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Inside the Lab Industry: COVID-19 Surge Lifts Overall Molecular Point of Care Testing Market to $900 Million

To the uninitiated, the term molecular point-of-care (POC) testing might sound like an oxymoron. After all, the science of molecular microbiology is all about detecting targeted bits of microbial genetic material from DNA or RNA that must be extracted directly from a patient sample. This seems like the kind of thing that can only be done in a lab. This is especially true for molecular tests that utilize polymerase chain reaction (PCR) technology to amplify and generate copies of the targeted genetic material. However, advances in technology

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FDA Watch: Agency Opens Premarket Pathway for Post-Emergency COVID-19 Test Marketing

The public health emergency that began last February will eventually end. But the demand for COVID-19 tests will not. The transition from the emergency to post-emergency test market unofficially began on March 17, 2021 when the FDA cleared a COVID-19 via its traditional premarketing pathway for the very first time.

BioFire FilmArray RP2.1 Panel Gets *De Novo* Clearance

Up to now, all of the several hundred COVID-19 tests that have reached the U.S. market have come through the FDA Emergency Use Authorization (EUA) pathway. EUA offers the advantage of expedited clearance; the downside is that EUA clearance ends when the emergency does. Of course, traditional premarket pathways allowing for marketing

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Inside the Lab Industry: COVID-19 Surge Lifts Overall Molecular Point of Care Testing Market to $900 Million, *from page 1*

have made it possible to perform these functions in any CLIA-waived settings, including at the point of care.

While molecular POC diagnostics had already been growing at a rapid rate for a long time, it has really taken off during the pandemic. Lab industry financial consulting firm Kalorama Institute estimates that demand for COVID-19 products will push the market for molecular POC testing to $900 million in 2021. While demand for COVID-19 products, which has become the largest segment of the market, will drive growth, other sectors, particularly respiratory and influenza test will also benefit from it.

The Molecular POC Market

Kalorama has been issuing annual or biannual reports on the molecular POCT market since 2013. Its newest report for 2021, "Market and Future Potential for Molecular Point of Care," defines molecular POC as near-patient PCR sequencing or other nucleic acid testing (NAT) testing utilizing small instrument size, near-patient placement and rapid test turnaround. The definition also includes CLIA-waived or tests requiring a lower threshold of operational training positioning them to earn CLIA waivers over the next five years. Notable examples of molecular POC systems listed in the report include:

- Abbott's IDNow;
- BioMérieux's BioFire;
- Cepheid's GeneXpert; and
- Roche's Cobas Liat.

The Pandemic Factor

Of course, all of these systems were well established before the pandemic. But, as Kalorama notes, because they're more expensive than other types of POC testing, molecular systems needed to demonstrate marginal worthiness to secure adoption. When COVID-19 hit, the dynamics changed. As molecular PCR assays became the COVID-19 assay modality of choice, testing labs felt more pressure to install molecular POC systems driving significant spikes in sales. Examples:

- Cepheid placed "a record number" of new GeneXpert systems in 2020, increasing its installed base 35 percent to more than 30,000 instruments globally;
- Roche's overall POC molecular business grew by 152 percent year over year;
- BioMérieux's BioFire product line grew 76 percent with the installation of nearly 1,400 FilmArray instruments in the fourth quarter alone.

The other way COVID-19 lifted the market was in accelerating the development and sales of PCR-based POC molecular tests for SARS-CoV-2. On March 1, Cepheid's Xpert Xpress SARS-CoV-2 test for use

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in moderate- and high-complexity CLIA labs became the first to secure FDA Emergency Use Authorization (EUA) for a rapid, near-patient test. Dozens would follow, including products from Abbott, Becton Dickinson, Bio-Rad, BioMérieux, LabCorp and Quest, to name just a few. As a result, as Kalorama notes, many companies reported increases in spending on consumables per system in the range of 50 percent to 60 percent.

Is It Sustainable?

The molecular POC testing market is likely to continue growing but not at nearly the same rates, according to Kalorama. Although most experts believe that steady demand for COVID-19 testing will continue for at least the next two years, the surge of 2020 was and is unsustainable. However, there's much more to molecular POC testing than COVID-19. Influenza and other respiratory testing is, by far, the biggest segment of the non-coronavirus market. Other notable segments include tests for hemagglutination inhibition (HAIs) and sexually transmitted infections (STIs).

Meanwhile, as technology gets smaller, cheaper and more sophisticated, new forms of POC innovation continue to emerge. One notable example is the lab-on-a-chip (LOC) requiring just a few drops of blood, which is currently in use and likely to become more widely deployed, especially in rural and other areas with limited healthcare resources. In addition, diagnostics companies are increasingly combining different technologies into single platforms enabling users to run multiple tests on a single sample. Thus, for example, Abbott's i-STAT 1 POC blood analyzer can perform tests for cardiac markers, coagulation, blood gases, chemistries, electrolytes and hematology on one cartridge. Roche's Cobas Liat PCR System can test for influenza A/B, respiratory syncytial virus and group A strep in about 20 minutes.

Takeway

Molecular POC testing was growing before the pandemic and will continue to do so after the pandemic, even as COVID-19 test volume recedes. "Less than 10 years since the launch of these systems," notes Kalorama, there's a marketplace with a real foundation in at least one testing segment, respiratory," and many more potential markets in other areas. At the same time, while not sustainable in the long-term, the COVID-19 surges of 2020 will sow the seeds of new growth in the future as companies reap the rewards of the molecular POC systems they placed during the year.

DX Deals: Abbott Lands $255 Million Rapid COVID-19 Antigen Test Pentagon Contract

In invoking the Defense Production Act (DPA), the Biden Administration has authorized the federal government to mobilize private industry in the war against coronavirus. The administration is also awarding lucrative contracts to companies to furnish COVID-19 tests, particularly rapid assays that can be used for screening purposes at the point of care. On March 19, Abbott Laboratories landed one of those juicy contracts: a $255 million deal from U.S. Department of Defense for SARS-CoV-2 rapid antigen tests.

Terms of the Contract

Awarded by the Defense Logistics Agency (DLA), the contract is an eight-month deal requiring Abbott to supply its BinaxNOW COVID-19 Ag Card rapid antigen tests for use in DLA Troop Support Program activities in Maine and Florida. The funding is coming from the Department of Health and Human Services' (HHS) Office of Assistant Secretary of Health.

The initial package calls for 50 million BinaxNOW tests at $255 million, but there may be many more to follow. That's because the deal is structured as a firm-fixed-price, indefinite-delivery/indefinite-quantity contract with no option periods. In other words, the DLA can order more tests before the ordering period ends on Oct. 31, up to a maximum of $766.4 million.

Abbott's Strategic Position in the Federal Government Contract Market

BinaxNOW is a lateral flow immunoassay that detects the nucleocapsid protein associated with the SARS-CoV-2 virus in 15 minutes. Abbott has done a lot of BinaxNOW business with the federal government since the pandemic began. In August, the test received Emergency Use Authorization (EUA) for use at the point of care. The very next day, HHS awarded Abbott a $760 million contract for the purchase of 150 million BinaxNOW tests (just a bit over $5 per test) to distribute to nursing homes, assisted living facilities, hospice agencies and other congregate care and vulnerable settings. Then, in December, when the FDA reissued the BinaxNOW EUA to allow for virtually guided home use with a prescription, HHS bought another $30 million worth of the test.

But there were also some rough patches in between. The Trump Administration halted shipments of BinaxNOW to eight states in November as part of a squabble between the president and governors over breakdowns in test distribution and who was at fault for causing them.

The new administration's COVID-19 testing plan provides $10 billion to states for tests enabling schools to safely reopen during the remainder of the academic year—including both PCR and rapid screening tests. BinaxNOW is considered a strong contender for the screening test portion

of the school testing program. The new DLA contract is separate from that program.

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Here's a summary of key strategic diagnostic deals announced in March 2021:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific	Color Health	• Objective: Provide COVID-19 testing for U.S. schools • Dynamic: Thermo Fisher to offer integrated COVID-19 testing to school districts nationwide via a network of testing labs, with support from Color • Funded through Biden Administration's allocation of $10 billion for COVID-19 testing
Thermo Fisher Scientific	Protein Metrics	• Objective: Comarket each firm's mass spectrometry data platforms for biopharma and proteomics • Dynamic: Non-exclusive agreement covers Thermo Scientific Chromeleon CDS software and Protein Metrics' Byos platform for protein characterization and Byosphere enterprise platform for automation, collaboration and data management
Thermo Fisher Scientific	Artificial	• Objective: Develop software automation platform for Thermo Fisher's COVID-19 testing platform • Dynamic: Artificial to provide access to its aLab Suite software, which integrates with Thermo Scientific Momentum Workflow software and robotics hardware
CellMax Life	Sebela Pharmaceuticals	• Objective: Complete commercial development of CellMax's FirstSight liquid biopsy assay • Dynamic: Sebela to seek FDA 510(k) approval for assay, which uses a microfluidic chip with a non-sticky nanolayer, high-affinity antibodies, and air-foam technology to capture and release cells
Lucence	Waseda University	• Objective: Develop rapid laser-based liquid biopsy platform to image circulating tumor cell (CTCs) and clusters in a patient's blood sample • Dynamic: Lucence to build a circulating cell atlas for analyzing CTCs and cell clusters with deep learning algorithms • Lucence gets exclusive licenses from Waseda to support the platform's development, with plans to commercialize it via its CLIA-licensed lab in Palo Alto, California

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Dx Deals, *from page 5*

Partner 1	Partner(s) 2+	Deal Summary
Aptamer Group	Mologic	• Objective: Develop rapid aptamer-based SARS-CoV-2 antigen test • Dynamic: Mologic will help Aptamer develop and eventually manufacture AptaDx rapid lateral flow assay to detect SARS-CoV-2 spike protein antigen in anterior nasal swabs
Genialis	BioLab	• Objective: Develop new algorithms and computing methods for choosing therapeutic options for patients based on disease subtype recombination deficiency (HRD) • Dynamic: Sponsored research agreement BioLab, the bioinformatics lab at University of Ljubljana in Slovenia
Stella Diagnostics	University of Kansas Medical Center	• Objective: Evaluate clinical use of Stella's proteomics panel for patients with Barrett's esophagus • Dynamic: A assess Stella's mass spectrometry-based STLA101 assay by quantifying novel proto-oncogenes in Barrett's esophagus tissue that have and haven't progressed to cancer
Illumina	Geneseeq Technology	• Objective: Develop next-generation sequencing (NGS)-based cancer profiling kits for China market • Dynamic: Geneseeq to develop kits for Illumina's NextSeq 550Dx platform based on GeneseeqPrime, a comprehensive genomic profiling panel that assesses tumor mutational burden (TMB) and microsatellite instability • Geneseeq to conduct studies with Illumina to provide IVD instruments and components • Tests to be made available directly to patients via Geneseeq and at hospital testing centers
NeoGenomics	Elevation Oncology	• Objective: Identify patients with a solid tumor who have an NRG1 fusion and may qualify for Elevation's Phase II CRESTONE study • Dynamic: CRESTONE trial is studying activity of the HER3 monoclonal antibody seribantumab in NRG1 fusion-positive tumor patients
iAssay	DDTD (Drugs &n Diagnostics for Tropical Diseases)	• Objective: Facilitate use of iAssay instrument to read, interpret and transmit test images and speed reporting of test results to physicians • Dynamic: Memorandum of Understanding MOU allowing organizations to provide DDTD's COVID-19 serology tests with automatic, digitized reads using iAssay's SimpleCloud Amazon Web Services portal to health records

Partner 1	Partner(s) 2+	Deal Summary
Proscia	Ibex Medical Analytics	• Objective: Create integrated product for artificial intelligence-based prostate cancer diagnosis • Dynamic: Combine Proscia's Concentriq image and data management platform with Ibex's AI-based Galen Prostate system
Foundation Medicine	InformedDNA	• Objective: Offer expanded access to genetic counseling and confirmatory genetic testing to patients with potential inherited cancer gene mutations • Dynamic: Patients receiving Foundation's comprehensive genomic profiling tests and get results showing potential inherited cancer gene variants to get option to be referred by physicians to InformedDNA's genetic counseling services and confirmatory genetic testing • If confirmatory testing is needed, InformedDNA genetic counselors will help patients determine the appropriate test
Bio-Rad Laboratories	Roche	• Objective: Provide Bio-Rad's InteliQ quality control products • Dynamic: Bio-Rad to offer Roche customers access to InteliQ QC tubes and Unity QC data management solutions
Genetic Technologies	Infinity Biologix	• Objective: Commercialize Genetic Technologies' COVID-19 risk test in U.S. • Dynamic: 3-year deal to collaborate on production, distribution, sales and marketing of test, which will be sold under the "powered by GeneType" • Infinity Biologix to make minimum payments to Genetic Technologies of $2.9 million over term of partnership to maintain exclusivity
Tempus	Precision Health Informatics (part of Texas Oncology)	• Objective: Advance precision oncology research and personalized treatment decisions • Dynamic: Precision Health Informatics to use Tempus' AI-powered platform and genomic sequencing capabilities with Tempus to also help Precision Health Informatics mine its database

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Dx Deals, *from page 7*

Partner 1	Partner(s) 2+	Deal Summary
Twist Bioscience	Watchmaker Genomics	• Objective: Develop high-throughput NGS applications for tumor profiling, inherited disease diagnostics, liquid biopsies and minimal residual disease (MRD) monitoring • Dynamic: Products to incorporate Watchmaker's high-fidelity library amplification master mix into Twist's enzymatic library preparation kit • Other potential application areas include cell-free DNA, circulating tumor DNA, single-cell genomics, low allele somatic variant detection and tumor mutation burden
Myriad Genetics	Intermountain Precision Genomics (Intermountain Healthcare)	• Objective: Offer tumor tissue profiling services • Dynamic: Combine Myriad's hereditary cancer risk tests, including Myriad's myRisk Hereditary Cancer test, and companion diagnostics into a single profiling service offered through Intermountain
Crown Bioscience	Cambridge Quantum Computing	• Objective: Identify new cancer treatment biomarkers • Dynamic: Combine CQC's quantum machine algorithms and software development capabilities with CrownBio's preclinical and translational research expertise to identify multi-gene biomarkers for use in cancer drug discovery

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Paige	Epredia	• Products: Paige Platform pathology image viewer and storage system and other diagnostic imaging products • Territory: Global with exclusivity in Japan
Namocell	OLS OMNI Life Science	• Products: Namocell's Single Cell Dispensers • Territory: Germany and Austria
SpeeDx	Neogen Diagnostik	• Products: SpeeDx's ResistancePlus and PlexPCR diagnostic tests • Territory: Turkey
Congenica	Amplitech	• Products: Congenica's clinical decision support platform • Territory: France, Belgium, Luxembourg, Switzerland

Partner 1	Partner(s) 2+	Deal Summary
Microbix Biosystems	Seegene Canada	• Products: Microbix's COVID-variant Quality Assessment Products (QAPs) to monitor the workflow accuracy of Seegene Allplex assays • Territory: Canada • Parties also extended the scope and duration of their existing hemostasis testing systems and reagents global distribution agreement
Abingdon Health	BioSure UK	• Products: Abingdon's AbC-19, a rapid SARS-CoV-2 neutralizing antibody test • Territory: UK, Europe • Non-exclusive
Agena Bioscience	Alliance Global	• Products: Agena's MassArray platform and related products • Territory: Middle East, Africa, Central Asia • Exclusive
Lumos Diagnostics	Northern Diagnostics	• Products: Lumos' FebriDx point-of-care acute respiratory infection assay • Canada

LICENSES

Licensor	Licensee	Deal Summary
Zora Biosciences	Quest Diagnostics	Quest gets non-exclusive license for Zora's Espoo ceramide biomarker technology for use to develop test identifying patients at risk of cardiovascular conditions and death
ERS Genomics	Setsuro Tech	Non-exclusive license to ERS' CRISPR-Cas9 patent portfolio in Japan to develop and supply cell and animal models
ERS Genomics	Otsuka Pharmaceutical	Non-exclusive license to ERS' CRISPR-Cas9 patent portfolio in Japan

SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Todos Medical	Majl Diagnostics	Todos to provide all of Majl's COVID-19 PCR testing reagents and supplies for
Abbott Rapid DX	U.S. Department of Defense	$255 million contract for Abbott to provide 50 million SARS-CoV-2 rapid point-of-care antigen tests
Roche	Government of Germany	Roche to provide up to 10.5 million SARS-CoV-2 Rapid Antigen Nasal Tests to German states for self-testing

M&A Report: Roche Merges with GenMark Diagnostics to Create Syndromic Testing Powerhouse

After a slow start to the year, M&A activity in the diagnostics space accelerated noticeably in March, both in terms of deal volume and impact. The highlight of the month was the March 15 announcement of Roche's agreement to acquire GenMark Diagnostics for approximately $1.8 billion in cash.

Terms of the Deal

The deal will actually take the form of a merger carried out in two stages:

- First, Roche will initiate a tender to acquire all outstanding shares of GenMark common stock at $24.05 per share, representing a premium of approximately 43 percent to the closing price on Feb. 10, the last day of trading before published reports rumoring a GenMark acquisition, which caused share prices to skyrocket by 27 percent; and
- Once the first merger ends, Roche will acquire the remaining common shares at the same price via a second step merger.

The deal has been unanimously approved by the boards of both companies and is slated to close in the second quarter.

Strategic Significance

Unlike some other recent high-profile M&A deals, there's a strong fit between Roche and GenMark. GenMark's portfolio of syndromic panel tests and products, including the ePlex platform, complement Roche's own molecular diagnostics product lines. GenMark's "proven expertise in syndromic panel testing provides faster targeted therapeutic intervention, resulting in improved patient outcomes and reduced hospital stays," noted Roche Diagnostics CEO Thomas Schinecker in a statement, "and will contribute to Roche's commitment to helping control infectious diseases and antibiotic resistance." And by joining forces with a global powerhouse like Roche GenMark will be able to vastly expand its market reach.

The firms even have complementary COVID-19 products. GenMark produces Respiratory Pathogen Panels for identifying pathogens associated with SARS-CoV-2 and other upper respiratory infections while Roche offers a variety of different COVID-19 tests.

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Here's a summary of the key new M&A diagnostic deals announced in February 2021:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Roche	GenMark Diagnostics	• Price: Roughly $1.8 billion in cash • Status: Expected to close in Q2 • Acquisition of GenMark's syndromic panel testing products complements and bolsters Roche's molecular diagnostics portfolio
Thermo Fisher Scientific	Mesa Biotech	• Price: Up to $591 million including $491 million cash up front and up to $100 million cash if milestones reached • Status: Closed • Acquisition of molecular test firm with 500 employees that sells PCR-based rapid point-of-care platform for infectious diseases, including SARS-CoV-2, influenza A and B, RSV and Strep A
Agilent Technologies	Resolution Bioscience	• Price: $550 million cash up front + up to $145 million more if performance milestones reached • Status: No closing date announced • Agilent moves into liquid biopsy market via acquisition of Revolution Bioscience's NGS-based noninvasive liquid biopsy test platform designed for both centralized CLIA test services and distributable kits
Hologic	Diagenode	• Price: $159 million in cash • Status: Closed • Acquisition of privately held molecular test maker that produces 30 real-time CE-marked PCR tests for bacteria, parasites, and viruses involved in sexually transmitted infections, respiratory diseases, meningitis and gastroenteritis
PerkinElmer	Oxford Immunotec	• Price: $591 million cash representing $22 for each outstanding share of Oxford, a 28.3% premium on Jan. 5 closing price • Status: Closed • Acquisition enables PerkinElmer to add tuberculosis detection to its infectious disease testing portfolio
Insightful Science	Dotmatics	• Price: Undisclosed • Status: Expected to close in Q2 • Merger integrating Insightful's bioinformatics with Dotmatics' enterprise data management technology to create scientific research platform to improve lab efficiency
DiamiR	Interpace Biosciences	• Price: Undisclosed • Status: Expected to close in April • DiamiR expands its capacity to develop and commercialize microRNA-based tests by acquiring Interpace's CLIA-certified lab in New Haven, CT

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M&A Report, *from page 11*

Acquiring Company	Target(s)	Deal Summary
CareDx	BFS Molecular	• Price: Undisclosed • Status: Closed • BFS Molecular produces software that uses NGS data to track the health of transplanted organs and stem cells over time
Veracyte	Decipher Biosciences	• Price: $600 million, including $250 million cash and $350 million in Veracyte shares, subject to Veracyte's option to pay some or all of that $350 million in cash rather than stock • Status: Closed • Acquisition of leading producer of urologic cancer diagnostics, including Decipher Prostate Biopsy and post-radical prostatectomy tests • Decipher to become wholly owned subsidiary of Veracyte
Integrated DNA Technologies (Danaher subsidiary)	Swift Biosciences	• Price: Undisclosed • Status: Closed • IDT acquires next-generation sequencing library preparation firm
Quest Diagnostics	Mercy	• Price: Undisclosed • Status: Closed • Quest acquires healthcare system's outreach lab services business consisting of 29 Mercy hospital labs and 2 independent clinical labs in Arkansas, Kansas, Missouri and Oklahoma
C2i Genomics	QNA Dx	• Price: Undisclosed • Status: Closed • Acquisition of CLIA-certified sequencing lab speeds C21's efforts to commercialize its MRDetect cancer monitoring platform
Bio-Techne	Asuragen	• Price: $215 million in cash up front + up to $105 million if Asuragen meets future milestones • Status: Expected to close in Q4 • Bio-Techne to use cash on hand and its own revolving fund to acquire developer of genetic carrier screening and oncology testing kits using proprietary chemistries for testing platforms that are widely available
10x Genomics	Tetramer Shop	• Price: Undisclosed • Status: Closed • Acquisition of Denmark-based T cell detection startup bolsters 10x Genomics' presence in the immunology space

Acquiring Company	Target(s)	Deal Summary
Oncocyte	Razor Genomics	• Price: $10 million cash + 982,318 shares of Oncocyte common stock • Status: Closed • Oncocyte becomes sole shareholder of firm, which developed what has now become the firm's first commercial assay, DetermaRx

Industry Buzz: Despite Improvements, Supplies Shortages Continue to Hinder COVID-19 Testing

More than a year into the pandemic, many labs and pathologists are still having a hard time securing the supplies they need to provide COVID-19 testing. According to a new nationwide survey by the College of American Pathologists (CAP) of pathologists, while the situation has improved since the nightmares of last June, finding a steady stream of reagents, pipettes, swabs and viral transport media remains a challenge for nearly half (45 percent) of testing labs. Here's a quick briefing on the key takeaways from the survey.

The CAP Survey

The leading trade association for board-certified pathologists, the CAP has been tracking the COVID-19 testing supplies situation since the early weeks of the pandemic. The most recent survey was carried out from Jan. 27 to Feb. 11, 2021 and asks about the experiences of the past three months. The CAP received responses from 680 board-certified pathologists, a 4.6 percent response rate, making the sample nationally representative with a +/-3.7 percent margin of error. Among the respondents:

- 45 percent reported that they were experiencing difficulties acquiring reagents within the past three months (as compared to 64 percent reported in the last survey conducted in June);
- 30 percent reported difficulties in acquiring pipette tips;
- 19 percent reported difficulties in securing supplies such as SARS-CoV-2 instruments;
- 18 percent reported difficulties in obtaining flocked nasopharyngeal swabs (as opposed to 60 percent in June); and
- 17 percent reported difficulties in obtaining viral transport media/ universal transport media (as opposed to 55 percent in June).

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Industry Buzz: Despite Improvements, Supplies Shortages Continue to Hinder COVID-19 Testing, *from page 13*

Hospital Lab Staff Getting COVID-19 Vaccination at Nearly Twice the Rate of Independent Lab Staff

The CAP survey also asked board-certified pathologists about their own and staff's access to the COVID-19 vaccine. Results: 94 percent reported that their colleagues have received the vaccination, and 89 percent said that they've received the vaccination themselves. The most glaring result was the disparity between hospital and independent lab testing staff, with 83 percent of hospital staffers saying they've gotten the vaccination compared to only 39 percent of testing personnel in independent labs.

Takeaway

The survey suggests that while things are moving in the right direction, the COVID-19 testing supplies shortages haven't yet been eliminated, particularly with regard to reagents. CAP is working with the Biden Administration to improve the supply chain situation. "As pathologists are the experts on medical diagnoses, pathologists share your desire to provide greater access to COVID-19 testing and we must also be part of the public policy decision- making process," said CAP President Patrick Godbey, MD, FCAP in a press release. "Specifically, our expertise can help address needed COVID-19 coverage and testing improvements, supply chain issues, required regulatory action, and the economics of laboratory medicine that ensure continued access to necessary services."

The Evolving COVID-19 Market: FDA Clears the Way for Asymptomatic Screening Products

A year after it came into being, the market for coronavirus diagnostics is dramatically evolving with the focus of growth inevitably shifting to products designed for serial screening of the asymptomatic at home and at the point of care. On March 16, the FDA took measures to accelerate this change in direction by issuing guidance to help developers of asymptomatic screening tests bring their products to market quickly and more easily. Here's a rundown of the new guidance "Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing" and what it portends for the future of COVID-19 diagnostics.

COVID-19 Testing 2.0

Notwithstanding the slight uptick of early March, COVID-19 case, hospitalization and death rates across the U.S. are falling and, knock on wood, will keep on declining in the coming months. Even so, COVID-19 isn't likely to disappear, and as long as the virus remains a menace, people will need to get tested for SARS-CoV-2. However, test demand

and utilization patterns will change. As cases fall, the emphasis will shift from testing the symptomatic for purposes of diagnosis and treatment to widespread screening of people in congregate settings regardless of whether they have symptoms.

Products meeting the new demands will have to get past the FDA goalie to reach the market. And therein lies the problem. Until now, all of the FDA's templates to help developers secure Emergency Use Authorization (EUA) for COVID-19 tests have been for testing patients with COVID-19 symptoms, recent exposure or other risk factors. Although the agency had signaled its willingness to consider tests performed on a serial basis on the asymptomatic as part of a screening program, it hadn't created any kind of template for those tests. And without guidance, many developers have been understandably reluctant to invest in serial tests. The new guidance may allay these fears and drive development of serial tests for use in screening.

The New Guidance

The new guidance isn't just advice. It opens a streamlined and expedited path for EUA of serial tests, specifically point of care (POC) and at-home tests with demonstrated strong performance in symptomatic persons. For the first time, the FDA has indicated that it will grant EUA for such tests for over-the-counter (OTC) use without first requiring them to be validated in asymptomatic individuals. In a statement, the FDA expressed its belief "that evidence of a test's strong performance in symptomatic patients combined with serial testing can mitigate the risk of false results when testing asymptomatic individuals."

The guidance explains what developers must do to demonstrate the effectiveness of a test's performance in symptomatic individuals to qualify for expedited EUA. Specifically, developers may generate validation data by testing symptomatic individuals serially according to the guidelines. According to the guidance, the FDA will consider authorizing serial tests for OTC use at-home and POC tests if they have a positive percent agreement of 80 percent or greater (compared to PCR) with 70 percent at the lower bound of the two-sided 95 percent confidence interval.

Serial tests with sensitivity in symptomatic individuals below 80 percent could still receive EUA; but the agency says that "clinical evaluation in an asymptomatic population would generally be expected prior to authorization of a screening claim, including for OTC use" for tests below the 80 percent mark.

Tests authorized for screening based on symptomatic data will also have to be validated in asymptomatic individuals within a certain timeframe. The FDA also says that it may revise or revoke the EUA of tests that aren't validated and that don't show adequate performance in asymptomatic individuals.

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The Evolving COVID-19 Market: FDA Clears the Way for Asymptomatic Screening Products, *from page 15*

Takeaway

Companies in a strong position to benefit from this new regime include Quidel, which is currently developing an OTC version of its QuickVue SARS test, as well as those who have products already cleared for at-home use (see the box below). To date, only three companies have gotten EUA for OTC COVID-19 diagnostic products:

- *Ellume for its all-in-one Ellume COVID-19 Home Test; and*
- *Cue Health for its Cue COVID-19 Test; and*
- *LabCorp for the Pixel by LabCorp COVID-19 Test Home Collection Kit.*

COVID-19 Products with EUA Clearance for At-Home Testing

- TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific)
- BinaxNow COVID-19 Ag Card (Abbott Laboratories)
- EmpowerDX At-Home COVID-19 PCR Test Kit (Clinical Enterprise, Inc.)

FDA Watch: Agency Opens Premarket Pathway for Post-Emergency COVID-19 Test Marketing, *from page 1*

beyond the emergency have been available all of this time. And 13 months into the emergency, a COVID-19 test maker has used it.

The first test to make the transition from EUA to *de novo* clearance status is BioFire Diagnostics' BioFire FilmArray Respiratory Panel (RP) 2.1, which detects 22 different viruses and bacteria associated with SARS-CoV-2 and other respiratory tract infections from a singly nasopharyngeal swab in 45 minutes. The FilmArray RP2.1, which was originally granted EUA clearance on May 1, 2020 (that EUA clearance has now been officially revoked as part of the transition to *de novo* status) runs on the firm's FilmArray 2.0 and higher-throughput BioFire Torch systems. BioMérieux subsidiary BioFire has developed a suite of SARS-CoV-2 diagnostic products, including, among others, a singleplex assay for the FilmArray system and the RP 2.1-EZ Panel that detects the coronavirus and 18 other pathogens in point of care and near patient CLIA-waived settings.

The FDA noted that it based its decision to grant *de novo* clearance, in part, on a review of analytical studies "which demonstrated a reasonable assurance that the BioFire RP2.1 was safe and effective at identification and differentiation of various respiratory viral and bacterial pathogens."

Impact on Future COVID-19 Test Development

The FDA specifically noted that the FilmArray RP2.1 EUA revocation and *de novo* authorization don't affect the availability of other EUA tests. However, while the EUA pathway remains open, the first *de novo*

clearance of a COVID-19 test signals that the traditional premarket pathway is also open to test makers looking to develop coronavirus products for the post-pandemic market. "While this is the first marketing authorization for a diagnostic test using a traditional premarket review process, we do not expect this to be the last and look forward to working with developers of medical products to move their products through our traditional review pathways," noted FDA acting commissioner Janet Woodcock in a statement.

The FilmArray RP2.1 *de novo* clearance also creates a new regulatory classification, which, according to the agency, "means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device."

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Here are the other key new FDA EUAs and clearances announced in March:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Twist Bioscience	EUA for SARS-CoV-2 Next-Generation Sequencing assay
Beckman Coulter	EUA for Access SARS-CoV-2 IgG II rapid antibody test
Color Health	EUA for Color SARS-CoV-2 RT-LAMP Diagnostic Assay
Color Health	EUA for DTC version of Color COVID-19 Self-Swab Collection Kit
BioFire Diagnostics (BioMeriéux subsidiary)	First ever *de novo* clearance for COVID-19 product for BioFire's Respiratory Panel 2.1
Abbott Laboratories	EUA for Alinity m Resp-4-Plex assay
Abbott Laboratories	EUA for AdviseDx SARS-CoV-2 IgG II test
Inivata	Breakthrough Device Designation for RaDaR liquid biopsy assay
Zymo Research	510(k) clearance for use of DNA/RNA Shield Collection Tube for SARS-CoV-2 testing
GetMyDNA (Gravity Diagnostics affiliate)	EUA for GetMyDNA COVID-19 Test Home Collection Kit
Gravity Diagnostics + Assurance Scientific Laboratories	EUA for Everlywell COVID-19 Test Home Collection Kit DTC
Broad Institute	EUA for CRSP SARS-CoV-2 Real-time Reverse Transcriptase-PCR Diagnostic Assay (Version 3)
Adaptive Technologies	EUA for T-Detect COVID-19 Test blood-based antibodies assay
Cue Health	EUA for Cue COVID-19 Test for home + over-the-counter use
Phosphorus Diagnostics LLC	EUA for Phosphorus COVID-19 RT-qPCR Test

Continued on page 18

FDA Watch: Agency Opens Premarket Pathway for Post-Emergency COVID-19 Test Marketing, *from page 17*

Manufacturer(s)	Product
Luminex	EUA for expanded version of multiplex NxTag Respiratory Pathogen Panel (RPP) that includes SARS-CoV-2 target
Fluidigm	EUA for Advanta Dx SARS-CoV-2 RT-PCR assay for use with Azova COVID-19 Test Collection Kit
Quidel	EUA for QuickVue At-Home COVID-19 rapid antigen test
Viracor Eurofins Clinical Diagnostics	EUA for Viracor SARS-CoV-2 assay
Clinical Enterprise, Inc.	EUA for EmpowerDX COVID-19 Home Collection Kit DTC
University of Illinois	EUA for CovidShield assay

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Novacyt	SNPsig VariPlex, PCR test for multiple SARS-CoV-2 variants
Novacyt	COVID-HT Direct, next-generation high-throughput COVID-19 PCR test
Exosome Diagnostics (Bio-Techne)	ExoDx Prostate test (EPI) kit
Macrogen	Axen COVID-19 IgM/IgG RAPID fast-test kit
XPhyto Therapeutics + 3a-diagnostics	Covid-ID Lab point-of-care SARS-CoV-2 RT-PCR test system
BioMérieux	Vidas TB-IGRA (interferon gamma release assay)
Roche	8 new configurations for its Cobas Pro Integrated Solutions analyzer
Roche	Cobas Pure Integrated Solutions Analyzer for small to medium labs
MicrosensDx	RapiPro LAMP SARS-CoV-2 test
Fujifilm	Rapid, point-of-care SARS-CoV-2 antigen test
Snibe Diagnostic	Maglumi SARS-CoV-2 Ag antigen test
Pelican Diagnostics	Pelican COVID-19 Ultra-Rapid Mobile Test
Datar Cancer Genetics	TruBlood liquid biopsy-based cancer diagnostic test
Agilent Technologies	Agilent SARS-CoV-2 qRT-PCR Dx kit
Ortho Clinical Diagnostics	Vitros Anti-SARS-CoV-2 IgG 2 Antibody assay
Ortho Clinical Diagnostics	Vitros Anti-SARS-CoV-2 Total 2 Antibody assay
Qiagen	QiaCube Connect MDx automated sample processing platforms
Guardant Health	Guardant360 CDx liquid biopsy test

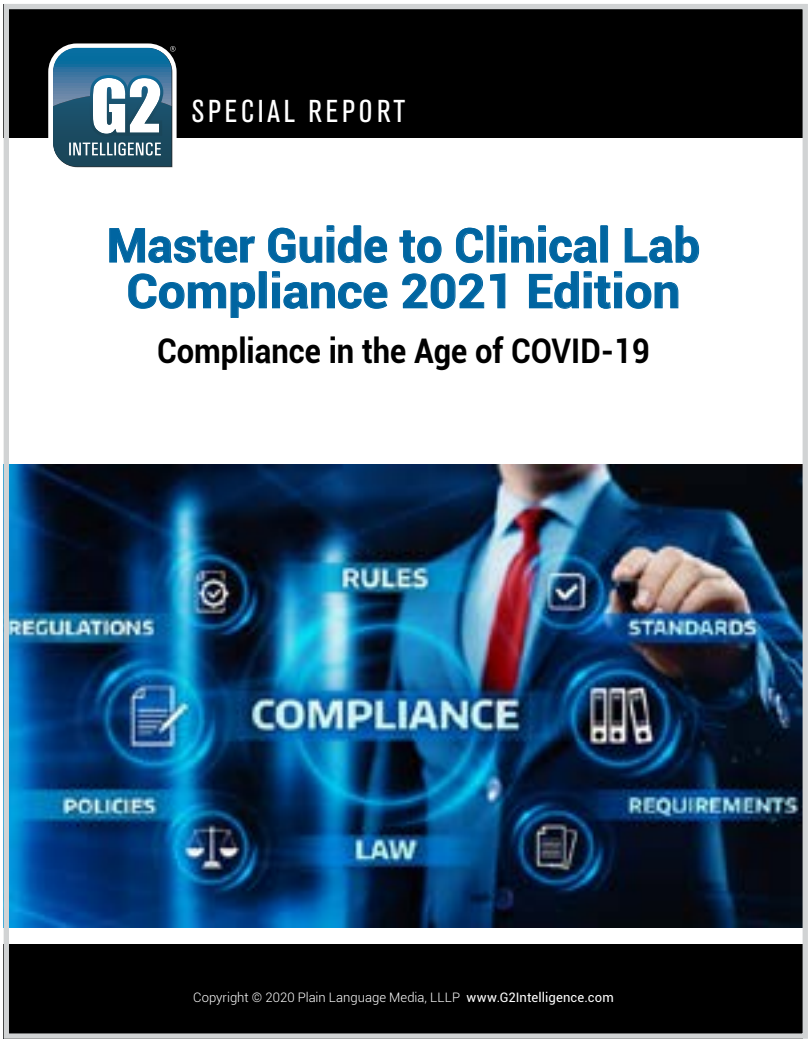
Manufacturer(s)	Product(s)
Mobidiag	Amplidiag Resp-4 molecular diagnostic test for SARS-CoV-2, influenza A virus, influenza B virus and respiratory syncytial virus

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Illumina	Russia	NextSeq 550Dx sequencing platform
OpGen	China	Curetis Unyvero system
Sysmex	Japan	HISCL Influenza Assay Kit
Roche	Germany	SARS-CoV-2 Rapid Antigen Test approved for at-home self-testing
Genome Diagnostics	Canada	* NGSgo-AmpX v2 for individual HLA gene amplification *NGSgo-MX6-1 for multiplexed amplification of 6 HLA genes
SD Biosensor	Canada	STANDARD Q COVID-19 Antigen Test Kit
Teracero Pharma + Nal von Minden	Canada	Nadal COVID-19 IgG/IgM Test

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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