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Inside the Lab Industry: Even Without COVID-19, Infectious Disease Test Market on Track for Steady Growth

From a purely business perspective, the pandemic has been a windfall for Abbott, Cepheid, PerkinElmer, Roche, Thermo Fisher Scientific and other COVID-19 testing companies. However, while the COVID-19 revenue windfalls of the past year are already starting to trail off, the long-term market for biomarker-based infectious disease testing is beyond sustainable. A new report from laboratory industry financial consulting firm Kalorama Institute says that the global market for such testing will reach nearly $15 billion in 2021. And that number does not even include COVID-19 testing.

The Biomarker Infectious Disease Test Market

Biomarkers are biological or biochemical molecules, genetic changes and other measurable characteristics that are used for diagnostic, treatment and medical research applications, including identifying diseases, prognosis, evaluating genetic

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Increasing Revenue: Manufacturers Wait Anxiously for CMS Decision on Automatic Medicare Coverage of MCIT Breakthrough Devices

Makers of innovative medical devices makers will remain on pins and needles after CMS's decision to once more delay a final rule that would automatically provide initial Medicare coverage for new medical products cleared by the FDA as breakthrough devices under Section 510(k). Finalized

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Inside the Lab Industry: Even Without COVID-19, Infectious Disease Test Market on Track for Steady Growth, *from page 1*

risks for certain conditions, disease monitoring, determining appropriate treatment options, etc. Biomarkers used to detect infectious agents include proteins (antigens), antibodies produced in response to the agents, genomic markers, etc.

Kalorama is one of the best sources of data and analysis profiling different segments of the laboratory testing market. Its new report "World Market for Diagnostic Biomarkers," predicts that global sales of biomarker-based infectious disease tests, excluding COVID-19 tests, will reach $14.8 billion in 2021. Kalorama also projects compound annual revenue growth of 5.8 percent per year from 2021 to 2027. Of course, those numbers become much bigger when the COVID-19 wildcard is included. These data are based on the three major types of biomarker-based infectious disease tests, in order of how fast they are expected to grow in volume and market share between now and 2027:

1. Molecular Tests

The segment of the biomarker infectious disease testing market that Kalorama expects to grow the fastest is molecular testing, including polymerase chain reaction (PCR), microarrays and other assays that detect nucleic acids, DNA, RNA and genes associated with particular pathogens. Rapidity of growth will be driven by the fact that molecular tests are more accurate than antigen and antibody tests, which makes them more likely to be used for more complex infectious disease testing applications and treatment settings requiring a more definitive diagnosis.

While it is not part of the Kalorama growth analysis, this is the same pattern that has played out with COVID-19 testing. In addition to COVID, molecular tests are commonly used to detect HPV, *Chlamydia trachomatis/Neisseria gonorrhoea* (CT/NG), and tuberculosis. Another growing application of molecular tests is the detection of resistance genes linked to healthcare-associated infections and disease-resistant pathogens.

2. Rapid Immunoassays

The Kalorama report predicts moderate growth for rapid immunoassays based on lateral flow immunochromatographic techniques capable of detecting pathogens in both medical treatment home and other point-of-care settings. There are currently rapid immunoassays for bacterial vaginosis (BV), chlamydia, dengue, Ebola, HIV, influenza, Legionnaires' disease, malaria, rotavirus, respiratory syncytial virus (RSV), group A *Streptococcus, Treponema pallidum,* and *Trichomonas vaginalis*.

3. Laboratory Immunoassays

Kalorama predicts slower growth for laboratory immunoassays, currently the largest segment of the biomarker infectious disease test market and

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which is expected to account for over 60 percent of global sales over the long term. The strength of this segment is the capacity of these assays, particularly enzyme-linked immunoassays, to detect antibodies and antigens associated with a wide range of common pathogens, including influenza, pneumonia, *Clostridium difficile* (C. diff), hepatitis C, HIV, herpes simplex virus (HSV) and Lyme disease.

Takeaway

Infectious disease testing based on biomarkers was on a steady arc well before the pandemic hit. The Kalorama report is useful in re-establishing the larger context without the unpredictable COVID-19 factor. What we do know is that COVID-19 will lift all segments. However, the pattern of growth, at least in the short term, will likely run against the grain of the larger infectious disease market, with laboratory immunoassays growing the fastest due to the need for rapid tests that can be used to screen the asymptomatic at home and other non-treatment settings.

FDA WATCH

A roundup of recent cases and enforcement actions involving the diagnostics industry

Agency Okays COVID-19 Blood Spot Self-Collection & Molecular Test Pooling

Pandemic pressures continue to produce unprecedented action from the FDA. The current imperative is to clear assays and collection kits for rapid and easy screening, including products that can be used in home settings. A new barrier was crossed on April 6 when the agency granted Emergency Use Authorization (EUA) for a SARS-CoV-2 antibody detection test used in dried blood spot samples collected at home.

The Symbiotica System

The groundbreaking EUA went to Symbiotica's COVID-19 Self-Collected Antibody Test System, a prescription-only test designed to detect immunoglobulin G against SARS-CoV-2 in dried blood spots obtained via fingerstick. The kit includes lancets that individuals can use to collect the blood samples themselves and mail to Symbiotica's California lab for analysis.

"The authorization of the first prescription use, home collection antibody test will play an important role in helping health care professionals identify individuals who have developed an adaptive immune response from a recent or prior COVID-19 infection," noted Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, in a statement.

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FDA Watch, *from page 3*

Molecular Test Pooling

Two weeks after clearing the Symbiotica system, the agency amended its guidelines to facilitate authorization for pooling by allowing molecular COVID-19 tests with EUA to be used with pooled samples performed to screen the asymptomatic as part of a "serial testing program," such as in a school or workplace setting. In other words, specific clearance for the use isn't required as long as the test developer self-certifies that it has validated the test for pooling and submits its validation data and pooling procedures.

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

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Diabetomics	EUA for CovAb SARS-CoV-2 Ab Test, first non-blood COVID-19 antibodies test approved with samples instead coming from painless mouth swabs
Wren Laboratories	EUA for COVID-19 PCR Test DTC, nonprescription version of previously approved test for over-the-counter sale
Siemens Healthineers	EUA for Advia Centaur SARS-CoV-2 IgG, or sCOVG, test
Roche	EUA for RT-PCR-based Cobas SARS-CoV-2 nucleic acid test for use on the Cobas Liat system
Yale School of Public Health	Reissued EUA allowing use of SalivaDirect SARS-CoV-2 test with additional thermocyclers
LetsGetChecked	Reissued EUA allowing use of at-home COVID-19 sample collection kit for children as young as age 2
Amazon.com via STS Lab Holdco subsidiary	EUA for Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2
Diabetomics	EUA for CovAb SARS-CoV-2 Ab Test
OraSure Technologies	EUA for InteliSwab COVID-19 Rapid Test for over-the-counter use
OraSure Technologies	EUA for InteliSwab COVID-19 Rapid Test Pro for professional use at point-of-care
OraSure Technologies	EUA for InteliSwab COVID-19 Rapid Test Rx for home use with a prescription
Sysmex America	Clearance for XN-10 Automated Hematology Analyzer with Blood Bank mode
Thermo Fisher Scientific	EUA for TaqPath COVID-19 Pooling Kit
Foundation Medicine	Accelerated approval for FoundationOne CDx to identify advanced cholangiocarcinoma patients with FGFR2 fusions or rearrangements who are eligible to receive newly approved BridgeBio Pharma and Helsinn Group's infigratinib (Truseltiq)

Manufacturer(s)	Product
Qiagen	Approval for Therascreen KRAS RGQ PCR kit as companion diagnostic for newly approved Amgen's sotorasib (Lumakras) for previously treated, locally advanced, or metastatic non-small cell lung cancer patients whose tumors harbor a KRAS G12C mutation
Guardant Health	Approval for s Guardant360 CDx as companion diagnostic for newly approved Amgen's sotorasib (Lumakras) for previously treated, locally advanced, or metastatic non-small cell lung cancer patients whose tumors harbor a KRAS G12C mutation

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Abbott	Panbio COVID-19 Antigen Self-Test
MFB Fertility	PdG tests get CE marking for self-testing
Hologic	Aptima CMV Quant assay
Thermo Fisher Scientific	TaqPath COVID-19 Fast PCR Combo Kit 2.0
Co-Diagnostics	Logix Smart SARS-CoV-2 DS, a PCR-based test
LumiraDx	SARS-CoV-2 Ag Pool Test
DiaSorin	Fully automated high-throughput Liaison Murex Anti-HEV IgG & IgM assay for diagnosis of hepatitis E virus (HEV)
Avacta	AffiDX SARS-CoV-2 antigen lateral flow test
Actim	Actim SARS-CoV-2 rapid antigen test
Pavmed	EsoGuard Esophageal DNA Test
Promega	Lumit Dx SARS-CoV-2 Immunoassay
Roche	SARS-CoV-2 Antigen Self Test Nasal CE marked for at-home testing
Bruker	FluoroType SARS-CoV-2 varID Q assay
Novacyt	Genesig COVID-19 3G test
iXensor	PixoTest POCT COVID-19 Antigen Test

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Lumivi Diagnostics	Canada	SARS-CoV-2 IgG Rapid test
Kantaro Biosciences	Canada	COVID-SeroKlir SARS-CoV-2 antibody test
PATH	Australia	SD Biosensor's Standard G6PD Test

DX Deals: Amazon Already Making a Mark on Direct-to-Consumer COVID-19 Test Market

Will Amazon transform diagnostic lab testing the way it did the retail industry?

Probably not. But the tech giant with the proven capacity to reach into the home and change the shopping patterns of consumers has determined to make an impact on health care. And after establishing its Amazon Care telehealth service and launching its own Halo wellness-tracking smartwatch, Amazon has made significant inroads into the COVID-19 diagnostics market.

The Amazon COVID-19 Kit

During the pandemic, Amazon developed a proprietary COVID-19 RT PCR test to screen its own employees. In March, the FDA granted emergency use authorization (EUA) for the Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 which detects the ORF1ab gene of the virus in anterior nasal swab specimens that can be self-collected using either the Amazon COVID-19 Collection Kit under the supervision of a healthcare provider or the Amazon COVID-19 Test Collection Kit unsupervised at home. On June 8, the FDA granted Amazon.com subsidiary STS Lab Holdco an EUA for a direct-to-consumer version of that test to be sold directly to consumers online.

Retailing at $39.99, the kit can be purchased without a prescription by any person age 18 or older, including for asymptomatic screening use. To purchase the kit, the customer must first register on Amazon's AmazonDx.com diagnostic portal using an Amazon account. Registered users can also watch a video demonstrating how to use the kit, which comes with a nose swab, collection tube and a specimen bag. Delivery can be made in as little as one day in some areas. Once they collect the samples, users ship them to an STS Lab Holdco lab using the prepaid shipping label for processing, with results delivered directly via text or internet.

The Amazon test is also authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens per pool that are collected in individual vials containing transport medium.

The Amazon website also sells direct-to-consumers COVID-19 tests from other companies ranging from Quidel's QuickVue rapid test for $24.95 to a 10-pack of EmpowerDX's self-collected PCR test kits at a price of $890.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Cytox	Infinity BiologiX	• Objective: Launch new liquid biopsy-based lab developed test for Alzheimer's disease risk in US • Dynamic: Test based on Cytox's GenoScore platform for predicting risk of cognitive decline due to Alzheimer's from a saliva or blood sample • IBX to offer test out of its CLIA-certified, CAP-accredited lab
G42 Healthcare	Seegene	• Objective: Provide fully equipped mobile diagnostics labs in Middle East and North Africa • Dynamic: Offer Seegene's Mobile Station, a laboratory-on-wheels facility for molecular diagnostic testing that includes equipment, RT-PCR reagents, consumables, IT solutions and technical support
Berry Oncology	Alibaba Health (part of Alibaba Group)	• Objective: Develop early cancer screening and healthcare platform • Dynamic: Offer Berry Oncology's Lai Si Ning NGS-based liver cancer screening test to people at high risk • Firms also offering medical insurance and cancer screening consultancy to liver disease patients via Alibaba's Taobao e-commerce platform
OncoDNA	Institut Jules Bordet	• Objective: Perform study on central nervous system metastases • Dynamic: BrainStorm study to enroll 600 patients newly diagnosed with solid tumors at clinical sites in France, Belgium and Luxembourg
Quest Diagnostics	Epizyme the	• Objective: Improve access to EZH2 mutation testing for patients with relapsed or refractory follicular lymphoma • Dynamic: EZH2Now Testing Program to provide free testing to qualified patients

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DX Deals, *from page 7*

Partner 1	Partner(s) 2+	Deal Summary
Enzo Biochem	CLX Health	• Objective: Provide rapid COVID-19 PCR testing for international travel • Dynamic: CLX Health to add Enzo's test processing locations in New York and New Jersey to its cloud-based TrustAssure platform enabling travelers to schedule COVID-19 testing at convenient locations convenient, get and transmit their results to their airline
BGI Americas	Champions Oncology	• Objective: Provide proteomics and multiomics tools for cancer biomarker discovery and validation • Dynamic: BGI to handle sample preparation and do mass spectrometry analysis of Champions' patient-derived xenograft samples to support biopharma drug discovery and development projects
Oncocyte	Echelon Diagnostics	• Objective: Develop analytical software to support commercial expansion of Oncocyte's tests • Dynamic: Leverage Echelon's AI imaging and big data solutions for molecular diagnostic technologies to support a pipeline of oncology diagnostic assays Oncocyte has acquired via acquisitions of other companies
Oncocyte	Gruppo Oncologico del Nord-Ovest (GONO Foundation)	• Objective: Evaluate Oncocyte's immunotherapy response predictor DetermaIO in metastatic colorectal cancer • Dynamic: DetermaIO measures expression of genes thought to play a role in interaction between a tumor and its immediate microenvironment
Caris Life Sciences	Elevation Oncology	• Objective: Identify oncogenic fusions and mutations and develop therapeutics targeting these newly identified alterations • Dynamic: Examine Caris' whole exome and transcriptome sequencing data on an ongoing basis, identify and evaluate potential new drug targets and then decide whether to initiate novel drug discovery programs or pursue licensing or product acquisitions

Partner 1	Partner(s) 2+	Deal Summary
Quidel	Mecwins	• Objective: Develop next-generation point-of-care testing instrument • Dynamic: Combine Mecwins' AVAC sensitive, high-throughput technology with Quidel's expertise in cartridge and immunoassay design
Celemics	Strand Life Sciences	• Objective: Develop single, comprehensive technology platform to support bioinformatics research • Dynamic: Combine Celemics' bioinformatics pipeline with Strand's StrandOmics tertiary analysis platform to create integrated offering that includes assay-specific variant filters to provide "guaranteed" clinical-grade data compliance for cancer and rare diseases research
Twist Bioscience	Regeneron Pharmaceuticals (via Regeneron Genetics Center subsidiary)	• Objective: Develop a custom next-generation sequencing genotyping assay for population genetics • Dynamic: Twist to market the Diversity SNP Panel worldwide
Veranome Biosystems	Portal Bioscience	• Objective: Develop new spatial transcriptomics products for cancer and other complex disease research • Dynamic: New products will use Veranome's high-definition imaging and data analysis technologies with Portal's Proxal probe ligation-based biochemistry to enable tracking of fragmented RNA, as well as detection of mutations, gene fusions and splice variants
Biocept	Cleared4	• Objective: Develop system for tracking and managing COVID-19 testing requirements and test results for Biocept customers • Dynamic: Service to use Cleared4's health platform, allowing Biocept COVID-19 testing clients to incorporate customized protocols and requirements • Platform to integrate results from Biocept's RT-PCR-based COVID-19 testing in real time, and administrators will be able to monitor the program via a secure dashboard
LivFul	Global Access Diagnostics	• Objective: Offer rapid SARS-CoV-2 antigen test developed by Mologic at affordable prices in lower income countries • Dynamic: Plan is to expand collaboration to other diagnostics later

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DX Deals, *from page 9*

Partner 1	Partner(s) 2+	Deal Summary
Akoya Biosciences	AstraZeneca	• Objective: Develop predictive assays and analysis frameworks to enable AstraZeneca and pharmaceutical industry to advance a spatial biomarker-informed drug development strategy for immunotherapy • Dynamic: Study drug mechanisms of action, confirm prevalence of targets and discover predictive signatures for trial designs using Akoya's Phenoptics platform and Advanced Biopharma Solutions services
Nucleix	University of Texas MD Anderson Cancer Center	• Objective: Evaluate and develop methylation assays focusing on lung cancer • Dynamic: Research and license agreement under which firms will evaluate methylation markers for characterizing lung cancer subtypes. using Nucleix's EpiCheck liquid biopsy platform • MD Anderson to validate the assays
Centogene	Alector	• Objective: Perform observational study to identify frontotemporal dementia patients with genetic mutations • Dynamic: Alector, a San Francisco-based immuno-neurology company developing treatments for neurodegenerative diseases, to provide undisclosed financial support for EFRONT study
Genomenon	Nostos Genomics	• Objective: Integrate Genomenon's Mastermind genomic search engine into Nostos AIon AI-driven variant interpretation platform to improve diagnosis of rare genetic diseases • Dynamic: Integration will allow AIon users to preview lists of published articles related to their searches from within the AIon interface
Illumina	Belgian Genetic Centers	• Objective: Evaluate whole-genome sequencing to diagnose patients with intellectual disabilities and developmental disorders in routine care • Dynamic: Belgian Resolve Rare Diseases group to run a study recruiting 800 pediatric patients and their parents

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Aiforia	Epredia	• Products: Aiforia's artificial intelligence-based pathology software • Territory: Global • Exclusive rights in globally, with exclusive rights in Japan, Germany, UK, Italy, Spain, Sweden, Norway, Denmark, Iceland, France, US
Avacta	Calibre Scientific	• Products: Avacta's AffiDX SARS-CoV-2 antigen lateral flow test • Territory: UK and European Economic Area • Nonexclusive
JADBio	Qiagen	• Products: JADBio's automated machine learning platform • Territory: Undisclosed • Qiagen to distribute platform within its Digital Insights portfolio
InBios International	Code 1 Supply	• Products: InBios International's point-of-care SCoV-2 Ag Detect Rapid Test for SARS-CoV-2 antigens • Territory: Undisclosed
Genetic Analysis	Eagle Biosciences	• Products: Genetic Analysis' GA-map Dysbiosis Test • Territory: US and Canada
Shoreline Biome	Inqaba Biotechnical Industries	• Products: Shoreline Biome's microbiome research products and services • Territory: Sub-Saharan Africa
Microbix Biosystems	SDT Molecular	• Products: Microbix's quality assessment products, or QAPs • Territory: Hong Kong, Indonesia, Malaysia, Singapore
Euformatics	A&C Group	• Products: Euformatics' Omnomics interpretation and validation software for next-generation sequencing • Territory: Bolivia, Peru, Paraguay

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DX Deals, *from page 11*

LICENSES

Licensor	Licensee	Deal Summary
Guardant Health	Foundation Medicine	Roche subsidiary pays $25 million plus royalties on future sales of Foundation's liquid biopsy products for nonexclusive license to Guardant's digital sequencing technology patents in agreement to settle Guardant's patent lawsuits against Foundation
221b Foundation (nonprofit organization established by Sherlock Biosciences)	Rokline Health Concepts	Rokline gets non-exclusive license to SHERLOCK (Specific High Sensitivity Enzymatic Reporter unLOCKing technology), which uses CRISPR for amplicon detection for single-molecule detection of nucleic acid targets to develop COVID-19 tests

SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Becton Dickinson	USA Track & Field	Becton Dickinson to provide rapid COVID-19 testing for USATF athletes with BD Veritor Plus system during Olympics qualifying events and trials

GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Leidos	US Centers for Disease Control and Prevention	Five-year contract worth up to $13 million for Leidos to provide IT and analytics support and management of very large datasets work to CDC's Office of Advanced Molecular Detection

M&A Report: 23andMe Goes Public While the Clock Ticks on Illumina's Grail Acquisition

M&A deal making in the diagnostics space remained hot and heavy in June. Key deals included Danaher's announced $9.6 billion acquisition of life sciences plasma DNA maker Aldevron and the closing of Hologic's acquisition of Finnish molecular infectious disease test firm Mobidiag for $795 million. But the big story was the closing of previously announced deals, one of which actually happened and another which may never come to pass.

23andMe Goes Public

Based purely on Wall Street reaction, the biggest M&A blockbuster of June was the coming out party of 23andMe, the pioneer of direct-to-consumer (DTC) at-home genetic tests. The company began selling saliva test kits at about $99 a pop for personalized medicine and ancestral lineage 15 years ago. Since then, it has built up a massive database of users analyzed for a comprehensive list of nearly 1,000,000 single nucleotide polymorphism genetic markers.

This compilation of personal genetic data on individuals and their probabilities of developing different medical conditions has engendered privacy concerns and sparked action from the FDA to ban unmedically justified disclosures. However, even amid the accusations that the agency was denying people the right to obtain information from their own genome, the FDA has broken ground in clearing 23andMe products for a wide variety of DTC uses.

The firm went public on June 17, 2021, after closing its merger with a Richard Branson-owned special purpose acquisition company called VG Acquisition Corp. First announced in February 2021, the deal placed 23andMe's enterprise value at roughly $3.5 billion. Since then, the high-profile creator of direct-to-consumer genetic tests has raised nearly $600 million which it plans to invest in its consumer health and therapeutics product lines and genetic and phenotypic database. Shares of the new entity (assigned ticker symbol ME) spiked as high as 22 percent on the very first day of trading on the Nasdaq.

Illumina's $8 Billion Grail Acquisition Hits a New Snag

Meanwhile, what would be among the year's most impactful deals, Illumina's $8 billion acquisition of former spinout Grail, remains very much in doubt. Concerns from the U.S. Federal Trade Commission (FTC) over the new cancer genomics powerhouse's potential dampening of competition were fairly easy to predict. However, what few probably saw coming is the regulatory opposition from across the Atlantic.

Last April, the European Commission's Directorate-General of Competition announced that it plans to review the deal under its controversial new guidance that enables the Commission to demand notification of a deal even when no such notification is required by the member states. "The combined [Illumina/Grail] entity "could restrict access to or increase prices of next-generation sequencers and reagents to the detriment of Grail's rivals active in genomic cancer tests following the transaction," according to a Commission statement.

Now a U.S. federal court has allowed the FTC to postpone legal action to block the deal pending resolution of the situation in Europe. Thus, even if it beats back the frying pan of the EC challenge, Illumina could be stepping

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M&A Report: 23andMe Goes Public While the Clock Ticks on Illumina's Grail Acquisition, *from page 13*

into the fire of FTC regulatory action and litigation. All the while, the clock ticks down to the contractual deadline that the deal close by the end of the year.

Illumina CEO Francis deSouza described the FTC's latest move as "time-wasting maneuverings." The report from the Financial Times also quotes deSouza as saying that "The biggest challenge is getting the FTC to move with the appropriate sense of urgency and getting. . . this case to trial."

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
23andMe	VG Acquisition Corp.	• Price: Merger deal valuing 23andMe at roughly $3.5 billion • Status: Closed • 23andMe goes public via merger with special purpose acquisition company
Danaher	Aldevron	• Price: Approximately $9.6 billion • Status: Definitive agreement with no closing date announced • Acquisition of North Dakota-based maker of plasmid DNA, mRNA and proteins for biotech and pharma customers, which will operate as standalone company and brand within Danaher's Life Sciences segment
Hologic	Mobidiag	• Price: Approximately $795 million, including $714 million cash + $81 million net debt • Status: Closed • Acquisition of Finland-based developer of molecular tests and instruments for infectious illnesses is Hologic's third recent strategic acquisition in molecular diagnostics space
Eurofins	DNA Diagnostics Center	• Price: Undisclosed • Status: To close in Q3 • Acquisition of maker of portfolio includes tests for paternity, fertility, COVID-19, ancestry and wellness with expected 2021 revenues of over $55 million
Tecan Group	Paramit	• Price: $1 billion • Status: Definitive agreement to purchase with no closing date announced • Acquisition of California-based manufacturer of medical devices and life sciences instruments

Acquiring Company	Target(s)	Deal Summary
MicroGenDx	RTL Genomics	• Price: Undisclosed • Status: Closed • Acquisition of next-generation sequencing lab bolsters MicroGenDx's nonclinical primary research capabilities
Dante Labs	Cambridge Cancer Genomics	• Price: Undisclosed • Status: Closed • Acquisition allows Dante Labs to combine its Immensa Genomics Interpretation Software with CCG's AI-based OncOS precision oncology software
NeoGenomics	Inivata	• Price: $390 million • Status: Closed • NeoGenomics exercises option to acquire remaining equity stake in liquid biopsy startup which is developing assays for cancer diagnosis and treatment and which will become a new division of the company
DCN Dx	PortaScience	• Price: Undisclosed • Status: Closed • Acquisition of point-of-care diagnostics company focused on dry chemistry technology
ATS Automation Tooling Systems	BioDot	• Price: $84 million in cash • Status: Closed • Acquisition of maker of automated fluid dispensing systems for point-of-care and clinical diagnostics lab automation end markets
PathGroup	SkinDx	• Price: Undisclosed • Status: Closed • Acquisition of Alabama-based dermatopathology lab expands PathGroup's presence in dermatopathology market
iVitalize	Geneus Health	• Price: Undisclosed • Status: Closed • Acquisition of Texas-based genetic testing lab for addiction therapy and management
Quantum-Si	HighCape Capital Acquisition	• Price: Approximately $534 million • Status: Closed • Merger with special purpose acquisition company raises capital for commercializing Quantum-Si's single-molecule, semiconductor chip-based protein sequencing and genomics technology

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M&A Report, *from page 15*

Acquiring Company	Target(s)	Deal Summary
Castle Biosciences	Myriad Genetics	• Price: $32.5 million in cash • Status: Closed • Castle expands dermatologic cancers tests pipeline via acquisition of Myriad myPath Melanoma test and Utah CLIA lab that performs it
CareDx	Transplant Hero	• Price: Undisclosed • Status: Closed • Acquisition of developer of smartphone app aimed at supporting needs of transplant patients expands CareDx's digital portfolio, which includes cloud-based solutions and software for transplant centers and dialysis providers
Veracyte	HalioDx	• Price: €260 million, including about €147 million in cash and up to approximately €113 million in stock (about $318 million total) • Status: Expected to close in Q3 • Acquisition of French immuno-oncology diagnostics firm and maker of Immunoscore colorectal cancer test, which will become a subsidiary of Veracyte

Increasing Revenue: Manufacturers Wait Anxiously for CMS Decision on Automatic Medicare Coverage of MCIT Breakthrough Devices, *from page 1*

during the Trump administration, the rule is a long-term project that was originally slated to go into effect on March 15, 2021. But after having already imposed a 60-day delay, CMS has once more put off the decision date so it can continue to study the issue.

The Ramifications for Makers of LDTs

There's a lot on the line for both diagnostics makers and patients. Under the final rule, newly approved breakthrough devices would be deemed to meet the "reasonable and necessary" standard set out in Section 1862((a)(1)(A) of the *Social Security Act* for purposes of Medicare coverage over a four-year period starting on the date of FDA market authorization. Once the initial period ends, CMS would perform a new "reasonable

and necessary" evaluation of the device based on clinical and real-world evidence of improved health outcomes. (For more on the rule, see *National Lab Reporter (NLR)*, May 10, 2021).

Technically, the rule applies only to devices that pass through the Medicare Coverage of Innovative Technology (MCIT) pathway, which doesn't include laboratory developed tests (LDTs). However, the larger idea of deferring to the FDA and not keep Medicare beneficiaries waiting for innovative medical technology would translate equally well to LDTs. In fact, CMS has sent clear signals that it looks at the MCIT rule as a template that could be extended to breakthrough diagnostics, drugs and/or biologics that aren't currently in the MCIT pathway, including LDTs.

CMS Refuses to Be Rushed

The MCIT Medicare coverage rule was one of the many eleventh hour rules finalized at the tail end of the previous administration affected by the freeze on new health care regulations imposed by the Biden regime in its first hours of office. Opponents of the rule, including the bipartisan Medicare Payment Advisory Committee (MedPAC) contend that FDA breakthrough device authorization and Medicare "reasonable and necessary" coverage approval is an apples-to-oranges comparison requiring different forms of medical evidence. Forcing CMS to cover new devices just because they get 510(k) certification would strip the agency of its scientific review responsibilities and expose Medicare patients to new technologies of unproven effectiveness and safety, they argue. "The Medicare program, not the FDA, should adjudicate coverage and spending determinations based on the specific needs of the Medicare population," commented MedPAC in providing public feedback to CMS.

In addition to MedPAC, 96 others submitted public comments during the latest delay period, including Swiss pharmaceutical giant Novartis, which came out in support of the rule, and the National Comprehensive Cancer Network, which opposed it.

Congress Asks CMS to Approve the Rule

With the May 15 deadline approaching, 37 Democratic members of Congress wrote a letter urging acting CMS Liz Richter administrator to "move forward with implementation as soon as possible." Four of the authors also penned a letter to CMS back in February urging the agency to stick with the original March 15, 2021 implementation. Hoping the new letter will have a more potent impact, they persuaded 33 of their colleagues to join them in signing the latest missive.

Time's a wasting, the letter stresses. "We remain concerned the delay may unfairly exclude breakthrough devices that would have been included in the original rule, had it been enacted on March 15, 2021." The letter calls

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Increasing Revenue: Manufacturers Wait Anxiously for CMS Decision on Automatic Medicare Coverage of MCIT Breakthrough Devices, *from page 17*

on CMS to allow products that would have been eligible had the rule taken effect on March 15 to remain eligible if and when the rule does become final regardless of the length of delay.

Takeaway

Assurance of Medicare coverage would go a long way toward breaking down barriers to research and development and incentivizing investment in novel diagnostics. Ultimately, that would likely extend beyond MCIT devices to LDTs. Raising the stakes even higher is the potential that the rule would include a "lookback" window covering devices approved within the two-year period before the rule took effect. Echoing the wishes of many in the device industry, the new letter from Congressional members urges CMS to extend the "lookback" window beyond two years to cover all breakthrough devices approved by the FDA so far.

At the end of the day, it seems likely that CMS will ultimately approve some form of Medicare coverage rule for breakthrough devices given the bipartisan support for the initiative. But the question of how extensive the rule will be and when it will take effect remain very much in suspense.