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Inside the Lab Industry: COVID-19 Drives Unprecedented but Ultimately Unsustainable Growth

As strange as it may sound, the COVID-19 pandemic has driven unprecedented revenue growth in the diagnostics industry. The fourth quarter of 2020 not only continued but accelerated the climb in earnings. But even as the earnings and revenues numbers approach epic dimensions, it's becoming increasingly clear that they aren't sustainable in the long term.

Revenues Up Across the Board

Of the 31 diagnostics firms that had reported their 2020 Q4 earnings as of the time we went to press, all but two

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Industry Buzz: Guardant Health Challenges Exact Sciences' Leadership of Colorectal Cancer Diagnostics Market

Colorectal cancer diagnostics is a multi-billion-dollar market that, at least before the pandemic, was projected to grow at an annual rate of nearly 6 percent. In recent months, two leading firms have made key strategic moves to bolster their position within the colorectal minimal residual disease segment (MRD). Those firms are Exact Sciences and Guardant Health.

Exact Sciences' Acquisition of Ashion Analytics

On Feb. 17, Exact Sciences announced that it has reached an agreement to acquire Ashion Analytics from the Translational Genomics Research Institute (TGen) for an undisclosed price. Ashion is a CLIA-certified and CAP-accredited sequencing

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achieved some level of positive revenue growth: Myriad Genetics and Pacific Biosciences were the lone exceptions. And even the two firms that experienced lower year-over-year revenue growth exceeded their Wall Street targets. Only one firm fell short of its top line number, Fluidigm, which posted 38 percent growth with $44.6 million in revenues but still missed its $50.7 million target.

Most eye-popping of all was the sheer extent of revenues growth among companies offering COVID-19-related products and services which not only matched but exceeded the gaudy growth numbers of Q3. And that includes most of the industry's largest and most mature firms:

Revenues Growth Upward Trajectory in Second Half of 2020

Company	Q3 Revenue Growth	Q4 Revenue Growth
Abbott	10%	29%
Becton Dickinson	4%	26%
Danaher	35%	39%
Hologic	56%	89%
LabCorp	33%	52%
Perkin Elmer	36%	68%
Quest	43%	56%
Roche Diagnostics	18%	20%
Thermo Fisher Scientific	36%	54%

However, performance on the bottom line was far less impressive with seven of 31 firms falling short of their earnings per share targets, including Fluidigm, Adaptive Biotech, Exact Sciences (whose net loss was stunningly higher than expected), Invitae, Luminex, 10X Genomics and Veracyte.

Don't Get Too Used to It

While it's not a bubble, the current surge in diagnostics earnings is unsustainable. The insatiable demand for COVID-19 tests and products will eventually fall off. Several companies, including LabCorp, Quest and PerkinElmer have warned investors to expect significant falloff as widespread vaccination drives down COVID-19 case numbers. Among these companies, LabCorp has offered the most detailed projections suggesting that COVID-19 testing revenues may fall by as much as 50% by the end of the year.

The good news for those highly invested in COVID-19 is that the wind down may take a long time. In addition, firms should be able to leverage their research and development from coronavirus for other infectious diseases. Meanwhile, labs and lab companies will continue to benefit from the rebound in elective, wellness and other non-COVID-19 testing as

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patients and providers scramble to make up for pandemic-related interruptions in care.

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Diagnostics Earning Reports for Q4
(period ended Dec. 31, 2020)
(Companies with at least $10 million in sales that have reported as of Feb. 25, 2021)

COMPANY	FY 2020 Q4			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	$10.7 billion ($9.94 billion)	+29% (+28% organic)	Adjusted +$1.45 (+$1.35)	DX up 111% to $4.35 billion. Core DX up 6% at $1.32 billion as base business slowly recovers; DX growth driven by massive demand for COVID tests, including 315% increase in molecular to $482 million; rapid diagnostics up 334% to $2.41 billion; point of care drops 6% to $129 million
Adaptive Biotech	$30.2 million ($26.9 million)	+25%	Net -$.33 (-$.29)	Growth driven by 69% in pharma studies to $17.5 million, which offset 8% declines in sequencing revenues to $12.7 million due to COVID, even though test volume for ClonoSeq increased 41% with 4,539 tests
***Agilent Technologies (FY 2021 Q1)**	$1.55 billion ($1.44 billion)	+14%	Adjusted +$1.06 (+$0.89)	Diagnostics and Genomic Group up 18% to $294 million, Life Sciences and Applied Markets up 13% to $722 million; CrossLab group up 13% to $532 million
***Becton Dickinson (FY 2021 Q1)**	$5.32 billion ($4.88 billion)	+26%	Adjusted +$4.55 (+$3.11)	Growth driven by COVID-19 testing, including newly launched Veritor assay and Veritor and BD Max platforms; COVID testing generates $867 million; Integrated DX solutions up 163% to $1.01 billion; Routine testing continues rebound but remains below pre-pandemic levels
BioMérieux	$908.2 million	+21%		Clinical applications up 17% to $884.13 million; BioFire Film Array products up 76%; Immunoassays down 5% at $148.39 million; Microbiology down 11% to $309.32; decline in microbiology
Bio-Rad Laboratories	$789.8 million ($686.8 million)	+27%	Adjusted +$4.01 (+$3.29)	Life Sciences up 77% to $428.5 million driven by PCR and Droplet Digital PCR products in response to COVID-19, which also drove Clinical DX down 5% to $359.6 million

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COMPANY	FY 2020 Q4			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Bio-Techne (2021 FY Q2)	$224.3 million ($206.5 million)	+21%	Adjusted +$1.62 (+$1.37)	DX & Genomics up 20% to $52.5 million; Protein Sciences up 22% to $172.2 million; Growth driven by Exosome DX business (up over 100%), higher collections from Medicare and private payors, and growth in test volumes
Bruker	$627.5 million ($602.0 million)	+5%	Adjusted +$0.58 (+$0.56)	Slow COVID rebound continues with Bruker Scientific Instruments up 5% to $574.7 million; Molecular DX and spectrometry both up double digits for full year
CareDx	$58.6 million ($55.5 million)	+64%	+$0.08 (+$0.02)	Testing services up 73% to $50.3 million driven by increase in AlloSure Kidney and AlloMap Heart sales; Products sales up 16% to $5. million; Digital and other revenues up 50% to $2.4 million
Danaher	$6.80 billion ($6.53 billion)	+39%	Adjusted +$2.08 (+$1.87)	DX up 24% to $2.23 billion, driven by over 100% growth of Cepheid which posted $2 billion in annual revenues for first time after hitting $1 billion for first time in 2019; more than 60% of respiratory tests were for COVID but pandemic also drove moderate declines for Beckman Coulter elective and wellness products; Life Sciences up 76% to $3.6 billion
Exact Sciences	$466.3 million ($446.2 million)	+58%	Net -$2.79 (-$0.22)	Screening revenues contribute $249.7 million, including Cologuard which over 8,000 providers ordered; Precision oncology $117.6 million; COVID testing $99.1 million
Fluidigm	$44.6 million ($50.7 million)	+38%	Adjusted -$0.13 (-$0.07)	6% decline in Instruments to $14.9 million and 9% decline in Cytometry to $19.5 million offset by COVID-driven gains, including 98% growth in Microfluidics to $21.0 million; Service revenues up 13% to $6.1 million
Guardant Health	$78.3 million ($76.7 million)	+25%	Net -$0.27 (-$0.57)	Precision oncology up 13% to $64.7 million; Development services up 148% to $13.6 million driven by new companion Dx products for biopharma

COMPANY	FY 2020 Q4 Total Revenue (vs. Wall Street)	FY 2020 Q4 YOY Revenues	FY 2020 Q4 EPS (vs. Wall Street)	DX Segment Performance
Hologic (FY 2021 Q1)	$1.61 billion ($1.40 billion)	+89%	Adjusted +$2.86 (+$2.17)	COVID surge continues with total DX up 262% to $1.13 billion driven, including over 500% growth in molecular diagnostics to $995.3 million, which more than offset decline in non-COVID tests, including 33% in blood screening ($8.1 million); 3% increase in cytology and perinatal revenues to $124.8 million
Invitae	$100.4 million ($98.4 million)	+51%	Non GAAP -$0.63 (-$0.55)	$96.8 million in testing revenues (238,000 tests billed) with test volumes bouncing back due to easing of COVID conditions; $3.6 million in non-testing revenues
LabCorp	$4.49 billion ($3.95 billion)	+52%	Adjusted +$10.56 (+$8.11)	Best year-over-year quarter since pandemic began, with diagnostics up 79% to $3.15 billion driven by COVID, which offset 6% drag from PAMA Medicare reimbursement cuts; Covance drug development up 17% to $1.40 billion
Luminex	$111.4 million ($104.6 million)	+35%	Net -$0.01 (+$0.13)	After Q3 89% COVID spike, assays were up only 41% to $51.3 million driven by 49% growth in molecular testing, which offset declines in clinical tools and life sciences; cytometry flat at $12 million
***Meridien Biosciences (FY 2021, Q1)**	$92.9 million ($83.9 million)	+96%	Adjusted +$0.65 (+$0.42)	Fivefold increase in life sciences and COVID products including Revogene drive massive growth; DX $30.3 million, which was actually down 13% year over year but up 2% as compared to Q4; molecular assays down 33% at $4.6 million; Immunoassays and blood chemistry down 8% at $25.7 million
Myriad Genetics (FY 2021, Q2)	$154.6 million ($150.4 million)	-21%	Adjusted -$0.12 (-$0.12)	Testing volumes still down across most segments (5% in total) due to COVID-19 but are recovering to near pre-pandemic levels with molecular DX down 21% to $143.9 million; Hereditary cancer down 33% to $78.7 million; Pre-natal up 29% to $18 million
NeoGenomics	$126.0 million ($123.5 million)	+18%	Adjusted +$0.14 (+$0.05)	All core divisions achieve positive growth for first time since pandemic began, including clinical services up 14% to $106.8 million, thanks to $9 million in COVID testing revenues; Pharma services up 43% to $19.3 million

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COMPANY	FY 2020 Q4 Total Revenue (vs. Wall Street)	FY 2020 Q4 YOY Revenues	FY 2020 Q4 EPS (vs. Wall Street)	DX Segment Performance
Opko Health	$494.6 million ($443.1 million)	+121%	Pro forma -$0.05 (+$0.04)	157% increase in services revenues to $457.9 million, due to COVID testing with BioReference Lab COVID test volume up 170%, including 19 million PCR (up 24%) and 220,000 tests performed; but product revenues down 4% to $30.8 million
Pacific Biosciences	$27.1 million ($25.4 million)	-3%	Net +$0.37 (+$0.32)	Product revenues down 4% at $23.6 million; Instruments down 11% to $13.6 million; Service and other revenues flat at $3.5 million
PerkinElmer	$1.35 billion ($1.22 billion)	+68%	Adjusted +$3.96 (+$3.00)	Follows massive Q3 with even strong Q4, driven by 176% growth in DX to $851.8 million, with COVID PCR tests and RNA extraction solutions each contributing over $300 million; Applied genomics up 420% and immunodiagnostics up 250%, including over 20% growth of Euroimmun subsidiary
Qiagen	$571.2 million ($548.9 million)	+38%	Adjusted +$0.68 (+$0.65)	36% growth in consumables to $494 million driven by continued demand for COVID testing cartridges, including 45% increase in molecular diagnostics to $287 million, as well as spikes in sales of reagents + RNA extraction kits; Life sciences also up 32% to $284 million; but non-COVID revenues flat at $371 million
Quest Diagnostics	$3.00 billion ($2.93 billion)	+56%	Adjusted +$4.48 (+$4.24)	Continued demand for COVID testing drives 27% increase in overall test volume (7% for all of 2020) and 25% growth in revenue per test (16% for all of 2020)
Quidel	$809.2 million ($809.1 million)	+>500%	Adjusted +$11.07 (+$10.14)	Incredible but ultimately unsustainable growth with COVID products bringing in $678.7 million; Molecular DX up over 1,200% to $89.4 million; Rapid immunoassays up nearly 10-fold to $678.7 million, including $587.6 million from Sofia SARS Antigen and Sofia 2 Flu + SARS Antigen test sales; Cardio immunoassays reverse 3% decline in Q3 to post 6% growth in Q4 at $70 million; Specialized DX down 20% to $11.5 million

COMPANY	FY 2020 Q4 Total Revenue (vs. Wall Street)	FY 2020 Q4 YOY Revenues	FY 2020 Q4 EPS (vs. Wall Street)	DX Segment Performance
Roche Diagnostics	$15.21 billion	+20%	Net +$21.14	Molecular DX for full year up 78% to $4.15 billion driven by COVID testing, which offset declines in routine testing; Centralized and Point of Care Solutions down 7% to $8.02 billion
*Siemens Healthineers (FY 2021, Q1)	$4.67 billion	+8%	Adjusted +$0.59	DX up 17% to $1.43 billion driven by rapid SARS-CoV-2 antigen and molecular tests; Recovery in core non-COVID businesses, which posted mid single-digit growth, including stabilized reagent volumes and Atellica sales
10x Genomics	$112.2 million ($100.4 million)	+49%	Net -$3.87 (-$0.23)	Continues the rebound began in Q2 with 49% increase in consumables to $96.5 million and 49% increase in Instruments to $14 million and 48% jump in Service revenues to $1.7 million
Thermo Fisher Scientific	$10.55 billion ($9.58 billion)	+54%	Adjusted +$7.09, (+$6.56)	COVID drives specialty DX to more than double to $1.97 billion; Routine DX rebound from Q3 but remain below pre-pandemic levels, especially immunodiagnostics and transplant; Laboratory products and services revenues up 28% to $3.62 billion
Twist Bioscience (FY 2021, Q1)	$28.2 million ($25.4 million)	+64%	Net -$0.72 (-$0.74)	Next-generation sequencing revenues, including SNP microarray conversions and liquid biopsy panels more than double to $15.6 million and contributed more than synthetic biology revenues ($11.5 million) for first time in company history
Veracyte	$34.5 million ($31.9 million)	+16%	Net -$0.15 (-$0.11)	Overall testing up 10% to $34.5 million, driven by 14% increase in volume (13,130 tests, including 11,221 genomic tests and 1,999 Prosigna tests)
Waters	$786.7 million ($713.7 million)	+10% (-2% for full year)	Non-GAAP +$2.16 (+$1.93)	Pharma up 15%, Industrial up 5%, Academic and government sales down 15%

Bold face: Companies that met or exceeded average or consensus Q3 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q4

FDA WATCH

The Month in Global New Diagnostic Test Approvals

Agency Clears Record Number of New Medical Devices in 2020

Spurred by the pandemic, the FDA authorized more novel medical devices in 2020 than it ever has in any single year. I know what you're thinking. "Of course, new medical device approvals were off the chart because it was a pandemic year." True, there was a significant volume of emergency use authorizations for devices to diagnose and treat COVID-19; but the flow of clearances for non-COVID-19-related devices was also unprecedented.

The Emergency Use Authorization Factor

Despite a slight dip in 2019, new medical device approvals have been steadily trending upward over the past decade. Even so, what occurred in 2020 represents an aberration from previous patterns, as total FDA new medical device approvals completely crushed the previous high of 2017.

Clearly, one major reason for the spike is that the 2020 totals include not just full-blown clearance but also EUAs, which represent a less rigorous pathway to approval that the FDA uses in response to public health emergencies. Although this was hardly the first time that the opening of the EUA pipeline benefited medical device makers, the COVID-19 crisis was—and remains—bigger and more urgent than any previous public health emergency to arise under the FDA's modern regulatory regime, paving the way for novel ventilators, laboratory tests, sample collection devices, personal protective equipment and other products to diagnose and treat the virus.

The Year in Device Approvals

A new article in the *New England Journal of Medicine* written by Jeff Shuren and William Maisel, respectively, the directors of the FDA's Center for Devices and Radiological Health (CDRH), and the CDRH Office of Product Evaluation and Quality documents what happened. The CDRH was stretched unusually thin during the year, the authors explain, due to a deluge of submissions coming, including both COVID-19 products coming through the EUA pathway. Shuren and Maisel said the agency Shuren and Maisel said the agency issued 625 EUAs for medical devices in 2020, including several designated as novel medical devices such as in vitro diagnostics for COVID-19.

Surprisingly, though, the deluge extended beyond coronavirus. The flow of submissions for non-COVID-19 products also exceeded previous years, with device makers seeking clearance via the 510(k), Breakthrough Device and De Novo pre-market approval channels, as well as the humanitarian device exemption. Non-COVID-19 novel medical devices products that the FDA cleared for the first time in 2020 included:

- The first liquid biopsy next generation-sequencing companion diagnostic test;
- The first cardiac ultrasound software using artificial intelligence to aid in capturing quality diagnostic images;
- An automated insulin delivery and monitoring system for young patients;
- An anterior cruciate ligament implant; and
- A game-based digital therapeutic to help children with attention deficit hyperactivity disorder.

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Meanwhile, here are the key new FDA EUAs and clearances announced in February:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Gravity Diagnostics + Assurance Scientific Laboratories	EUA for Everlywell COVID-19 Test Home Collection Kit DTC
Grifols	EUA for Procleix SARS-CoV-2 Assay
Immunodiagnostic Systems	EUA for IDS SARS-CoV-2 IgG automated chemiluminescent immunoassay
Thermo Fisher Scientific	EUA for Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo Kit
Becton Dickinson	EUA for BD SARS-CoV-2/Flu assay run on firm's BD Max platform
Bio-Rad	EUA for combined COVID-19, influenza A, and influenza B multiplex syndromic RT-PCR test
Roche	Breakthrough Device designation for Elecsys Growth Differentiation Factor-15 (GDF-15) test for use as companion diagnostic in patients with solid tumors for treatment with Pfizer's investigational drug PF-069446860
Roche	510(k) clearance for Cobas BKV test expanded to include use with stabilized urine samples (previously cleared for use with ethylenediaminetetraacetic acid (EDTA) plasma samples)
Visby Medical	EUA for single-use, rapid point-of-care COVID-19 PCR test
Clinomics	EUA for TrioDx RT-PCR COVID-19 Test
Princeton BioMeditech	EUA for Status COVID-19/Flu antigen test
Siemens Healthineers	510(k) clearance for Cobas Immulite, Immulite 1000, and Immulite 2000 analyzers and immunoassays for quantitative measurement of cortisol in serum

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FDA Watch, *from page 9*

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
ProciseDx	Procise FCP point-of-care test for inflammatory bowel disease
Siemens Healthineers	CoV2Ag, a SARS-CoV-2 antigen assay
Cue Health	Molecular point-of-care COVID-19 test
PerkinElmer	PerkinElmer COVID-19 Antigen Test
Horiba Medical	Microsemi CRP LC-767G, a CRP hematology analyzer
Alveo Technologies	Be.well COVID-19 Flex Test
Eurofins	GSD NovaLisa SARS-CoV-2 antibody test
Thermo Fisher Scientific	Applied Biosystems TaqPath COVID-19 HT Kit
Becton Dickinson	CE for BD Multitest 6-Color TBNK Reagent with BD Trucount Tubes expanded to include use to help manage COVID-19 patients
BioMérieux	Nephrocheck assay to detect kidney stress in patients at risk of acute kidney injury (AKI)
Roche	SARS-CoV-2 Rapid Antigen Nasal Test

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Sysmex	Japan	HISCL Influenza Assay Kit
Verify Diagnostics	Canada	Assure Tech Ecotest COVID-19 serological rapid test
Roche	Canada	SARS-CoV-2 Rapid Antigen Test
Saladax Biomedical	Canada	5 of firm's MyCare Psychiatry Laboratory Assays for use in patients prescribed 6 antipsychotic drugs

DX Deals: Hologic Leverages Google Cloud Machine Learning to Boost Cervical Cancer Screening

Hologic has its head in a cloud. And that's a good thing. On Feb. 1, the Massachusetts-based medical technology firm announced that it has entered into a strategic collaboration with Google Cloud to develop an advanced platform for screening of cervical cancer. The strategy is to combine Hologic's Genius Digital Diagnostics System with Google Cloud's machine learning (ML) capabilities to create a digital cytology platform "to transform screening and accelerate the eradication of cervical cancer across the globe." Here's the lowdown:

Product Strategy: Hologic AI + Google Cloud ML = Digital Cytology Powerhouse

Hologic claims that its Genius Digital Diagnostics System is the first digital cytology platform to combine artificial intelligence (AI) with advanced digital imaging to help identify pre-cancerous lesions and cancer cells in women. The collaboration enables the company to leverage Google Cloud's state of the art ML technology to enhance the system's deep learning component so that it will provide "more actionable insights from cytology slides for cytotechnologists and pathologists." Hologic will also use be able to use Google Cloud's reliable and secure cloud data architecture to further improve the system.

Business Strategy

It's hard to know what the business strategy is because the firms didn't disclose the financial details of their collaboration, other than the fact that it's a multi-year arrangement. What we do know is that the Genius Digital Diagnostics System is CE marked in Europe but isn't yet available in the U.S. Getting FDA approval may be tricky given the current uncertainties surrounding the agency's regulation of ML-based software for medical device applications.

These have been active times for Hologic. At the end of February, the firm announced that it has completed its $230 million strategic acquisition of Biotheranostics, a San Diego-based, privately held producer of genetics diagnostics products for breast and metastatic cancers, including the PCR-based Breast Cancer Index and CancerType ID tests. Just two days before revealing the Biotheranostics play, Hologic announced that it had expanded its presence in Europe by acquiring Berlin, Germany-based women's health provider Somatex Medical, for $64 million.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Qiagen	Inovio Pharmaceuticals	• Objective: Develop next-generation sequencing-based liquid biopsy companion diagnostic tests for use with Inovio therapies • Dynamic: Expanded collaboration initially targeting diagnostic test to identify women most likely to benefit from Inovio's VGX-3100 immunotherapy for advanced cervical dysplasia associated with HPV infection

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DX Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Adaptive Biotechnologies	Laboratory Corporation of America	• Objective: Provide access to Adaptive's immune-driven clinical diagnostic and research products • Dynamic: Expand current collaboration and servicing agreement covering ClonoSeq and ImmunoSeq assays to Adaptive's T-Detect COVID test
Becton Dickinson	Scanwell Health	• Objective: Develop an at-home rapid test for SARS-CoV-2 • Dynamic: BD to create a lateral flow antigen test and pair it with Scanwell Health mobile app
Thermo Fisher Scientific	Mindray	• Objective: Offer drug screening technology to clinical and drug court labs in US and Canada • Dynamic: Exclusive agreement to offer Mindray's BS-480 and BA-800M analyzers together with Thermo Fisher's DRI and CEDIA drugs of abuse immunoassay reagents for drug screening of urine samples
Hologic	Google Cloud	• Objective: Bolster Hologic's digital cytology platform • Dynamic: Multi-year collaboration to integrate Google Cloud's machine learning technologies into Hologic's Genius Digital Diagnostics digital cytology platform, which combines artificial intelligence and advanced digital imaging to help identify pre-cancerous lesions and cancer cells in women
AmoyDx	AstraZeneca	• Objective: Develop companion diagnostic for treating ovarian cancer patients with homologous recombination deficiency (HRD) • Dynamic: Deal comes after firms agreed to collaborate on molecular diagnostics development for gynecological indications including those characterized by HRD
Kroger Health	Gauss	• Objective: Offer Gauss' smartphone-enabled, at-home COVID-19 Rapid Antigen Test Kit at Kroger retail locations • Dynamic: Kroger Health to offer kit online and at counters of its 2,200 pharmacies across U.S. once it gets EUA from the FDA

Partner 1	Partner(s) 2+	Deal Summary
Stella Diagnostics	Mayo Clinic	• Objective: Evaluate Stella's test for predicting disease progression in Barrett's esophagus • Dynamic: Use targeted mass spectrometry to assess potential of multiple protein markers for progression of Barrett's esophagus, including the proteins that compose Stella's STLA101 panel
Twist Bioscience	Berry Genomics	• Objective: Develop next generation sequencing target enrichment and library preparation tools for inherited diseases • Dynamic: Berry Genomics to also offer Twist's NGS panels for cancer diagnosis
Twist Bioscience	Victorian Clinical Genetic Services (VCGS) of Australia	• Objective: Develop whole-exome capture assay for VCGS to use as a clinical diagnostic test • Dynamic: Assay combines Twist's Human Comprehensive Exome with VCGS' customized content for rare and inherited diseases to minimize gaps in clinically relevant genes and transcripts
GBS (iQ Group subsidiary)	Johns Hopkins Bloomberg School of Public Health	• Objective: Accelerate development of saliva-based diagnostic tests for coronavirus • Dynamic: Sponsored research agreement to support GBS' research into saliva testing for use in commercializing two of its rapid point-of-care tests, the SARS-CoV-2 Antibody Biosensor and Saliva Glucose Biosensor
LifeLabs	Multiplex Genomics	• Objective: Perform SARS-CoV-2 testing and track virus variants in Canada • Dynamic: LifeLabs to provide Multiplex Genomics SARS-CoV-2 samples for testing and the latter will then sequence positive samples to assign them to SARS-CoV-2 variants
Natera	Personalis	• Objective: Develop cancer treatment monitoring and molecular residual disease (MRD) testing • Dynamic: Natera to use matched tumor and normal exome sequencing data generated by Personalis to validate design of its Signatera personalized circulating tumor DNA assays • Natera to commercialize assays
Fulgent Genetics	BioIQ	• Objective: Use next-generation sequencing to identify SARS-CoV-2 variants • Dynamic: BioIQ to offer Fulgent's coronavirus genome sequencing assay on its diagnostics software platform to inform testing regimens, clinical treatment protocols and vaccination strategies

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DX Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Avricore Health	Avrok Laboratories	• Objective: Provide rapid SARS-CoV-2 antigen testing for international travelers • Dynamic: Avrok, which operates a CLIA-certified lab in California, to oversee testing of travelers in Canada, U.S., Mexico and the Caribbean, with test results reported directly via Avricore's HealthTab point-of-care screening platform
Kantaro Biosciences	Atrys Health	• Objective: Distribute Kantaro's SARS-CoV-2 antibody tests • Dynamic: Atrys to offer Kantaro's COVID-SeroKlir and COVID-SeroIndex tests in parts of Europe and South America, including Spain, Portugal, Colombia, Brazil, Peru, and Chile • Deal also includes Bio-Techne, which is Kantaro's manufacturing partner
Avacta	Mologic	• Objective: Develop, manufacture and distribute Avacta's SARS-CoV-2 tests • Dynamic: Mologic to manage CE marking of Avacta's AffiDx SARS-CoV-2 lateral flow rapid antigen test under its existing ISO13485 quality system and transfer the CE mark once it's issued • Mologic to also distribute Avacta's SARS-CoV-2 spike antigen test in undisclosed low- and middle-income countries
NeoGenomics	Parexel	• Objective: Advance application of precision medicine in clinical trials • Dynamic: Use real-world genomics data to accelerate patient matching and optimize trial design, site selection, clinical development and translational research
Tecan	UgenTec	• Objective: Offer labs integrated sample-to-answer PCR workflows • Dynamic: Market Tecan's liquid handling and automation workstations in combination with UgenTec's FastFinder PCR analysis software
Congenica	Gabriel Precision Oncology	• Objective: Develop clinical interpretation software platform for somatic cancer • Dynamic: Combine technologies to build automated system enabling next-generation sequencing-based cancer molecular diagnostics from multiple genomic assays

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Binx Health	McKesson	• Products: Binx io molecular diagnostic testing platform • Territory: U.S.
Fluidigm	Zhejiang PuLuoTing Health Technology	• Products: Fluidigm CyTOF technology, panels and reagents • Territory: China
Genedrive	Beckman Coulter Life Sciences	• Products: Genedrive's 96 SARS-CoV-2 test • Territory: U.S. and Europe
Product Owner	**Distributor**	**Deal Summary**
Epimune	Tanner Pharma (via its TannerLAC unit)	• Products: Epimune's I.Mune TBNK lymphocyte quantification test • Territory: Latin America
Sysmex	Siemens Healthineers	• Products: Sysmex's CN-Series line of automated blood coagulation analyzers • Territory: Global • Parties also extended the scope and duration of their existing hemostasis testing systems and reagents global distribution agreement
PixCell Medical	Aidian	• Products: PixCell's HemoScreen point-of-care hematology analyzer • Territory: Finland, Norway, Denmark, Latvia, Estonia • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
Baseclick	DNA Script	Exclusive license to Baseclick's Click chemistry for printing modified DNA
ERS Genomics	G+FLAS Life Sciences of South Korea	Non-exclusive license to ERS' CRISPR-Cas9 patent portfolio
ERS Genomics	ZeClinics	Non-exclusive license to ERS' CRISPR-Cas9 patent portfolio

SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
Quest Diagnostics	Emblem Health	Quest to serve as sole national lab for all Emblem Health Insurance Plan of New York products in 2021

Health Care Reform: New Administration May Not Be Enough to Save the ACA

Patients, payors and health exchanges await nervously as the drama over the *Affordable Care Act* (ACA, aka Obamacare) continues to play out. It looked like the U.S. Supreme Court had settled the issue once and for all in 2012 by upholding the law's constitutionality in a case called *NFIB v. Sebelius*. But after capturing all three branches of the federal government in 2016, the Republicans decided to make one more run at the law. The actual case came from the states level with 20 GOP governors leading the charge.

Republicans also had new legal ammunition. That's because the basis of the *Sebelius* ruling was that the ACA represented a constitutional exercise of Congress' right to tax. But in Dec. 20, 2017, Congress enacted the *Tax Cuts and Jobs Act* establishing a $0 mandate penalty. The plaintiffs in the new case contend that a $0 penalty is *not* a tax and thus no longer supportable as an exercise of Congressional taxing powers. And since the individual mandate isn't severable from the rest of the ACA, they asked the federal court to strike down the entire law.

The case ping ponged around the Texas federal courts, with the district court siding with the Republicans, only to be rebuffed by the Fifth Circuit's order to go back to the drawing table. All the while, insurers, the health markets and especially individuals who depend on the ACA for health coverage twisted in the wind. So, in response to urgent pleas, the Supreme Court made the unusual decision to rule on the case without waiting for a final judgment from the lower courts.

Elections Have Consequences

When the Supreme Court heard oral arguments on the latest court challenge to the ACA back in November, the DOJ took the position that the entire law was unconstitutional and needed to be struck down. Of course, a lot has changed since then, most notably the management of the DOJ, whose boss was a part of the Obama administration that championed the enactment of the ACA.

Although the Biden DOJ can't end the case, it can and is determined to influence its outcome. With that in mind, new Deputy Solicitor General Edwin Kneedler sent the Justices a letter in early February arguing that "rather than imposing a new burden on covered individuals, the [individual mandate] preserved the choice between lawful options and simply eliminated any financial or negative legal consequence from choosing not to enroll in health coverage. Kneedler didn't request new oral arguments or additional briefing from the state attorneys general.

Takeaway

So, what happens next? As it was back in November, the answer is "we don't know." For what it's worth, Court watchers that observed

the November oral hearings came away with the impression that all nine Justices appeared to be highly skeptical of the legal arguments for striking down the entire ACA. But predicting how Justices will rule on a case based on their line of questioning during oral hearings is anything but an exact science.

While not totally insignificant, the transition of the DOJ from Republican to Democratic leadership will likely have little effect on the ultimate ruling. Of greater potential significance is Democratic control over the White House and both houses of Congress, which provides a window for adopting new legislation in the event that the Court does find the entire ACA unconstitutional. Whether a new healthcare plan is a realistic sustainable resolution remains an unknown and perhaps ultimately moot issue.

M&A Report: Investors Skeptical of Qiagen-Quidel Merger but Believe GenMark Diagnostics Acquisition Rumor

With pandemic pain slowly residing and lab companies awash in COVID-19 testing revenues, it's not surprising that the M&A cauldron is heating up. While volume has yet to rebound to pre-pandemic levels, we are seeing distinct rise in the number of deals in recent weeks. But perhaps the biggest M&A story in February is the buzz about the supposed blockbuster deals to come.

A Qiagen-Quidel Merger?

On Feb. 8, Bloomberg reported that two of the lab industry's big "Qs," Qiagen and Quidel, were in early merger discussions. The report cites unnamed sources as saying that Quidel approached Qiagen to gauge interest in joining forces. While both firms have successfully pivoted to meet the need for COVID-19 test products, there are strong concerns that current demands are unsustainable and that significant declines are imminent.

It sounds plausible enough. Qiagen's molecular products fit nicely with Quidel's point-of-care antigen and medical equipment portfolio. Qiagen has also been in play, having come within a whisker of being acquired by Thermo Fisher Scientific last year. However, the Bloomberg report was met with almost universal skepticism. Naturally, neither firm would comment on "rumors." Quidel CEO Doug Bryant was somewhat noncommittal and noted that the company is always open to "opportunities to leverage our global infrastructure or contribute to

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M&A Report: Investors Skeptical of Qiagen-Quidel Merger but Believe GenMark Diagnostics Acquisition Rumor, *from page 17*

our interest in digital and telehealth." Qiagen CEO Thierry Bernard was sharper and more direct in his denials, suggesting that the merger would dilute the firm's activities.

Wall Street analysts aren't buying it, either. For one thing, because Quidel is so much larger, a merger would engulf Qiagen. And it's not just size but what one William Blair analyst describes as the "lack of obvious revenue or operating synergies" between the firms. "Qiagen is more of a life sciences company that specializes in supplying raw materials, reagents and assays for molecular analysis with a 'diagnostics tilt,'" the analyst suggests.

Acquisition Rumors Send GenMark Diagnostics Shares into Orbit

Qiagen-Quidel wasn't the only Bloomberg diagnostics M&A story of note in February. The financial reporting firm also cited unnamed sources as suggesting that GenMark Diagnostics is putting itself up for sale. Predictably, GenMark declined to comment on rumors. However, the story apparently had much more credence with investors, who snapped up shares of the Carlsbad-California-based company the next day, causing the stock to rise 27 percent to $21.47.

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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
Hologic	Biotheranostics	• Price: $230 million • Status: Closed • Acquisition of producer of molecular tests for breast and metastatic cancers boosts Hologic's position in women's health market
Thermo Fisher Scientific	Propel Labs (wholly owned subsidiary of Sidis)	• Price: Undisclosed • Status: Closed • Acquisition of biotech instrumentation company whose Bigfoot Spectral Cell Sorter technology will become part of Thermo Fisher's Biosciences business in the Life Sciences Solutions segment
Exact Sciences	Translational Genomics Research Institute (TGen)	• Price: Undisclosed • Status: Expected to close in Q2 • Acquisition of TGen's CLIA-certified and CAP-accredited sequencing lab Ashion Analytics to boost Exact Sciences' efforts to develop precision oncology products, including minimal residual disease (MRD) and other sequencing-based tests

Acquiring Company	Target(s)	Deal Summary
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: Expected to close by May • 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
Oncocyte	Chronix Biomedical	• Price: Includes $2.675 million in cash and $1.5 million of Oncocyte common stock; Oncocyte to also assume up to $5.5 million in Chronix liabilities and pay share on net collected revenues for certain tests, as well as up to $14 million in cash or stock if certain milestones are achieved • Status: Expected to close by end of April • Merger enabling Oncocyte to acquire Chronix's cancer immunotherapy monitoring test, TheraSure-CNI Monitor, and organ transplant monitoring technology patents
Cellink	Ginolis	• Price: €70 million ($84.8 million), including 60% in cash and 40% in Cellink series B shares • Status: Expected to close in March • Ginolis provides robotics systems for manufacturing COVID-19 tests, multiplex tests, lateral flow, point-of-care tests and medical devices
LGC	Technopath Clinical Diagnostics	• Price: Undisclosed • Status: No closing date announced • LGC acquires manufacturer of chemistry and immunoassay quality controls which will be absorbed into firm's clinical diagnostics business unit
Horiba	MedTest Holdings	• Price: Undisclosed • Status: Closed • Firms in MedTest Holdings include MedTest Dx, Pointe Scientific, Clinitox Diagnostix and Medical Laboratory Solutions
MicroGem	Jump Start Manufacturing	• Price: Undisclosed • Status: Closed • Acquisition of engineering and manufacturing firm enables MicroGem to scale up production of its Spitfire6830 PCR-based SARS-CoV-2 saliva test
Tataa Biocenter	Life Genomics	• Price: Undisclosed • Status: Closed • Tataa acquires majority stake in Swedish genetic testing company whose offerings include Roche's Harmony noninvasive prenatal test (NIPT) for chromosomal abnormalities, a genetic disease carrier test and a test for Alzheimer's disease risk

■ Industry Buzz: Guardant Health Challenges Exact Sciences' Leadership of Colorectal Cancer Diagnostics Market, *from page 1*

lab whose genomic testing assets will bolster Exact's efforts to enhance its Cologuard product and develop new precision oncology diagnostics for MRD and other cancers. Those Ashion assets include the GEM ExTra comprehensive cancer test, as well as whole-exome, matched germline and transcriptome sequencing capabilities.

The Ashion acquisition, which is scheduled to close in the second quarter, is just one element of Exact's larger strategic collaboration with TGen. A month earlier, the Wisconsin-based molecular diagnostics firm announced that it had signed a worldwide exclusive license to TGen's Targeted Digital Sequencing (TARDIS) technology, which will now be incorporated into Cologuard. The collaboration also includes 10-year research agreement for development of patents and clinical evidence to support the scientific reliability of MRD testing necessary to secure coverage from payors.

Guardant Health Takes on Cologuard

Exact's principle rival is Guardant Health. Last year at this time (February 2020), Guardant, which produces its own Guardant360 liquid biopsy assay for MRD, unveiled plans to invest heavily in new products to take on Cologuard and cash in on "significant market opportunities" in the colorectal and MRD space. In 2019, the Redwood, CA-based precision oncology firm launched its Lunar assay, but only for research and drug development use. Meanwhile, stronger than expected Guardant360 sales helped minimize net losses generated by the firm's stepped-up R&D efforts.

On the very same day that Exact announced that it was acquiring Ashion, its rival launched Guardant Reveal, a commercial version of the Lunar

assay. Guardant claims the new test is the first blood-only liquid biopsy test for detection of residual and recurrent disease from a simple blood draw. According to the firm, the new test improves management of early-stage colorectal cancer patients by detecting circulating tumor DNA in blood after surgery to identify patients with MRD who may benefit most from adjuvant therapy and by detecting recurrence months earlier than current standard of care methods like imaging or carcinoembryonic antigen (CAE) tests.

Takeaway

At this point, Exact Sciences and Guardant Health aren't so much competing for as sharing the colorectal and MRD market. Cologuard still reins supreme in screening. But Guardant is spending big bucks to develop a rival screening product to compete with Cologuard. Meanwhile, dual residual and recurrence capabilities of the new Guardant Reveal product move the company deeper into the cancer care pathway. But just as Guardant is working to close the gap with Exact in screening, Exact is collaborating with TGen to expand its presence in colorectal and MRD cancer treatment and case management.