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Inside the Lab Industry: Resurgence of COVID-19 Cases Threatens to Derail Recovery of Core Business

Back on July 1, the perception was that the demand for COVID-19 testing was falling off faster than predicted. The silver lining to this cloud was the stronger than expected recovery of core non-COVID-19 revenues. The Q2 earnings reflect both of these trends. But now, more than halfway into Q3, things have changed dramatically as a result of the delta variant and surge of new COVID-19 cases. This plus the downward pressure that the previous outbreak exerted on the FY 2020 Q2 year-over-year baseline means that the analysis of the 2021 Q2 earnings trends must be taken with a large grain of salt.

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M&A Report: Illumina Makes Audacious Move by Completing Grail Acquisition Without Regulatory Approval

It's damn the torpedoes and full speed ahead for Illumina. Recognizing that it had no chance of securing the necessary regulatory approval in time to make the hard closing deadline and staring a $300 million termination fee in the face, Illumina did the unthinkable by completing the deal without clearance from regulators in the U.S. or Europe. Close-now-get-approval-later is a highly dangerous strategy that could blow up in the San Diego-based genetic testing giant's face.

The Illumina Acquisition of Grail

On September 21, 2020, Illumina announced that it had signed a definitive agreement to acquire Grail, the liquid

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Growth Continues but at a Slower Pace

Of the 37 diagnostics firms (not counting DiaSorin, Roche and Siemens Healthineers) that had reported their 2021 Q2 earnings as of press time, only five missed their top-line Wall Street earnings targets—Berkeley Lights, Fulgent Genetics, Meridian Biosciences, Opko Health and Quidel. Fourteen different companies increased their revenues projections for the remainder of 2021, including Fulgent Genetics which fell short of Q2 projections.

However, while COVID-19 tests, collection kits and instruments continued to fuel growth in diagnostics revenues, demand fell off noticeably starting in May. This trend is reflected when Q2 top-line growth rates are compared sequentially to Q1 growth rates. Examples:

Sequential FY 2021 Quarterly Revenue Growth Rates

Company	Q2 Rate	Q1 Rate
Danaher	34 percent	58 percent
Hologic	42 percent	104 percent
Meridian Biosciences	-25 percent	48 percent
Opko Health	47 percent	>200 percent
PerkinElmer	51 percent	100 percent
Qiagen	28 percent	52 percent
Quidel	-12 percent	115 percent
Thermo Fisher Scientific	34 percent	59 percent

Abbott, Quest and LabCorp also saw their sequential growth rates fall back, albeit at a lesser rate.

The Falloff in COVID-19 Test Demands

As in Q1, increased sales of rapid point-of-care (POC) and antigen COVID-19 testing partially offset the declines in molecular PCR-based tests. However, POC products also delivered results below expectations. Thus, for example, Abbott reported seeing lower demand in the US for COVID-19 testing volumes in the US for both RT-PCR testing and rapid testing; slightly higher than expected demand in international markets helped make up for the US losses. But this wasn't enough to keep Abbott from reducing its full-year and Q3 and Q4 revenue projections for 2021. Qiagen and Quidel were among other companies projecting lower COVID-19 revenues for the rest of the year.

The Continued Rebound of Core Markets

Just as coronavirus testing gains came at the expense of core products, the fall off in COVID-19 products was accompanied by a recovery in base

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business. For the first time since the public health emergency began, companies began reporting gains in genomics, immunoassays, cancer, reproductive health and other non-COVID-19 businesses devastated by the pandemic. In some cases, growth was above 2019 rates and wiped out pandemic-related losses.

Unfortunately, the bottom line was somewhat less positive, with 12 companies missing their Wall Street earnings per share targets, as compared to just eight in Q1.

The Post-Q2 Resurgence of Demand for COVID-19 Tests

Regrettably, Q3 will probably not continue the theme of goodbye COVID, hello business as usual. The sad irony is that the 90 percent decline in COVID-19 testing demand experienced in Q2 feels like a lost memory from a long bygone era. Thanks to soaring cases and the reopening of schools, the U.S. is once again facing a COVID-19 test shortage as companies like Abbott that shut down production lines and destroyed hundreds of thousands of test cards seek to rebuild and remobilize their COVID-19 production capacities. Meanwhile, non-COVID-19 testing activities that were just starting to regain their legs face an uncertain future.

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Diagnostics Earning Reports for 2021 Q2 (period ended June 30, 2021)
(Companies with at least $15 million in sales)

COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
****Abbott Laboratories**	$10.22 billion ($9.69 billion)	+39% (+35% organic)	Adjusted +$1.17 (+$1.02)	DX up from $1.99 to $3.25 billion. Core DX up 33% to $1.31 billion as base business continues to recover; Molecular down 19% to $290 million; Rapid diagnostics up over 100% to $1.51 billion; Point of care drops 16% to $137 million; COVID testing revenues of $1.3 billion, including $1.0 billion from BinaxNow, Panbio and ID Now rapid testing platforms—but steady decline in COVID demand leads to downward adjustment of projected earnings
Adaptive Biotech	$38.5 million ($31.3 million)	+83%	Net -$.35 (-$.42)	Sequencing revenues continue rebound more than doubling to $18.6 million due to COVID, test volume for ClonoSeq up 75%, 15% sequentially; Development revenues up 54% to $20.0 million driven by higher demand for biopharma services
***Agilent Technologies (FY 2021 Q3)**	$1.59 billion ($1.54 billion)	+26%	Adjusted +$1.10 (+$0.99)	Diagnostics and genomics up 44% to $346 million; Life sciences and applied market groups up 22% to $680 million

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COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
***Becton Dickinson (FY 2021 Q3)**	$4.89billion ($4.51 billion)	+27%	Adjusted +$2.74 (+$2.44)	Life sciences up 51% to $1.43 billion; Biosciences up 33% to $316 million, including $300 million from COVID testing on BD Veritor Plus ($212 million) and BD Max Systems ($88 million); But pandemic-related costs and manufacturing variances negatively affect gross margins
Berkeley Lights	$19.3 million ($19.6 million)	+82%	Net -$0.27 (-$0.24)	Product revenues up 43% to $13.0 million; Direct platform revenues, including instruments, license agreements and platform support, up 51% to $11.4 million
***Bio-Rad Laboratories**	$715.9 million ($631.8 million)	+33%	Adjusted +$3.54 (+$2.66)	Life Sciences up 33% to $334.2 million driven by qPCR and Droplet Digital PCR products in response to COVID; Clinical DX rebounds from Q1 decline with 34% increase to $380.2 million driven by recovery across all product lines; $68 million in COVID revenues with expectation of $210 million for year
Bio-Techne (2021 FY Q4)	$259.0 million ($244.6 million)	+47%	Adjusted +$1.87 (+$1.70)	DX & Genomics up 38% to $67.1 million; Protein Sciences up 51% to $192.3 million
***Bruker**	$570.8 million ($538.3 million)	+34%	Adjusted +$0.44 (+$0.38)	CALID group, which houses life science mass spectrometry, up 46% to $193.3 million driven by strong demand for high-performance instruments; BioSpin group up 19% to $148.5 million; Nano group up 40% to $175.3 million; COVID PCR testing contributes $6 million
***CareDx**	$74.2 million ($67.6 million)	+77%	Adjusted +$0.11 (+$0.02)	Testing services nearly double to $64.9 million driven by increase in AlloSure Kidney and AlloMap Heart sales; Products sales up 23% to $5.8 million; Digital and other revenues up $200,000 to $2.4 million
Co-Diagnostics	$27.4 million ($20.8 million)	+14%	Net +$0.33 (+$0.22)	Continuing strong demand for Logix Smart COVID-19 test in US and Europe generates lion's share of revenues
Danaher	$7.22 billion ($6.72 billion)	+37%	Adjusted +$2.46 (+$2.05)	Growth driven by life sciences, which increased 41% to $3.73 billion; Diagnostics also up 41% to $2.34 billion, driven by 50% growth in Cepheid unit; Leica Biosystems and Beckman Diagnostics each up more than 30% as patient volume and clinical diagnostic activity returns to pre-pandemic levels; Non-COVID bioprocessing up in low double digits
DiaSorin	$295.4 million	+20%		CLIA test revenues up 25% to $172 million; ELISA test revenues up 4% to $16.7 million; Molecular up 23% to $81.6 million; Instruments down 7% to $22.1 million

COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Fluidigm	$31.0 million ($30.6 million)	+19%	Adjusted -$0.12 (-$0.20)	Product revenues up 30% to $22.6 million; Service revenues up 29% to $6.6 million; Lower COVID revenues projected; Mass cytometry continues steady recovery driven by suspension and imaging applications
*Fulgent Genetics	$153.6 million ($197.3 million)	Up nearly 9-fold	Adjusted +$2.55 (+$2.81)	Billable tests increase from 181,000 to 1.86 million but COVID RT-PCR test demand falls faster than expected—but that was before the surge
***Exact Sciences**	$434.8 million ($421.3 million)	+62%	Net -$0.45 (-$0.76)	Screening revenues, including Cologuard (60,000 tests, a new high) and Biomatrica, double to $263.9 million; Precision oncology, including Oncotype products, which were up just 1% in Q1, increase 34% to $137.8 million; COVID testing drops 4% to $33.1 million
Guardant Health	$92.1million ($84.6 million)	+39%	Net -$0.61 (-$0.87)	Oncology testing up 42% to $72.6 million; Development services up 27% to $19.5 million; Liquid biopsy recovers but still not back to pre-COVID levels
Hologic (FY 2021 Q3)	$1.17 billion ($1.04 billion)	+42% (as opposed to 104% in Q2)	Adjusted +$1.33 (+$1.12)	COVID surge slows with total DX up 25% (vs. 233% in Q2) to $665.5 million, including 17% (vs. 391% in Q2) growth in molecular diagnostics to $460.3 million; Cytology and perinatal revenues up 81% (vs. 3%) to $64.1 million; Non-COVID segments recover, including Breast Health (up 56% to $349.0 million), Gyn surgical (up 148% to $127.9 million) and Skeletal health (up 70% to $25.9 million)
***Illumina**	$1.13 billion ($1.01 billion)	+78%	Net +$1.87 +$1.35	Sequencing accounts for 91% of total revenues, with sequencing systems more than doubling to $189 million and sequencing consumables up 82% to $704 million; Sequencing services and other revenues up 41% to $128 million due, in part to one-time recognition of royalties income; COVID surveillance testing above expectations, contributing $40 million in consumables and $20 million in instruments
***Invitae**	$116.3 million ($108.3 million)	+152%	Non GAAP -$0.85 (-$0.65)	Testing more than doubles at $111.5 million driven by 154% increase in billable test volume (287,000 tests billed); Other revenues up over 400% to $4.8 million
***LabCorp**	$3.84 billion ($3.61 billion)	+39%	Adjusted +$6.13 (+$5.57)	Pace of growth continues to decline slightly with DX up 40% to $2.36 billion and molecular COVID testing flat at $440 million (average 54,000 tests per day); Organic base business up 38%; Covance up 37% to $1.50 billion

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COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Meridien Biosciences (FY 2021, Q3)	$63.5 million ($77.2 million)	-25%	Adjusted +$0.22 (+$0.31)	After doubling in Q2, life sciences fell 49% to $32.3 million due to decline in demand for COVID testing reagents; $12.5 million from COVID molecular and $2 million from COVID immunological products; But DX bounces back from Q2 decline of 9% with 44% growth to $31.2, with molecular assays down 39% to $4.4 million and non-molecular assays flat at $27.6 million
Myriad Genetics	$189.4 million ($165.4 million)	More than doubled (vs +6% in last quarter)	Adjusted -$0.12 (-$0.09)	Huge quarter with Molecular DX up 115% (vs. 6% increase in last quarter) to $178.7 million); Hereditary cancer reverses previous quarters' declines to post 116% growth to $86 million; Prenatal up 77% to $29.4 million; Tumor profiling up 178% to $29.2 million driven by Prolaris and myChoiceCDx; Vectra, which Myriad just sold to LabCorp, up 40% to $10.2 million
***Nanostring Technologies**	$33.8 million ($32.4 million)	+50%	Adjusted Not given (-$0.54)	Growth driven by instruments (up 21% to $11.8 million, including $7.4 from GeoMx Digital Spatial Profiler) and consumables (up over 100% to $18 million, with NGS readout systems accounting for 2/3 revenues on GeoMx systems)
***Natera**	$142.0 million ($127.5 million)	+64%	Net -$1.32 (-$1.08)	Fastest YOY growth quarter since Natera went public thanks to higher than expected 61% increase in test volumes (375,700 tests), which leads firm to increase its guidance for the rest of 2021
NeoGenomics	$121.7 million ($118.2 million)	+40%	Adjusted -$0.01 (-$0.06)	Growth driven by 37% increase in clinical services (up 41% excluding COVID PCR testing) to $101.4 million; average revenue per test up 3% to $360; Pharma services up 55% to $20.3 million due to increase in clinical trials and informatics
Opko Health	$442.4 million ($456.4 million)	+47% (vs. 200% increase in Q1)	Pro forma -$0.03 (-$0.02)	COVID and genomic testing drives increase in Services from $251 million to $397.2 million, including 32% increase in BioReference Laboratories' test volumes; Solid-tumor, hematological liquid tumor and cancer genomics testing more than doubled, as compared to pre-COVID revenues; Product revenues up 22% to $35.7 million
OraSure Technologies	$57.6 million ($56.7 million)	+97%	Net -$0.02 (+$0.04)	Continued recovery in core businesses, including Molecular DX, up 103% to $38.3 million, driven by tripling of genomics collection kits to $19.7 million; Sample collection devices for COVID testing up 36% to $11.5 million (vs. $15.9 million in Q1); COVID PCR test volume declines significantly but total infectious diseases up 79% to $15.6 million

COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
***Ortho Clinical Diagnostics**	$492.5 million ($475.9 million)	+26%	Adjusted +$0.16 (+$0.14)	Core revenues, excluding contract manufacturing and other licensing, up 26% to $487.5 million with solid growth in all segments
Pacific Biosciences	$30.6 million ($29.9 million)	+79%	Net -$0.21 (-$0.20)	Second straight quarter of growth driven by Instrument to $14.3; Consumables more than double to $12.2 million, with 85% coming from sales for Sequel II and IIe systems; 38 Sequel II and IIe systems placed, increasing overall total to 282 (vs. 148 in Q2 2020)
PerkinElmer	$1.23 billion ($1.12 billion)	+51% (vs. 100% in Q1)	Adjusted +$2.83 (+$2.41)	After COVID boom, growth slows to pre-pandemic levels with DX up 70% to $715.6 million driven by over 100% growth in immunodiagnostics and strong rebound of Euroimmun; Applied genomics up over 20% on non-COVID demand
Qiagen	$567.3 million ($554.4 million)	+28% (vs. 52% in Q1)	Adjusted +$0.67 (+$0.62)	COVID products down 17% to $159.7 million; Non-COVID products continue recovery, growing 52% to $407.6 million, or 72% of total sales; Molecular DX up 28% to $272 million; Life sciences up 20% to $296 million; Sample technologies down 3% to $203 million as COVID kits decline and non-COVID kits bring in 70% of segment's revenue
Quest Diagnostics	$2.55 billion ($2.38 billion)	+40% (vs. 49% in Q1)	Adjusted +$3.18 (+$2.86)	Base testing up 7% (2% excluding acquisitions) and exceeds 2019 levels for first time since pandemic began, and growth is robust as compared to 2019; Test volume up 45% but revenue per requisition down 4%; Strong recovery in routine testing, especially general health, cardiometric and advanced diagnostics; Prescription drug monitoring and toxicology remain sluggish and below pre-pandemic levels
Quidel	$176.6 million ($194.5 million)	-12% (vs. 115% growth in Q1)	Adjusted +$0.75 (+$1.46)	Losses driven by falling demand for Sofia and PCR COVID testing and influenza products; Molecular DX down 38% to $34.5 million, with sharp declines in Lyra PCR tests only partially offset by increases in Solana; Core products, excluding COVID and influenza, up 24% to $91.5 million, including Cardiometabolic immunoassays up 32% to $71.7 million; Specialized DX continues slide, falling 12% to $10.4 million

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COMPANY	FY 2021 Q2			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Roche Diagnostics (FY 2021, H1)	$33.4 billion	+51%	Net $11.52 (down 3% YOY)	Total DX up 49% to $9.86 billion, including $2.73 billion from COVID products; Core lab revenues up 32% to $4.07 billion driven by recovery in routine testing; Immunodiagnostics up 40% and clinical chemistry up 25%; Molecular DX up 42% to $2.42 billion driven by COVID testing; Virology up 60% and Point of Care Solutions more than triple to $1.77 billion
Siemens Healthineers (FY 2021, Q3)	$5.94 billion	+51%	Adjusted +$0.66	DX up 98% to $2.03 billion, driven by $708 million in rapid SARS-CoV-2 antigen tests; Continued recovery in core non-COVID businesses, with roughly 30% growth
***Thermo Fisher Scientific**	$9.27 billion ($8.77 billion)	+34% (vs. 59% in Q1)	Adjusted +$5.60 (+$5.49)	Life sciences up 37% (vs. 137% in Q1) to $3.56 billion; Specialty DX up 25% (about vs. 69% in Q1) to $1.62 billion; Analytical instruments up 26% to $1.24 billion; Laboratory products and services revenues up 29% to $3.58 billion
***Twist Bioscience (FY 2021, Q3)**	$35.0 million ($32.3 million)	+65% (vs. 62% in Q1)	Net -$0.82 (-$0.75)	Next-generation sequencing revenues, including SNP microarray conversions and liquid biopsy panels more than double to $18.7 million, topping Synthetic biology revenues (up 21% to $14.3 million) for third quarter in a row
Veracyte	$55.1 million ($48.1 million)	+166% (vs. 18% in Q1)	Net -$0.13 (-$0.25)	Overall testing up 230% to $50.8 million driven by urologic and thyroid cancer; Product revenues, which were down in Q1, rose 59% to $2.7 million; Test volume more than triples (nearly 21,000 tests); including 14% decline in Prosigna (2,144 tests)
Waters	$681.6 million ($621.5 million)	+31%	Non-GAAP +$2.60 (+$2.24)	Second quarter in a row with 31% growth and easily exceeding Wall Street projections; Growth driven by Pharma and Industrial; Services and consumables up 22% to $367.2 million; Instruments up 43% to $314.5 million

Bold face: Companies that met or exceeded average or consensus Q2 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q2

** Companies that lowered their revenue or EPS guidance during Q2

FDA WATCH

Final Rule Clarifies Liability for Off-Label Uses and Lab's Right to Create LDTs

On August 2, 2021, the FDA published the long-awaited final rule updating its "intended use" regulations for medical devices and drugs. Here's a quick briefing of the new rules, which take effect on September 1.

The "Intended Use" Regulations

In 2015, FDA proposed to eliminate a regulatory requirement that a manufacturer "provide adequate labeling" to account for unapproved, i.e., off-label uses, about which it "knows, or has knowledge of facts that would give him notice." A 2017 final rule did remove the provision but also required manufacturer to incorporate an unapproved use into the labeling if the "totality of the evidence" establishes that the manufacturer objectively intended to introduce the product for that use. But the agency delayed the effective date of the final rule in response to industry concerns over the "totality of the evidence" clause.

So, the agency went back to the drawing board, issuing a new proposed rule in September 2020, clarifying that:

- Knowledge of off-label use of a product by a physician can't by itself establish a manufacturer's intended use for the product; and
- Any relevant source of evidence may be considered as establishing "intended use," not just the manufacturer's promotional claims about the product.

The 2021 Final Rule

The newly published final rule reaffirms that the agency may consider "any relevant source of evidence," including "a variety of direct and circumstantial evidence" in determining "intended use." Nothing in the Federal *Food, Drug, and Cosmetic Act* (FDCA) limits FDA to relying only on promotional statements. Besides, the final rule adds, the ability to rely on a broader base of evidence about a product's intended use enables the agency to curb "distribution of dangerous and fraudulent products" more effectively.

However, the final rule reassures that a manufacturer won't be automatically deemed to have intended an off-label use based solely on knowledge that its approved product is being used or prescribed off-label. The basis of this approach is FDA's longstanding "practice of medicine exemption" of not regulating off-label use of a lawfully marketed drug/device by a licensed health care practitioner in the context of caring for an individual patient.

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FDA Watch, Final Rule Clarifies Liability for Off-Label Uses and Lab's Right to Create LDTs, *from page 9*

The LDTs Provisions

Of more direct concern to lab test makers, the final rule language also preserves the ability of labs to develop laboratory-developed tests (LDTs) using either in vitro diagnostic (IVD) or research use only (RUO) components, provided that the LDTs comply with *Clinical Laboratory Improvement Amendments* (CLIA) regulations in their development and are offered on the order of a health care provider.

Note that the final rule applies to both devices granted marketing authorization (thus covering those brought to market via the *de novo* pathway) and those brought to market through 510(k) clearance or PMA approval, as well as to those exempt from premarket notification.

FDA also left in place a complimentary provision under which a third party may be held liable for furthering an off-label use. Specifically, a distributor, seller or other person who receives an article and furthers its commercialization for a different, unapproved purpose is required to supply adequate labeling for that use, or risk liability for marketing a misbranded article.

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Here are some of the key new FDA EUAs and clearances announced in August 2021:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
InBios International	EUA for point-of-care SCoV-2 Detect IgG Rapid Test
Visby Medical	510(k) clearance and CLIA waiver for Visby Medical Sexual Health Click Test
Mount Sinai Hospital	EUA for Mount Sinai SARS-CoV-2 Assay
Empire City Laboratories	EUA for ECL COVID Test System and ECL COVID Test System-1
CellMax Life	Breakthrough Device Designation for FirstSight colorectal precancer and cancer detection blood test
Thermo Fisher Scientific	Clearance for Thermo Scientific EliA SmDP-S test for aiding in diagnosis of systemic lupus erythematosus (SLE)
Thermo Fisher Scientific	Pre-market approval for Oncomine Dx Target Test as companion diagnostic to identify isocitrate dehydrogenase-1 (IDH1) mutated cholangiocarcinoma (CCA) patients who may benefit from treatment with ivosidenib (Servier Pharmaceuticals' Tibsovo)
Becton Dickinson	EUA for BD Veritor At-Home COVID-19 Test
Becton Dickinson	Clearance for BD Cor system along with BD Onclarity HPV Assay for extended genotyping of human papillomavirus

Manufacturer(s)	Product
Siemens Healthineers	*de novo* authorization for Enhanced Liver Fibrosis blood test
Kwokman Diagnostics	EUA for Kwokman Diagnostics COVID-19 Home Collection Kit
Roche	Clearance for Ventana MMR RxDx immunohistochemistry panel as a companion diagnostic to select patients for treatment with GlaxoSmithKline's newly cleared anti-PD-1 agent dostarlimab-gxly (Jemperli) for patients with previously treated, mismatch repair-deficient, or dMMR, solid cancers
Roche	EUA for RT-PCR-based Cobas SARS-CoV-2 nucleic acid test for use on the Cobas Liat system
STS Lab Holdco (Amazon subsidiary)	EUA for Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test
Cleveland Clinic	EUA for SelfCheck COVID-19 TaqPath Multiplex PCR test
Qiagen + Ellume	EUA for QiaReach SARS-CoV-2 Antigen Test
Pillar Biosciences	Premarket approval for OncoReveal Dx Lung and Colon Cancer Assay tissue-based companion diagnostic test for qualitative detection of somatic mutations in DNA from non-small cell lung cancer and colorectal cancer tissue samples
Thermo Fisher Scientific	EUA for COVID-19 Fast PCR Combo Kit 2.0 to detect SARS-CoV-2 nucleic acid in saliva samples
Thermo Fisher Scientific	EUA for TaqPath COVID-19 MS2 Combo Kit 2.0 PCR-based test
Access Bio	EUA for CareStart COVID-19 Antigen Home Test chromatographic, digital immunoassay
LumiraDx	EUA for SARS-CoV-2 Ab Test (total antibodies test)
Phase Scientific International	EUA for Indicaid COVID-19 Rapid Antigen Test
NYU Langone Health	510(k) clearance for Genome PACT genetic test for solid tumors

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Agilent Technologies	Expanded use of PD-L1 IHC 22C3 pharmDx companion diagnostic assay for identifying esophageal cancer patients for treatment with anti-PD-1 cancer drug pembrolizumab (Merck's Keytruda) using a combined positive score of at least 10
DiaCarta	QuantiVirus SARS-CoV-2 Variant Detection Test
Prenetics	Circle HealthPod point-of-care SARS-CoV-2 testing system
Becton Dickinson and CerTest Biotec	Viasure SARS-CoV-2 Variant Real Time PCR Detection Kit for BD Max
Accelerate Diagnostics	New configuration of Accelerate PhenoTest BC kit
EliTechGroup	SARS-CoV-2 Elite MGB Kit for use with saliva

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FDA Watch, *from page 11*

Manufacturer(s)	Product(s)
Cepheid	Xpert HIV-1 Viral Load XC PCR-based test
Cepheid	Xpert HIV-1 Qual XC PCR-based test

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Aegirbio	Thailand	Saliva test for COVID-19 detection
Exact Sciences	Japan	Oncotype DX Breast Recurrence Score test and software
Amoy Diagnostics, Riken Genesis and Precision Medicine Asia	Japan	AmoyDx PLC Panel as a companion diagnostic to identify non-small cell lung cancer patients eligible for Merck KGaA's tepotinib (Tepmetko)
SpeeDx	Australia	PlexPCR SARS-CoV-2 test

DX Deals: Labcorp Teams with Oncology Research Startup to Eliminate Demographic Disparities in Cancer Treatment

Studies show that demographic differences can impact cancer care and that disadvantaged populations suffer from a lack of access to advanced precision cancer diagnostics and treatments. Evaluating and eliminating these disparities is the objective of a newly announced collaboration between Laboratory Corporation of America and Community Clinical Oncology Research Network (CCORN).

Demographic Diversity and Precision Oncology

A 2020 American Association for Cancer Research report on cancer disparities estimates that 34 percent of cancer deaths among US adults age 25 to 74 could be prevented if disparities in clinical trial participation were actively addressed.

National Comprehensive Cancer Network guidelines recommend clinical trials as a treatment option for cancer. However, less than 5 percent of patients diagnosed with cancer are enrolled in trials. Reasons for this include lack of awareness, social determinants of health and geographic and logistical obstacles. In addition to the social justice implications, ensuring diversity in trials enables the oncology researchers and providers to gain a deeper understanding of how to continue advancing personalized medicine in cancer care for all populations of patients.

The Labcorp-CCORN Collaboration

The newly announced collaboration pairs the nation's second largest testing lab with a startup research company formed by oncologists dedicated to closing disparities in cancer burden, cancer care and precision medicine. The sides will work together to create a patient registry called PREFER—for Prospective rEgistry oF advanced stage cancer—that will enroll up to 2,500 advanced solid cancer patients across the US. The registry will include patient data from Labcorp's advanced diagnostic testing and genomic data from its OmniSeq Insight tissue-based genomic and immune-profiling test to help identify the prevalence of actionable biomarkers and driver mutations that are unique to different ethnicities. Data from the registry will inform research into patients' actionable biomarkers and driver mutations that may be unique to their ethnicities.

Labcorp and CCORN will also create a biobank enabling the broader oncology community to access real-world evidence and identify the source of disparities. Information from the biobank and PREFER patient registry will then be available for use in improving the design of oncology clinical trials, assisting in patient recruitment efforts, and helping encourage the expansion of genomic profiling testing in diverse populations.

"Diverse populations already suffer from a lack of access to adequate cancer diagnosis and treatment," noted Dr. Kashyap Patel, founder and Chairman of CCORN. "Drug development processes have been relatively unsuccessful in reflecting demographic diversity in clinical trials, which further contributes to disparities in care and outcomes for those groups. It's imperative that we determine how and why disparities occur, and this collaboration with Labcorp will be a major step in this regard."

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
LabCorp	Community Clinical Oncology Research Network	• Objective: Boost precision oncology diversity and reduce disparities in access to clinical trials, advanced diagnostic testing and genomic sequencing • Dynamic: Create PREFER (PRospective rEgistry oF advanced stage cancer) patient registry to enroll up to 2,500 US advanced solid cancer patients from sites across the US, and patient data from LabCorp's advanced diagnostic testing and genomic data gleaned from its OmniSeq Insight

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DX Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Foundation Medicine	Epic Systems	• Objective: Integrate Foundation's testing services with Epic's electronic medical record system • Dynamic: Allow physicians to electronically order Foundation's genomic profiling test and testing services within the Epic network • Clinicians will also be able to receive and review results directly within their existing workflow
Amoy Diagnostics	Amgen	• Objective: Develop a companion diagnostic to identify non-small cell lung cancer patients for Amgen's KRAS G12C inhibitor, sotorasib (Lumakras) in Japanese market • Dynamic: AmoyDx to develop its AmoyDx Pan Lung Cancer PCR Panel PCR-based test to screen NSCLC patients for sotorasib eligibility
Twist Bioscience	SomaLogic	• Objective: Discover novel therapeutic targets and antibodies • Dynamic: Twist to identify antibodies against targets coming out of SomaLogic's SomaScan proteomics platform
Partek	Agilent Technologies	• Objective: Integrate iPartek Flow bioinformatics software with Agilent Alissa Clinical Informatics platform to provide end-to-end analysis workflow customizable for Agilent customers • Dynamic: Partek Flow automatically analyzes data in the background, and passes results to Agilent Alissa Interpret platform where results are combined into a report • Partek allows Agilent to resell Partek Flow software via Agilent Alissa portal
Tesis Labs	Personal Genome Diagnostics	• Objective: Develop new genomic tests that combine somatic and germline variant results for cancer patients • Dynamic: Combine Tesis' genomic data and reporting capabilities with somatic variant outputs from tissue tests to create comprehensive platform that provides germline and somatic variants in single report
Cardinal Health	Abbott	• Objective: Broaden access to Abbott's BinaxNow COVID-19 over-the-counter rapid antigen self-test • Dynamic: Leverage Cardinal Health's distribution network to support access to test
Cardinal Health	Quidel	• Objective: Broaden access to Quidel's QuickVue At-Home OTC COVID-19 test • Dynamic: Leverage Cardinal Health's distribution network to support access to test

Partner 1	Partner(s) 2+	Deal Summary
Sema4	Avera Health	• Objective: Create data-driven precision medicine program for Avera's healthcare system • Dynamic: Use Sema4's Centrellis cloud-based health intelligence platform to manage, structure, analyze and integrate genomic and clinical data collected through Avera Cancer Institute • Method will also be applied to fields outside oncology later
Adaptive Biotechnologies	Curebase	• Objective: Expand patient participation in Adaptive's clinical studies • Dynamic: Leverage Curebase's decentralized clinical trial platform allowing investigators to conduct studies across more diverse populations for studies evaluating Adaptive's T-Detect test
Fulgent Genetics	Helio Health	• Objective: Commercialize Helio's liquid biopsies tests in North America • Dynamic: Exclusive arrangement to begin with Helio's HelioLiver liver cancer assay
Ambry Genetics	Lightbeam Health Solutions	• Objective: Provide genetic testing data to help organizations predict patients' increased risk for common cancers and chronic conditions • Dynamic: Integrate Ambry's CARE (Comprehensive, Assessment, Risk, and Education) Program into the Lightbeam Platform
Qiagen	OncXerna Therapeutics	• Objective: Develop NGS companion diagnostic for navicixizumab, which OncXerna is developing as a treatment for ovarian cancer • Dynamic: Qiagen gets nonexclusive license to OncXerna's Xerna TME (tumor microenvironment) panel, for which firms will seek in vitro diagnostic regulatory approval as an NGS companion diagnostic for navicixizumab
Qiagen	GT Molecular	• Objective: Provide SARS-CoV-2 wastewater detection assays on a digital PCR platform • Dynamic: "Complete wastewater solution" to combine Qiagen's QIAcuity digital PCR instruments and sample preparation with GT's molecular assays for detecting SARS-CoV-2 in wastewater
Mylab Discovery Solutions	Hemex Health	• Objective: Develop point-of-care diagnostic tests for COVID-19 and other diseases • Dynamic: India-based Mylab to develop assays with Hemex to provide its portable Gazelle POC testing • Firms to use fluorescence immunoassays and electrophoresis-based diagnostics to create tests for joint global launch in US, Europe and Asia

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DX Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
Fluidigm	Ultivue	• Objective: Comarket Fluidigm's Imaging Mass Cytometry technology platform • Dynamic: Leverage Ultivue's InSituPlex technology to offer comprehensive portfolio of solutions for biomarker discovery and drug development
Fluidigm	ImaBiotech	• Objective: Comarket Fluidigm's Imaging Mass Cytometry technology platform • Dynamic: ImaBiotech to use Fluidigm's Hyperion Imaging System to offer mass cytometry as one of its core technologies out of its GLP research facilities in US and Europe
AnPac Bio-Medical Science	Roche Pharmaceuticals China	• Objective: Combine respective cancer screening, diagnostic and treatment-guiding technologies into personalized product lines for Chinese market • Dynamic: AnPac, which has two clinical laboratories in China, to create product packages to improve personalized care test affordability in addition to personalized care • Roche to contribute its subsidiary Foundation Medicine's FoundationOne CDx comprehensive genomic profiling test to offer "complete solution"
Promega	Henlius Biotech	• Develop and commercialize a microsatellite instability (MSI) companion diagnostic for an investigational cancer drug in China • Dynamic: Use Promega's multiplex PCR-based technology for MSI status detection to develop test to identify patients likely to benefit from serplulimab, an anti-PD-1 monoclonal antibody developed by Henlius for MSI-high solid tumors that's currently under review by Chinese regulators
Burning Rock Biotech	Impact Therapeutics	• Objective: Develop companion diagnostics for Impact's anti-DNA damage repair therapies, beginning with its PARP inhibitor senaparib • Dynamic: Burning Rock to support global registrational trials and lead effort to secure CDx regulatory approval in multiple global regions
Lunaphore Technologies	University of Bern	• Objective: Research tumor budding in colorectal cancer • Dynamic: Use Lunaphore Comet immunostaining platform to study colorectal cancer tumor buds

Partner 1	Partner(s) 2+	Deal Summary
Switch Health	Anven Biosciences	• Objective: Develop new class of artificial antibodies for use in point-of-care SARS-CoV-2 tests • Dynamic: Leverage novel small molecules with monoclonal antibody-like properties that Anven is developing

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
InBios International	Chembio Diagnostics	• Products: InBios' SCoV-2 Ag Detect Rapid Test • Territory: US
Myriad Genetics	Noviscend	• Products: Myriad Genetics' EndoPredict, myRisk, myRisk – Hereditary and Single Gene Panel, myChoiceCDx, GeneSight and Prolaris tests • Territory: Canada • Exclusive
Oxford Nanopore Technologies	Avantor	• Products: Oxford Nanopore's MinIon nanopore sequencing devices and consumables • Territory: US and Europe, with Canada and other territories to be added in 2022

LICENSES

Licensor	Licensee	Deal Summary
Pacific Northwest National Laboratory	BICO company Scienion and its subsidiary Cellenion	Exclusive license to Nanodroplet Processing in One pot for Trace Samples (NanoPOTS) platform for commercial use
ERS Genomics	Cellular Engineering Technologies	Stem cell company gets nonexclusive access to ERS' CRISPR-Cas9 patents to create next-generation stem cells

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

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DX Deals, *from page 17*

GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Qiagen	US Department of Defense	$600,000 contract to expand manufacturing capacity of enzymatic reagents and reagent kits used in COVID-19 molecular tests
Thriva	UK Department of Health and Social Care	Two-year £124.4 million ($172.9 million) contract with blood-testing firm to enable delivery of at-home COVID-19 antibody tests for UK population

M&A Report: Illumina Makes Audacious Move by Completing Grail Acquisition Without Regulatory Approval, *from page 1*

biopsy firm it spun off in 2016 for $8 billion, including $3.5 billion in cash and $4.5 billion in shares of Illumina common stock. The acquisition agreement also provided Grail shareholders payments of 2.5 percent off the first $1 billion of Grail-related revenues and 9 percent off revenues above $1 billion per year over 12 years.

While the price was high—too high in the eyes of many investors—the deal strongly bolsters Illumina's position in early cancer diagnostics. Grail, which was itself getting set to go public, has just launched a highly touted blood-based screening test called Galleri that uses methylation sequencing for ultra-early detection of over 50 different types of cancers. Illumina's president and CEO described Galleri as being "among the most promising new tools in the fight against cancer," and said that the acquisition would help Illumina "transform cancer care using genomics and our NGS platform." Illumina, which currently owns 12 percent of its former spinoff, is also the supplier of the sequencers that Grail uses for performing its genomic tests. Bringing the two companies back together would put the testing and sequencing under one roof.

The Regulatory Hurdles

Of course, it was these very advantages that caused the regulatory problems with which Illumina is currently struggling. Soon after the deal was announced, the U.S. Federal Trade Commission (FTC) expressed

concerns over the new cancer genomics powerhouse's potential to dampen competition. But while Illumina was probably prepared for potential opposition from the FTC, it didn't expect a deal forged in the U.S. to encounter regulatory turbulence in Europe.

The company's rude awakening was served up in April 2021, when the European Commission (EC) Directorate-General of Competition announced that it planned to review the Grail acquisition under controversial new guidance that enables the Commission to demand notification of deals 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.

Illumina challenged the Commission's jurisdiction. But the Commission had time on its side and delayed its investigation in what Illumina described was an "attempt to run out the clock" before the deal closing deadline. Meanwhile, the Commission's opposition enabled the FTC to temporarily stand down by securing federal court approval to postpone legal action to block the deal pending resolution of the situation in Europe.

Illumina Hurls Down the Gauntlet

But Illumina decided that it wasn't going to wait for the regulators to come around. On August 18, the company announced that it has gone ahead and acquired Grail, which it will hold as a wholly-owned company that will operate independently while the EU reviews the deal. "The stakes here are high because, simply put, this deal saves lives," Illumina CEO Francis deSouza told investors.

Truer words were never spoken. The stakes are indeed high, especially for Illumina. In addition to opposing the deal, the Commission is now investigating whether to impose a fine of 10 percent of Illumina's consolidated annual turnover for closing without approval. Illumina may well go to court to challenge not just the fine but the Commission's jurisdiction over the deal. Of course, litigation is never a sure thing. And even if Illumina prevailed in court, it would still face potential opposition from the FTC. One way or another, Illumina may end up having to wind down the acquisition, resulting in a massive distraction and waste of money, time and energy.

LumiraDx Revises Terms of Its CAHC Merger

On August 23, point-of-care diagnostics firm LumiraDx and special purpose acquisition company CA Healthcare Acquisition said that they've revised the terms of the merger they previously announced in April. The new terms lower the enterprise value of the combined company from $5 billion to $3 billion. The move is an attempt to make the company, to be

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M&A Report: Illumina Makes Audacious Move by Completing Grail Acquisition Without Regulatory Approval, *from page 19*

called LumiraDx and listed on the Nasdaq under the ticker symbol LMDX, more attractive to investors. The deal is scheduled to close this fall.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Illumina	Grail	• Price: $8 billion, including $3.5 billion cash + $4.5 billion shares of Illumina common stock; Grail shareholders to also get payments of 2.5% off first $1 billion of Grail revenue + 9% off revenues above $1 billion per year over 12 years • Status: Closed without regulatory approval in US or EU, raising risk deal may have to be later unwound • Acquisition of former spinoff significantly expands Illumina's position in early cancer detection and producer of Galleri, with Grail to operate as standalone division within Illumina • Illumina may have to pay fines and unwind deal if regulators don't approve
Quest Diagnostics	National Laboratory Services	• Price: Undisclosed • Status: Closed • Quest acquires several NLS patient service centers in South Florida with testing services previously provided by NLS moving to Quest's Miramar, Florida, lab
AccessDx Holdings	2bPrecise	• Price: Undisclosed • Status: Closed • Acquisition of tech provider that integrates genetic and genomic test results into electronic health records, from EHR giant Allscripts Healthcare Solutions
Genetic Technologies	EasyDNA	• Price: $2 million cash up front + $1.5 million in Genetic Technologies American Depository Receipts + $500,000 in cash on first anniversary of closing • Status: Closed • Genetic Technologies acquires all websites, brand identities, lab testing and distribution agreements associated with General Genetics Corporation, which trades as EasyDNA
BioReference Laboratories (Opko subsidiary)	Roche	• Price: Undisclosed • Status: Closed • Acquisition of Roche's US Ariosa centralized lab prenatal testing business, which produces Harmony Prenatal Test, complements BioReference's GenPath specialty health division (which currently offers ClariTest Core assay)

Acquiring Company	Target(s)	Deal Summary
HiberCell	Genuity Science	• Price: Undisclosed all-stock deal • Status: Closed • Newly acquired provider of contract genomics and AI-driven data sourcing and analytics services for drug development becomes wholly-owned subsidiary of HiberCell
Clarified Precision	Interpares Biomedicine	• Price: Undisclosed • Status: Closed • Acquisition of molecular diagnostics firm and provider OncoGuardian genetic sequencing test
Labcorp	Ovia Health	• Price: Undisclosed • Status: Closed • Acquisition of a digital health platform offering women information and support with family planning, pregnancy and parenting with annual revenues of about $20 million
ProPhase Labs	Nebula Genomics	• Price: $14.6 million stock and cash • Status: Closed • Acquisition of direct-to-consumer genome testing firm, which will be integrated into new ProPhase Precision Medicine genetic testing subsidiary
Fulgent Genetics	CSI Laboratories	• Price: Undisclosed • Status: Closed • Acquisition of Georgia-based cancer testing lab, coupled with newly announced exclusive partnership to commercialize Helio Health's liquid biopsies tests in North America, bolsters Fulgent's position in molecular diagnostics and oncology testing markets
Veracyte	HalioDx	• Price: €260 million, including about €147 million in cash and up to approximately €113 million in stock (about $318 million total) • Status: Closed • Acquisition of French immuno-oncology diagnostics firm and maker of Immunoscore colorectal cancer test, which will become a subsidiary of Veracyte
Meridian Bioscience	Otsuka America Pharmaceutical	• Price: $20 million cash • Status: Closed • Meridian acquires Otsuka's BreathTek, a urea breath test for detection of Helicobacter pylori
Todos Medical	Provista Diagnostics	• Price: $1.25 million in cash upfront + $1.25 million cash payment before July 1 + $1.5 million in Todos common stock priced at $.0512 per share + $3.5 million convertible promissory note • Status: Closed • Israel-based Todos bolsters presence in U.S. market via acquisition of Provista's Videssa proteomic breast cancer test and a PCR- and ELISA-capable lab currently performing SARS-CoV-2 testing

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M&A Report,
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Acquiring Company	Target(s)	Deal Summary
MyHeritage	Filae	• Price: €30.5 million ($42.4 million) • Status: No closing date announced • MyHeritage to acquire 90.9 percent of share capital and 89.1 percent of voting rights of family history service based in France
Pacific Biosciences	Circulomics	• Price: Undisclosed • Status: Closed • Pac Bio acquires producer of kits for extracting high molecular weight DNA
Abcam	BioVision	• Price: $340 million • Status: No closing date announced • Acquisition of global supplier of products for research, diagnostics and drug discovery with revenues of $33.8 million in 2020, operating profit of $12.6 million and net assets of $21.9 million
Immunai	Nebion	• Price: Undisclosed • Status: Closed • Acquisition of Swiss bioinformatics firm bolsters Immunai's target discovery and drug development capabilities