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DX Earnings Report: Strong Q1 Earnings Belie the True Financial Devastation of COVID-19

The bad news is that COVID-19 is very, very bad for business; the good news—sort of—is that the pandemic had just the last few weeks of March to wreak havoc on 2020 Q1 earnings reports. And even that flimsiest of silver linings doesn't apply to diagnostics firms that do heavy business in China and other East Asian markets where the virus first hit in January.

Gainers

Many companies were able to get the fiscal year off to a strong start and build up enough of a cushion in January and February to finish Q1 with positive growth. Thus, of the

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Diagnostics Deals: Pandemic Infuses New Urgency Into Effort to Develop Genomics-Based Early PTSD Detection Diagnostics

In addition to death and dislocation, the global COVID-19 pandemic is likely to spawn a crisis in mental health, including a spike in post-traumatic syndrome disorder (PTSD) cases. With this in mind, a pair of diagnostic firms—one in genomics and the other in AI—have teamed up to develop new biomarkers and methodologies that can be used for early detection of the condition.

The Partners

The current survey-based methods of early PTSD identification tend to be subjective and biased due to the stigma associated with the condition. Recognizing the need for unbiased genomic and data-driven technologies, TruGenomix, a Maryland-based developer of next-generation-

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M&A Report: Thermo Fisher Acquisition of Qiagen Remains on Track, *from page 1*

39 companies that had published earnings results for the quarter as of the time we went to press, all but 10 had higher 2020 Q1 revenues, as compared to the same period in 2019. Gainers included not only emerging genetic and molecular testing firms with relatively low revenues but also mature giants like Abbott, Danaher, LabCorp, Roche and Thermo Fisher. Alas, Quest posted a 4% year over year decline but did top its Wall Street targets on both the top and bottom lines.

Among companies with reported Wall Street earnings estimates, 28 hit their targets and only eight came up short. But three companies in the latter group—Fluidigm, Pacific Biosciences and Waters—actually reported higher than expected earnings per share.

The Pandemic Effect

Once the pandemic hit, all hell broke loose. Labs stood hopelessly by as doctors, clinics and other key customers temporarily shut down or severely curtailed their operations. As just about all forms of non-urgent testing came to a screeching halt, being in the COVID-19 space became pretty much the only way for labs to make money. However, most lab companies weren't positioned to provide COVID-19 testing, which must be performed by Level 2 labs on platforms costing anywhere from $250,000 to $1 million, to say nothing of scarce supplies like cotton swabs, reagents, PPE and, of course, trained testing personnel.

In addition, while the demand for COVID-19 testing is unprecedented, the reimbursement is rather modest. Thus, even the companies with the wherewithal and resources to offer COVID-19 testing, including big companies like Abbott, LabCorp and Quest, couldn't make enough to offset the massive overall volume losses in other areas.

The Pandemic Positives

On the bright side, there were a few firms that were able to take maximum advantage of the unprecedented demand for COVID-19 tests, instruments, platforms, reagents and other related products and services, including BioMérieux whose BioFire FilmArray products grew 67% year over year thanks to "exceptionally high" use of its respiratory and pneumonia panels. Sales for DNA/RNA extraction instruments and reagents were also off the charts.

The severe flu season and subsequent COVID-19 was also good for business at Danaher, where diagnostics revenues increased 6% to $1.63 billion driven by 40% growth in revenues for Cepheid point-of-care respiratory testing.

Another company that made hay on COVID-19 was Meridian Bioscience. After five quarters of decline in a row, Meridian's diagnostics division turned things around by posting positive growth of 4%. And while most

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companies were withdrawing their 2020 financial guidance due to COVID-19 uncertainty, Meridien not only stuck with but increased its guidance based on expectations of greater demand for its molecular and serology SARS-CoV-2 reagents.

Other companies that posted a strong Q1 either because of or despite the pandemic:

- Qiagen, one of the few companies where coronavirus revenues offset the losses in other businesses and which is dramatically ramping up production of its COVID-19 reagents and RNA extraction kits;
- Natera, whose diagnostics division been enjoying its biggest sequential quarter-on-quarter segment growth in company history before the pandemic, and which was able to minimize COVID-19 disruption by making fast and effective improvements to its remote ordering capabilities; and
- GenMark Diagnostics, where revenues increased 80% and which raised its guidance after the FDA gave Emergency Use Authorization for its ePlex SARS-CoV-2 Test run on the firm's ePlex system.

Takeaway

According to several reports, the COVID-19 revenue losses that began in March continued into April and the first two weeks of May. As reopening progresses and elective surgeries and non-urgent health care services resume, the rebound will likely continue, albeit at a modest rate through June and July. Thus, the true extent of the economic horrors will become clear not in Q1 but the earnings reports for Q2. No wonder so many firms have withdrawn their financial guidance.

Diagnostics Earning Reports for Q1 (period ended March 31, 2020)

(At least $10 million in sales)

COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	$7.73 billion ($7.34 billion)	+3% (+4% organic)	Adjusted +$0.65 (+$0.58)	DX down 1% to $1.83 billion, wit core lab revenues down 7% at $989 million, molecular up 29% to $139 million, POC up 2% to $138 million, rapid diagnostics up 4% to $560 million
Adaptive Biotech	$20.9 million ($22.7 million)	+65%	Net -$.25 (-$.21)	Test volumes started quarter strong but fell dramatically due to COVID-19 pandemic; ClonoSeq testing up 75% to 3,518 tests

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COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Agilent Technologies (FY 2Q)	$1.24 billion ($1.21 billion)	-2%	Adjusted +$0.71 (+$0.61)	Diagnostics and Genomic Group up 4% to $263 million, Life Sciences and Applied Markets down 1% to $526 million due to lower equipment purchases during pandemic; CrossLab group down 1% to $449 million
Becton Dickinson (FY Q2)	$4.25 billion ($4.16 billion)	+1%	Adjusted +$2.55 (+$2.36)	Pandemic-fueled decline in elective testing and non-urgent hospital procedures results in at least $40 million in DX revenues lost
Bio-Mérieux	$836.6 million	+22% (+21% organic)	Not reported	Molecular biology up 70% to $319.5 driven by not only unprecedented demand for COVID-19 testing which also led to abnormally high sales of DNA/RNA extraction instruments and reagents
Bio-Rad Laboratories	$571.6 million ($554.9 million)	+3%	Non-GAAP +$1.91 (+$1.61)	Strong quarter with DX up 2% to $340.3 million driven by quality controls and blood typing, which offset losses in immunology and diabetes products; net loss of $258.8 million as a result of investment losses
Bio-Techne (FY Q3)	$194.7 million ($185.4 million)	+5%	Adjusted +$1.39 (+$1.15)	Despite pandemic headwinds, DX & Genomics up %5 to $49.4 million and Protein Sciences up 6% to $145.5 million
CareDx	$38.4 million ($38.0 million)	+48%	-$0.14 (-$0.03)	Testing services up 46% to $31.4 million driven by 50% increase in AlloSure and AlloMap sales
Centogene (FY Q4)	$16.4 million ($15.05 million)	+52%	Net Loss of $5.45 million	Diagnostics up 16% to over $7 million
Danaher	$4.34 billion ($4.29 billion)	+3%	Adjusted +$1.05 (+$1.01)	DX up 6% to $1.63 billion; Cepheid point-of-care up over 40% driven by severe flu season followed by COVID-19 outbreak; Beckman Coulter DX revenues up in high-single digits
Exact Sciences	$347.8 million ($350.4 million)	+115%	-$0.71 (-$0.61)	Precision oncology up 18% to $128.4 million despite 36% drop in Cologuard test volume in final 3 weeks of quarter—9,000 new providers ordered assay during quarter
Fluidigm	$27.6 million ($29.0 million)	-8%	Adjusted -$0.13 (-$0.15)	Pandemic hurts sales of both mass cytometry (down 26% to $11.5 million) and microfluidics products (down 20% to $7.5 million)

COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
GenMark Diagnostics*	$38.7 million ($29.8 million)	+80%	Net -$0.12 (-$0.14)	Pandemic drives 119% increase in ePlex systems to $34.3 million (54 new systems placed during quarter)
Guardant Health	$67.5 million ($56.5 million)	+84%	Net -$0.29 (-$0.39)	Precision oncology up 109% to $60.2 million with 60% increase in clinical test volume (15,257 test results); development services down 7% to $7.3 million driven by new companion Dx products for biopharma
Hologic (FY Q2)	$756.1 million ($745.9 million)	-8%	Adjusted +$0.57 (+$0.57)	Global DX up 8% to $319.2 million driven by 14% growth in molecular diagnostics to $190.6 million, best Q since 2012 for that segment,and blood screening up 14% to $15.2 million but cytology + perinatal down 2% at $113.4 million
Illumina	$859 million ($854 million)	+2%	+$1.17 (+$1.25)	Strong demand for COVID-19 testing reagents fuels growth in sequencing consumables and service revenues but is offset by decline in sequencing services revenues
Invitae	$64.2 million ($59.4 million)	+58%	Non GAAP -$0.80 (-$0.76)	Strong start of Q provides cushion for 50% decline in testing volume in March; 154,000 samples accessioned in total for Q vs. 94,000 in Q1 2019
LabCorp	$2.82 billion ($2.74 billion)	+1%	Adjusted +$2.37 (+$1.95)	Growth driven by acquisitions which contributed 3%; organic revenue down 2% due to PAMA produces (-1% impact) and pandemic (-5%); overall demand for testing down 50%, despite surging demand for COVID-19 testing organic volume up less than 1% with managed care contracting changes producing -1% impact
Luminex	$90.4 million ($84.1 million)	+10%	Net +$0.01 (-$0.03)	Assays revenue up 26% to $43.7 million; molecular DX up 28% to $45.2 million; flow cytometry down 42% to $6.5 million
Meridian Bioscience (FY Q2)*	$57.3 million ($49.3 million)	+14%	Adjusted +$0.23 (+$0.08)	DX up 4% to $34.9 million, first YOY growth for division in 5 quarters, including 2% growth in molecular tests to $7.2 million, and 5% growth in immunoassay and blood chemistry to $27.7 million driven by demand for COVID-19 testing; gastrointestinal products biggest contributor within DX with $14 million in revenues

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M&A Report: Thermo Fisher Acquisition of Qiagen Remains on Track, *from page 5*

COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Myriad Genetics (FY Q3)	$164 million ($167.2 million)	-24%	Adjusted -$0.08 (-$0.02)	Overall testing volumes down between 20% and 75% across all segments due to COVID-19, with molecular DX down 25% to $150.5 million, including 28% drop in hereditary cancer ($85.2 million), 31% decline in GeneSight ($20.4 million), 7% decline in Vectra ($10.5 million), 1% drop in Prolaris ($6.8 million); EndoPredict actually up 25% to $3.5 million; ($2.3 million); but prenatal testing up 30% to $23.5 million and Prolaris up 5% to $6.2 million
NanoString Technologies	$26.6 million ($25.4 million)	-4%	Net -$1.04 (-$1.04)	Pandemic drives 15% increase in product and service revenues to $24.5 million and more than doubles instruments revenue to $9.8 million, including $6.5 million from newly launched GeoMx system
Natera	$94 million ($85 million)	+41%	Net -$0.45 (-$0.56)	Biggest sequential Q-on-Q segment growth in company history despite COVID-19 disruption in March; lab has operated without disruption, processing 222,400 of total 235,000 tests thanks to improvements to remote ordering capabilities
NeoGenomics	$106 million ($104.6 million))	+11%	Adjusted -$0.02 (+$0.02)	Clinical service revenues up 8% growth to $93 million and pharma services up 39% to $13 million, despite COVID-19 disruptions to both divisions; requisitions up 5% to 144,319, tests performed up 7% to 250,376 and average revenues per test up 1% to $371
Oxford Immunotec	$13.9 million ($13.5 million)	-6%	Pro forma -$0.23 (-$0.15)	Asian revenues down 22% due to impact of pandemic in China; US revenues start strong but fall off severely in March as a result of declining test volumes
Pacific Biosciences	$15.6 million ($20.1 million)	-5%	Net -$0.01 (-$0.16)	Pandemic severely hurts instruments sales across all geographic regions
PerkinElmer	$652.4 million ($652.7 million)	+1%	+$0.67 (+$0.55)	DX down 2% to $254 million with weakness in immunodiagnostics + reproductive health more than offsetting strength in applied genomics; COVID-19 exerts $46 million drag on overall revenues
Personalis	$19.2 million ($17.2 million)	+36%	Net -$0.29 (-$0.25)	Able to record record earnings again despite COVID-19 thanks to expansion of US Dept of Veterans Affair contract revenues
Qiagen	$372.1 million ($344.9 million)	+7%	Adjusted +$0.34 (+$0.27)	Steep demands for COVID-19 testing more than offsets losses in all other kinds of testing

COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Quanterix	$15.7 million ($13.3 million)	+27%	Not reported	Services revenues more than double to $5.8 million thanks to increased use by lab customers experiencing COVID-19 disruptions; Products up 3% to $9.8 million
Quest Diagnostics	$1.82 billion ($1.75 billion)	-4%	Adjusted +$0.94 (+$0.89)	COVID-19 causes 40% decline in last two weeks of DX Information Services revenues and $7.1 million loss for Q; Declines continue into April with expectation of bottoming out at 50% to 60%; meanwhile, higher reimbursement pressure causes 1.2% decline in revenue per requisition
Quidel	$174.7 million ($158.1 million)	-13%	Adjusted +$1.22 (+$0.98)	Rapid immunoassays up 54% to $95.9 million driven by $30.3 million increase in influenza revenues; Cardiometabolic immunoassays down18% to $53.9 million; Molecular DX up 45% to $8.5 million driven by 41% increase in Solana sales; Specialized DX up 1% to $13.9 million
Roche Diagnostics	$15.65 billion	+7%	Not reported	DX sales flat despite 22% growth in molecular flu and SARS-CoV-2 diagnostics. Centralized + point-of-care (POC) down 6% to $1.63 billion, including 4% decline in immunodiagnostics, flat clinical chemistry sales. Other strong segments included driven blood screening (up 6%) and cervical cancer microbiology (up 17%)
Siemens Healthineers (FY Q2)	$4.0 billion	+5%	Net +$0.45	COVID-19 blunts demand for testing in China and other markets and drags overall revenues down 4%, including 1% decline in DX revenues to $1.12 billion
10x Genomics	$71.9 million ($73.4 million)	+34%	Net -$0.22 (-$0.13)	COVID-19 marginal bump in immune profiling and instruments more than offset by losses in consumables resulting from closure of 75% of customers in North America and Europe
Thermo Fisher	$6.23 billion ($6.17 billion)	+2%	Adjusted +$2.81 (+$2.79)	Specialty DX flat at $958 million due to divestment of Anatomical Pathology business in June; Lab products + services up 9% (6% organic) to $2.73 billion driven by pharma services and research + safety
Twist Biosciences	$19.3 million ($18.3 million)	+42%	Net +$0.85 (-$0.75)	Despite COVID-19, synthetic biology, including gene pools, libraries and oligo pools reached $11 million
Veracyte	$31.1 million ($30.6 million)	+5%	Net -$0.24 (-$0.20)	Overall genomic testing volume up 15% to 10,559 tests, despite 50% decline in second half of March due to COVID-19; 17% spike in operating costs lead to 516% increase in net loss to $11.7 million

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M&A Report: Thermo Fisher Acquisition of Qiagen Remains on Track, *from page 7*

COMPANY	FY 2020 Q1			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Waters	$464.9 million ($488.5 million)	-10%	Non-GAAP +$1.15 (+1.47)	COVID-19 outbreak in China decreases sales in that market by 45% and 8% overall

Bold face: Companies that met or exceeded average or consensus Q1 Wall Street revenue estimates

Italics: Companies that missed average or consensus Q1 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q1

Market Trends: New Survey Documents Extent of Lab Business Damage Inflicted by COVID-19

The fact that the lab business is taking a beating as a result of the COVID-19 pandemic is hardly news. But a recent survey sheds important new light on the extent of the devastation.

The Kalorama Survey

Healthcare market data and consulting firm Kalorama Information conducted the survey of 191 clinical labs across the U.S. (most of them hospital-based), excluding New York City, New Orleans and other pandemic hot spots to avoid skewing the results. The survey, which was conducted in the third week of April, shows a massive reduction in testing volume due to the pandemic. Overall, 59% of labs surveyed reported COVID-19 as having a significant impact on lab operations with larger labs more likely to report significant impact than smaller labs.

Survey respondents and magnitude of pandemic impact

No. of employees at facility	Representation in survey	Experiencing significant impact on lab operations
1 to 100	18%	40%
101 to 1,000	27%	58%
More than 1,000	40%	67%

Source: Kalorama Information

Testing volume was down across all therapeutic areas, with histology (32.8% decline) and tumor marker cancer diagnostics (22% decline) taking particularly hard hits. Urinalysis and immunoassays were also down significantly.

Not surprisingly, the one area of testing that was up was polymerase chain reaction molecular assays used to diagnose COVID-19 and rule out flu, which increased 7.7% increase. Procalcitonin tests used in critically ill patients to show the severity of COVID-19 increased 1.7%.

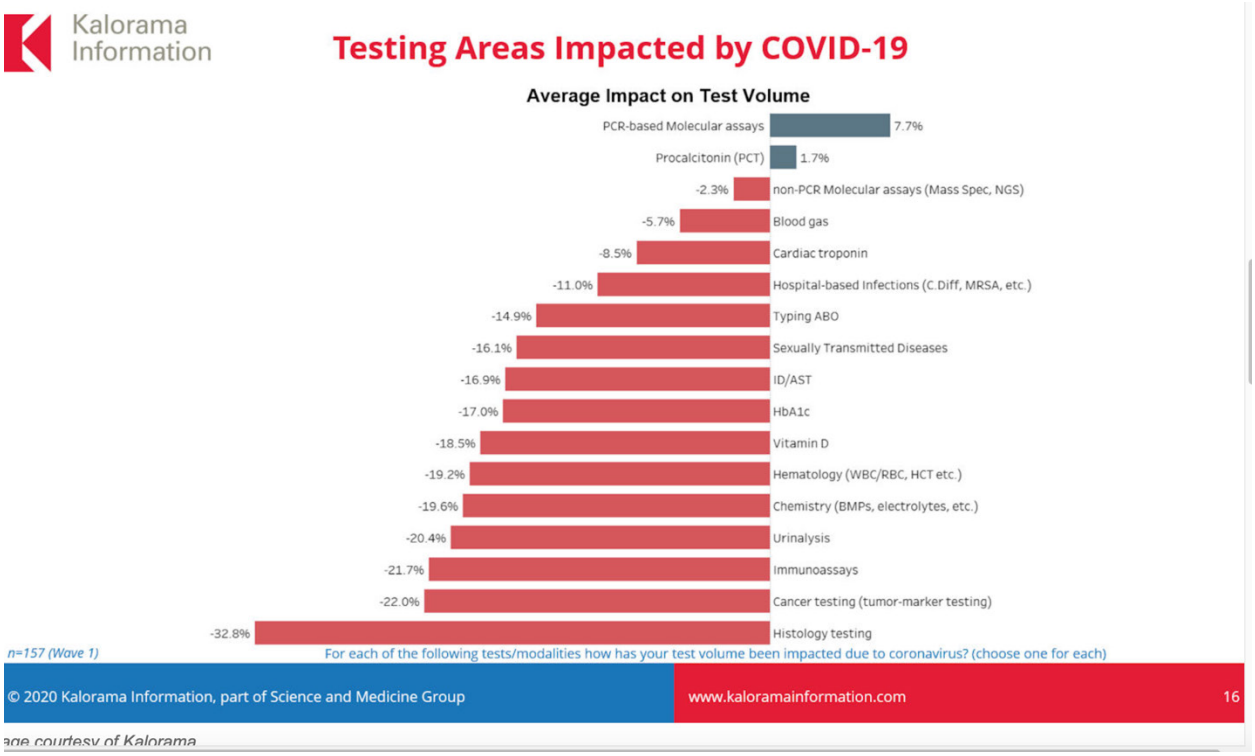

Image courtesy of Kalorama

FDA WATCH

Agency Draws a New Line on SARS-CoV-2 Antibody Serology Tests

It took a while but the FDA has finally come to the realization that letting blood-based serology tests for detection of SARS-CoV-2 antibody tests into the U.S. market without requiring test makers to prove the value of their products was a bad idea. And now the agency is walking back the policy, at least in part.

The Umbrella Pathway

After producers disregarded recommendations to do so voluntary, the FDA

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FDA Watch, *from page 9*

decided to *require* serology test makers to submit their products to federal labs for independent evaluation. The new "umbrella" pathway, which the agency unveiled on April 29, calls for an interagency testing group at the National Cancer Institute to assess the approximate specificity, sensitivity and overall predictive value of submitted tests against a panel of samples confirmed positive for anti-SARS CoV-2 IgM and IgG antibodies, as well as against confirmed antibody negative samples or pre-COVID-19 samples, with 10 of these 80 negative samples being HIV positive. To pass:

- Tests reporting on both IgM and IgG must show 90% overall sensitivity and 95% specificity;
- Tests reporting the immunoglobulins separately must have 70% sensitivity for IgM and 90% for IgG; and
- Tests must show no cross-reactivity with HIV.

FDA Delists 27 SARS-CoV-2 Serology Assays

The new evaluation process and standards apply to all serology SARS-CoV-2 assays, including the purported gold standard tests that received Emergency Use Authorization (EUA) under Policy C. But on May 4, the FDA put an end to its controversial Policy D, the less rigorous pathway allowing test makers to introduce their products immediately upon internal validation without seeking EUA clearance. All the test maker had to do was notify the agency in an email listing cursory validation data and product labeling. From now on, all SARS-CoV-2 serology kits will require EUA.

And now the FDA is peeling back the roster of tests that came through Policy D. Of the approximately 214 serology test kits previously listed as allowed for U.S. distribution under Policy D, 27 have been removed for failing to meet the new Umbrella pathway standards or submit the data necessary to perform the independent evaluation, including nine products that were withdrawn voluntarily. Most of the removed tests are manufactured overseas but the list also includes tests made by:

- Vita Testing (based in Beverly Hills);
- Diazyme Laboratories, a subsidiary of defense contracting giant General Atomics;
- Pharmatech, which was acquired by Caris Life Sciences last year; and
- BioMedomics, which developed a rapid fingerstick test formerly sold by Becton Dickinson.

Here are some of the key new FDA clearances announced in May:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
SpectronRx	EUA for Hymon SARS-CoV-2 Test Kit
Exact Sciences	EUA for SARS-CoV-2 (N gene detection) Test
Express Gene Molecular Diagnostics Laboratory	EUA for 2019-nCoV RT-PCR Diagnostic Panel
Avera Institute for Human Genetics	EUA for SARS-CoV-2 assay run on the Applied Biosystems Quant Studio 7 Flex
P23 Labs	EUA for TaqPath SARS-CoV-2 test
BioCore	EUA for 2019-nCoV Real Time PCR Kit
SolGent	EUA for DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit
Seasun Biomaterials	EUA for AQ-TOP COVID-19 Rapid Detection Kit
Color	EUA for Color SARS-CoV-2 LAMP Diagnostic Assay using loop-mediated isothermal amplification (LAMP) technology
Myriad Genetics	Clearance for BRACAnalysis CDx as companion diagnostic to identify patients with germline BRCA1/2 mutations who can benefit from newly approved AstraZeneca and Merck's olaparib (Lynparza) drug
Foundation Medicine	Clearance for FoundationOne CDx as companion diagnostic to identify patients with to identify patients with HRR-mutated genes who can benefit from newly approved AstraZeneca and Merck's olaparib (Lynparza) drug
Ventana Medical Systems	Clearance for VENTANA PD-L1 SP142 Assay as companion diagnostic device for identifying metastatic non-small cell lung cancer (NSCLC) patients who can benefit from Genentech's newly approved atezolizumab (Tecentriq) drug
Agilent Technologies	Clearance for expanded use of PD-L1 IHC 28-8 pharmDx as companion diagnostic to identify NSCLC patients who can benefit Bristol Myers Squib's Opdivo and Yervoy's from NSCLC who are appropriate for treatment with nivolumab and ipilimumab drug
Bio-Rad	Clearance for CFX96 Dx real-time PCR instrument for in vitro diagnostic testing
Quidel	Expanded EUA for Lyra SARS-CoV-2 assay to detect virus without an upfront nucleic acid extraction step
Quidel	EUA for Sofia 2 SARS Antigen FIA assay
Everlywell	EUA for COVID-19 Test Home Collection kit
Fulgent Therapeutics	EUA for Fulgent COVID-19 by RT-PCR Test
Assurance Scientific Laboratories	EUA for SARS-CoV-2 Panel
GeneMatrix	EUA for NeoPlex COVID-19 Detection Kit
Hologic	EUA for Aptima SARS-CoV-2 assay
Cedars-Sinai Medical Center	EUA for SARS-CoV-2 RT-PCR assay
One Health Laboratories	EUA for SARS-CoV-2 Real-Time RT-PCR Test
Applied DNA Sciences	EUA for Linea COVID-19 RT-PCR test
Columbia University	EUA for Triplex CII-SARS-CoV-2 rRT-PCR test
Thermo Fisher Scientific	Expanded EUA for Applied Biosystems TaqPath COVID-19 Combo Kit

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FDA Watch, *from page 11*

Manufacturer(s)	Product
Abbott Molecular	Clearance for Vysis ALK Break Apart FISH Probe Kit for use as companion diagnostic to identify patients with ALK rearrangements likely to benefit from Takeda Pharmaceuticals' newly approved brigatinib drug
Abbott	EUA for Alinity m SARS-CoV-2 assay
1drop	EUA for 1copy COVID-19 qPCR Multi Kit
BioMérieux	EUA for SARS-CoV-2 R-Gene test kit
Opti Medical Systems	EUA for Opti SARS-CoV-2 RT-PCR kit
Sherlock Biosciences	EUA for Sherlock CRISPR SARS-CoV-2 kit
Grifols Diagnostic Solutions	Clearance for Procelix Panther System featuring Automation Ready Technology (ART)
Siemens Healthineers	EUA for Fast Track Diagnostics SARS-CoV-2 test
Euroimmun (owned by PerkinElmer)	EUA for Anti-SARS-CoV-2 ELISA serology test
Roche	EUA for Elecsys Anti-SARS-CoV-2 antibody serology test
Bio-Rad Laboratories	EUA for 2019-nCoV CDC ddPCR Triplex Probe Assay for use on firm's QX200 and QXDx Droplet Digital PCR systems
BioFire Diagnostics	EUA for Respiratory Panel 2.1

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
GenScript Biotech Europe	cPass-SARS-CoV-2 Surrogate Virus Neutralization Test
ArcDia International	SARS-CoV-2 antigen point-of-care test
Xiamen Wiz Biotech	SARS-CoV-2 rapid antibody-detection kit
Bio-Techne + Leica Biosystems	Bio-Techne's RNAscope In Situ Hybridization Detection Kit for automation on Leica Biosystems Bond-III staining platform
Siemens Healthineers	Test detecting SARS-CoV-2 IgM + IgG antibodies in blood
Genedrive	Genedrive 96 SARS-CoV-2 Kit
HiberGene Diagnostics	Rapid molecular test for SARS-CoV-2
BioMérieux	Two different SARS-CoV-2 serology tests
Advanced Biological Laboratories	DeepChek sequencing-based assays for HIV genotyping and drug resistance testing
Ortho Clinical Diagnostics	Vitros Immunodiagnostic Products Anti-SARS-CoV-2 IgG Test
CareDx	AlloSeq Tx 17 HLA typing product
CeGaT	ELISA-based SARS-CoV-2 Corona Antibody Test
Biomerica	COVID-19 IgG/IgM Rapid Test
Eurofins Technologies	GSD NovaPrime SARS-CoV-2 test

Manufacturer(s)	Product(s)
NeuMoDx	NeuMoDx SARS-CoV-2 Assay
PlexBio	IntelliPlex SARS-CoV-2 Detection Kit
Quotient Limited	MosaiQ COVID-19 Antibody Microarray
BAG Diagnostics	ViroQ SARS-CoV-2 rapid PCR test
Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR Kit
	MosaiQ COVID-19 Antibody Microarray

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Rendu Biotechnology	China	National Medical Products Administration emergency approval for SARS-CoV-2 nucleic acid detection kit

Emerging Markets: After Early Skepticism, FDA Warms to At-Home Sample Collection for COVID-19 Testing

Even before the pandemic began, concerns over the marketing of fraudulent home testing kits had been a sore spot with the FDA. So, when the agency first began to roll out its liberalized clearance scheme for COVID-19 diagnostic testing, it didn't apply to at-home testing. However, the agency has reversed that policy and recently broke new ground by authorizing coronavirus testing by multiple labs in nasal samples collected by consumers using an at-home kit.

The Rutgers & LabCorp Assays

At-home sample collection of COVID-19 test samples offers some obvious advantages over the standard method in which a qualified health care professional armed to the teeth in personal protective equipment inserts a swab into the nostrils to access and perform a tissue scrape of the nasopharynx at the back of the nasal cavity. On April 13, the FDA granted Emergency Use Authorization (EUA) to the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay, version of the Thermo Fisher Scientific Applied Biosystems TaqPath COVID-19 Combo Kit modified to allow for testing on saliva samples that can be collected at home. Just over a week later, the agency gave LabCorp the go-ahead for at-home sample collection.

However, these approvals of at-home sample collection had only marginal impact on overall COVID-19 testing capacity since in each case, the EUA

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was limited to testing at each approvee's respective lab. As a result, neither Rutgers nor LabCorp are authorized to ship the at-home samples collected using their kits to third party labs for analysis.

The Everlywell At-Home Collection Kit

But on May 15, the FDA went to the next level by granting EUA clearance to a kit created by Austin, Texas-based Everlywell for COVID-19 testing by separate CLIA-certified labs using assays that also received EUA clearance that same day. Specifically, the Everlywell COVID-19 Test Home Collection Kit has now been cleared for self-collection of nasal samples and subsequent analysis by Fulgent Therapeutics using the Fulgent COVID-19 by RT-PCR Test and by Assurance Scientific Laboratories using the Assurance SARS-CoV-2 Panel.

The Everlywell EUA also includes language leaving open the possibility of authorizing other high complexity-certified CLIA labs to perform testing using the Everlywell kit, "provided that the data are submitted in an EUA request that demonstrate the accuracy of each test," according to the agency.

The Quest Self-Collection Kit

The next step forward came on May 28, when Quest Diagnostics announced that it had received EUA for its own kit enabling individuals to self-collect nasal specimens at home for testing with the firm's SARS-CoV-2 RT-PCR assay. For now, Quest will distribute the kits to providers and organizations running return-to-work testing programs but says it plans to give to their patients but says it plans to eventually make them directly available to patients via its QuestDirect platform.

M&A Report: Thermo Fisher Acquisition of Qiagen Remains on Track

COVID-19 continues to cast a pall on strategic M&A activity in the diagnostics space with the key players monitoring events before making their moves. However, there are still a few smaller deals being made. Perhaps more significantly, the blockbusters that were announced before the pandemic remain on track.

Thermo Fisher Makes Progress on Qiagen Acquisition

After last month's completion of Danaher's $21.4 billion acquisition of GE's Biopharma business (For complete analysis, see, *Laboratory Industry Report*, May 8, 2020), the $11.5 billion Thermo Fisher Scientific takeover of Qiagen seems to be heading for closing. A key hurdle was

cleared when the German Federal Financial Supervisory Authority, the German analog to the U.S. Federal Trade Commission, approved the deal. On May 18, Thermo Fisher published the official tender offer document.

Qiagen shareholders are expected to vote on the deal at their upcoming June 30 general meeting. At least one shareholder is likely to vote NO, namely, common shareholder and investor Milton Pfeiffer, who has brought a lawsuit to stop the acquisition contending that Qiagen directors violated the federal Securities Exchange Act by failing to disclose the necessary information about the deal.

• • •

Here's a summary of the key M&A diagnostic deals announced in May 2020:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Roche	Stratos Genomics	• Price: Undisclosed • Status: Closed • Acquisition of Seattle-based early-stage sequencing technology firm bid will support Roche's nanopore sequencer development efforts
Curative	Korva Labs	• Price: Undisclosed • Status: Closed • Firms had previously partnered to create new COVID-19 drive thru testing lab in Southern California
Sartorius	Danaher	• Price: $825 million • Status: Closed • Danaher sells off its biomolecular characterization, chromatography hardware, microcarriers, tangential flow filtration systems and other businesses to secure regulatory approval for upcoming GE Biopharma acquisition
The DNA Company	My Pain Sensei	• Price: $30 million • Status: Closed • New company, rebranded as My Next Health, to combine precision medicine and digital therapeutics to develop health management applications based on individual genotypes

Continued on page 16

M&A Report: Thermo Fisher Acquisition of Qiagen Remains on Track, *from page 15*

Acquiring Company	Target(s)	Deal Summary
Olink Proteomics	Agriser	• Price: Undisclosed • Status: Closed • Olink, which protein biomarker discovery products based on proximity extension assay technology acquires Swedish antibody manufacturer
Accelmed Partners	TearLab	• Price: $25 million over two tranches • Status: Expected to close in Q2 • TearLab to delist from over-the-counter market and become private company with Accelmed as controlling shareholder
Meridian Bioscience	Exalenz Bioscience	• Price: $49 million • Status: Closed • Acquisition of breath diagnostics firm based in Israel
DiscernDx	Luminist Labs	• Price: Undisclosed • Status: Closed • Acquisition of privately held developer of diagnostic technology for nonalcoholic steatohepatitis (NASH) and other liver diseases

Diagnostics Deals: Pandemic Infuses New Urgency Into Effort to Develop Genomics-Based Early PTSD Detection Diagnostics, *from page 1*

based genomic tests for PTSD formed by a pair of military veterans steeped in behavioral health research, entered into talks with BlueBee, the California-based provider of a rapidly configurable omics data platform, about collaborating to create a biomarker-based risk assessment for early PTSD identification. When the pandemic hit, it infused the project with a new sense of urgency.

The Partnership

On May 20, the companies announced their new strategic partnership. The plan calls for combining BlueBee's expertise in AI and optimizing data flow with TruGenomix's PTSD genomics data and analytics. Specifically, the partners will leverage BlueBee's platform to aggregate, train and model DNA, RNA and methylation data alongside patient data and metadata from TruGenomix.

The End Game

The ambitions behind the collaboration are huge. TruGenomix and BlueBee have set out to fuse genomics and digital technology to revolutionize behavioral healthcare by speeding up insight generation and laying the foundation for an industrial-scale, clinical-grade data operation that can be applied not only to PTSD but other conditions. "For something as complex as human behavioral and mental health, a data strategy must be at the core of R&D," noted TruGenomix co-founder and Chief Scientific Officer Tshaka Cunningham in a statement.

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Here's a summary of other key strategic diagnostic deals announced in May 2020:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Bio-Techne	Mount Sinai Health System	• Objective: Produce and distribute Mount Sinai SARS-CoV-2 serology testing kit • Dynamic: Bio-Techne to collaborate with Kantaro Biosciences, a joint venture of Mount Sinai and Renalytix AI
Thermo Fisher Scientific	WuXi Diagnostics + Mayo Clinic	• Objective: Develop COVID-19 total antibody test • Dynamic: Mayo Clinic clinically evaluating Thermo Scientific OmniPath COVID-19 Total Antibody ELISA test to run on open instrument platform for diagnosis of COVID-19 during acute and recovery stages

Continued on page 18

Diagnostic Deals, *from page 17*

Partner 1	Partner(s) 2+	Deal Summary
Ambry Genetics	Volpara Health Technologies	• Objective: Link Volpara's cancer screening and practice management platform with Ambry Genetics' program for identifying high-risk breast cancer patients • Dynamic: Volpara Aspen Breast software to include online ordering process for Ambry genetic tests • Volpara Density software for assessing volumetric breast density to be included in Ambry's Comprehensive, Assessment, Risk, and Education (CARE) program
Genetron Health	Darui Biotechnology	• Objective: Develop pathogenic microorganism detection products on Genetron sequencer • Dynamic: Detection kits to run on Genetron S5 next-generation sequencer • Genetron to help Darui seek regulatory registration of its reagent kits
Proteomedix	Dynex Technologies	• Objective: Develop automated workflows for Proteomedix's Proclarix prostate cancer test • Dynamic: Proteomedix to sell Proclarix with the Dynex instrumentation on which test was clinically validated • Make protocols for test available for Dynex DS2 and Agility platforms
Bayer	ArcherDX	• Objective: Broaden patient access to comprehensive genomic testing that includes NTRK1, NTRK2 and NTRK3 gene fusions and improve identification of treatment options for patients with TRK fusion cancer • Dynamic: Develop NGS-based companion diagnostic test for Bayer's Vitrakvi (larotrectinib)
Bayer	OrigiMed	• Objective: Develop NGS-based companion diagnostic for cancer drug larotrectinib (Vitrakvi) for Chinese market
Mologic	BioSure	• Objective: Develop SARS-CoV-2 antibody self-test • Dynamic: Test to combine Mologic's lateral flow assay with BioSure's self-test design
CareDx	Weill Cornell Medicine	• Objective: Develop urine-based gene expression test for acute cellular rejection in kidney transplant recipients called UroMap • Dynamic: Multiyear exclusive research collaboration with Weill Cornell to have exclusive rights to provide UroMap, which is based on technology licensed from Cornell Medicine, to patients
Roswell Biotechnologies	Imec	• Objective: Develop biosensor chips for use in molecular testing and DNA storage • Dynamic: Key proof-of-concept work already successfully completed and products to become available in 2021
Avrobio	Saladax Biomedical	• Objective: Develop automated nanoparticle immunoassay kit for busulfan therapeutic drug monitoring (TDM) • Dynamic: Saladax developing a blood-based assay kit • Avrobio to provide funding to support development of assay, but Saladax to retain all product rights

Partner 1	Partner(s) 2+	Deal Summary
Avacta	Adeptrix	• Objective: Develop high-throughput COVID-19 antigen test • Dynamic: Test to test that combine Avacta's Affimer-based antigens that bind to the SARS-CoV-2 virus with Adeptrix's bead-assisted mass spectrometry (BAMS) platform • Avacta to receive royalty on Adeptrix's sales of test kits

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Veracyte	CareDx	• Products: Solid organ transplant rejection tests on Veracyte's nCounter Flex Analysis diagnostic platform • Territory: Worldwide • Exclusive
Ubiquitome	DiethelmKellerSiberHegner (DKSH)	• Products: Ubiquitome's Liberty 16 mobile PCR-based COVID-19 testing platform Liberty16 • Territory: Australia, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Thailand, Vietnam • Exclusive
Chembio Diagnostics	Thermo Fisher Scientific	• Products: Chembio's DPP COVID-19 System • Territory: US • Non-exclusive
EKF Diagnostics	Tosoh Europe	• Products: EKF's point-of-care Quo-Test HbA1c analyzer • Territory: Middle East and Africa • 3-year deal
Sienna Cancer Diagnostics	Scientle Innovations	• Products: Sienna's hTERT test for bladder cancer • Territory: New Zealand • Exclusive
NG Biotech	Eurobio Scientific	• Products: Eurobio's NG Biotech's COVID-19 NG-Test IgG-IgM rapid serology test • Territory: France
Osang Healthcare	SG Blocks	• Products: Osang's GeneFinder COVID-19 Plus RealAmp Kit • Territory: US • Non-exclusive, 1-year deal
Spartan Bio	Cardinal Health	• Products: Spartan's CYP2C19 assay • Territory: US
Quest Diagnostics	Centene	• Products: 25,000 Quest rRT-PCR-based SARS-CoV-2 test kits per week • Territory: Federally Qualified Health Centers in 10 US states or districts

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Diagnostic Deals, *from page 19*

LICENSES

Licensor	Licensee	Deal Summary
Brigham and Women's Hospital	Quanterix	Quanterix acquires non-exclusive rights to use SARS-CoV-2 serology test on its Simoa multiplex immunoassay platform

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
Quotient	Hvivo	Quotient to supply its SARS-CoV-2 antibody microarray test to UK-based contract research organization for use in viral challenge studies

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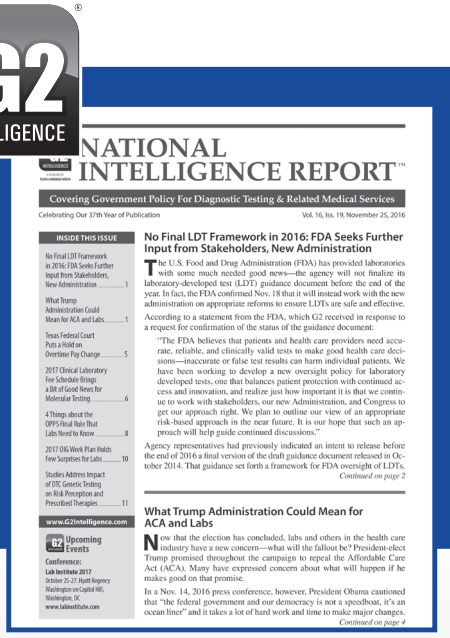
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Conferences:
Lab Institute 2017
October 25-27, Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration

The U.S. Food and Drug Administration (FDA) has provided laboratories with some much needed good news—the agency will not finalize its laboratory-developed test (LDT) guidance document before the end of the year. In fact, the FDA confirmed Nov. 18 that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

> "The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions—inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right. We plan to outline our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide continued discussions."

Agency representatives had previously indicated an intent to release before the end of 2016 a final version of the draft guidance document released in October 2014. That guidance set forth a framework for FDA oversight of LDTs.

Continued on page 2

What Trump Administration Could Mean for ACA and Labs

Now that the election has concluded, labs and others in the health care industry have a new concern—what will the fallout be? President-elect Trump promised throughout the campaign to repeal the Affordable Care Act (ACA). Many have expressed concern about what will happen if he makes good on that promise.

In a Nov. 14, 2016 press conference, however, President Obama cautioned that "the federal government and our democracy is not a speedboat, it's an ocean liner" and it takes a lot of hard work and time to make major changes.

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DTC Test Results Don't Lead to Dramatic Changes in Health Care Use

The U.S. Food and Drug Administration (FDA) has frequently expressed concern about direct-to-consumer (DTC) marketing of genetic testing. For example, the FDA required pre-market approval for 23andMe's Personal Genome Service. One of the FDA's stated concerns is that in the case of DTC genetic tests no physician is involved to provide consumers guidance in utilizing these results and there is a danger that consumers will make their own decisions about treatment or use of prescription medicines that can create risks to their health. Recent studies provide some insight regarding consumers' perceptions of these genetic test results.

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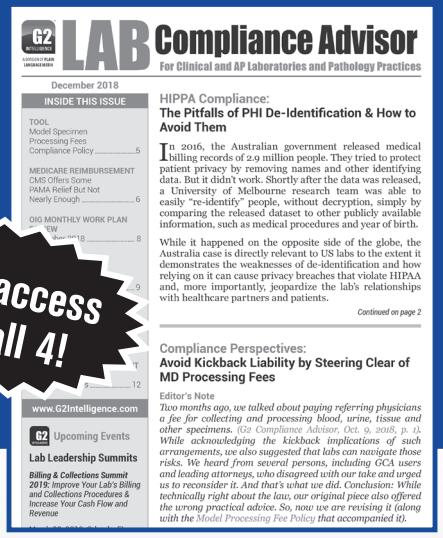
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December 2018

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Upcoming Events

Lab Leadership Summits

Billing & Collections Summit 2019: Improve Your Lab's Billing and Collections Procedures & Increase Your Cash Flow and Revenue

HIPPA Compliance:
The Pitfalls of PHI De-Identification & How to Avoid Them

In 2016, the Australian government released medical billing records of 2.9 million people. They tried to protect patient privacy by removing names and other identifying data. But it didn't work. Shortly after the data was released, a University of Melbourne research team was able to easily "re-identify" people, without decryption, simply by comparing the released dataset to other publicly available information, such as medical procedures and year of birth.

While it happened on the opposite side of the globe, the Australia case is directly relevant to US labs to the extent it demonstrates the weaknesses of de-identification and how relying on it can cause privacy breaches that violate HIPAA and, more importantly, jeopardize the lab's relationships with healthcare partners and patients.

Continued on page 2

Compliance Perspectives:
Avoid Kickback Liability by Steering Clear of MD Processing Fees

Editor's Note

Two months ago, we talked about paying referring physicians a fee for collecting and processing blood, urine, tissue and other specimens. (G2 Compliance Advisor, Oct. 9, 2018, p. 1). While acknowledging the kickback implications of such arrangements, we also suggested that labs can navigate those risks. We heard from several persons, including GCA users and leading attorneys, who disagreed with our take and urged us to reconsider it. And that's what we did. Conclusion: While technically right about the law, our original piece also offered the wrong practical advice. So, now we are revising it (along with the Model Processing Fee Policy that accompanied it).

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