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Profiles in Leadership
From CEOs to Nobel laureates, women are making their mark in the clinical sciences

By Laurie Bonner

14

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Gender Matters

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Does gender matter when it comes to science? We all know it shouldn't, of course. Data and reproducible results, by definition, need to be independent of the scientists who generate it. But we also all know that gender can make a huge difference—in prevailing social attitudes, opportunities presented, recognitions awarded.

How many women over the years—such as chemist Rosalind Franklin and physicist Jocelyn Bell Burnell—were passed by while Nobel Prizes were awarded to their male colleagues? The good news is that the times, at last, seem to be changing. Since the first Nobel Prizes were awarded in 1901, a grand total of 58 in all categories have been given to women—and nearly half, 28, happened since 2001.[1]

The prizes for chemistry and physics have been especially deficient in female representation. In 2020, the Nobel for physics was awarded to a woman—Andrea Ghez, PhD—for only the fourth time in history; also this year, Jennifer Doudna, PhD, and Emmanuelle Charpentier, PhD, inventors of CRISPR/Cas9, became the sixth and seventh women to win the Nobel in chemistry.

Recognitions like this matter, in part because it helps to inspire new generations of young women to pursue careers in the sciences.

"I hope this award shows young women that a career in lab science is not only a real possibility, but that the community wants them and needs them," says Doudna, in an interview with *CLP*.

To support that effort, *CLP* has profiled Doudna, along with six other women whose leadership and innovation are contributing to clinical lab sciences (see "Profiles in Leadership," page 14). Their profiles stand alongside the work of two other highly accomplished women: Nancy Stratton, CEO of COLA (see "The Virus That Took Over the World," page 12), and Jean Patel, PhD (see "Fighting Antimicrobial-Resistant HAIs," page 32).

Of course, the dominant headline of 2020 is still covid-19. Stratton's interview along with Albino Troilo, PhD's article, "Current Challenges in Covid-19 Testing" (page 20), both explore the impact the pandemic has had on clinical labs, what effects may become long-lasting or permanent, and what changes may still be to come. Michael Fiebig, PhD's "Better Controls for Covid-19 Diagnostics" (page 26) describes the race to develop effective controls for covid-19 testing and research.

What do you think?

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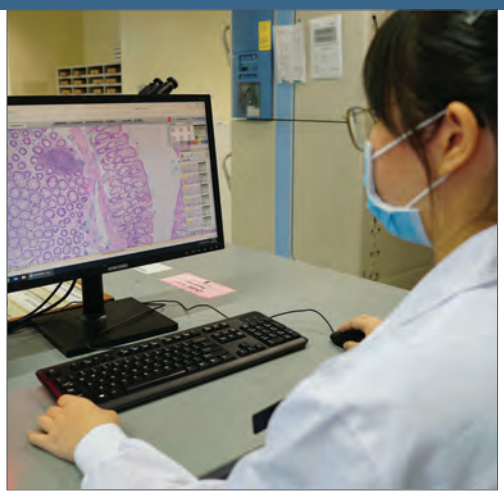

Digital pathology at Singapore General Hospital. Photo courtesy Philips.

Philips, Singapore General Hospital to Establish Digital and Computational Pathology Center of Excellence

Royal Philips, Amsterdam, announced a collaboration with Singapore General Hospital (SGH) to establish the Singapore General Hospital Digital and Computational Pathology Center of Excellence. The SGH Center of Excellence aims to advance pathology practice by implementing a fully digital histopathology workflow and deploying artificial intelligence (AI) to increase productivity and enhance patient care.

Located within SGH's Division of Pathology, one of the largest pathology laboratories in ASEAN, the Center of Excellence aims to establish ASEAN's first fully digitized histopathology laboratory by expanding its digital pathology capabilities for primary diagnosis, training, and research with the Philips IntelliSite Pathology Solution. Both SGH and Philips will also work closely on other diverse areas, including streamlining of the histopathology laboratory's digital workflow.

As in other parts of the world, the demand for cancer diagnosis in Singapore is increasing while pathologists remain scarce. A recent study, conducted by SGH and Philips, revealed that full digitization of SGH's histopathology laboratory will improve efficiency. It has the potential to enable time savings in the pathology workflow and allow the pathology department to increase its capacity by another 7% while retaining the same number of employees.

Through optimization of digital pathology at SGH, the hospital will be able to further its research in AI. AI-based tools can aid pathologists in diagnosing diseases such as cancer—the leading cause of mortality in Singapore—and empower them to face the current challenges in pathology. The increasing number of cancer cases, an aging population, and rapid advances in personalized medicine have resulted in significant complexity of pathological diagnostics, adding to the workload of pathologists. AI will allow pathologists to focus more on challenging tasks and unusual cases that require a higher degree of expertise and skills.

Siemens, CDC Collaborating to Define Threshold for Covid-19 Immunity

Siemens Healthineers announced a collaboration with the United States Centers for Disease Control and Prevention (CDC) and the JRC (Joint Research Centre) of the European Commission on a research project to develop a novel process for standardizing SARS-CoV-2 assays.

Headquarters of the Centers for Disease Control and Prevention. Photo courtesy Dreamstime.

Antibody tests differ among test manufacturers and currently cannot be analytically compared because they target different SARS-CoV-2 proteins. These include the spike protein, S1/S2, S1 RBD, and N protein, which are found in different parts of the SARS-CoV-2 virus. As the pandemic has evolved, antibody test results have progressed from qualitative positive/negative results to more recent assays capable of numerical measurements that gauge the level of IgG antibodies in a patient's blood sample.

The reportable numerical patient results of the current semiquantitative assays are expressed in units that are not actual concentrations of antibodies, but rather the antibody activity to the virus. Because comparing test results across manufacturers has not been possible, establishing immunity associated with these tests has been challenging. Siemens Healthineers' collaboration with the CDC and the JRC will develop a novel process for standardizing SARS-CoV-2 assays by anchoring each protein to a neutralization antibody titer—a level of antibody present to block virus from entering cells in laboratory experiments.

Global Partnership to Offer 120 Million Covid-19 Rapid Tests for Low- and Middle-Income Countries

The Access to Covid-19 Tools (ACT) Accelerator—a global collaboration to accelerate the development, production, and equitable access to covid-19 tests, treatments, and vaccines that includes the World Health Organization, the European Commission, and the Bill & Melinda Gates Foundation—has announced a set of agreements to make affordable, high-quality covid-19 antigen rapid tests available for low- and middle-income countries (LMICs).

As part of this comprehensive effort, the Bill & Melinda Gates Foundation has executed separate volume guarantee agreements with rapid diagnostic test (RDT) producers Abbott, Chicago, and South Korea-based SD Biosensor. These two arrangements will make available to LMICs 120 million antigen rapid diagnostic tests (Ag RDTs)—priced at a maximum of $5 per unit—over a period of 6 months. These tests provide results in 15 to 30 minutes and will enable expansion of testing, particularly in countries that do not have extensive laboratory facilities or trained health workers to implement molecular tests.

The tests developed by Abbott and SD Biosensor are highly portable, reliable, and easy to administer, making testing possible in near-person, decentralized healthcare settings. Both companies' tests are faster and cheaper than laboratory-based tests, enabling countries to increase the pace of testing, tracing, and treating people for covid-19 at the point of care particularly in areas with under-resourced health systems. A number of other Ag RDTs are at various stages of development and assessment.

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Significant Step Toward Blood Test for Alzheimer's Disease

Researchers at Washington University School of Medicine in St. Louis have developed a technique to detect minute amounts of a protein fragment linked to Alzheimer's disease in the blood. The study shows that levels of p-tau-217 are elevated during the early stages of Alzheimer's disease and could lead to a simple blood test capable of diagnosing the neurodegenerative disorder years before any symptoms begin to appear.[1]

Randall Bateman, Nicolas Barthélemy, and colleagues at Washington University School of Medicine in St. Louis previously found that a modified fragment of tau, known as p-tau-217, accumulates in the cerebrospinal fluid of Alzheimer's patients before the onset of cognitive symptoms, increases with disease progression, and can accurately predict the formation of amyloid plaques. The researchers suspected that p-tau-217 might also be present in the blood of Alzheimer's patients, albeit at very low levels that would make it difficult to detect.

Barthélemy and colleagues developed a mass spectrometry-based method to measure the amount of p-tau-217 and other tau fragments in as little as 4 ml of blood, even though such small samples may contain less than a trillionth of a gram of p-tau-217.

The researchers found that, similar to p-tau-217 levels in cerebrospinal fluid, p-tau-217 levels in the blood were extremely low in healthy volunteers but elevated in patients with amyloid plaques, even in those who had yet to develop cognitive symptoms.

REFERENCE

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New CPT Codes for Covid-19 Multivirus Tests

The American Medical Association (AMA) has published an update to the Current Procedural Terminology (CPT) code set that includes new code additions and editorial revisions for reporting medical services sparked by the public health response to the covid-19 pandemic.

The update to the CPT code set was approved by the CPT Editorial Panel, the independent body convened by the AMA with authority to review and approve proposed additions and revisions to the CPT code set. The new additions and revisions to the CPT code set have been approved for immediate use.

"Two of the newly approved codes report nucleic acid assays that allow a single test to simultaneously detect the novel coronavirus and a combination of common viral infectious agents, including influenza A/B and respiratory syncytial virus," says AMA President Susan R. Bailey, MD. "Concurrent detection promises to conserve important testing resources, allowing for ongoing surveillance of influenza while testing for the novel coronavirus."

For quick reference, the new category I CPT codes and long descriptors are:

87636. Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique

87637. Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique.

The CPT Editorial Panel also revised CPT codes ranging from 87301 to 87430 by removing the undefined term "multi step method" from code descriptors.

NASA Creates Breath Analyzer to Diagnose Multiple Illnesses

The National Aeronautics and Space Administration (NASA) representatives presented new medical diagnostic technology, the E-Nose Breathanalyzer, to members of David Grant USAF Medical Center Oct. 21, 2020, at Travis Air Force Base.

The E-Nose Breathanalyzer, under development at NASA's Ames Research Center in Silicon Valley, will have the capability of analyzing compounds found within a person's breath to diagnose a battery of illnesses and abnormalities including respiratory illnesses, infectious diseases, and cardiovascular conditions. As the science continues to be explored, the breath analyzer may one day be used to diagnose cancer. Travis AFB Airmen are hosting the NASA technology and collaborative research at the DGMC clinical investigation facility.

"The technology is designed to make rapid measurements, in less than 5 minutes, at the point of care, in a way that is completely noninvasive. When fully realized, the NASA E-Nose will open a new realm of medical care to both the warfighter and potential space travelers," says David Loftus, MD, PhD, NASA Ames Research Center medical officer and principal investigator of the Space Biosciences Research Branch.

"The technology itself is handheld," Loftus says. "This makes it valuable not only to the U.S. Air Force during aeromedical evacuation, but also to NASA, as a tool for monitoring the health of astronauts far from medical centers on Earth. Human exploration of space, to the Moon and Mars, will require compact medical diagnostics technologies that can be ruggedized for field use. The Air Force and other branches of the military share this requirement."

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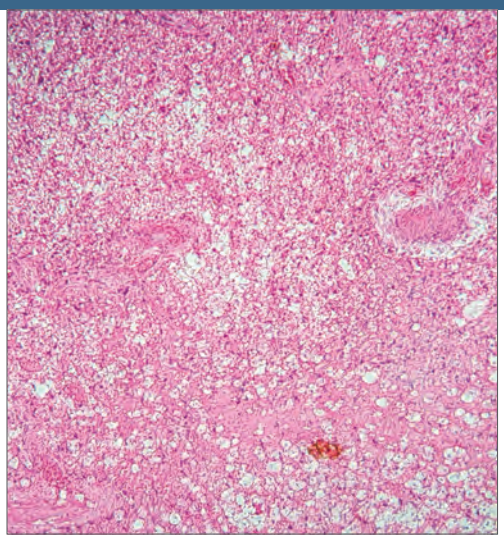

Glioma tumor with diseased tissue. Photo © Dr. Norbert Lange, Dreamstime.com

Breakthrough Blood Test Developed for Brain Tumors

Genetic mutations that promote the growth of the most common type of adult brain tumors can be accurately detected and monitored in blood samples using an enhanced form of liquid biopsy developed by researchers at Massachusetts General Hospital.[1]

Comparing blood samples from patients with gliomas with tumor biopsy tissues from the same patients, Leonora Balaj, PhD, Bob S. Carter, MD, and other MGH investigators in the Department of Neurosurgery found that a novel digital droplet polymerase chain reaction (ddPCR) blood test they pioneered could accurately detect and monitor two mutations of the gene TERT. The mutations, labeled C228T and C250T, are known to promote cancer growth and are present in more than 60% of all gliomas and in 80% of all high-grade gliomas, the most aggressive and life-threatening type. The discovery has the potential to substantially improve the diagnosis and monitoring of gliomas.

Liquid biopsy is a method for detecting cancer by looking for fragments of tumor DNA that circulate in blood. The technique has been shown to be sensitive at detecting the presence of some forms of cancer, but brain tumors have until now posed a formidable barrier.

"Liquid biopsy is particularly challenging in brain tumors because mutant DNA is shed into the bloodstream at a much lower level than any other types of tumors," Balaj says. "By 'supercharging' our ddPCR assay with novel technical improvements, we showed for the first time that the most prevalent mutation in malignant gliomas can be detected in blood, opening a new landscape for detection and monitoring of the tumors."

The team's goal is to expand this blood test to be able to differentiate many types of brain tumors.

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Prototype Device Lets Patients Monitor Their Own Blood for Cancer Biomarkers

Researchers at McMaster and Brock universities have created the prototype for a handheld device to measure a biomarker for cancer, paving the way for home-based cancer monitoring and to improve access to diagnostic testing.[1]

The handheld device measures a biomarker for cancer, paving the way for home-based cancer monitoring. Photo courtesy McMaster University.

The device works much like the monitors that people with diabetes use to test their blood-sugar levels and could be used in a medical clinic or at home, all without labwork, greatly simplifying the process for testing blood for cancer's signature.

A user would mix a droplet of blood in a vial of reactive liquid, then place the mixture onto a strip and insert it into a reader. In minutes, the device would measure an antigen that indicates the degree to which cancer is present.

The prototype has been designed to monitor prostate specific antigen (PSA), and the technology can readily be adapted to measure other markers, depending on the form of cancer or other chronic disease.

"This is another step toward truly personalized medicine," says McMaster's Leyla Soleymani, a biomedical engineer and Canada Research Chair in Miniaturized Biomedical Devices. "We're getting away from centralized, lab-based equipment for this kind of testing. This would make monitoring much more accessible and cut down on the number of times patients need to leave home to provide blood samples."

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Blood Test Predicts Which Covid-19 Patients Will Develop Severe Infection

Scientists have developed, for the first time, a score that can accurately predict which patients will develop a severe form of covid-19.[1] The measurement, called the Dublin-Boston score, is designed to enable clinicians to make more informed decisions when identifying patients who may benefit from therapies such as steroids and admission to intensive care units.

Until this study, led by researchers at RCSI University of Medicine and Health Sciences in Dublin, Ireland, no covid-19-specific prognostic scores were available to guide clinical decision-making. The Dublin-Boston score can now accurately predict how severe the infection will be on day 7 after measuring the patient's blood for the first 4 days.

The blood test works by measuring the levels of two molecules: interleukin (IL)-6, which is pro-inflammatory, and IL-10, which is anti-inflammatory. The levels of both are altered in severe covid-19 patients.

Based on the changes in the ratio of these two molecules over time, the researchers developed a point system where each single-point increase was associated with a 5.6-times increased odds for a more severe outcome. "The Dublin-Boston score is easily calculated and can be applied to all hospitalized covid-19 patients," says RCSI Professor of Medicine Gerry McElvaney.

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1. McElvaney OJ, Hobbs BD, Qiao D, et al. A linear prognostic score based on the ratio of interleukin-6 to interleukin-10 predicts outcomes in COVID-19. *EBioMedicine.*Epub. October 8, 2020. doi: 10.1016/j.ebiom.2020.103026.

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The Virus That Took Over the World

The changes wrought by covid-19 may be felt for years to come

Nancy Stratton, COLA.

Interview by Laurie Bonner

In the January/February 2020 issue of *CLP*, then-chief editor Steve Halasey interviewed Amesh Adalja, MD, FIDSA, senior scholar in the Center for Health Security at Johns Hopkins University, about an emerging viral infection that had only just appeared on the horizon. The first US case of what was then called "2019-nCoV" infection was confirmed on January 20, 2020, and as of January 30, 2020, a total of 9,976 cases had been reported in 21 countries. For most Americans at the time, the threat seemed distant, and few were sounding the alarm.

Since then, of course, the entire world has changed. As of October 8, 2020, the count of global cases of covid-19 had risen to 36,281,192, with 1,057,625 deaths; for statistics by country, the United States was number one on both lists, with 7,564,279 cases and 212,154 deaths.

The effects of the global pandemic have reverberated throughout the entire healthcare industry, in the United States and around the world. For one perspective on the impact covid-19 has had on clinical labs, *CLP* interviewed Nancy Stratton, chief executive officer of COLA.

CLP: How has covid-19 affected operations at COLA? Have your educational offerings and accreditation services changed in any way? If so, what changes do you anticipate might become a permanent "new normal" and why?

Nancy Stratton: The pandemic has had a profound effect on the day-to-day business of accrediting laboratories. During the pandemic COLA has been able to provide uninterrupted customer support to our accredited laboratories, having implemented our virtual work policy. The most obvious adjustment to normal operations was COLA's suspension of routine surveys from mid-March to mid-May and the subsequent intense review of pandemic data to identify areas of the country where it is safe to perform surveys. This has been a challenge because the incidence of the virus in specific areas can change rapidly.

Our Surveyor team are all COLA employees, so we have had the flexibility to resume surveys using our own discretion and risk assessment. When COLA resumed surveying, at a limited capacity, in mid-May, we decided to allow our Surveyors to travel only to laboratories within driving distance of their homes, to minimize their risk of exposure. We have also gave our Surveyors masks, disinfecting wipes, and hand sanitizer and provided them, as well as our laboratories, with precautions that they are expected to observe during the survey.

Although we would like to resume air travel, there are just so many variables and risks to consider. As a result of the high incidence of the virus in some states, and as a result of suspending air travel for an extended period of time, surveys have been delayed, not just for COLA laboratories, but for other regulatory agencies as well.

In late May, CMS notified the Accrediting Organizations that, with CMS approval, they could define and implement processes for remote, or virtual, surveys. This flexibility allows Accrediting Organizations to review laboratory processes via other means, until an on-site visit is safe. COLA's virtual survey process was approved by CMS in July and has been launched. COLA's virtual survey process includes three components: documentation review; video conference; and brief on-site visit, when it is safe to do so.

Of course, we do prefer to perform the normal on-site survey where we can, and we are reserving the virtual survey process for laboratories located in areas where we have not been able to travel.

During the pandemic we have also shifted our educational focus to covid-19. We have posted regular updates on our customer portal and provided links to critical information on the FDA, CMS, and CDC websites. We have provided our laboratories with a technical bulletin with information on the FDA's emergency use authorization (EUA) process and have given virtual presentations for the laboratory industry at every opportunity. We keep laboratories informed about all of the notifications coming from the CDC Laboratory Outreach Communication System (LOCS) and encourage them to listen in to the biweekly CDC conference calls.

We have also recently initiated an online chat feature Monday through Friday from 1 pm to 5 pm EDT on cola.org. This service is open to all laboratory professionals.

We are definitely experiencing a "new normal." I think our industry may have to adapt some long-term new habits, such as virtual conferences, and find creative ways to network and learn together in a virtual world. Although we do not expect to continue with the virtual survey process after the pandemic subsides, it is possible that some of the enhanced precautions that we are taking now will become routine. Perhaps some laboratory documentation will be routinely reviewed prior to survey. If we can use learnings from the pandemic to make the accreditation process better for everyone, we will embrace changes as we look to the future, whatever it may hold.

CLP: What impact has the surging demand for covid-19 diagnostic testing had on the business of clinical laboratory management? What additional education/support is COLA offering labs during this time?

Stratton: Many laboratories want to contribute to the public health effort by offering covid-19 testing to their communities, but there have been supply chain challenges. This seems to be getting better, although we have heard that some laboratories have acquired equipment to do the testing but have been unable to obtain enough testing supplies to keep up with the volume.

Providing off-site collection sites and/or temporary testing sites has been a trend, but

these models also come with regulatory constraints, and laboratories need information to make sure that these are being operated as required by CLIA and by the various states.

Laboratories also must be informed about requirements for covid-19 testing, including notification of all results, both positive and negative, to the public health agencies. Specific demographic information is required.

There have also been EUAs that have been revoked, and the FDA has provided guidance on what a lab needs to do if the test system it had been using has had its EUA revoked. So it is essential that laboratory management keep on top of the news, read the LOCS alerts, and listen in to the CDC meetings.

As mentioned, COLA has stepped up the provision of information and guidance to our laboratories, via technical bulletins, online chat, and regular updates on our customer portal. We have also identified dedicated Technical Advisors to field calls and emails specifically on covid-19 testing. We believe that sharing vital information during the pandemic is important for all laboratorians, so we have shared information using social media, blog posts, professional publications, and virtual presentations. This demonstrates our commitment to the entire industry and the patients that we serve.

CLP: Initiatives such as RADx are driving innovation, development, and implementation of testing for covid-19. Do you think laboratories will be able to meet the demand?

Stratton: We applaud the National Institute of Health's RADx initiative for encouraging the rapid development of needed diagnostic testing, especially testing that can be turned around quickly. We have all heard how important it is to get results quickly, to support effective contact tracing. I do think that laboratories will get to the point where they can keep up with the demand. A national testing strategy and a standardized prioritization for testing would be helpful toward this goal.

We also need to make sure that covid-19 testing can be performed, or at least have samples collected, in schools and businesses that partner with local laboratories to provide rapid and accurate test results in a timeframe that allows mitigation of the spread of the infection.

CLP: What advice would you offer to clinical lab managers to better prepare for the future as the pandemic continues to unfold?

Stratton: By now, every laboratory should be establishing procedures to be implemented during public health crises such as a pandemic. This may include emergency staffing procedures, partnerships with regional or national reference laboratories, additional precautions for staff to observe, and test menu prioritizations.

While we don't recommend stockpiling large amounts of laboratory supplies, it might be a good idea to define a minimum amount of safety supplies, such as gloves, gowns, and face shields, to keep on hand. And make sure you have identified alternate suppliers should some of these or other supplies become difficult to obtain.

This pandemic has been tragic in so many ways, but it will be even more tragic if we don't learn from what we have seen over the past months. ●

Laurie Bonner *is chief editor of* CLP.

Profiles in Leadership

From CEOs to Nobel laureates, women are making their mark in the clinical sciences

By Laurie Bonner

On October 7, 2020, news broke that the 2020 Nobel Prize in Chemistry had been awarded to Emmanuelle Charpentier, PhD, and Jennifer Doudna, PhD, "for the development of a method of genome editing." Charpentier, of the Max Planck Unit for the Science of Pathogens in Berlin, and Doudna, of the University of California, Berkeley, developed the CRISPR/Cas9 genetic scissors—"one of gene technology's sharpest tools," according to the statement from the Royal Swedish Academy of Sciences. "Using these, researchers can change the DNA of animals, plants, and microorganisms with extremely high precision. This technology has had a revolutionary impact on the life sciences, is contributing to new cancer therapies, and may make the dream of curing inherited diseases come true."

Much of the international news coverage mentioned one fact: Charpentier and Doudna are the first team of women to win the Nobel Prize in Chemistry together. Prior to this year, only five women had ever received this award—Ada E. Yonath (2009) and Irene Joliot-Curie (1935) shared the prize with male partners, and Frances H. Arnold (2018), Dorothy Crowfoot Hodgkin (1964), and Marie Curie (1911) earned the prize solo.

Charpentier and Doudna (pictured above receiving the 2017 Japan Prize) are not the only women building successful careers in the clinical lab sciences. *CLP* reached out to Doudna—and six other women whose leadership and innovations are reshaping the field—to ask how gender matters and about the prospects for women in clinical lab sciences. Here's what they said.

Jennifer Doudna, PhD

Li Ka Shing Chancellor's Chair/Professor
University of California, Berkeley
Investigator
Howard Hughes Medical Institute

With collaborator Emmanuelle Charpentier, PhD, Doudna developed CRISPR/Cas9, genome-editing technology that has redirected the course of healthcare and agricultural research. Doudna is also a leader in public discussion of the ethical and other implications of genome editing for human biology and societies, and she advocates for thoughtful approaches to the development of policies around the use of CRISPR-Cas9. In 2017, Doudna co-founded Mammoth Biosciences, a business focused on improving access to biosensing tests. She earned a PhD in biological chemistry and molecular pharmacology from Harvard Medical School.

CLP: ***Can you describe what it means to you to have your work recognized with a Nobel Prize?***
Doudna: I'm really proud. I'm proud to represent a public university like UC Berkeley that supports great science and education, one that serves the public good and welcomes people of all backgrounds. It's also a great moment for basic science. We didn't start studying CRISPR with the idea that it would turn into a tool with so many applications. I was driven by scientific curiosity, and I'm so fortunate to have been supported to follow that curiosity and to have built a community of colleagues along the way.

CLP: ***Does gender matter? What does female leadership bring to the clinical lab sciences?***
Doudna: Gender absolutely matters. I'm proud to be a female scientist. There are people of all types who are great scientists—or they could be if given the opportunity. Growing up, I couldn't possibly have imagined a future that looks like the life I lead now, because I had never seen it with my own eyes. I hope this award shows young women that a career in lab science is not only a real possibility, but that the community wants them and needs them. Scientific advances take creativity and new ways of thinking, and we get that by inviting different perspectives to take a seat at the bench.

CLP: ***What advice do you offer to young people aspiring to a career path like yours?***
Doudna: You don't have to act or look a certain way to be a scientist; you just have to pursue what interests you and know that you belong there. Surround yourself with people who support your dreams and share your curiosity. I wouldn't be sitting here today offering this advice if I hadn't had a strong community that helped me along the way.

Crystal Icenhour, PhD

Chief Executive Officer and Co-Founder
Aperiomics, Sterling, Va

With more than 25 years of clinical research expertise, Crystal R. Icenhour, PhD, founded Aperiomics with the mission to harness next-generation DNA sequencing and artificial intelligence to identify every known pathogen—bacteria, viruses, fungi, and parasites—using a single test. Icenhour holds two patents, has authored and co-authored numerous research articles and theses, and has been a prolific speaker at scientific conferences. As a world-renowned expert in microbiology, she has served on review panels for the National Science Foundation, the Environmental Protection Agency, and National Institutes of Health Small Business Innovation Research Program.

CLP: ***Tell us about your proudest career achievement.***
Icenhour: My proudest career achievement has been leading Aperiomics' effort to disrupt and advance the way our healthcare system approaches pathogen identification. By integrating innovative technology, entrepreneurial savvy, and industry expertise to improve clinical outcomes for patients, I have helped spearhead the creation of Aperiomics' cutting edge technology to identify every pathogen known to modern science. Using Deep Shotgun Metagenomic DNA sequencing, advanced bioinformatics, and artificial intelligence, our team is able to test the widest range of clinical sample types (skin, urine, fecal, blood, spinal fluid, environmental samples, etc.) for all possible microorganisms, advancing positive clinical outcomes for patients across the country.

CLP: ***Does gender matter? What does female leadership bring to the clinical lab sciences?***
Icenhour: As the chief executive officer of a fast-growing biotechnology company within a male-dominated industry, I know firsthand how gender can factor into the equation. As the first woman Board Chairman in the history of the Virginia Biotechnology Association, I devoted countless hours of my time and energy to setting an example for both men and women in the industry. I tend to see beyond gender by focusing on people as individuals and empowering both men and women to rise up and thrive.

I also know how critically important female leadership can be for clinical lab sciences. Raised in rural West Texas, many of the closest women in my life frequently failed to receive sufficient medical care. My grandmother suffered from undiagnosed chronic pain that doctors regularly dismissed—an issue that far too many women have experienced. That is why I remain steadfast in my commitment to improve the way diseases are understood and tested—not only to raise the standard of care that the women in my family were not afforded, but also to ensure patients experiencing chronic pain are heard, diagnosed properly, and effectively cared for.

CLP: ***What advice do you offer to young people aspiring to a career path like yours?***
Icenhour: I like to tell young people they don't have to choose between a family and a career in science. I believe family support and encouragement allow for one to have both. I am the CEO and co-founder of my own business, an active advocate in the biotechnology industry, and also raising four kids. When you have a nursing infant and need to travel for business, attend a conference, or meet with an investor, it seems to me the only solution is: You take the baby with you. There's certainly no better ice breaker! There is even a photo of me (discreetly!) nursing my daughter Sabrina at a meeting with

the Governor of Virginia. I encourage others to not let societal pressures prevent you from doing what is best for you and your family.

Lily Li, MD, PhD

Medical Safety Officer
Ortho Clinical
Diagnostics, Raritan, NJ

Lily Li, MD, PhD, is the medical safety officer at Ortho Clinical Diagnostics responsible for evaluating potential medical risks and guiding risk mitigation of all marketed products. She also serves as a director at medical and scientific affairs providing evidence-based support to Ortho's current and future products. Li obtained her medical degree from Peking University, China, her PhD in Immunology from the University of Alberta, Canada, and an MBA from Temple University. Lily is the author of more than 40 scientific articles and has filed 17 patent applications.

CLP: *Tell us about your proudest career achievement.*
Li: All my career successes are attached to great teamwork, and I have been fortunate to be part of several high-performance teams. Most recently, in response to the urgent needs for serological tests for covid-19, Ortho formed an amazing team with experienced and fully dedicated people and developed two high-quality SARS-CoV-2 antibody tests at record speed. I am very proud to be part of this team supporting the development of medical contents and providing internal and external trainings on the clinical utilities of the assays.

CLP: *Does gender matter? What does female leadership bring to the clinical lab sciences?*
Li: No, in clinical lab sciences, gender does not matter and there is nothing female scientists and leaders cannot do. I believe female leaders often demonstrate ownership, accountability, and dedication, and we pay attention to details and are willing to work behind-the-scenes, all of which are crucial to the type of work we do.

CLP: *What advice do you offer to young people aspiring to a career path like yours?*
Li: No doubt a career in healthcare industry is very rewarding. Know your passion and what you are good at, and if you can combine these two, hard work often becomes enjoyable. Do not stop learning and always try to expand your horizons; you may be amazed to find new talents! Treasure teamwork, and remember that people are always more important than projects. Regardless of your level or role in your organization, you can always enable, encourage, and motivate others, and together you can achieve something bigger and better than you could have ever dreamed.

Kathleen Orland

Senior Vice President and General Manager
Beckman Coulter,
Brea, Calif

As senior vice president and general manager for Beckman Coulter's Clinical Chemistry Immunoassay (CCIA) business unit, Kathleen Orland leads product strategy and new product development programs across eight global sites. Since joining Beckman Coulter as a senior product manager for Immunoassay in 2005, she has served in multiple positions including vice president of CCIA product management. Orland has a bachelor's degree in microbiology from University of Illinois at Urbana-Champaign, and she earned her Medical Technologist MT(ASCP) credential from NorthShore University HealthSystem.

CLP: *Tell us about your proudest career achievement.*
Orland: I have had many career achievements that I am proud of since starting my career as a medical technologist, working in the hospital laboratory, and later transitioning into marketing and product management. In my current role at Beckman Coulter, my proudest career achievement has been leading the business through the successful launch of important assays, namely receiving emergency use authorization for our Access SARS-CoV-2 IgG and IgM assays as well as for IL-6.

There has certainly never been a point in time like the present, where the clinical laboratories and their important work to serve clinicians' needs and, ultimately, the patients they serve are so needed. The diagnostic industry has a spotlight to bring products to market in record time to provide the best solutions to clinicians in the fight against covid-19.

CLP: *Does gender matter? What does female leadership bring to the clinical lab sciences?*
Orland: My mission and vision to pursue a career in clinical lab sciences stem from my mother passing away from breast cancer when I was 11. From that time, I always wanted to play a role in the medical arena. Through my current role, I feel I'm bringing about my own life's purpose to make a difference.

Because my mother passed away when I was so young, my father raised my two younger brothers and me. I have often found myself to be the only female in the room. I rarely think about gender; I simply do my best every day to support our team to meet our mutual objectives.

When you have female leadership in clinical lab sciences, you bring a different thought process to the table. Men and women may think of things differently, and having a woman in clinical lab leadership brings a diversity of thought when a man might not share the same perspective.

The necessity for diversity is not only gender-related but cultural as well. Diversity of thought brings about different perspectives and creativity. Ultimately, when diversity of thought is present across your team, you achieve better results when unique perspectives come together holistically to challenge the status quo.

CLP: *What advice do you offer to young people aspiring to a career path like yours?*
Orland: Believe you can achieve anything. People are very generous with their time to mentor or coach; if you have questions, or want to reach different career opportunities, don't feel limited or intimidated. Reach out, talk to people. See if you can job shadow, learn, and explore. You can do anything you set your mind to, so set your sights high, have a vision for your future, and pursue it. Never be

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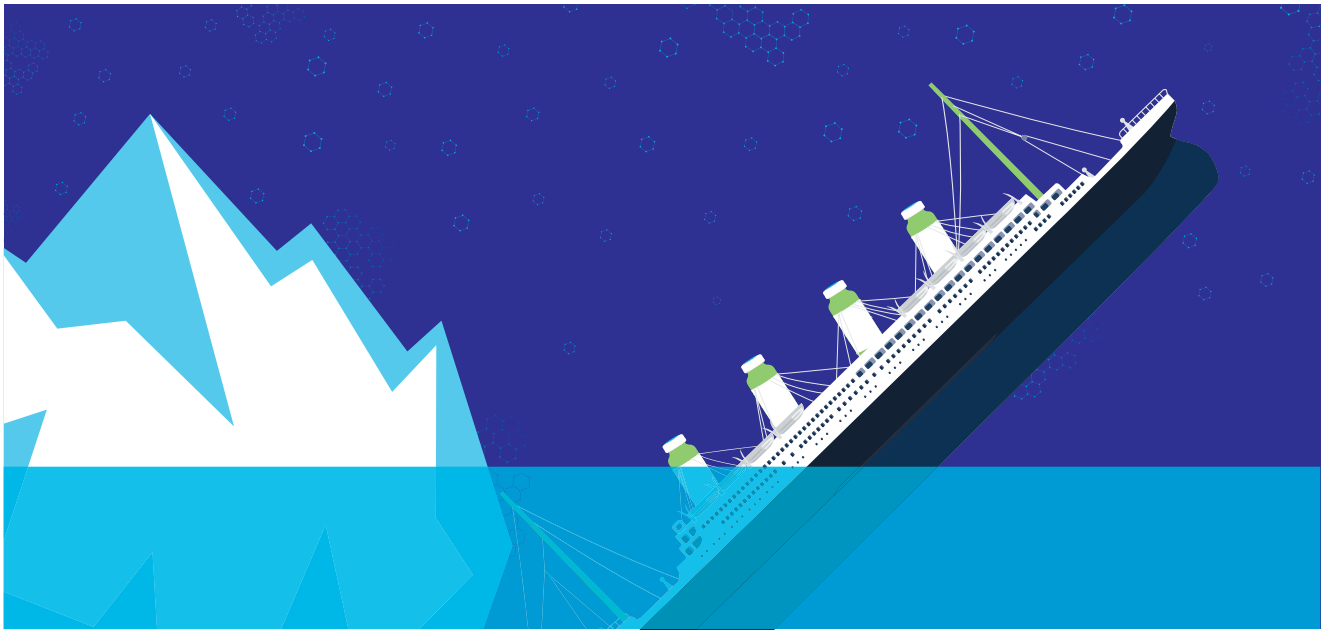

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Also, continually explore, aspire, and challenge yourself. Listen and thank people when they provide feedback to you—incorporate their suggestions into your professional progression. Own your career development and drive it—nobody can do this, but you.

Some women will shrink when it comes to taking leadership roles—instead, you need to be willing to take your space. You have an equal seat at the table, just like any other person, male or female. You deserve that spot, so own it and never shy away from achieving your goals.

Stephanie Post

Senior Director, Marketing Communications, Center for Learning & Program Management
Sysmex America, Lincolnshire, Ill

In her current role at Sysmex America, Stephanie Post is known as a champion of change with "out-of-the-box" thinking to lead a high-performing department focused on customer training, sales training, technical training, instructional design, studio production, project management, and marketing communications. Post is a board-certified clinical laboratory scientist and holds certifications in the training field as a training director, instructor/facilitator, sales trainer, and performance consultant.

CLP: *Tell us about your proudest career achievement.*
Post: Working as a visionary change agent, I shifted Sysmex America away from its traditional in-house train-the-trainer model for instrument training to respond to changing needs of Sysmex's growing customer and employee base. The success of our Virtual Instructor-Led Training (VILT), available for all of our instruments today, initiated and drove a multimillion-dollar project to build a state-of-the-art Center for Learning. Housing seven production studios to live-stream training over the internet, we hired camera people, directors, and producers—not the norm for a laboratory medical device company—and our instructors learned how to be on-camera talent.

The idea was born in 2010, but big change doesn't happen overnight. I had to convince many who were concerned that customers would not adapt to the new learning method. In 2014, Sysmex delivered its first VILT class, enabling every user in the lab to receive the same training experience from subject matter experts. In 2018, we opened the doors to our Center for Learning, which boasts more than 17,000 customers trained across the United States, Canada, and Latin America (a four-fold training increase), a 92% customer satisfaction rate, and excellence in technology and learning awards.

CLP: *Does gender matter? What does female leadership bring to the clinical lab sciences?*
Post: The underrepresentation of women in science, or any field, slows the progress of discovery and innovation by excluding people who have the ability to make significant contributions. Clinical laboratory scientists are smart, competent, and strategic. Female leadership in clinical lab science roles must use this foundation to create a culture to empower their teams'—both male and female—capabilities, aptitudes, and positive attitudes. We must put leaders and their staff in positions that are a "jacket size too big" to inspire continual development and curiosity to break paradigms. We must pair leaders with different skillsets, genders, and experiences to complement each other, learn from each other, and challenge each other. Innovations like VILT for Sysmex have come from this type of leadership and opportunity to stretch individuals beyond their wildest dreams.

CLP: *What advice do you offer to young people aspiring to a career path like yours?*
Post: Prioritize your own learning, recognizing all the ways to gain new knowledge and experience. Find a mentor who is a leader, and don't be afraid to say "Yes" to new experiences. I started with a passion for laboratory medicine and a degree in clinical laboratory science. Using those foundational skills, I pushed boundaries into sales, marketing, training and development, and studio production leadership.

Write down what you see, know, and observe about what works and what doesn't. Identify people you admire and learn from them even if via a TED talk or by reading a few pages out of a book. I would have never pictured my career being so diverse, broad, and rewarding. I couldn't have done it without leadership who believed in me (more than I did myself at times) and a strong committed team. Overall, it's important to make time in your schedule to stretch your horizons.

Tamara Ranalli, PhD

Vice President, Molecular Business Unit
Quidel, San Diego

Tamara Ranalli, PhD, was named senior vice president of Quidel's Molecular Business Unit in August 2020. Previously, she was the director of business development at BioHelix Corporation, where she was instrumental in both the development of the novel isothermal technology used in the AmpliVue and Solana platforms as well as the establishment of the collaboration between BioHelix and Quidel that led to the eventual acquisition of BioHelix in 2013. Ranalli holds a BA in biology from Cornell University and a PhD in biochemistry from University of Rochester School of Medicine.

CLP: *Tell us about your proudest career achievement.*
Ranalli: I think one of the career achievements that I've been most proud of was taking over the VP of Marketing position at Quidel. I'm a biochemist by training, and it was incredibly exciting and rewarding for me to be able to fulfill a role in the organization that is not traditionally led by a PhD scientist. My passion for our products and for our company, and my love of making sure we are represented well out in the world, I think comes through, and it's made me incredibly proud that Quidel would grant me the opportunity to take on that role and work in that area.

CLP: *Does gender matter?*
Ranalli: Definitely. When I was in graduate school in my 20s, my class was balanced between men and women. However, in postgraduate school, the numbers

drastically changed, as many women had to make the choice between their careers and starting a family. That's really where we need to make strides going forward, because it's very challenging for advanced scientists to have this balance, especially in academia.

I think companies do a far better job now in finding a balance for women who want to use their degrees and have fulfilling careers. Many companies can provide benefits such as flexible working environments, daycare options, and other arrangements that allow women to maintain their career path while taking care of their own personal needs. I think that is tremendous.

I've worked with many women, both on my team and on other teams, who have taken their maternity leave, started a family, and come back, and that's really never presented a challenge to their progression at Quidel.

CLP: *What does female leadership bring to the clinical lab sciences?*

Ranalli: Aside from some truly world-class minds that bring different perspectives to leadership teams? Diversity in leadership has been shown to increase both creativity and productivity within organizations. Representation matters, and the ability to have a female mentor, or merely see other successful women in leadership positions, is really important to those starting out in any field. In addition, I think everyone on our executive leadership team, whether male or female, has a responsibility to ensure that the next generation of leaders at our company are properly mentored and supported. I think mentorship is incredibly important, and I try to pay it forward every day.

CLP: *What advice do you offer to young people aspiring to a career path like yours?*

Ranalli: I think the advice I would give most people would be: follow what you love, right? If you're not passionate about what you're doing, I don't think you'll be as successful. If you're just doing the job to do your job and it's not something you care deeply about, then you're not going to go the extra mile. Also, I think it's critical to never stop learning. Regardless of your degree, regardless of your background or role in an organization, there's always something new you can be learning and applying to your career.

Finally, it's important to seek out and accept constructive criticism in order to improve your skillset. Being able to understand what you do well, and what you need to work on, and then putting the work in on those areas that you need to improve is incredibly important in both your career as well as your personal life.

Sarah Levy Schrier

Chief Technology Officer
Sight Diagnostics,
Tel Aviv, Israel

Sarah Levy Schrier leads the research and development, regulation and manufacturing operations teams at Sight Diagnostics. At 18, she joined Talpiot, an elite Israeli military program that Forbes *described as equivalent to a "Rhodes scholarship, a presidential fellowship, and a Harvard MBA rolled into one." Since joining Sight, Schrier has recruited most of the company's employees and, today, over 40% are women. Sarah has been a speaker and lecturer at Women Tech Makers, Hebrew University of Jerusalem, and Weissman Institute, where she's led discussions around women in technology leadership. She holds an MSc in condensed matter physics from the Weizmann Institute of Science.*

CLP: *Tell us about your proudest career achievement.*

Schrier: My proudest career achievement was developing the proprietary technology behind Sight Olo, the first FDA-cleared direct-from-fingerstick complete blood count (CBC) analyzer. CBC is one of the most essential and ubiquitous blood tests that provides a picture of an individual's health, and so far, Olo has enabled some of the world's leading health institutions to perform more than 100,000 tests that deliver lab-grade results in minutes from just two drops of blood.

CLP: *Does gender matter? What does female leadership bring to the clinical lab sciences?*

Schrier: As a woman in a leadership position working in a male-dominated industry, I've encountered some awkward situations. Once, someone met me in the office for the first time and immediately assumed I was the secretary and that I reported to the man next to me. These situations can be funny, embarrassing, or even inappropriate, but soon after, I don't feel the gender issue plays a role once the interaction becomes professional.

Women add diverse perspectives and insights that are crucial to the success of all businesses. For the life sciences industry in particular, our contributions not only affect the diagnostic products and therapeutics that impact women, who account for 50% of the global population, but we also make decisions that impact our future generations.

For example, when I designed Olo, I made sure that it would be accessible to children as young as 3 months old. As a mother, when I bring my child to the doctor, I want the experience to be as painless and efficient as possible. Since Olo requires only two drops of blood to provide a CBC and delivers results within minutes, it makes the entire experience easier, quicker, and less scary for my kids. Including women's ideas and experiences in a company's product development and strategy can help create a more well-rounded end-user experience.

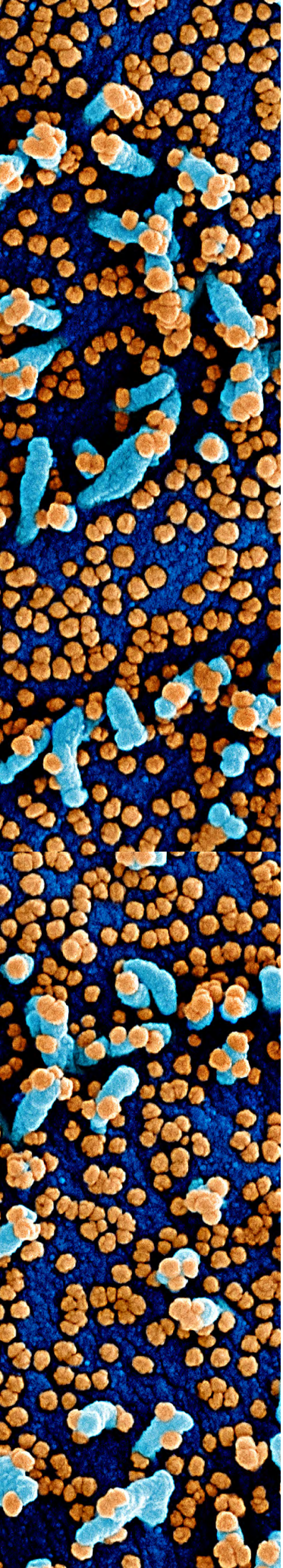
CLP: *What advice do you offer to young people aspiring to a career like yours?*

Schrier: My two major pieces of advice for young people are (1) Don't panic, everything is possible—just do it one step at a time; and (2) There is always a reason to stay optimistic.

In the military, I learned that knowledge, will, and dedication make the impossible possible. I continually apply this lesson to my own career, and I think this has played a large role in getting me to where I am today.

Throughout the years, I have learned that your success depends on the success of your team. It's important to genuinely listen to others and implement feedback so that they feel heard. In order to be a strong leader, you must ensure everyone is motivated. You have to encourage and empower them with responsibility, trust, and positive reinforcement. ●

***Laurie Bonner** is chief editor of* CLP.



Current Challenges in Covid-19 Testing

Where we are now, and what comes next

By Albino Troilo, PhD

The unprecedented public health crisis caused by covid-19 has led to illness, death, and worldwide economic disaster. Symptoms of severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) infection range from none at all to mild fevers and coughs, to severe pneumonia and multi-organ failure.[1] From the beginning, diagnostic testing—to determine if a patient has an active or a past infection—has been critical to monitoring and treating patients and controlling the spread of this disease.

Currently, there are two general types of covid-19 tests:

Diagnostic tests are used to determine whether a patient has an active infection and needs to be quarantined to prevent further spread of the disease. Most of these are *molecular tests,* which are generally categorized as nucleic acid amplification tests (NAATs) because they detect viral RNA in patients' samples, usually from nasopharyngeal swab specimens. Molecular tests rely on reverse transcription (RT) of the viral RNA into DNA, followed by polymerase chain reaction (PCR) amplification of the DNA and subsequent detection. Most frequently, the detection is based on reverse-transcription quantitative PCR (RT-qPCR).

The underlying principle of these RT-qPCR-based tests is simple (Figure 1): Specific genetic sequences are used to detect the virus. A nasal or throat swab is performed to harvest viral particles and virus-infected mucosa cells. The swab sample is then lysed and the viral RNA is extracted and reverse-transcribed into cDNA. The cDNA in the processed sample is then quantified by qPCR to detect the presence of the virus's genome and therefore confirm infection. Different test methods use varying steps to obtain the same result; automatization and optimization of sample preparation and reverse transcription can reduce the time it takes to get results from several days to under an hour. Molecular tests are reliable and accurate and are performed by specialized clinical laboratories.

Antigen tests, which detect specific proteins on the surface of the virus, are an alternative diagnostic for covid-19. These tests detect viral antigens in nasal or throat swab samples using antibody-based assays against specific SARS-CoV-2 viral proteins. Although these tests are specific for the virus and faster and less expensive than molecular tests, they aren't as sensitive as PCR tests. For a positive result, antigen tests require the presence of a considerable amount of viral proteins in the specimen samples,[2] which increases the chances of false negative results in low-grade infected patients.[3] For this reason, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions.

Antibody tests detect antibodies that are produced by the immune system in response

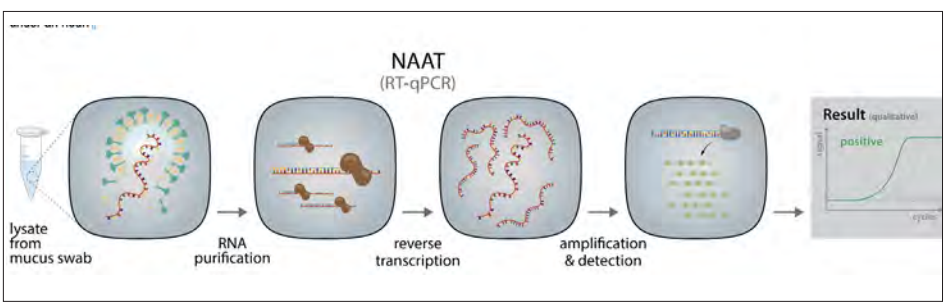


Figure 1. Basic Principle of NAAT COVID-19 Test. Viral RNA is harvested and purified, transcripted into cDNA, and amplified and detected by quantitative PCR.

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to an infection. While molecular tests serve as the frontline diagnostic tools to monitor and combat the covid-19 pandemic, antibody tests, also called immunogenic serology tests, are used to detect antibodies produced by the patient's immune system in response to a prior infection. Serological detection of SARS-CoV-2 antibodies determines whether patients have been exposed to SARS-CoV-2, even if they are currently asymptomatic.

Antibodies—immunoglobulins categorized as IgM, IgA, and IgG—can take several days or weeks to develop after an infection and may stay in the blood for several weeks or more after recovery. IgM is released as a pentameric antibody and is generally among the first responses of the humoral immune system. IgA is secreted as a dimeric antibody and plays a major role in the defense of the mucosal epithelia of the respiratory airways and the intestine. IgG typically appears later and becomes a major component of the immune memory response and immunity. Seroconversion, which is the time period needed until specific antibodies are detectable in the blood, is typically within the first 2 weeks.[4-7]

Due to the delay between infection, symptomatic onset, and the detectable presence of antibodies, serological tests should not be used to diagnose active infection. However, they can be used to confirm past infection in recovered patients or to screen asymptomatic patients. Additionally, these tests can aid in the better characterization of the disease, including: understanding the kinetics of the immune response to infection; understanding the immune response relative to disease severity and timeline; clarifying whether cross-reactivity with other coronaviruses leads to cross-protection; understanding whether past infection protects from future infection and how long immunity will last; determining the correlates of protection that can guide public health measures; selecting potential blood donors of convalescent plasma, which may serve as a possible treatment for seriously ill covid-19 patients; and seroepidemiological studies to understand the extent of covid-19's spread.

Three different types of antibody tests can be used for covid-19:

• *Plaque reduction neutralization test* (PRNT) is performed in a laboratory setting and identifies antibodies that can neutralize a viral infection (Figure 2). PRNT requires whole blood, serum, or plasma from the patient. The sample is diluted, mixed, and incubated with a viral suspension to allow the antibodies to react with the antigens present on the surface of the virus. Following the incubation period, the solution is poured on a layer of host cells that allow for the growth of SARS-CoV-2 virus. The host cells are then covered with a layer of agar or cellulose to prevent viral spreading, and localized plaques (infected regions) form after a few days. The plaques are then measured by microscopy observation or fluorescent dyes that react with the infected cells. Plaque formation is affected by the presence of neutralizing antibodies in the patient's serum. The concentration of serum to reduce the number of plaques by 50% compared to a control sample without serum provides the PRNT50 value, which is the measure of how much antibodies are present in the sample and how effective they are.

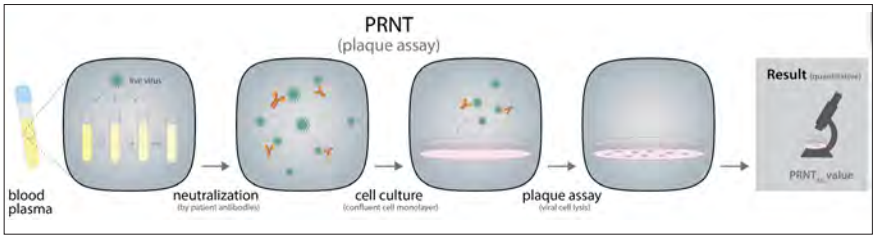

Figure 2. Basic Principle of Neutralization Tests. Serial dilution of a blood plasma sample is mixed and incubated with viral suspension. Virus and antibody-containing serum is plated on a monolayer of host cells, which is then covered with agar or cellulose for a few days. Plaque forming units appear on the plate and can be quantified by microscope. The number of plaques is affected by the presence of neutralizing antibodies in the patient's sample.

PRNT is considered to be the gold standard for detecting and measuring neutralizing antibodies for a specific virus.[8,9] However, due to the test's complexity and slow turnaround time, it is not suitable for high-throughput screenings.

• *Immunochromographic strip test* (IST) is a qualitative (positive or negative) lateral flow assay that is small, portable, and affordable, and can be used in point-of-care settings. Often performed using a few blood drops from a finger prick, this rapid diagnostic test (RDT) looks like a common pregnancy test (Figure 3). ISTs rely on immobilized antibodies and detection with colloidal gold-conjugated SARS-CoV-2 antigens. Colloidal gold is composed of very small gold particles (5-100nm), which are an intense red color. A few drops of blood, serum, or plasma are added onto a sample pad and passed over a detection strip by capillary tension. As it moves, the sample passes a conjugate/reagent pad, where it is mixed with the conjugated viral antigens. When the blood contains antibodies that bind with the viral antigen-conjugate, an antigen-antibody complex is formed. The sample-conjugate mix then passes over detection stripes, zones where anti-human IgG or IgM antibodies have been placed. Here, the antibodies contained in the sample will be immobilized, and if they are bound to conjugated viral antigens, the detection stripe will stain red. By having independent stripes of anti-IgM and anti-IgG antibodies, both subclasses of virus-specific antibodies can be detected individually. A positive control consisting of an antibody of a different species and the respective conjugate is included to indicate that the test was carried out correctly.

Point-of-care RDTs offer ease of use and rapid results, but they are intrinsically hampered by the short incubation times defined by the capillary flow, the comparably small sample amounts, and the lack of wash steps, which limits the sensitivity and specificity of the assay type.

• *Enzyme-linked immunosorbent assays* (ELISA) offer significantly better specificity and sensitivity compared to RDTs. These tests are generally performed in a laboratory and provide quantitative and qualitative results. Due to the microplate-based design of ELISAs, these tests can be easily automated, which allows for high-throughput screening of hundreds of patient samples at a time. Serological ELISA tests rely on very similar principles as lateral flow tests (Figure 4), most frequently with the roles of the antigen and

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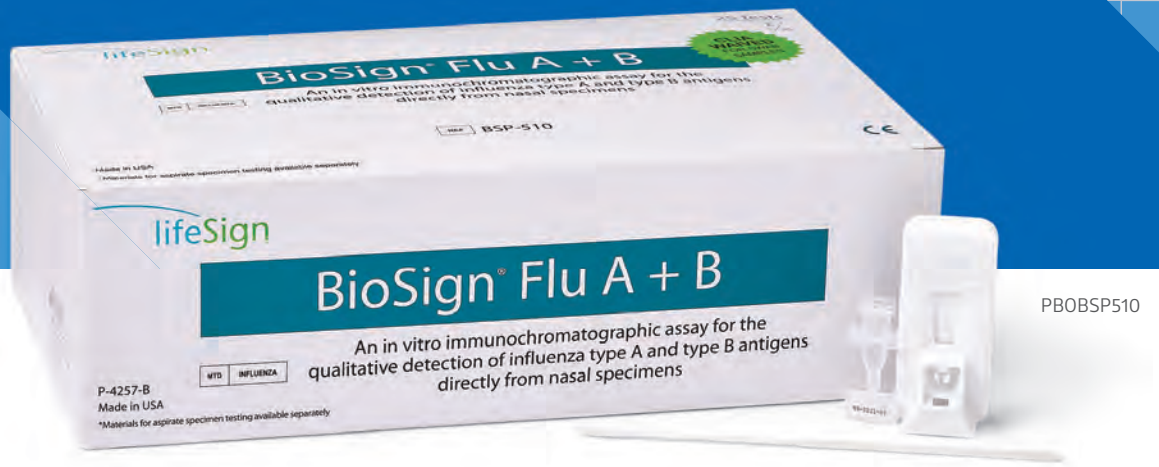

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detecting antibody reversed. The microplate is coated with SARS-CoV-2 antigens, with the antigen of choice most frequently being some variant of the spike protein. The spike protein (S) receptor binding domain (RBD) is thought to be among the most immunogenic epitopes on the viral capsid and is therefore frequently used as an antigen in this test. Another antigen that is highly immunogenic and that plays a major role in T cell responses is the nucleocapsid N. Some ELISA tests use combinations of S and N to increase sensitivity at the cost of a slight reduction in specificity.

The sample, most often blood plasma or serum, is then added to the well, and SARS-CoV-2-specific antibodies contained in the sample will bind to the antigen. An anti-human immunoglobulin antibody conjugated to an enzyme is added, and the antibody-conjugate binds to human antibodies that are bound to the antigen immobilized in the well. Most ELISAs detect either anti-SARS-CoV-2 IgG, IgM, or IgA, requiring the use of distinct ELISA tests in parallel to detect all three subtypes of immunoglobulins. Wash steps in between every binding step ensure that unbound or lightly unspecific bound components do not interfere. A chromogenic substrate is used to quantify the amount of antibody-conjugate in a color reaction. The strength of the color reaction is directly proportional to the amount of bound antibody. This allows for a semiquantitative interpretation of the antibody levels in a patient's blood sample, but different binding affinities of the sample antibodies and antibodies contained in the controls impede a fully quantitative analysis. Nonetheless, ELISA tests allow conclusions to be drawn regarding the strength of the immune system's reaction in addition to the improved sensitivity and specificity over IST. Also, ELISA tests are used to draw conclusions regarding the seroconversion of each immunoglobulin subclass.

Variants of ELISA are chemiluminescent (CLIA) and fluorescent (FIA) immune assays, where the enzymatic reaction converts a substrate to a chemiluminescent or fluorescent reaction product.

Current Challenges

Scale up of covid-19 diagnostics. Since covid-19 was identified in December 2019, a considerable number of tests have been developed by numerous companies.[10] In March 2020, the World Health Organization urged countries to "test, test, test."[11] Widespread testing is critical to map covid-19, monitor its progression rate, and identify hot spots and at-risk populations. However, the number of diagnostic tests currently available on the market does not satisfy the global demand. Many countries are struggling to scale up testing in order to diagnose all symptomatic patients and trace all contacts. In the United States, testing capacity stands at 2.78 tests per thousand people,[12] which is 912,396 tests per day. This number is far below the 10 to 30 million tests per day that is estimated to be required to fully reopen the economy while still controlling outbreaks.[13,14] The lack of adequate testing prevents early covid-19 detection, which results in continued, unmonitored transmission of the disease.

Rapid antigen detection tests could be a potential alternative solution to molecular testing, due to their suitability for point-of-care settings, short turnaround time, and affordability. However, rapid antigen detection tests show suboptimal sensitivity compared to highly sensitive molecular tests, and for this reason the few antigen tests that have been approved under FDA's emergency use authorizations (EUA) are recommended to be used only with individuals who are suspected of covid-19 by their healthcare provider within a number of days after the onset of symptoms.[15,16] Moreover, the US National Institutes of Health has launched an initiative called Rapid Acceleration of Diagnostics (RADx) to provide a solution to this urgent need for accurate, affordable, easily accessible, and scalable diagnostic testing. RADx has already tasked seven biomedical diagnostic companies to develop a range of new lab-based and point-of-care tests that would improve test availability by millions per week already within the flu season 2020-2021. With national demand estimated to grow rapidly, expectations are high for these new tests to make a significant contribution to monitoring and containing the pandemic.[17]

European countries are also concerned about testing capacity as they are now facing a second wave of infection. For instance, the UK, which is one of the countries with the highest number of positive cases per day,[18] is experiencing a shortage in testing reagents,[19] which prevents the effort of a few months ago to scale up the diagnostic testing capacity from 340,000 to 500,000 tests per day by the end of October.[20]

Better understanding of the immune response to SARS-CoV-2. One of the biggest challenges of this pandemic is to capture the true extent of the virus's spread and its infection/fatality ratio. Because of the high proportion of asymptomatic or mild infections (approximately 80%), data restricted to laboratory-confirmed cases is not sufficient to provide comprehensive infor-

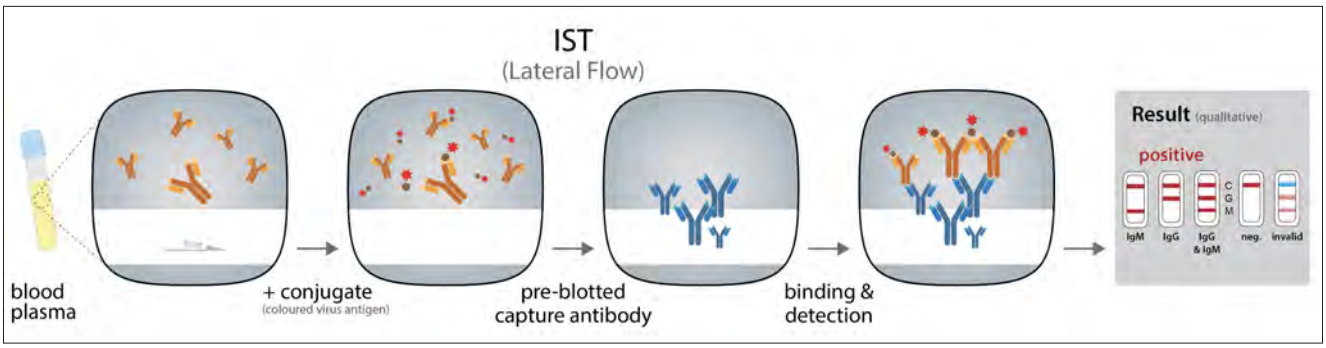


Figure 3. Basic Principle of Rapid Diagnostic Tests. A blood sample is applied to the quick strip test. A buffer is applied to the reservoir, which distributes the sample through the test using capillary forces. The sample passes a reagent reservoir, gets mixed with antigen-conjugate and then passes through a detection stripe where IgM or IgG antibodies are bound by capture antibodies. If antigen-binding antibodies were present in the sample, the detection stripe appears red.

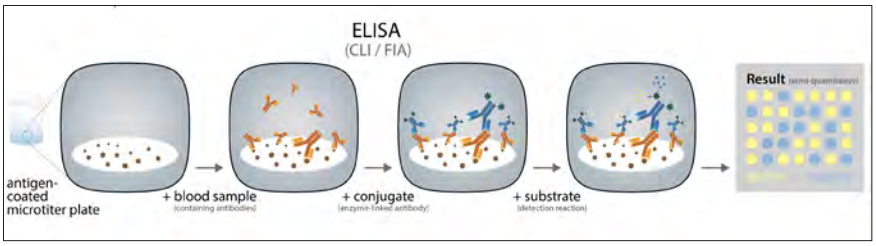


Figure 4. Basic Principle of Enzyme-Linked Immunosorbent Assay (ELISA) Serological Tests. Antigen-coated microplates are used and a blood sample, most frequently plasma, is applied. The anti-SARS-CoV-2 antibodies contained in the blood sample will be immobilized by binding to the coated antigen. A detection conjugate—an enzyme-coupled secondary antibody—binds to the immobilized antibody and catalyzes a chromogenic reaction.

mation.[21] Therefore, serological detection of specific antibodies against SARS-CoV-2, applied in designed seroprevalence studies, is needed to better estimate the true scale of infections. This approach will provide data on SARS-CoV-2 seroprevalence in different geographical areas or in specific populations such as healthcare workers, pregnant women, or immunosuppressed people. The collected data can then be used by governments to implement public health measures and control strategies and by the private sector to define back-to-work policies.

Seroprevalence studies aim also to understand how the humoral immune response to SARS-CoV-2 infection works and what is the duration of this immunity. Recent studies show that moderate to severe cases of covid-19 will mount a strong humoral immune response, with up to 90% of cases showing robust serum levels of anti-SARS-CoV-2 IgG[22-24] with some studies claiming 100% seroconversion rate.[25,26]

On the other hand, studies looking at asymptomatic patients[23] or across a wide range of patients[27] show not only a much lower seroconversion rate, but also a correlation of IgG serum positivity and titer with the severity of the disease course. Additionally, asymptomatic cases seem to lose IgG seropositivity faster and more frequently.[23] This data suggests that it is still unclear how robust the immune response against an asymptomatic disease manifestation is and whether it will be sufficient to grant immunity against reinfection.

Recently, a virtual workshop on covid-19 serology studies was held to review all the ongoing SARS-CoV-2 serosurvey studies and serological assay performance, as well as identify scientific gaps and develop recommendations for future studies. The conclusion was that although multiple ongoing seroprevalence studies are contributing to a better understanding of the level of SARS-CoV-2 seroconversion in various populations and communities, additional data is still needed to increase our understanding of the immune responses that lead to protection and duration of protection. Such data includes the specific antibody titers that correlate with protection from the disease and viral shedding upon reinfection.[26]

T cells may also play a critical role in fighting a SARS-CoV-2 infection. It has been shown that patients who have high levels of neutralizing anti-RBD-antibodies are likely to have high levels of nucleocapsid-responsive T cells[29] and that SARS-CoV-2-specific CD4+ and CD8+ are frequently found in covid-19 patients.[30] Moreover, elevated T cell responses are correlated with recovery,[31] and circulating follicular helper T cells reactive to the spike protein are elevated after SARS-CoV-2 exposure and correlate with a patient's ability to neutralize viral infections.[32] Although accumulating evidence supports a role for T cells in covid-19, additional studies are needed to confirm whether they may provide long-term protection from reinfection.

Conclusions

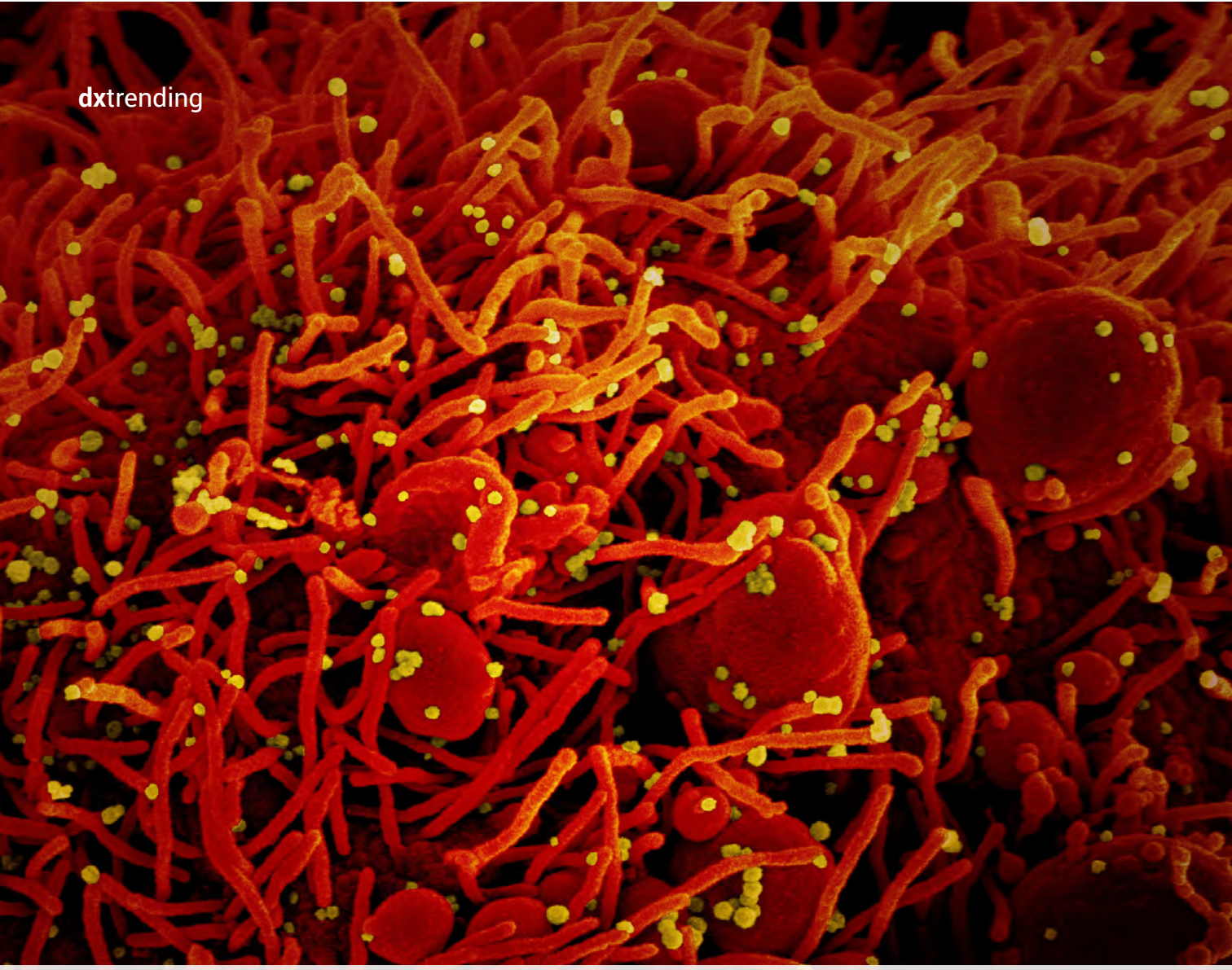
In the past months, we have learned a great deal about this pathogen. The fast spread of the disease and the yet unknown rate of asymptomatic infections, although suggested to be at around 40%, highlight our vulnerability. Early detection of active infections and identification of SARS-CoV-2 seroprevalence combined with public health measures such as social distancing and contact tracing are the best tools that we have to combat the pandemic.

The previously described constraints in diagnostic testing capacity that have emerged suggest that we have to do more to bridge the supply/demand gap. Clinical laboratories can either maximize their existing capacity or establish new capacity. In the first case, clinical labs would need to: compile a full inventory of their installed equipment base, distinguishing between open and closed systems; calculate the maximum theoretical laboratory capacity; and evaluate the potential need for new workflows, additional personnel or alternative suppliers of reagents if open-source systems are used. In the second case, clinical laboratories may consider increasing their equipment footprint by establishing new, high-capacity systems. Closed systems require proprietary reagents and do not provide much flexibility; open systems run a wider range of test methods from multiple suppliers, thereby providing more flexibility and better cost-effective options.

Of course, diagnosis of active infections is not enough to capture the true extent of the viral spread as well as its infection/fatality ratio. More studies need to be done to explain how our immune systems respond to SARS-CoV-2 infection and how long immunity lasts. Financial support from international research agencies and organizations, the coordination of research efforts, and the development of sustained partnerships are essential to providing the best opportunity for controlling this pandemic. ●

Albino Troilo, PhD, *is a senior marketing manager at Enzo responsible for marketing strategies and marketing communication. He has made major contributions in setting up the molecular diagnostic division at Enzo, which resulted in the launch of several molecular diagnostic products and clinical tests. He is currently leading the global COVID-19 campaign. Troilo holds a PhD in Molecular Health Sciences from ETH Zurich.*

View the expanded text and references for this article at https://clpmag.com/disease-states/infectious-diseases/covid-19/current-challenges-covid-19-testing/.



Better Controls for Covid-19 Diagnostics

Engineered recombinant antibodies offer advantages over serum-based controls

By Michael Fiebig, PhD

Serological immunoassays detect specific antibodies in patient samples, with the most relevant example currently being the detection of coronavirus antibodies in covid-19 diagnostic tests. To function correctly, immunoassays rely on calibrators to determine sensitivity and positive controls to ensure an individual test ran correctly. The calibrators and control sera used in diagnostic tests are typically patient-derived, resulting in challenges such as sourcing difficulties, lot-to-lot variability, and undefined characterization.

Coronavirus controls can be particularly hard to obtain from patient material due to biohazard concerns and limited supply. Engineered recombinant antibodies provide a reliable alternative to serum-based controls, offering high batch-to-batch reproducibility for the entire lifespan of an assay, as well as the ability to tailor a control's isotype or subtype to meet specific assay requirements. Diagnostic developers are therefore choosing to utilize engineered recombinant antibodies in their covid-19 assays. This article will explore the different engineered antibodies being used in covid-19 diagnostic tests and look specifically at new recombinant nanobodies against the SARS-CoV-2 receptor binding domain.

Recombinant Antibody Technology for Diagnostics

Recombinant antibodies are absolutely defined by their amino acid sequence and manufactured in vitro using synthetic genes. Though recombinant antibodies are standard in the pharmaceutical industry, these antibodies have not been as widely available

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for research and diagnostics applications. This is starting to change, however, due to the benefits recombinant antibodies offer over polyclonal and hybridoma-produced monoclonal antibodies.

Because they are produced in vitro, recombinant antibodies are precisely defined with no variation in binding specificity or affinity. Furthermore, they are not susceptible to supply chain problems such as contamination, genetic drift, or other loss; with recombinant production, the same fully characterized antibody can always be manufactured in unlimited quantities. Recombinant antibodies therefore provide the highest possible batch-to-batch reproducibility for the entire life span of a diagnostic.

In addition, recombinant production allows for antibody engineering, through which any antibody can be converted into any species, isotype, or subtype. This enables diagnostic developers to tailor their antibody controls to assay requirements, removing the need for a suboptimal pairing that could affect assay sensitivity and background. For example, antibody engineering can be used to standardize all antibody constant domains (also called Fc domains) within an assay to streamline conjugation and immobilization protocols.

Recombinant technologies have enabled the large-scale production of engineered antibodies for diagnostic tests. With antibody sequencing, the exact amino acid sequence of an existing hybridoma cell line or purified monoclonal antibody can be determined (and recently, strides have been made for sequencing polyclonal antibodies as well). Once the amino acid sequence is obtained, the original antibody can be engineered into any species, isotype, or subtype and recombinantly produced with precisely defined protein concentration and product formulation. In the Absolute Antibody laboratory, we use serum-free mammalian transient expression to produce recombinant antibodies in any format at milligram-to-gram scale. Figure 1 illustrates the variety of engineered antibody formats that can be produced for use as serological controls. The different recombinant formats are available off the shelf in our reagents catalog, while our custom antibody services enable diagnostic developers to rapidly reformat and recombinantly express their own antibodies.

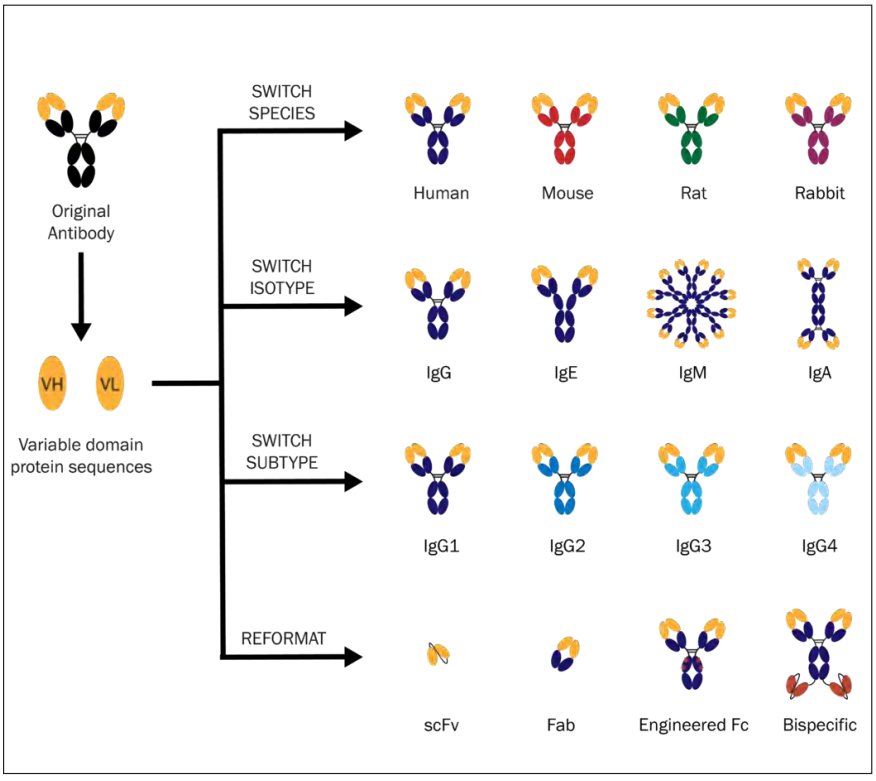

Figure 1: Recombinant antibody technology enables the creation of antibodies in any species, isotype, subtype, or other format. This allows diagnostic developers to tailor antibody controls to meet assay requirements.

Recombinant Controls for Coronavirus

Engineered antibody controls have shown particular utility for the development of covid-19 diagnostic tests. The first wave of diagnostic assays relied on human IgM and human IgG1 coronavirus antibodies, as they typically lead the primary immune response; however, there is more to serology than just those antibody formats. For example, IgA has been shown to dominate the early neutralizing antibody response to SARS-CoV-2,[1] while IgG3 appears to be a highly robust marker for a covid-19 immune response.[2] With recombinant antibody engineering, any isotype or subtype is easily obtainable. This allows assay developers to select controls tailored to specific covid-19 requirements, rather than building assays around suboptimal antibody formats.

For example, diagnostic developers are blending human SARS-CoV-2 antibodies of different subtypes into precisely defined standards for use as calibrators and controls. First, the different subtypes can be mixed at ratios representative of an average coronavirus patient. This type of standard can be spiked into normal serum to reliably re-create covid-19 patient serum, or it can be used for controlling the performance of serological assays at representative antibody isotype and subtype abundances. The different subtypes can also be combined in equal amounts, which enables the precise calibration of assays seeking to quantify the relative and absolute abundances of the main antibody types induced in covid-19. These types of recombinant SARS-CoV-2 standards aid in the development of precisely calibrated covid-19 assays that remain accurate across a wide range of antibody concentrations. Moreover, this permits setting absolute standards and cutoffs across testing platforms, allowing data from different sources to be integrated into a wider testing and public health strategy.

When the coronavirus pandemic started earlier this year, our laboratory began by repurposing anti-SARS-CoV-1 antibodies for covid-19 research and diagnostics. In early 2020, researchers demonstrated that the anti-SARS spike glycoprotein antibody clone CR3022, first described in 2006, had high affinity for the new

Figure 2. Recombinant IgG and IgM anti-nucleoprotein antibodies being used as positive controls in covid-19 rapid diagnostic tests.

coronavirus. Scientists worldwide began exploring it for use as a reagent in covid-19 diagnostic assays, as well as a candidate for mono- or combination-therapy development.

Our team used transient antibody production to quickly manufacture recombinant CR3022 antibodies in all isotypes and subtypes to act as controls in serological tests. Transient expression—a faster, more affordable alternative to stable CHO cell line generation—was vital to rapidly scaling up and meeting global demand for the antibodies. The engineered recombinant CR3022 antibodies have since been shown in peer-reviewed literature to act as positive controls for SARS-CoV-2 antibodies and are now being used in diagnostic kits that test for covid-19 positive patients.

In addition to spike glycoprotein antibodies, anti-SARS nucleoprotein (N) antibodies have also been shown to detect the new coronavirus, in particular the clones CR3009 and CR3018. Again, our laboratory generated engineered versions of the original antibody clones, and they have been utilized as positive controls in covid-19 rapid diagnostic tests (Figure 2). Anti-SARS-CoV-1 antibodies shown to also bind the new SARS-CoV-2 have been extremely valuable for efforts to develop covid-19 diagnostics as quickly as possible. By repurposing existing antibodies, covid-19 research, diagnostics, and therapeutic development were able to move forward while binders specific to SARS-CoV-2 were being generated.

New SARS-CoV-2 Nanobodies

Working in partnership with the University of Zurich, we recently began offering engineered synthetic nanobodies—known as sybodies—against the SARS-CoV-2 receptor binding domain (RBD). Nanobodies are small antibody fragments that can reach previously inaccessible parts of the body due to their compact size. Their better tissue penetration makes nanobodies particularly useful for super-resolution in vivo imaging in research applications, and therapeutic developers are also exploring how to exploit nanobodies' small size to deliver drugs throughout the human body. For covid-19 therapeutic development, researchers are exploring nanobodies' potential as inhalable drugs, which would be easier to administer and reach patients' lungs faster than other treatment formulations.

To generate synthetic nanobodies against the RBD of SARS-CoV-2, the laboratory of Markus Seeger at University of Zurich developed a rapid in vitro selection platform. Within a 2-week timeframe, the lab had identified more than 60 unique anti-RBD sybodies from combinatorial display libraries. Further research showed that six of the sybodies bound SARS-CoV-2 spike protein with very high affin-

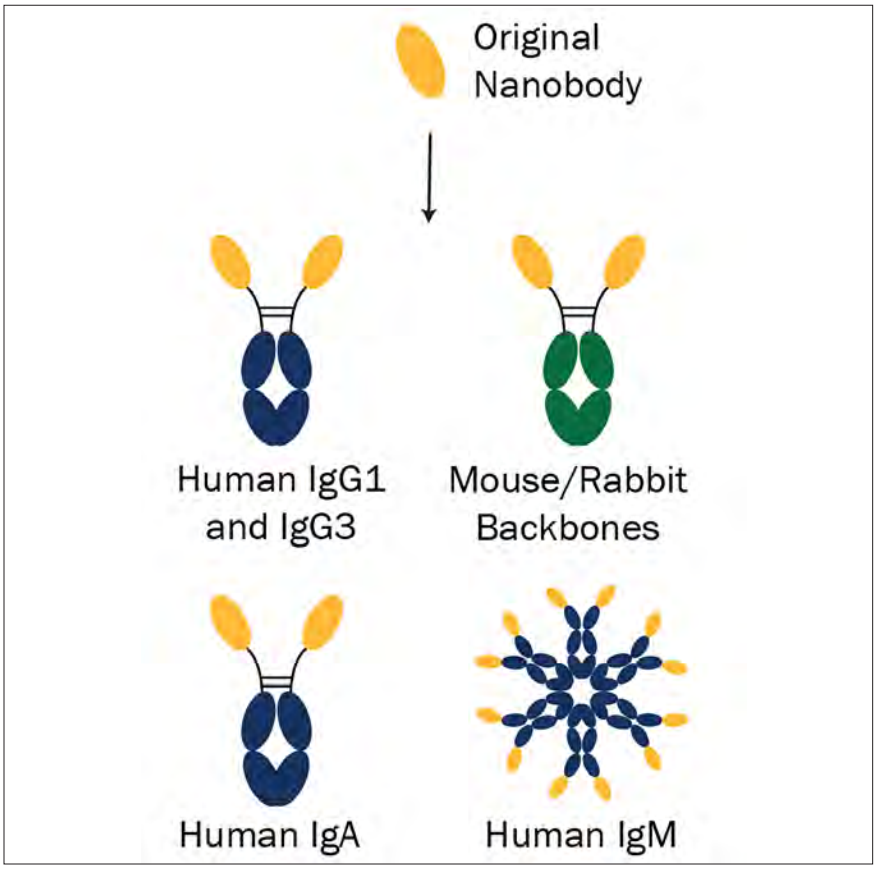

Figure 3. A diagram illustrating how Absolute Antibody engineered the original SARS-CoV-2 RBD synthetic nanobodies developed by University of Zurich into different formats to extend their utility in research and diagnostic applications.

ity, while five of those also inhibited ACE2, the host cell receptor to which SARS-CoV-2 binds to initiate the covid-19 infection. Moreover, two of the sybodies can simultaneously bind the RBD, which could enable the construction of a polyvalent antiviral drug.

To extend the reach and potential applications of the synthetic nanobodies, the Seeger laboratory partnered with Absolute Antibody. We used antibody engineering to fuse the nanobodies to Fc domains in different species, isotypes, and subtypes (Figure 3). For example, the anti-RBD binders are now available with human IgG1, IgG3, IgM, and IgA domains for use as serological controls in diagnostic assays.

The added Fc domains further extend the applications of the sybodies by varying effector function and permitting increased half-life in in vivo studies. The original nanobodies and newly engineered formats are all recombinantly produced, for ensured batch-to-batch reproducibility, high purity, and low endotoxin levels. The engineered nanobodies with added Fc domains are particularly useful for diagnostic development, as the different isotypes and subtypes provide control choice during assay design.

In addition, recent data from our laboratory has shown that two of the nanobody clones form a matched antibody pair, which is useful for sandwich assays. Sandwich assays use two monoclonal antibodies to improve the specificity of antigen detection assays, by requiring detection of a target via two distinct epitopes. The bridged conformation of the final immune complexes also underpins the design of lateral flow immunoassays or rapid tests. It can often be challenging to find matched antibody pairs from a single source, resulting in complicated and sometimes unstable supply chains. Using two of the SARS-CoV-2 nanobodies prevents that problem and enables improved performance in antigen detection assays.

Recombinant Technology for All

Absolute Antibody was founded with a vision to make engineered recombinant antibodies available to all, in particular for research and diagnostic applications where access to recombinant antibody technology is typically rare. For diagnostic developers, recombinant antibodies provide batch-to-batch reproducibility for the entire life span of an assay, as well as the ability to develop complex controls with absolute precision.

When the covid-19 pandemic began, we used our antibody engineering and recombinant production technology to quickly provide antibody controls for diagnostic developers around the world. We harnessed the potential of existing antibodies, such as the CR3022 clone, as well as partnered with academic laboratories to offer new SARS-CoV-2 binders in engineered formats.

New developments keep occurring; for example, we recently began offering SARS-CoV-2 neutralizing antibodies derived from the blood cells of a covid-19 infected patient. The antibodies were originally generated by Fred Hutchinson Cancer Research Center, and we engineered them into new species, isotypes, and subtypes. We hope that unique antibody controls such as these and the engineered nanobodies provide researchers and diagnostic developers with the tools they need to continue the global fight against the coronavirus pandemic. ●

Figure 4. A laboratory within the Absolute Antibody manufacturing facility.

Michael Fiebig, PhD, *is vice president of product portfolio and innovation at Absolute Antibody. Fiebig studied biochemistry before obtaining his doctoral degree at the Sir William Dunn School of Pathology, University of Oxford. He joined Absolute Antibody in 2014 and is responsible for the catalog and new applications of Absolute Antibody's technologies across the research reagents and diagnostics markets.*

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Fighting Antimicrobial-Resistant HAIs

Diagnostics are key to preventing and controlling this growing global threat

By Jean B. Patel, PhD D(ABMM)

There was a time when antimicrobial-resistant infections occurred only in healthcare settings. Now, although resistant pathogens do appear in communities as well as in hospitals and other healthcare facilities, it is rare for a community-associated infection to be hard-to-treat or nearly untreatable.

Unfortunately, these infections are all-too common in healthcare settings. Nearly all pathogens that top the Centers for Diseases Control's list of antibiotic resistant (AR) threats as well as the World Health Organization's list of antimicrobial resistance priority pathogens are frequent causes of healthcare-associated infections (HAIs).[1,2]

Most new types of antimicrobial resistant pathogens are first identified as the cause of HAIs. At first, a healthcare facility may identify a single case and then sporadic cases. Left unchecked, these cases progress to outbreaks and then endemic transmission of the AR pathogen. According to CDC point prevalence study, at any given time, about 1 in 25 inpatients—hospitalized for reasons including cancer, heart disease, or covid-19—have an infection related to hospital care.[3] For patients like these, infection with a drug-resistant pathogen is too often a life-threatening event. Preventing HAIs is possible, but it is important to get ahead of the curve. A robust prevention program depends upon fast and accurate detection of resistant pathogens, an ongoing site-specific surveillance program that tracks infection trends, dedicated infection prevention staff, and organizational buy-in to make infection prevention a priority. For additional details, see the CDC's Healthcare Infection Control Practices Advisory Committee (HICPACC) recommendations for HAI prevention.[4]

An HAI is generally defined as an infection with onset greater than 48 hours after admission to a healthcare facility. In additional to bacterial, HAIs can also be fungal, especially *Candida* spp., and viral, such as norovirus and those that cause hepatitis. This article focuses on drug-resistant infections caused by bacteria and *Candida* spp.—these are the infections that have the biggest impact on patients and healthcare systems.

CDC identifies five pathogens as "urgent threats," four of which commonly cause HAIs: *Clostridioides (Clostridium) difficile,* carbapenem-resistant *Enterobacteriaceae,* carbapenem-resistant *Acinetobacter,* and *Candida auris.* Each of these pathogens is listed as urgent for several reasons including high-infection rates, few treatment options, increased mortality for serious infections, and the ability to share resistance with other bacteria because the mechanism is on a mobile genetic element (that is, a plasmid). Methicillin-resistant *Staphylococcus aureus* (MRSA) is one of the most common HAI pathogens, but this one is considered a serious, not urgent, AR threat because more drugs are still available to treat MRSA infections than to treat infections caused by gram-negative bacteria.

Role of Laboratory Testing

General infection control practices are essential for preventing HAIs, but when rates of infection increase, more focused interventions may be required.[5,6] The laboratory plays a critical role here. Lab data are used to identify infection trends, to identify new types of resistant pathogens, and to identify patients colonized with HAI pathogens who might be a source of transmission. Perhaps the most consequential function is detecting new resistance. For example, when KPC-mediated carbapenem-resistant

General infection control practices are essential for preventing HAIs, but when rates of infection increase, more focused interventions may be required. The laboratory plays a critical role here.

Enterobacteriaceae (CRE) first emerged in the United States, cases were missed and outbreaks were not recognized because some of the most common antimicrobial susceptibility testing (AST) systems demonstrated poor performance for detecting KPC-mediated resistance.[7,8]

Sometimes laboratory testing is accurate, but the significance of new resistance is not recognized. After CRE emerged in the United States, CDC recommended that all hospitals review their lab records for previous cases.[7] Often hospitals found previous cases that were correctly detected in the laboratory, but no infection control concern was recognized. The Clinical and Laboratory Standards Institute (CLSI) subcommittee for AST addressed this issue by publishing a table that recommends specific actions based upon specific resistance findings in the laboratory (Appendix A of CLSI M100).[9] Recommendations include when to confirm results, when to contact infection control, and when to alert the local public health authority. An important function of the CDC AR lab network is to confirm and characterize isolates with new or rare types of resistance.[10] National public health authorities may decide that a new type of resistance warrants communication to the World Health Organization, which will share this information with AR points of contact in member countries.

Laboratory tests to identify patients with resistant pathogens are commonly called active surveillance testing. These tests are used to make infection control decisions either for the patient or for a larger population. The patient-centric decision is usually whether the person needs to be placed in contact precautions. In cases of MRSA nasal colonization testing, the decision may also include whether to decolonize the nasal passages with a drug like mupirocin or retapamulin. Population-based decisions might range from cohorting patients during an outbreak to implementing intra-facility communication and infection control measures to prevent regional transmission. CDC recommends active surveillance testing for CRE as a primary intervention strategy, although it is recognized that this may be more important in some settings than others. See CDC's CRE Prevention Toolkit for specific recommendations.[11]

CRE active surveillance testing is so important for prevention that CDC placed this testing in the AR Lab Network to support infection control efforts by healthcare facilities. *Candida auris* active surveillance testing is also recommended whenever cases are identified in hospitals. Currently, there are no commercial assays, but testing is available in the CDC AR Lab Network. Active surveillance testing for MRSA is often used when enhanced infection control measures are needed.[6] Many hospitals have implemented universal decolonization strategies for patients at risk of MRSA infection and implement MRSA-specific testing when infections rates are increasing despite these efforts. Multidrug resistant organism (MDRO)-specific surveillance testing to guide infection control decisions has proven effective when tests are readily available and results are timely. The challenge is that there are few FDA-approved tests, and, for most labs, these tests are not performed daily, which means maintaining proficiency is challenging and costly.

Molecular typing of HAI pathogens can be used to characterize transmission dynamics during an outbreak or to identify a point source for transmission. Pulse field gel electrophoresis (PFGE) or next generation sequencing are the technologies most commonly used for molecular typing. PFGE linked 39 cases of CRE infections from one hospital to a single duodenoscope.[12] This and similar investigations ultimately led to new recommendations for sterilizing these devices. Molecular typing is uncommonly performed in hospital microbiology labs, but this testing is available in reference labs and public health labs including those that are part of the CDC AR Lab Network.

Figure 1. Medical illustration of Clostridioides difficile *bacteria, formerly known as* Clostridium difficile, *from the CDC publication* Antibiotic Resistance Threats in the United States, 2019. *Medical Illustrator Jennifer Oosthuizen, courtesy CDC.*

CDC's 2019 AR Threats Report showed, for the first time, a downward slope for several antibiotic-resistant pathogens. Great news, but any loss in focus could reverse those trends.

Looking Forward

In the future, microbiome analysis may enable clinicians to predict HAIs before they occur. The human microbiome is the collection of health bacteria that colonize our gastrointestinal (GI) tract, respiratory tract, and skin. These healthy bacteria are may be our best defense against a range of diverse health issues including heart disease, diabetes, and weight gain. A diverse microbiome may also be a patient's best defense against HAIs.

Several studies have demonstrated that HAIs are preceded by a disruption of the gastrointestinal microbiome and a shift in the population of GI bacteria from diverse species to the predominance of a pathogen.[13] Furthermore, the HAI causative agent is the same pathogen (that is, clonal relationship) to the pathogen that predominates in the GI microbiome. This makes intuitive sense. We know that patients may be admitted to the hospital already colonized with a MDRO or acquire MDRO colonization during their stay. We also know that MDRO colonization is a risk factor for infection and that prolonged exposure to antibiotics disrupts the normal microbiome and allows for MDRO overgrowth. All of this adds up—but what do we do with the information?

If we had diagnostic tools to assess a patient's microbiome status (diverse population or predominance of a pathogen) and then to characterize the pathogen, a clinician would have enough information to treat a HAI at early onset. Better yet, imagine if a clinician could be armed with therapeutic interventions to restore a disrupted microbiome, thus inhibiting MDRO overgrowth and preventing HAIs. This approach could be an important new strategy to defeat HAI, but a lot of work needs to happen first. Several technologies could be applicable for microbiome diagnostics, and these range greatly in test complexity and cost. It is good to have options, but commercial product development will not occur in earnest until a clinical need is established. Studies are needed to evaluate the clinical impact of microbiome analysis to treat or prevent HAIs.

As the science of HAI prevention progresses, keeping up with and implementing existing tools is necessary to minimize the clinical impact of infections. It is easy to find these tools. Guidance for infection control practice are available from CDC/HICPAC (www.cdc.gov/hicpac/), Association for Professionals in Infection Control and Epidemiology (www.apic.org), and Society for Healthcare Epidemiology of America (www.shea-online.org). Surveillance tools for reporting and benchmarking infection rates can be found in the CDC National Healthcare Safety Network (www.cdc.gov/nhsn/) and laboratory guidance for diagnostic testing can be found in CLSI documents (www.CLSI.org) and CDC's website (www.cdc.gov/hai/).

Implementation is harder. As stated earlier, this takes organizational commitment and resources. We know prevention works. This was a primary message of CDC's 2019 AR Threats Report update. For the first time, trend charts for several AR threat pathogens had a downward slope. Great news, but any loss in focus could reverse these trends, and there is always a new challenge on the horizon. We have more work to do. ●

Jean B. Patel, PhD, D(ABMM), *is principal scientist, scientific affairs at Beckman Coulter Diagnostics who works within Beckman Coulter Microbiology to support innovation and assay implementation. Previously, she served nearly 17 years on the antibiotic resistance coordination and strategy unit at the Centers for Disease Control and Prevention. During her tenure there, she led the implementation of the Antibiotic Resistance Laboratory Network and the CDC and FDA Antibiotic Resistance Isolate Bank. Patel has served as chair and vice chair of the Clinical and Laboratory Standards Institute (CSLI) Subcommittee for Antimicrobial Susceptibility Testing and has been a member of the Trans-Atlantic Task Force on Antimicrobial Resistance. She also works with the World Health Organization to develop technical guidance for detecting resistance and strengthening global surveillance of antimicrobial resistance.*

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tech guide

Calibrators, Controls, Reference Standards, and Interlaboratory Peer-Reporting Programs

	Audit MicroControls	Audit MicroControls	Audit MicroControls
	Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com
1. What is the brand name of your company's calibrator or quality control product or product line?	Control LQ Covid-19 Antibodies	CalVer FLQ Drugs of Abuse for Beckman AU	CalVer FLQ Drugs of Abuse for Roche Systems
2. What year was the product first released to market?	2020	2020	2020
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class 1 exempt, 2020	FDA Class 1 exempt, 2020	FDA Class 1 exempt, 2020
4. What is the intended use or primary function of the product?	Daily quality control	Calibration verification	Calibration verification
5. With what companies, brands, or models of instruments are your products intended to be used?		Beckman AU systems	Roche systems
6. Where is the product used (check all that apply)?	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
7. If you answered "elsewhere," explain briefly.	N/A	N/A	N/A
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.
9. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	N/A	N/A
10. What is the typical training time for the product?	No training is required; material is run as a patient sample.	No training is required; material is run as a patient sample.	No training is required; material is run as a patient sample.
11. What types of technical support are available?	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.
12. What capabilities, features, or accessories distinguish this product from others on the market?	The product is a stable, ready-to-use liquid, bilevel control for use with assays designed to produce qualitative results for Covid-19 Total Antibodies and Covid-19 IgG Antibodies. It is intended to simulate negative and positive human patient samples.	The product is intended to simulate human patient samples for use in calibration verification and the verification of reportable range for the following analytes: 6-AM, AMPH, BARB, BENZ, Benzoylecgonine, BUP, METH, OPIA, OXY, PCP, THC.	The product is intended to simulate human patient samples for use in calibration verification and the verification of reportable range for the following analytes: 6-AM, AMPH, BARB, BENZ, BUP, COCA, METH, OPIA, OXY, PCP, THC.

Bio-Rad Laboratories	Bio-Rad Laboratories	Bio-Rad Laboratories	Bio-Rad Laboratories
Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com
InteliQ Immunology Control	InteliQ Cardiac Markers Plus Control LT	VIROTROL SARS-CoV-2	VIROCLEAR SARS-CoV-2
2020	2020	2020	2020
FDA Class I, 510(k) exempt; Europe, nonlist A/B	FDA 510(k) exempt; CE mark 2020	FDA Class 1 Exempt, 2020; CE mark, 2020	FDA Class 1 Exempt, 2020; CE mark, 2020
Intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Intended for use as an assayed quality control serum to monitor the precision of cardiac testing procedures for the analytes listed in the package insert.	Intended for use as an unassayed reactive quality control with in vitro assay procedures for determination of SARS-CoV-2 total IgG/IgM and SARS-CoV-2 IgG in human serum or plasma.	Intended for use as an unassayed nonreactive quality control with in vitro assay procedures for determination of SARS-CoV-2 total IgG/IgM and SARS-CoV-2 IgG in human serum or plasma.
Any high-throughput, automated chemistry instrument such as Siemens Atellica and Abbott Alinity.	Any high-throughput, automated immunoassay instrument such as Siemens Atellica, Abbott Alinity, and Roche Cobas series.	Roche Elecsys Anti-SARS-CoV-2 (Total - IgG/IgM); Abbott SARS-CoV-2 (IgG); Ortho Anti-SARS-CoV-2 (Total IgG/IgM/IgA & IgG); Siemens SARS-CoV-2 (Total IgG/IgM); DiaSorin Liaison (XL) SARS-CoV-2 S1/S2 (IgG); bioMerieux VIDAS anti-SARS-CoV-2 (IgG); Beckman SARS-CoV-2 (IgG); Bio-Rad Platelia SARS-CoV-2 (Total IgG/IgM/IgA); EuroImmun SARS-CoV-2 (IgG); Cellex qSARS-CoV-2 IgG/IgM Rapid Test	Roche Elecsys Anti-SARS-CoV-2 (Total - IgG/IgM); Abbott SARS-CoV-2 (IgG); Ortho Anti-SARS-CoV-2 (Total IgG/IgM/IgA & IgG); Siemens SARS-CoV-2 (Total IgG/IgM); DiaSorin Liaison (XL) SARS-CoV-2 S1/S2 (IgG); bioMerieux VIDAS anti-SARS-CoV-2 (IgG); Beckman SARS-CoV-2 (IgG); Bio-Rad Platelia SARS-CoV-2 (Total IgG/IgM/IgA); EuroImmun SARS-CoV-2 (IgG); Cellex qSARS-CoV-2 IgG/IgM Rapid Test
❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
The InteliQ load-and-go tubes are designed to significantly reduce hands-on time. The time to first result is dependent on the instrument being used.	The InteliQ load-and-go tubes are designed to significantly reduce hands-on time. The time to first result is dependent on the instrument being used.	Varies by analyzer	Varies by analyzer
This control is supported by the Unity interlaboratory quality control data management program.	This control is supported by the Unity interlaboratory quality control data management program.	This control is supported by the Unity interlaboratory quality control data management program.	This control is supported by the Unity interlaboratory quality control data management program.
No training is required; material is run as a patient sample.	No training is required; material is run as a patient sample.	No training required	No training required
Training, expert support, and postmarket service.	Training, expert support, and postmarket service.	Technical support is available by phone at 800-854 6737 and via email at qsd.techservice@bio-rad.com. Individualized customer support is provided as needed.	Technical support is available by phone at 800-854 6737 and via email at qsd.techservice@bio-rad.com. Individualized customer support is provided as needed.
These barcoded, load-and-go quality controls reduce hands-on time and manual errors, streamlining the QC workflow. Together with Unity's interlaboratory advanced data management tools, InteliQ controls improve laboratory efficiency.	These barcoded, load-and-go quality controls reduce hands-on time and manual errors, streamlining the QC workflow. Together with Unity's interlaboratory advanced data management tools, InteliQ controls improve laboratory efficiency.	VIROTROL SARS-CoV-2 provides a long shelf life and open vial stability. It has the ability to challenge the assay cutoff of a broad range of methodologies.	VIROCLEAR SARS-CoV-2 provides a long shelf life and open vial stability. It has the ability to challenge the assay cutoff of a broad range of methodologies.

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Order Number: K931M-4

Package Size: 4 x 3 mL

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Detectabuse Liquid Urine Controls, Stat-Skreen	Pregnancy-Skreen Liquid HCG Controls	CueSee Hypoxic	HemoTrol Duo
1992	2005	2016	2020
FDA 510(k), CE mark	FDA 510(k), CE mark	FDA 510(k), 2016	FDA 510(k), 2019
Drugs of abuse human urine matrix liquid quality controls for screening and confirmation testing	HCG human urine liquid quality controls	Hypoxic is a pretonometered bovine oxyhemoglobin (O2Hb) quality control material for professional use in the performance assessment of blood gas analyzers, especially in the critically low pO2 value range.	A hemoglobin solution matrix intended for use in the verification of the precision and accuracy of the HemoCue Hb301 and Hb 801 systems.
Independent third-party external control; works with all devices	Independent third-party external control; works with all devices	All common blood gas instruments	HemoCue Hb 301 and Hb 801 systems
■ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	■ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
Analyzer dependent	Analyzer dependent	Quality controls are used on compatible instruments; results read directly from instrument.	Quality controls are used on compatible instruments; results read directly from instrument.
N/A	N/A	All common blood gas instruments+K14	Eurotrol provides all customers with CueSee, a free online service for comparing quality control data with peers. Users enter results anonymously and generate statistical reports to compare data. Users share data to improve patient care.
Minimal	Minimal	Minimal	Minimal
Technical support is available at 631-595-9200 and via email at support@biochemicaldiagnostics.com.	Technical support is available at 631-595-9200 and via email at support@biochemicaldiagnostics.com.	Staff are always available to assist in placing an order, evaluating a sample, or responding to questions or feedback.	Staff are always available to assist in placing an order, evaluating a sample, or responding to questions or feedback.
Human urine matrix mimics patient samples with a broad range of stock and custom DOA formulations; 30-day open stability, up to 3 years unopened.	Human urine matrix mimics patient samples. Positive, negative levels available.	The only low pO2 control that behaves like real blood, CueSee Hypoxic has true hemoglobin buffering with 10 min open ampule stability. CueSee Hypoxic offers comparable result to whole blood tonometry and is compatible with all common blood gas instruments.	The hemoglobin solution matrix is based on a purified hemolysate and provides superior quality control for the HemoCue Hb 301 and HemoCue Hb 801 System. It features 30-day open vial stability. Developed in cooperation with HemoCue and recommended as the company's preferred quality control.

Kova International	Kova International	Maine Molecular Quality Controls	More Diagnostics
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Kova Liqua-Trol	Kova POC	Introl	Immunosuppressant Rap/Tac/CsA Control (order Cat #290)
1994	2018	2005	2005
FDA 510(k), CE mark	FDA 510(k), CE mark	FDA 510(k), 2006	CE mark; 510(k) 2005
Urinalysis control	Urinalysis control	Multiplex quality controls to assess molecular testing, including the extraction, amplification, and detection steps. Immediate detection of errors, shifts, or trends caused by changes in the environment and test system components.	To be used as a whole blood precision control product to check calibration in chemistry analyzers which measure rapamycin (sirolimus), tacrolimus, and cyclosporine.
Independent third-party control works for use manually or with automated systems (Siemens, Roche, Dirui, Mindray, McKesson)	Independent third-party control works for use manually or with automated systems (Siemens, Roche, Dirui, Mindray, McKesson)	Controls for laboratory developed tests and platforms by BioFire, Cepheid, Curetis, GenMark, Illumina (NGS), Luminex, Qiagen. Custom products for assay manufacturers.	Siemens Atellica Solution, Siemens Dimension and Vista; Siemens Syva EMIT 2000, Abbott Architect and LC-MS/MS; also appropriate for other automated immunoassay systems that correlate with chromatographic methods.
❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
Instrument dependent; LCD display or printed	Instrument dependent; LCD display or printed	Assay dependent	N/A
Results can be sent to laboratory information system if automated device reader is used.	Results can be sent to laboratory information system if automated device reader is used.	N/A	Customer may participate in a free peer-to-peer quality control data program.
Less than 30 minutes	Less than 30 minutes	Minimal	No training required; material is run as patient sample.
Technical support is available at 855-217-6399 or techservices@kovaintl.com.	Technical support is available at 855-217-6399 or techservices@kovaintl.com.	Email and phone support. Troubleshooting materials.	Technical support may be reached at 800-758-0978 or support@morediagnostics.com.
Human urine matrix mimics patients samples. Multiple analytes and microscopic cells/artifacts.	Human urine matrix mimics patients samples. Multiple analytes and microscopic cells/artifacts.	The synthetic controls are 100% safe, nonhazardous, robust, and stable.	Immunosuppressant Rap/Tac/CsA Control is an easy-to-use liquid whole blood product with 5 mL fill volume. This product has a 4-year frozen shelf life and 45 days open vial stability when stored at 2°C to 8°C.

More Diagnostics	Quantimetrix	Quantimetrix	Qnostics
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Ev/Rap/Tac/CsA Control (order Cat #285)	Dipper POCT Liquid Urinalysis Quality Control	Chromascopics Urinalysis Control with Microscopics	Qnostics
2005	2018	2018	2017
510(k) 2005	CE mark, 2018; FDA 510(k) exempt.	CE mark, 2018; FDA 510(k) exempt.	CE mark, FDA 510(k)
A whole blood precision control product to check calibration in chemistry analyzers that measure everolimus, rapamycin (sirolimus), tacrolimus, and cyclosporine.	Monitor the performance of visual and instrument readings of urinalysis dipsticks by immersing the dipstick into the control, in the same way that patient samples are tested.	Monitor the performance of visual and instrument readings of urinalysis dipsticks by immersing the dipstick into the control, in the same way that patient samples are tested.	Quality control solutions for molecular infectious disease testing.
Chromatography methods, assayed for LC-MS/MS.	Dipper POCT is designed for use in every testing environment including: central labs, reference labs, nursing stations, and doctors' offices.	Clinitek Novus, Clinitek Advantus, Clintek Atlas, Clinitek Status, Clinitek Status Plus, Clinitek 50, Clinitek 500, Atellica UAS 800, Atellica 1500 Automated Urinalysis System.	Range comprises hundreds of characterized viral, bacterial, and fungal targets that cover a wide range of diseases and are available for a wide range of platforms.
❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
N/A	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program.	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program.	N/A
Customer may participate in a free peer-to-peer quality control data program.	N/A	N/A	N/A
No training required; material is run as patient sample.	N/A	N/A	Qnostics controls require professional use; however, some products are perfect for staff training.
Technical support may be reached at 800-758-0978 or support@morediagnostics.com.	Technical support is available at 310-536-0006, Ext: 213; via techsupport@quantimetrix.com; or via live chat at quantimetrix.com.	Technical support is available at 310-536-0006, Ext: 213; via techsupport@quantimetrix.com; or via live chat at quantimetrix.com.	A technical support department is available to deal with all queries via telephone, email, and occasional visits.
An easy-to-use liquid whole blood product with 4 levels and 4 analytes. This product has a 4-year frozen shelf life and 45 days open vial stability when stored at 2°C to 8°C.	The control is stable for 3 months when stored at room temperature, and up to 3 years when stored at 2°C to 8°C; full dipstick immersion; zero wasted QC product.	Microscopics sediment elements include calcium oxalate dihydrate crystals, *E. coli* bacteria, red blood cells, and white blood cells. Can also be used for βhCG screening methods and for confirmatory tests such as K-Check and Ictotest.	Whole pathogen controls designed to mimic patient samples can be used to monitor entire testing process including extraction, amplification, and detection. Samples are supplied in convenient liquid formats requiring little to no preparation. Targets covered include transplant associated, respiratory, blood borne, gastrointestinal, covid, and more.

InteliQ.
Smarter, Simpler QC.

Optimize Workflow

Increase productivity and improve turnaround time by eliminating manual steps.

Increase Efficiency

Unique sample tracking and easy XML data upload of lot-specific QC values.

Improve Performance

Access Unity data management program and large peer groups.

Achieve Quality Goals

Use advanced Unity software tools to support your lab's risk management program and simplify compliance reporting

Simplify your QC workflow with load-and-go efficiency and robust data management.

InteliQ quality controls automate your QC on next generation platforms. These barcoded, load-and-go controls reduce hands-on time and manual errors, streamlining your workflow and giving you more freedom. InteliQ controls, together with Unity's advanced data management tools, improve workflow efficiency. InteliQ. It's simply smarter QC!

How will InteliQ help you work smarter?
Visit: qcnet.com/InteliQ

BIO-RAD

InteliQ is compatible with chemistry and immunoassay diagnostic platforms as listed in the product insert.

Randox Laboratories	**Streck**	**Streck**	**Utak Laboratories**
Crumlin, United Kingdom +44 (0) 28 9442 2413 www.randox.com	La Vista, Neb 800-843-0912 www.streck.com	La Vista, Neb 800-843-0912 www.streck.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com
Acusera	UA-Cellular Complete	Sperm-Chex and Sperm-Chex Post VC	Covid TDM QC
2010	2014	2015	2020
CE mark, FDA 510(k)	CE mark, 2014; 510(k), 2014, 2017	CE mark, 2015; 510(k), 2004	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015
Designed to deliver a cost-effective yet high-quality solution for any lab regardless of size or budget.	Ready-to-use tri-level liquid urine control comprised of true cellular urine sediment components and common urine chemistry analytes plus hCG.	Manual sperm count controls to help validate the quantification of sperm counting by manual methods.	Outsourced, third-party, unbiased quality control
Control portfolio is wide and includes a vast array of instruments, methods, and companies that can use our products.	Siemens Clinitek Atlas/Sysmex UF-1000i, Arkray Aution Hybrid AU-4050, Clinitek Status automated chemistry strip readers, Siemens Multistix 10SG manual reagent strips, Siemens Clinitest hCG Pregnancy test	Hemacytometer, Makler counting chamber	Mass Spectrometry
❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ■ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
N/A	Dependent on the analysis method in use.	Dependent on the analysis method in use.	N/A
Live, cloud-based interlaboratory data management and peer group reporting software intended to assist in the management of daily QC activities.	N/A	N/A	N/A
Some controls require little training; others require laboratory experience.	No additional training required	Requires minimal training	None required
Technical support is available via email, telephone, and an online help chat.	Medical technologists are readily available during business hours to assist with technical questions via technicalservices@streck.com.	Medical technologists are readily available during business hours to assist with technical questions via phone or via email.	Support available by phone or email.
True third-party controls; choice of assayed or unassayed, liquid or lyophilized, single or multi-analyte; controls are designed to mimic the patient sample, therefore helping to meet ISO 15189:2012 requirements, while minimizing costly shifts in QC when changing reagent batches.	Combined chemistry and sediment control performs as a patient sample and can replace multiple separate controls for instruments from manual dip-strip through high-throughput automated microscopy platforms. Real cellular components test the entire system.	The only sperm count controls that contain real sperm cells. Available in two clinically significant levels. Same chamber-loading or optical characteristics as a patient sample. Compatible with hemacytometers and other counting chambers. Offers 42-day open-vial stability; 12-month closed-vial stability.	100% real human matrix matched quality control.

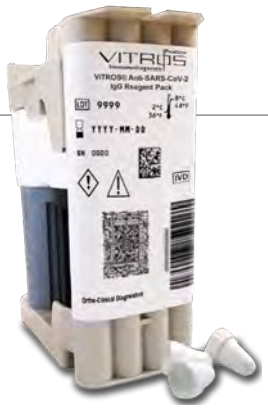
Utak Laboratories	**Utak Laboratories**	**Utak Laboratories**	**Verichem Laboratories**
Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Providence, RI 800-552-5859 customerservice@verichemlabs.com www.verichemlabs.com
Hydrolysis QC	Pain Management QC	Drugs of Abuse QC	Matrix Plus Chemisty Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard
2020	2007	2003	1988
CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	All products are FDA 510(k) cleared.
Outsourced, third-party, unbiased quality control	Outsourced, third-party, unbiased quality control	Outsourced, third-party, unbiased quality control	Gravimetric standards, linearity verifiers, and reference materials used for calibration or calibration verification of wet chemistry assays on automated clinical testing systems.
Mass Spectrometry	Mass Spectrometry	Mass Spectrometry	Compatible with wet chemistry analyzers available from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, Instrumentation Laboratory, Medica, Randox, and others.
❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	❑ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ❑ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ❑ Elsewhere	■ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ❑ In a patient's home or other self-testing ■ Elsewhere
N/A	N/A	N/A	IVD manufacturer instrument/assay development, analytical measurement range monitoring, clinical assay troubleshooting, bias to true value product development applications, and tracking normal range drift.
N/A	N/A	N/A	All products are treated like patient specimens; time to first result depends on the analyzer.
N/A	N/A	N/A	Calibration verification and quality assurance program is offered free to all customers and offers CLIA-compliant test report verifying accuracy, linearity, calibration verification, and reportable range.
None required	None required	None required	None required
Support available by phone or email.	Support available by phone or email.	Support available by phone or email.	Support available via phone, email, website, and on-site.
100% real human matrix matched quality control.	100% real human matrix matched quality control.	100% real human matrix matched quality control.	Products are compatible with all major wet chemistry systems; are CLIA compliant; have certified accuracy using available USP, ACS, NIST materials. Most include a lot-specific certificate of analysis, are liquid stable and ready-to-use, and offer long shelf-life claims and lot-to-lot consistency.

NxTAG RPP + SARS-CoV-2

Detects 23 pathogens

The NxTAG Respiratory Pathogen Panel + SARS-CoV-2 (NxTAG RPP + SARS-CoV-2) from Luminex is a qualitative test for the detection of nucleic acids from multiple respiratory viruses and bacteria in nasopharyngeal swabs, oropharyngeal swabs, nasal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, and nasal washes. This assay is designed for use on the Magpix System. Comprehensive Panel detects 20 viral pathogens, including SARS-CoV-2 (*ORF1ab* and *M* gene), and three bacterial pathogens in a single well. Scalable throughput enables processing of up to 96 samples in less than 3 hours postextraction, accommodating variable, day-to-day testing demand. Preplated, lyophilized reagents enable a simple workflow with just one pipetting step.

Luminex
512-219-8020; orders@luminexcorp.com;
www.luminexcorp.com



Vitros Anti-SARS-CoV-2 IgG

To identify adaptive immune responses

Ortho Clinical Diagnostics' Vitros Anti-SARS-CoV-2 IgG test is a chemiluminescent immunoassay for the detection of IgG antibodies to SARS-CoV-2 in human serum. It aids in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating a recent or prior infection. The FDA has issued an emergency use authorization for convalescent plasma requiring donor blood units be tested only with Ortho's Covid-19 IgG Antibody Test as a manufacturing step before release to hospitals and patients. The test targets antibodies to the S1 spike protein of the SARS-CoV-2 virus that may have a closer association with protective immune response. The test runs on high-throughput, random access, fully automated Vitros systems and has demonstrated 100% specificity and excellent sensitivity.

Ortho Clinical Diagnostics
908-285-0175; media@orthoclinicaldiagnostics.com;
www.orthoclinicaldiagnostics.com

SARS-CoV-2 and Flu Molecular Quality Solutions

Sequential and multiplex testing workflows

LGC SeraCare's proprietary AccuPlex technology mimics wild-type pathogenic viruses but is safe, noninfectious, and replication deficient. Composed of a true viral envelope, these materials serve as full-process quality solutions that challenge the entire PCR test procedure, making them the preferred alternative to infectious materials. The product contains multiplexed viral targets for SARS-CoV-2, Flu A/B, and respiratory syncytial virus and is available as a verification panel for assay installation or reference material kit for daily assay performance monitoring. These products offer a solution for clinical laboratories looking for a safe and effective tool to verify and monitor molecular assay performance, whether utilizing sequential or multiplex testing workflows.

Sera Care
508-244-6400; info@seracare.com; www.seracare.com

Captia SARS-CoV-2 IgG EIA Kit

Qualitative 96-well microplate ELISA

The Captia SARS-CoV-2 IgG EIA Kit from Trinity Biotech is a qualitative, 96-well, microplate ELISA, detecting IgG antibodies to S1 and S2 spike antigens of SARS CoV-2 in serum and plasma. The assay is manufactured with recombinant antigens, crucial for maximum sensitivity and specificity. The kit has excellent performance: 95.1% sensitivity (for samples >14 days from symptom onset), 98.2% specificity, and a fast assay time, with an all-room-temperature incubation. The kit is easily adaptable to multiple platforms. FDA emergency use authorization is pending.

Trinity Biotech
800-325-3424; salesmarketing@trinityusa.com;
www.TrinityBiotech.com

Allplex SARS-CoV-2/FluA/FluB/ RSV Assay

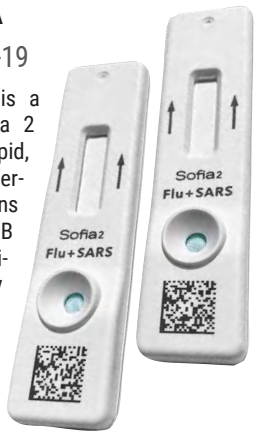
Automated multiplex solutions

A single tube real-time RT-PCR assay, Allplex SARS-CoV-2/FluA/FluB/RSV Assay from Seegene Technologies simultaneously detects and differentiates influenza A, influenza B, RSV A/B, and three different target genes of covid-19 (*S, RdRP,* and *N* genes). The assay also includes dual targets for internal control (exogenous and endogenous) that run in the same reaction tube, which allow verification of the whole test process as well as proper sampling. The assay is currently validated with a wide range of extraction systems (Seegene STARlet, Seeprep32, KingFisher Flex, MagNA Pure 96, NucliSENS EasyMag, GeneAll Ribospin vRD Viral RNA/DNA Extraction Kit, QIAamp DSP Viral RNA Mini kit) and plans to expand further upon market demand. For PCR instruments, Bio-Rad CFX96 systems can be used.

Seegene Technologies
info@seegenetech.com; www.seegene.com

Sofia 2 Flu + SARS Antigen FIA

Rapid antigen for influenza and covid-19



Quidel's Sofia 2 Flu + SARS Antigen FIA is a rapid point-of-care test used with the Sofia 2 Fluorescent Immunoassay Analyzer for the rapid, simultaneous qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, influenza A, and influenza B in direct nasopharyngeal and nasal swab specimens from individuals suspected of respiratory viral infection consistent with covid-19 by their healthcare provider within the first 5 days of the onset of symptoms. The Sofia test delivers a fast, highly accurate result for all three viruses from one swab sample in just 15 minutes.

Quidel
800-874-1517; www.quidel.com

Rapid Portable Covid-19 Test

Results in 15 minutes at point of care

BD's rapid, point-of-care antigen test for SARS-CoV-2 is available for use with the BD Veritor Plus System, which is slightly larger than a cell phone and is currently in use at 25,000 US hospitals and other sites. Under an FDA emergency use authorization, the test is designed to be used in healthcare settings to provide an aid to rapid diagnosis of covid-19 in symptomatic individuals. BD clinical studies demonstrated that the test is capable of achieving 84% sensitivity and 100% specificity. Similar to all immunoassay tests, FDA recommends that negative test results be confirmed by a molecular method to confirm the result, if necessary, for patient management.

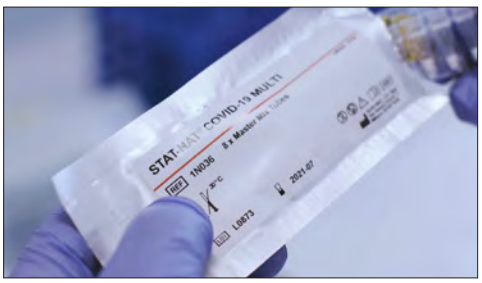
BD
844-823-5433; www.bd.com

Serological Controls for Covid-19

Positive and negative quality controls

VIROTROL SARS-CoV-2 and VIROCLEAR SARS-CoV-2 are Bio-Rad's independent positive and negative quality controls for use in SARS-CoV-2 antibody testing, the virus associated with covid-19 disease. VIROTROL SARS-CoV-2 quality controls are independent, positive controls designed to detect whether patients have the antibodies for SARS-CoV-2. The VIROCLEAR SARS-CoV-2 can be used as a negative control across all SARS-CoV-2 antibody assays and methodologies and has been demonstrated to be free of any of the SARS-CoV-2 antibodies for that purpose. These products are available for IVD use in the USA and are CE-marked for the European market.

Bio-Rad
949-598-1200; www.bio-rad.com



Stat-Nat Covid-19 Multi Kit

One-step multigene RT-PCR assay

The Stat-Nat Covid-19 Multi kit from Sentinel Diagnostics is a ready to use, one-step, multigene, real-time RT-PCR qualitative assay based on nucleic acid amplification for the identification of the novel coronavirus RNA in human respiratory tract specimens. The kit is a multiplex assay based on the simultaneous detection of *RdRP* and *ORF1b* genes for the sure identification of SARS-CoV-2 infection. The use of the same fluorophore for both genes and the presence of the endogenous housekeeping gene (human *RNAse P*) as internal control make this kit easy to use and, at the same time, guarantee the identification of the covid-19 infection in human respiratory tract specimens. The kit is lyophilized and can be shipped stored at room temperature.

Sentinel Diagnostics
+39 02 3455141; sentinel@sentinel.it;
www.sentinel.com

Aptima SARS-CoV-2 assay

More accessible testing for covid-19

Hologic's Aptima SARS-CoV-2 assay is an in vitro diagnostic test that utilizes proprietary TMA technology. It runs on Hologic's widely available Panther molecular diagnostics system, a fully automated, sample-to-result platform that can be used in low-, medium-, or high-throughput laboratories. With more than 1,000 systems already installed in clinical laboratories throughout all 50 states in the nation, the Panther can provide initial results to the Aptima SARS-CoV-2 assay in approximately 3 hours and process more than 1,000 coronavirus tests in 24 hours.

Hologic
508-263-2471; www.hologic.com

Fastep Covid-19 IgG/IgM Rapid Test Device

First POC antibody test for covid-19

The Fastep Covid-19 IgG/IgM Rapid Test Device by Assure Tech, distributed in the United States by Carolina Liquid Chemistries, has FDA emergency use authorization for use with fingerstick whole blood specimens at the point of care, in patient care settings operating under CLIA Certificate of Waiver such as doctor's offices, hospitals, urgent-care centers, and emergency rooms. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. The lateral flow test provides results in 15 minutes.

Carolina Liquid Chemistries
877-722-8910; contactsales@carolinachemistries.com;
www.carolinachemistries.com

ePlex Respiratory Pathogen Panel 2

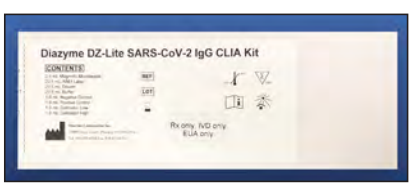
Results for more than 20 viruses and bacteria

ePlex Respiratory Pathogen Panel 2 from GenMark Diagnostics in less than 2 hours provides results for more than 20 viruses and bacteria that cause common and often serious respiratory infections, including covid-19, flu, bronchitis, and the common cold. The RP2 Panel provides rapid results for infections with similar symptoms such as fever, cough, and body aches, which will be essential in preparing for fall and winter as the flu season coincides with the ongoing risk of covid-19. The ePlex RP2 Panel is designed for use with the company's ePlex system. The test has received FDA emergency use authorization and has achieved a CE Mark.

GenMark Diagnostics
800-373-6767; info@genmarkdx.com; www.genmarkdx.com

DZ-LITE SARS-CoV-2 IgG and IgM CLIA Kits

Targets antibodies to N and S viral proteins



Diazyme's DZ-LITE SARS-COV-2 IgG and IgM CLIA Kits specifically target IgG antibodies to the N and S viral proteins, with no cross-reactivity to other coronaviruses or influenza A and B viruses. Overall percent positive agreement with RT-PCR >7 days post symptom onset: 96.23% for IgG and 92.1% for IgM. Percent positive agreement with RT-PCR ≥15 days post symptom onset: 100% for IgG and 94.4% for IgM. The kits run on the fully automated DZ-Lite 3000 Plus chemiluminescence analyzer. These tests have been authorized by FDA under an emergency use authorization for use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

Diazyme Laboratories
858-455-4768; sales@diazyme.com; www.diazyme.com

GenFlex Molecular System

For SARS-CoV-2 detection

Enzo's GenFlex Molecular System is a high-throughput, automated, and scalable instrument for processing molecular diagnostic tests for the SARS-CoV-2 virus with the FDA emergency use authorized AmpiProbe SARS-CoV-2 Test within a clinical production setting. GenFlex features a pipetting module for sample preparation and PCR set-up and a qPCR module for nucleic acid amplification and detection. The fully automated workflow has a turnaround time of 5 hours for the first 96 samples, with a daily capacity of 384 samples. When combined with additional instruments, overall capacity can increase to over 1,000 samples per day.

Enzo
646-831-1501; GHeinrich@enzo.com;
www.enzolifesciences.com

SARS-CoV-2 IgG (COV2G) Assay

Helps assess immunity over time

The Siemens Healthineers SARS-CoV-2 IgG (COV2G) Assay is the first FDA EUA-authorized semi-quantitative assay to help clinicians assess the level of an individual's immune response over time. The COV2G assay is a qualitative and semi-quantitative SARS-CoV-2 antibody assay that enables clinicians to detect the level of IgG antibodies in a patient's blood sample and assess relative changes over time. With this numerical value, clinicians will have a baseline and be better equipped to track the long-term duration of an individual's immune response. The COV2G assay produces results in as little as 25 minutes on the Atellica IM Analyzer with a capacity to process up to 440 assays per hour (dependent upon test mix). The SARS-CoV-2 IgG antibody test offers 100% sensitivity (samples collected ≥14 days after positive PCR result) and 99.9% specificity, which is critical for detecting adaptive immune response accurately.

Siemens Healthineers
888-826-9702; www.siemens-healthineers.com

ELISA SARS-CoV-2 IgG Test System

For qualitative detection in human serum and plasma

Zeus Scientific has received emergency use authorization for its Zeus ELISA SARS-CoV-2 IgG Test System for the qualitative detection of IgG antibodies to the SARS-CoV-2 virus in human serum and plasma. The assay utilizes a dual antigen combination of recombinant S1 receptor binding domain (RBD) viral protein and recombinant nucleoprotein for optimal performance. Compared with EUA-approved PCR methods and pre-pandemic samples, the assay demonstrated 100% positive percent agreement and 99.1% negative percent agreement. Following Zeus's universal ELISA protocol which uses many common components, the assay can be run manually or with full automation on the Dynex Agility Automated ELISA System.

Zeus Scientific
908-526-3744; orders@zeusscientific.com
www.zeusscientific.com

Amplitude Solution

Enables labs to double or triple testing capacity

Thermo Fisher Scientific's highly automated, real-time PCR solution is designed to analyze over 7,000 samples in a single day to meet increasing global demand for covid-19 testing. The high-throughput system enables laboratories to double or even triple their testing capacity to support global efforts to help communities return to work and school. The Amplitude Solution is a molecular diagnostic testing system that leverages the company's Applied Biosystems QuantStudio 7 Flex Real-time PCR instruments along with liquid handling products from Tecan Group. The modular solution delivers test results in a four-step process requiring minimal hands-on time, laboratory space, and staffing resources.

Thermo Fisher Scientific
800-955-6288; customercare@thermofisher.com
www.thermofisher.com

Respiratory 2.1 (RP2.1) Panel

Tests for 22 common respiratory pathogens

SARS-CoV-2 is a top concern, but other respiratory illnesses cause similar, overlapping symptoms. The BioFire Respiratory 2.1 (RP2.1) Panel—now available under an FDA emergency use authorization—can test for 22 common respiratory pathogens, including SARS-CoV-2. Syndromic testing means all it takes is one test and just 45 minutes to identify SARS-CoV-2 as well as all the other usual respiratory suspects. Rapid answers on a broad range of pathogens can inform patient management and alleviate the concerns of patients and staff alike.

BioFire
801-736-6354; info@biofiredx.com; www.biofiredx.com

CRISPR SARS-CoV-2 Kit

First FDA-authorized CRISPR-based EUA diagnostic

The Sherlock CRISPR SARS-CoV-2 kit, for qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory tract and bronchoalveolar lavage samples, provides specific and sensitive identification of fragments in the SARS-CoV-2 Open Reading Frame *(ORF1ab)* and Nucleocapsid *(N)* genes. The assay has two steps. Step one is RT-LAMP, where targeted SARS-CoV-2 genomic RNA is reverse transcribed to DNA, then amplified by a strand-displacing DNA polymerase. Step two transcribes the amplified DNA to activate collateral cleavage activity of a CRISPR complex programmed to the target RNA sequence. Cleavage of nucleic acid reporters results in a fluorescent readout detectable by a microplate reader.

Sherlock
617-702-6263; support@sherlock.bio
www.sherlock.bio

Multiplex Microarray Test

Using convenient mouthwash rinse

PathogenDx has developed a covid-19 Multiplex Microarray that delivers class-leading sensitivity and specificity for human IVD and environmental testing. The human testing uses an easy and convenient oral mouthwash rinse that is run on a 96-well plate with an RNA free extraction protocol. It will test for covid-19, influenza A and B, and RSV. Testing can be done on a one-to-one basis or via the company's specimen pooling protocol to allow 4x to 8x testing throughput in a single shift. PathogenDx environmental testing, via swabs, can ensure a workplace, school, or other establishment is clean and virus free to help employees, students, or customers know they are safe.

PathogenDx
800-641-5751; info@pathogendx.com
pathogendx.com

Myeloid Activation Antibody Cocktail

Visualizing immune responses

CD64, CD169, and HLA-DR are activation markers expressed by myeloid cells as an early response to infection. These markers are differentially expressed when the innate immune system is challenged with bacteria or viruses. The three-marker combination is an excellent research tool to visualize the entire innate immune response during infections using flow cytometry. This research-use-only cocktail has been used in clinical research, not diagnosis, to monitor progression and clearance of viral disease in HIV and pulmonary viral infections, including covid-19.

Beckman Coulter
800-526-3821; www.beckmancoulter.com

Molecular Diagnostics

Fully automated analyzers

The NeuMoDx Molecular Systems are fully automated analyzers that use proprietary NeuDry technology, magnetic particle affinity capture, and real-time PCR chemistry in a multisample microfluidic cartridge. The patented, "sample-to-result" platform offers unprecedented workflow optimization, test consolidation, and sustainable productivity. Operators have the ability to load up to 288 patient samples in a continuous, random-access workflow, resulting in on-demand, high-throughput testing.

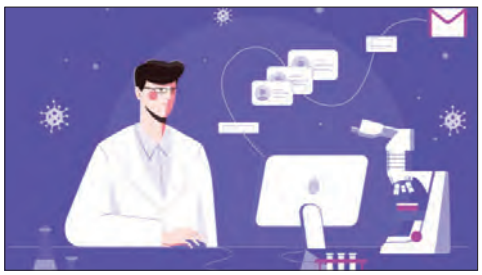
Qiagen
888-301-NMDX; info@neumodx.com; www.neumodx.com

Cold Storage

For covid-19 testing

Helmer Scientific offers a full range of laboratory refrigerators (4°C), freezers (minus 30°C), and ultra-low temperature freezers (minus 86°C) with superior temperature uniformity, recovery, and stability for safely storing temperature-sensitive patient specimens, reagents, and test kits. GX Solutions professional, medical-grade refrigerators are powered by OptiCool technology, which pairs a variable capacity compressor and natural hydrocarbon refrigerants to achieve a superior storage environment with optimized temperature uniformity, recovery, and stability; reduced noise levels—three times quieter than conventional medical-grade refrigerators; and reduced energy levels that are 50% to 65% more efficient than conventional medical-grade refrigerators.

Helmer Scientific
800-743-5637; sales@helmerinc.com; www.helmerinc.com



Direct-to-Consumer Portal

Eliminate barriers to reporting delays for covid-19

The TestDirectly Direct-to-Consumer Portal gives laboratories an innovative tool to scale up covid-19 collection, testing, and reporting by sending results directly to patients. The portal works with any laboratory information system (LIS) to replace paper requisitions and manual labor with an electronic workflow. This eliminates bottlenecks, boosts testing capacity, and improves turnaround times. TestDirectly supports the complete life cycle of a case and a specimen, including patient self-registration, scheduling, specimen collection, laboratory processing, report delivery, and billing. Reports are automatically delivered from the LIS to the portal, and patients are notified (via email and/or SMS). The portal also provides public health officials with real-time test results and prevalence.

TestDirectly
818-395-4659; solutions.testdirectly.com

High-Performance Refrigerator

For use in busy clinics

The PHCbi brand MPR-S300H-PA pharmaceutical refrigerator is designed to meet CDC requirements for safe storage. Engineered for use in busy pharmacies and clinics, this refrigerator features cooling technology using SNAP-compliant natural refrigerants, energy-saving variable-speed compressors, and strategically directed airflow for temperature uniformity even at load capacity. It is designed to achieve quick temperature recovery after door openings and to tolerate high ambient temperatures. An automatic defrost function maintains proper cooling performance, without impacting storage temperatures. Dual, sliding doors conserve floor space and permit installation in tight areas.

PHC Corporation of North America
800-858-8442; info@us.phchd.com; www.phchd.com

Centrifuge Tubes

For standard laboratory needs

Manufactured from ultra-clear virgin polypropylene for good sample visibility, the Wheaton Centrifuge Tube range meets the needs of most laboratory users for routine centrifugation applications. Available in sizes 15 mL and 50 mL, with a leak-free cap and large writing area, they are ideal for a wide range of sample handling applications. The flat caps offer leak-free performance and are easy to write on to mark samples. The RNase- and DNase-free tubes function for operating temperatures from minus 140°C to 121°C. The tubes come bulk-packed in peel-open bags and are easy to handle with gloved hands.

DWK Life Sciences
800-225-1437; US.CustomerService@DWK.com; www.dwk.com

Disinfecting Wipes

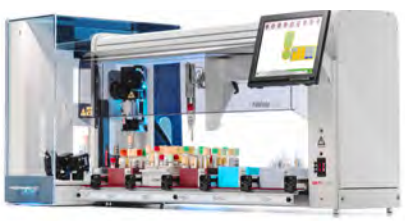
Can be used against SARS-CoV-2

Hype-Wipe bleach towelettes are on EPA List N as a disinfectant effective against SARS-CoV-2 (covid-19) when used according to label directions. The 6- by 12-inch hospital-grade disinfecting wipes are packaged in individual foil pouches embossed with an 18-month expiration date and contain 1:10 (.525%) stabilized bleach. Hype-Wipes are convenient and portable, and they don't dry out like canister wipes so there is less waste. Hype-Wipes can be used against SARS-CoV-2 when used in accordance with directions for use against norovirus on hard nonporous surfaces, with a 1-minute kill time.

Current Technologies
765-364-0490; customerservice@currtech.net; www.currtechinc.com

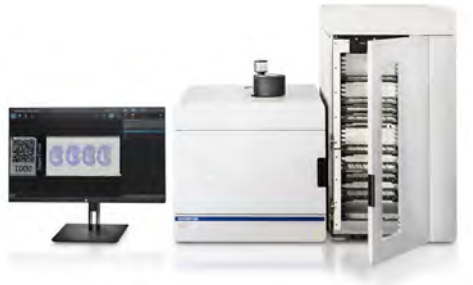
Decapper Sorter

Minimizes risk to staff



The PathFinder 350D Decapper Sorter is a benchtop preanalytical robotic workstation designed for automating the decapping of liquid media tubes and loading them into one or more analyzer racks. With the unprecedented demand for liquid media swab tubes created by the covid-19 pandemic, continuity of supply from preferred sources has proven difficult and has led to securing new sources of swab tubes based on availability. The PF350D has the flexibility to handle different sized swab tubes. It decaps UTM or VTM swab tubes and tubes up to 85mm high with the swab captured in the cap. Throughput is up to 350 swab tubes per hour.

Aim Lab Automation Technologies
+61 7 3897 1600; aimlab@aimlab.com; www.aimlab.com



High-Throughput Slide Scanning

For research and drug discovery

To support covid-19 research, the new Olympus VS200 SlideView Scanner captures high-quality virtual slide images and offers flexibility to empower advanced quantitative image analysis for research as well as drug discovery. Five imaging modes allow the user to switch between brightfield, fluorescence, darkfield, phase contrast, and simple polarization. Multiple slides can be scanned at once in four sizes ranging from 1 inch by 3 inches to 4 inches by 5 inches. The system is optimized for Olympus X Line objectives with a specially designed light path to provide more homogeneous illumination. The system accommodates up to 35 sample trays with 210 1- by 3-inch slides to be digitized in one batch.

Olympus Life Science
888-553-4448; Olympus-lifescience.com

All-in-One Saliva Self-Collection

For safe transport of samples

OmniGene·Oral is an all-in-one system for the self-collection, stabilization, transportation, and storage of DNA and RNA from bacteria and viruses such as SARS-CoV-2 in saliva. OmniGene·Oral stabilizes RNA at room temperature, providing easy self-collection of high-quality RNA from oral samples. It eliminates the need for cold chain storage and is compatible with downstream applications such as RT-qPCR and sequencing.

OraSure Technologies
613-723-5757; info@dnagenotek.com
dnagenotek.com

Flow Cytometry in Clinical Labs

Advancements in automation are poised to expand the use of this technology

Troy Rudzinski, MBA, MLS (ASCP), SCYM, Sysmex America.

By Troy Rudzinski, MBA, MLS (ASCP), SCYM

Today's flow cytometry labs are pressured to provide accurate, rapid, and high-quality test results, while meeting administrative expectations of increased productivity, training, and retention of technologists, all despite tightened budgets. Compared to other clinical laboratory specialties such as chemistry, hematology, urinalysis, and coagulation, flow cytometry testing has remained a manual process requiring highly skilled laboratory technologists.

Commercial flow cytometry began in the 1960s. At the time, testing involved the measurement of a single marker and required a flow cytometer and computer system that often took up an entire room. Due to space limitations, flow cytometry was primarily limited to research applications at large institutions. Clinical flow cytometry can be traced to the emergence of HIV in the early 1980s, when it was used for testing CD4 levels in patients.

Since then, continued advances in clinical flow cytometry have included the discoveries of additional CD markers, an expansion in the number of available monoclonal antibodies, increases in the variety of conjugated fluorescent dyes, and expanded lasers with additional fluorescent channels for testing. These advances have broadened the scope of available tests for clinical flow cytometry, with many labs commonly performing immunophenotyping of leukemia and lymphomas and immunodeficiency as well as TBNK, CD 3/4/8, and stem cell quantification.

Current Clinical Flow Testing

The technology associated with clinical flow cytometers has rapidly advanced as well. Today's clinical flow cytometers commonly have eight or more fluorescence channels, multiple lasers, and complex optical components, and they are small enough to fit on a laboratory benchtop. Advancements in flow cytometry have primarily focused on improving and expanding functionality and capabilities while adding to the number and variety of monoclonal antibodies available for testing.

There are two different clinical flow cytometry testing classes: IVD-cleared testing and laboratory-developed testing (LDT). Clinical flow cytometry IVD testing consists of certain test kits that have undergone thorough performance testing, have specified assigned systems, and have established quality control requirements. The majority of the test protocols and requirements are established by the manufacturer, and the lab is responsible for verifying their performance prior to and during testing. These tests are standardized with specified procedures and reagents, and generated results are quantified based on obtained target cell percentages and number of cells per unit of sample. Challenges with these tests commonly arise from testing process variations such as incorrect pipetting volumes, incorrect reagent usage, or variable incubation times.

Clinical flow cytometry testing for immunophenotyping for leukemias, lymphomas, or immunodeficiency testing can be conducted with IVD-cleared tests or often with LDTs. LDTs present challenges for clinical labs, because testing protocols and characteristics are determined by the individual lab and not by the manufacturer. Laboratories are also responsible for performing quality control, quality assurance, and any troubleshooting arising from tests that have no established performance characteristics outside of their laboratory. Often, laboratories use multiple manufacturers' antibodies, different antibody panel combinations, and variable processing and staining procedures to obtain test results. These tests are challenging because they routinely generate qualitative test results as opposed to the customary quantitative result obtained in other lab areas.

In addition, the same challenges seen in process variations in IVD testing can be present in LDT. For example, unanticipated deviations of validated protocols—such as incorrect pipetting of antibodies and reagents, inadequate or excessive incubation times, and variable staff techniques during sample processing—can be difficult to identify and troubleshoot.

Future of Flow Cytometry

Increases in antibodies, laser lines, and fluorescent channels have allowed for a wealth of flexibility and customization, which have expanded testing options and methodologies. However, automation in flow cytometry has fallen behind other laboratory specialties because technologists need to perform much of the sample preparation, antibody and reagent pipetting, and wash steps.

Sysmex America's highly automated and flexible PS-10 Sample Preparation System for use in flow cytometry offers labs improved standardization and increased throughput and confidence in test results. The reagent block system allows for barcoding of Sysmex flow cytometry antibodies for cooled onboard storage, as well as for other, non-Sysmex brand antibody use. Programmable panels facilitate automated cocktailing of antibodies or addition of individual antibodies into specific daughter tubes, to reduce the possibility of incorrect antibody additions and ensure correct results.

The system also connects with a Helmer UltraCW II Cell Washer, allowing full automation of the entire staining, lysing, and washing protocol. ●

Troy Rudzinski, MBA, MLS (ASCP), SCYM, *is the product marketing manager for the PS-10 at Sysmex America.*

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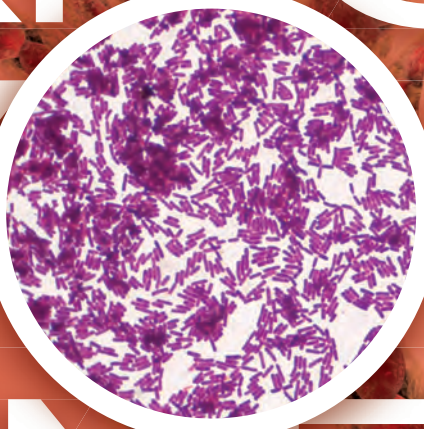

ePlex® Blood Culture Identification Panels offer the broadest coverage of organisms and resistance genes, detecting >95% of the organisms that cause sepsis

Sepsis is a common complication of COVID-19 and rapid diagnosis is key to proper treatment.

ePlex Blood Culture Identification (BCID) Panels detect more of the organisms that cause sepsis than any other molecular panel. Armed with this critical information, healthcare providers can prescribe the right treatment within hours – rather than days – improving patient care and reducing the inappropriate use of antimicrobials.

The ePlex system's simple workflow requires less than 2 minutes of hands-on time, helping increase lab efficiency. This allows hospitals, laboratories, and health care providers to focus on delilvering efficient and effective care.

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