw sewage.

Ahmed tweeted that they should get in

Later that afternoon, three researchers from the University of Queensland rang him. As part of routine drug monitoring, hourly samples were already being collected at treatment plants handling wastewater from Brisbane, Queensland's capital. From these, they created 24-hour composite samples, each murky container representing hundreds of thousands of people. All they needed was the test.

### Pool-testing 600,000 people at once

The samples arrived at the CSIRO laboratory the next day. After first concentrating and then extracting the tiny amounts of RNA from the raw sewage, RT-qPCR tests found what they were looking for: faint but definite traces of SARS-CoV-2 RNA. Using a simple model, they roughly estimated that 171 to 1,090 people in the catchment area, which covers about 600,000 people, were potentially infected.

It was the first confirmed evidence of SARS-CoV-2 RNA in wastewater in Australia. and, says Ahmed, "the results were proof this method could potentially be used to identify hotspots and infected people." They had struck upon what might prove to be a cost-effective way to pool-test entire communities for the disease.

When Ahmed and his colleagues published their proof-of-concept research, it created ripples in the scientific community.

INSIGHTS BEYOND

"If you monitor wastewater, you can potentially screen 10,000 people, 100,000 people, by analyzing one sample."

Dr. Warish Ahmed



Dr. Warish Ahmed is a senior research scientist in CSIRO Land & Water. He enjoys troubleshooting problems, implementing new ideas and putting them to the test. "I have studied science since my childhood," he says. "I wanted to have a PhD in science, which was a very cool thing for a small-town boy from Barisal, Bangladesh."



DIGITAL PCR

Dr. Suzanne Metcalfe is a research projects officer specializing in molecular biology and genomics. Suzanne has an MSc in Biochemistry and worked in medical pathology and university research labs before joining CSIRO Land & Water. Prior to turning her attention to COVID-19 wastewater testing, she applied metagenomic techniques to monitoring drinking water quality, and investigated genetic indicators of insecticide resistance.



### Incorporating wastewater testing into public health

A collaboration between CSIRO, the University of Queensland and Queensland Health, the state health gaency, soon followed: a pilot study to incorporate wastewater-based epidemiology (WBE) as a tool in COVID-19 surveillance. Initially designed as a three-month project, the program has since become a routine monitoring program. The surveillance includes >43 sites of all steps in the dPCR workflow along the east coast from which CSIRO has and employs novel nanoplate analyzed more than 1,900 samples to date. Results for each of the monitoring sites (detected, not detected, or no samples taken) are published weekly on the Queensland Health website.

As the number of samples has increased, "we really needed an automated system for sample preparation," Ahmed says. "We have two QIAcube Connect which are quite useful for automated RNA extraction from concentrated sewage samples."

### Digital PCR with QIAcuity

Digital PCR is a highly precise approach to sensitive and reproducible nucleic acid detection and quantification. It can be used for many of the applications which currently use quantitative PCR, and more.

The QIAcuity is QIAGEN's answer to dPCR. The instrument provides complete integration technology.

Since its launch in September 2020. over 200 QIAcuity instruments have been sold to labs around the world, where it is already proving its utility in, among other things, testing for the SARS-CoV-2 virus in

"The QIAcube platform is robust. It's consistent in its end results, and its ergonomic design makes it easy to use," says Suzanne Metcalfe, a research projects officer with CSIRO, who collaborates with Ahmed on several projects. "We spend a little bit of effort preparing the samples, but once we set everything up, we just press the start button, and can then get on with other tasks, so maximizing productivity."

### Honing the focus

WBE is also being explored for use in smaller-scale monitoring: sampling wastewater from nursing homes, retirement villages, cruise ships and planes packed with repatriating Australians. Ahmed and Metcalfe are working with Qantas Airlines and University of Queensland to test airplane wastewater for repatriation flights and monitor the presence of SARS-CoV-2 virus. "We've been able to report back to Qantas on which planes have come in with positive samples," says Metcalfe.

"Samples are collected from aircraft following outgoing passenger-free and incoming repatriation legs of the journey. Wastewater monitoring results have indicated ~90% accuracy of detecting COVID-19 tested by analyzing wastewater compared to clinical swab testing."

### The future of WBE and COVID-19

Even as vaccines become more available, there will still be a need for public health agencies to surveil COVID-19 circulation on a mass - and affordable - scale. "WBE is cheaper than individual testing, which costs about \$75 per person and gives just a snapshot of a single person at a particular time," Ahmed says. "If you monitor wastewater, you can potentially screen 10,000 people, 100,000 people, by analyzing one sample." Regional medical professionals are also interested in expanding the work westward across the state to support the Indigenous and other vulnerable communities in Australia.

INSIGHTS BEYOND

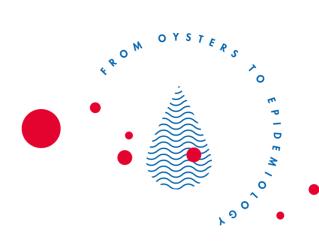
As vaccines reduce the number of COVID-19 infections it will become harder to detect in the wastewater, as the viral concentration will be very low. Their solution, Ahmed says, "is incorporating new sensitive detection methods – for example. the QIAcuity."

QIAGEN'S QIAcuity nanoplate digital PCR system is designed to find such faint genetic signals. It partitions the sample into 26,000 individual reactions, making it far easier to pinpoint a single positive. They're beginning to test the QIAcuity. Ahmed says, "We believe digital PCR is going to increase the sensitivity at least five- to ten-fold."

### Wastewater-based epidemiology (WBE)

is a method of monitoring disease circulation in a community in real time. Poliovirus was the first virus to be seriously tracked in sewage. Since then, many other viruses have come on the radar.

In the case of COVID-19, a person starts shedding viral RNA into their feces two to three days after infection. Once flushed, it takes a couple of days to reach a wastewater treatment plant. Since COVID-19 symptoms develop five to 14 days after infection, if researchers immediately test for RNA fragments, they can learn of a person's infection before that person is aware they are ill. Of course. WBE can't detect a single person's infection in a large wastewater sample, but multiply that single case by a cluster of infections or an outbreak, and SARS-CoV-2 becomes much more apparent.



Scientists in Montpellier, France, have also been turning to dPCR to tackle population-wide screening in wastewater.

When local authorities asked French startup I.A.G.E. to assess the potential impact of the SARS-CoV-2 virus, on a local oyster farm, it did not come as a surprise. recalls co-founder and head of business development Oliver Couillerot. Specializing in environmental biological analysis and dPCR, the company had collaborated in the past to measure the impact of human activities on the Thau lagoon, home to a thriving shellfish industry and 10% of France's annual oyster production. Oysters are known for their ability to clean the waters they call home because as they feed, they trap bacteria and other harmful contaminants. The impact of wastewater overflow had long been a concern of oyster farmers in the area, and now they faced a new threat - SARS-CoV-2.

Scientists at I.A.G.E. had already established a robust approach to quantify the SARS-CoV-2 virus in wastewater, incorporating QIAGEN's QIAcuity instrument.

"Our diagnostic test relies on digital PCR." Couillerot says. "because it's a very sensitive and reproducible tool to measure the amount of DNA and RNA molecules in a sample."

DIGITAL PCR

What they found in the samples taken near the lagoon was more than a bia surprise: their test revealed not only SARS-CoV-2 but the UK variant of the virus the first evidence of this variant in France.

The dPCR test has since shown its value in correlating viral loads in sewage with diagnostic testing and tracing variants of SARS-CoV-2. "It allowed us to perform alobal and massive monitorina of the infection levels in a population within a city, and even smaller communities, such as residential settings for elderly people," says Couillerot. The company plans to make the tool available at a reasonable cost to researchers for whom sophisticated assays might otherwise be out of reach. "And to do that. we rely on the QIAcuity, because of its rapidity in processing samples, reliability of results obtained, simplicity of use and affordable price."

# have have always been here

FOR OUR CUSTOMERS

"These have been some of the most challenging times in living memory. The COVID-19 pandemic has changed our lives and the way we work. But one thing will remain unchanged: We at QIAGEN will continue to be there for our customers, so their work can keep making improvements in life possible."



Francesca Di Pasquale, Associate Director for Research and Development, QIAGEN, Hilden, Germany.

Francesca has been a scientist with QIAGEN for 12 years. She is also the familiar face found inside QIAGEN's iconic blue kit boxes. For QIAGEN customers around the world, Francesca has come to stand for QIAGEN quality and reliability. As one scientist on social media put it in a recent Reddit post: "Not all heroes wear capes. This woman is an inspiration."

During the pandemic she once again became the face of QIAGEN's ongoing support of our customers. Her message today...

# and we will continue to be



BEYOND THE PANDEMIC

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In this annual report QIAGEN uses the term molecular diagnostics. The use of this term is in reference to certain countries, such as the United States, and limited to products subject to regulatory requirements.

As of February 2021, QIAGEN molecular diagnostics products included 24 FDA (PMA-approved or 510 (k)-cleared) products, 18 clinical sample concentrator products (14 kits and 4 instruments), 60 EU CE IVD assays, 17 EU CE IVD sample preparation products, 18 EU CE IVD instruments for sample purification or detection, 34 China CFDA IVD assays/sample preparations and 9 China CFDA IVD instruments.

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### SAMPLE TO INSIGHT

### The molecular revolution

A scientific revolution is rapidly evolving our understanding of DNA and RNA - the building blocks of life. It's affecting us in ways we don't even realize.







Genomic Data = >1.5B DVDs annually





Costly





The challenge

Gaining access to valuable molecular

insights – and understanding their impact –

remains elusive and challenging.



Lengthy

Unreliable

### THAT'S WHY QIAGEN EXISTS

Every day we help more than 500,000 customers gain the valuable molecular insights they need



### HOW WE DO IT



Offer a targeted product

from samples for virtually

any application involving

the building blocks of life.

portfolio to enable insights





Keep a finger on the pulse

latest scientific breakthroughs

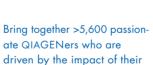
of innovation to turn the

into useful products.



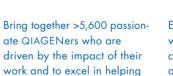






customers exceed their own

expectations





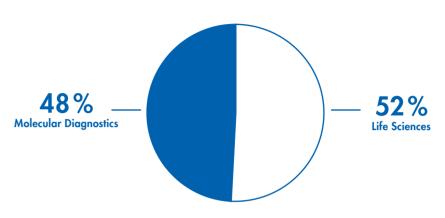
Extend our global reach so we're everywhere our customers are — in countries around the world and even in space.

### MAKING IMPROVEMENTS IN LIFE POSSIBLE

### OUR COMPANY

### **Customer Classes**

share of 2020 net sales



### **Product Categories**

share of 2020 net sales

14%







are used with consumables, enabling customers to automate processes from the preparation of clinical samples to the delivery of valuable results.

### Consumables and related products

are specialized kits that contain all necessary materials to support the use of sample and/or assay technologies as well as bioinformatics solutions for analysis, interpretation and reporting of biological data.

### **Global Presence**

of total QIAGEN 2020 sales



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