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## DX Deals: Exact Sciences Ends Cologuard Co-promotion Partnership with Pfizer

One of the most dynamic and significant marketing arrangements in the genetic cancer lab testing market over the last few years is coming to an end. On Nov. 30, Exact Sciences told investors it is ending its collaboration with Pfizer to co-promote the firm's flagship Cologuard colorectal cancer screening test. Not only will Pfizer stop co-promoting Cologuard to labs and other health care providers, but will also stop selling the test.

### The Rise & Fall of the Cologuard Collaboration

In 2014, Cologuard became the first FDA-approved non-invasive DNA screening test for colorectal cancer.

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## M&A Report: The Top 10 Diagnostics Deals of 2021

As expected, M&A activity in the labs and medical diagnostics space bounced back in terms of both deal volume and value this year. There were seven different billion-dollar acquisitions in 2021, one more than in top-heavy 2020 where the relatively high number of 9-figure deals belied the significant drop in deal numbers. Here's a quick rundown of the M&A highlights of 2021.

### Top 10 Diagnostic M&A Deals of 2021 (By Deal Value)

Rank	Buyer	Target	Reported Price
1	Thermo Fisher	PPD	\$17.4 billion
2	Siemens Healthineers	Varian Medical Systems	\$16.4 billion all cash

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## LIR

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The American Cancer Society included the product in its 2018 colorectal cancer screening guidelines and many payors cover it. While it now has competition, Cologuard remains the clear leader in the at-home colorectal cancer screening market with over 254,000 providers having ordered the test since its launch.

Cologuard has also benefited from highly successful marketing. A turning point came in August 2018 when Exact Sciences announced that it had enlisted Pfizer to co-promote the test. The agreement, which ran through the end of 2021, enabled Exact to work with Pfizer's seasoned sales force and promotion network to persuade providers and health systems to use Cologuard. Exact maintained responsibility for all aspects of Cologuard manufacturing and lab operations, while Pfizer paid a share of the marketing expenses and received 50 percent of gross profits above an agreed baseline.

Although the collaboration has been largely successful, it remained unclear whether the arrangement would be renewed when it expired at the end of this year. [In announcing its Q3 2021 earnings](#), Exact noted that Cologuard sales for the quarter grew less than expected, attributing the disappointing sales to rising COVID-19 cases and "actions taken by Pfizer" in pulling its sales reps out of the field in late July and then reducing the size of its internal medicine team in mid-September. "Combined, the Delta variant and our partner Pfizer's decision caused our in-person sales calls to decrease 70 percent during this time period," according to Kevin Conroy, Exact's chairman and CEO.

A month earlier, Exact announced that it had nearly doubled its field sales team to 850 by hiring approximately 400 new sales representatives, many of whom were former Pfizer sales reps assigned to promoting Cologuard that had lost their jobs. Exact also let it be known that it was in talks with Pfizer about making significant changes to the co-promotion agreement up for renewal.

But instead of renewing, Exact has decided to end the co-promotion agreement. The firms will work together to wind down the arrangement over the first three quarters of 2022. In its recent SEC Form 8-K, Exact disclosed that it will pay Pfizer \$35.9 million in three installments during 2022, and that it will no longer be obligated to pay the pharmaceutical giant royalties or other fees (other than certain media and advertising fees) for promoting Cologuard before Nov. 30. Pfizer will also continue to purchase advertising for Cologuard on Exact's behalf through the third quarter of 2022, while supporting the transition of ad purchasing responsibilities to Exact.



Here's a summary of some of the other key strategic diagnostic deals announced in December 2021:

### STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
SkylineDx	VIB (Belgian life science research institute)	<ul style="list-style-type: none"> <li>Objective: Develop new molecular diagnostics for unmet medical needs</li> <li>Dynamic: Three-year partnership to combine VIB's single-cell analysis and biomarker discovery expertise with SkylineDx's global network of clinical centers and physicians</li> </ul>
LumiraDx	Audere	<ul style="list-style-type: none"> <li>Objective: Offer at-home COVID-19 specimen collection kit for use with LumiraDx's SARS-CoV-2 test</li> <li>Dynamic: Integrate Audere's testing solution, HealthPulse@home into lab systems using LumiraDx's SARS-CoV-2 RNA STAR Complete test</li> </ul>
Illumina	Gretel (data privacy firm)	<ul style="list-style-type: none"> <li>Objective: Generate artificial genomic data for use in medical research</li> <li>Dynamic: Firms to provide researchers statistically accurate, artificial versions of genomic datasets that meet GDPR, CCPA and other privacy laws</li> </ul>
Qiagen	Denovo Biopharma	<ul style="list-style-type: none"> <li>Objective: Develop companion diagnostic (CDx) test to identify diffuse large B-cell lymphoma (DLBCL) patients expressing a biomarker</li> <li>Dynamic: Qiagen to develop test capable of detecting the Denovo Genomic Marker 1 (DGM1) in DLBCL patients, as well as a PCR CDx for use on its Rotor-Gene Q MDx instrument and seek FDA premarket approval for new test</li> </ul>
Mainz Biomed	Ganzimmun Diagnostics	<ul style="list-style-type: none"> <li>Objective: Commercialize Mainz Biomed's ColoAlert colorectal cancer detection test</li> <li>Dynamic: Mainz Biomed to co-brand ColoAlert with Ganzimmun and sell its customized PCR assay kits to German stool lab on an on-demand basis</li> </ul>
BostonGene	NEC	<ul style="list-style-type: none"> <li>Objective: Offer BostonGene's Tumor Portrait tests outside US for first time</li> <li>Dynamic: Provide test to hospitals in NEC's home country of Japan and expand to other, unspecified international markets later</li> <li>In 2020, firms began collaboration to analyze molecular profiles and tumor microenvironments of cancer patients enrolled in NEC's clinical trials</li> </ul>

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Partner 1	Partner(s) 2+	Deal Summary
OncoHost	Heidelberg University Hospital (Germany)	<ul style="list-style-type: none"> <li>Objective: Discover new lung cancer biomarkers</li> <li>Dynamic: OncoHost to collaborate with Lung Biobank Heidelberg to collect and analyze blood samples to identify novel biomarkers and therapeutic targets for lung cancer</li> </ul>
Akoya Biosciences	PathAI	<ul style="list-style-type: none"> <li>Objective: Identify and validate biomarkers for predicting patient response to cancer immunotherapies</li> <li>Dynamic: Combine Akoya's Phenoptics spatial biology platform and Advanced Biopharma Solutions (ABS) services with PathAI's artificial intelligence tools to identify predictive biomarkers</li> </ul>
Pacific Biosciences	University of California, Los Angeles	<ul style="list-style-type: none"> <li>Objective: Sequence patients with rare, undiagnosed pediatric diseases</li> <li>Dynamic: Study the effect of combining PacBio's HiFi long-read whole-genome sequencing and RNA isoform sequencing (Iso-Seq) on diagnostic yield in rare disease cases</li> </ul>
Caris Life Sciences	Redx Pharma	<ul style="list-style-type: none"> <li>Objective: Clinical trial recruitment</li> <li>Dynamic: Leverage Caris' whole-transcriptome and whole-exome sequencing platform and right-in-time clinical trial solutions to boost US patient accrual for Redx's Phase II trial of RXC004 investigational Porcupine inhibitor in colorectal cancer</li> </ul>
Biodesix	Spesana	<ul style="list-style-type: none"> <li>Objective: Automate use of molecular diagnostics in clinical workflows for lung cancer</li> <li>Dynamic: Spesana to integrate electronic ordering of Biodesix tests, including Nodify Lung and IQlung and provide clinical education and virtual engagement platform</li> </ul>
LabCorp	ConcertAI	<ul style="list-style-type: none"> <li>Objective: Optimize precision oncology clinical trials</li> <li>Dynamic: LabCorp to use ConcertAI's artificial intelligence and real-world data platforms to design more effective and inclusive trials</li> </ul>
Siemens Healthineers	Freenome	<ul style="list-style-type: none"> <li>Objective: Identify blood-based biomarkers for breast cancer detection</li> <li>Dynamic: Use epigenetic, proteomic, genomic, immunologic, and other data to identify blood markers to complement current imaging technologies for early diagnosis</li> </ul>
Genetron	AstraZeneca R&D	<ul style="list-style-type: none"> <li>Objective: Jointly develop next-generation sequencing-based tumor-informed minimal residual disease tests for various solid tumor types in China</li> <li>Dynamic: Firms to invest capital to support validation of these personalized MRD assays for cancer monitoring and recurrence assays</li> </ul>

Partner 1	Partner(s) 2+	Deal Summary
GE Healthcare	Cambridge and Cambridge University Hospitals (UK)	<ul style="list-style-type: none"> <li>Objective: Develop artificial intelligence-based app for precision cancer care</li> <li>Dynamic: Integrate clinical, imaging and genomic data from multiple sources into single interface for use by oncologists, surgeons, radiologists, pathologists and clinical nurse specialists to create personalized treatment plans for each patient</li> </ul>
Radiomics	OncoDNA	<ul style="list-style-type: none"> <li>Objective: Improve the biological understanding and treatment of non-small cell lung cancer (NSCLC)</li> <li>Dynamic: Combine firms' expertise in machine learning-enabled analysis of medical images and molecular biomarker evaluation within the prospective Measure Lung Cancer Biology and Treatment Response via Imaging trial, dubbed SALMON, to validate Radiomics' artificial intelligence-based medical imaging analysis technology and create a "radiomics atlas of oncogenic biomarkers"</li> </ul>

### DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
DnaNudge	DAM Health	<ul style="list-style-type: none"> <li>Products: DnaNudge's COVID-19 PCR test</li> <li>Territory: UK, Spain, Mexico</li> </ul>
Dotz Nano	ScienceVision	<ul style="list-style-type: none"> <li>Products: Dotz Nano's point-of-care SARS-CoV-2 testing platform, the Dotz Mega-Diagnostic Platform</li> <li>Territory: Malaysia</li> </ul>
Dotz Nano	World Siam Group	<ul style="list-style-type: none"> <li>Products: Dotz Nano's point-of-care SARS-CoV-2 testing platform, the Dotz Mega-Diagnostic Platform</li> <li>Territory: Thailand</li> </ul>
Cytена	Applitech Pharmaceutical Equipment Technology	<ul style="list-style-type: none"> <li>Products: Cytena's single-cell isolators</li> <li>Territory: China</li> <li>Two-year deal</li> </ul>

### LICENSES

Licensor	Licensee	Deal Summary
Fred Hutchinson Cancer Research Center	EpiCypher	Co-exclusive license to CUT&RUN (Cleavage Under Targets and Release Using Nuclease) and CUT&Tag chromatin profiling technologies

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## GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Yourgene Health	UK Department of Health and Social Care	Yourgene Genomic Services business to provide COVID-19 winter surge testing in UK through March 31, 2022

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# FDA WATCH

## Agency Unveils Guidance for Full Approval of SARS-CoV-2 Tests

Even though the COVID-19 public health emergency (PHE) can't last forever, according to US chief medical advisor Anthony Fauci, coronavirus may never completely disappear from the face of the earth. And that means that producers of tests detecting the SARS-CoV-2 virus should expect to be in it for the long haul. With that in mind, the FDA released [draft guidance](#) on making the transition from Emergency Use Authorization (EUA) to full marketing and regulatory approval.

### SARS-CoV-2 Tests Have Traveled the EUA Pathway

Because SARS-CoV-2 was a totally unknown virus, there were no tests designed to detect it when the PHE began. As a result, FDA authorized, and continues to authorize, SARS-CoV-2 tests on an emergency basis using its authority (under Section 564 of the Food, Drug & Cosmetics Act) to authorize unapproved products in the event of an emergency. Since the PHE began, more than 300 SARS-CoV-2 diagnostic products have reached the US market via the EUA pathway.

EUA authorization remains valid for as long as the PHE that prompted it remains in effect. While it seems unimaginable that this PHE will ever come to an end, some form of normalcy is bound to return sooner or later. So, if the virus is still around when the Department of Health and Human Services (HHS) declares an end to the COVID-19 PHE, there may not be enough fully authorized tests that labs can use to diagnose it.

### From EUA to Full Regulatory Approval

The point of the new FDA draft guidance is to prevent disruption of test supplies and provide for an orderly and timely transition from PHE to normal operations. The guidance says that SARS-CoV-2 tests with

EUA approval produced by manufacturers that don't intend to seek full marketing approval and that have already been distributed may be used for two years after the EUA termination date, or until they expire.

But the key part of the guidance is addressed to manufacturers who do plan to seek full approval for their tests. FDA calls on those manufacturers to include in their submissions a transition plan for dealing with products they've already distributed. The transition plan should include:

- ▶ The estimated number of tests currently in distribution in the US;
- ▶ An explanation of how the manufacturer will dispose of products that it's already distributed if FDA denies its application for marketing approval; and
- ▶ An explanation of how the manufacturer will deal with previously distributed products if FDA approves the marketing submission.

If the manufacturer proposes to leave the already distributed products in place, the transition plan should explain the rationale for doing so and set out a process for notifying providers, health care facilities, distributors, patients and consumers of the product's regulatory status.

The guidance also says the plan should provide for what happens if a submission is denied—with already distributed products left on the market—by including a process and timeline for both restoring those devices to the previously FDA-cleared or approved version and “providing publicly available labeling that accurately describes the product features and regulatory status.” The plan should also include a maintenance plan for distributed products.

In addition, there should be a process and timeline for providing users updated labeling or components reflecting changes made to the product if a marketing submission is approved, according to the guidance.

If the manufacturer has submitted its test for marketing approval and had it accepted by the FDA before the EUA termination date, the guidance adds, the test may continue to be distributed, with updated labeling, until the agency reaches a final decision.



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

#### New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
GenBody America	Expanded EUA for use of GenBody COVID-19 Ag antigen test kit for testing asymptomatic individuals
University of California, San Diego	EUA for UCSD EXCITE COVID-19 Test at EXCITE labs

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Manufacturer(s)	Product
Applied BioCode	EUA for BioCode CoV-2 Flu Plus Assay
Nano-Ditech	EUA for point-of-care Nano-Check COVID-19 Antigen Test
Pattern Bioscience	Breakthrough device designation for Pneumonia Action Panel
Thermo Fisher Scientific	Premarket approval for Oncomine Dx Target Test as companion diagnostic for Janssen Biotech's targeted lung cancer treatment amivantamab-vmjw (Rybrevant)
OPKO Health	510(k) clearance for 4KScore prostate cancer test
Foundation Medicine (Roche)	510(k) clearance for FoundationOne CDx as companion diagnostic for two groups of BRAF inhibitor therapies for melanoma
Audere	EUA for The HealthPulse@home kit for self-collection of anterior nasal swab specimens
Immunexpress	510(k) clearance for SeptiCyte RAPID sepsis assay
Qiagen and DiaSorin	510(k) clearance for LIAISON QuantiFERON-TB Gold Plus assay for latent tuberculosis testing on DiaSorin's LIAISON XS benchtop platform
Siemens Healthineers	510(k) clearance for Atellica CH Enzymatic Creatinine 3 (ECre3) assay for quantitative determination of creatinine
Roche	510(k) clearance for cobas Cdiff real-time PCR nucleic acid test run on firm's cobas Liat point-of-care system
Abbott Laboratories	510(k) clearance for BCG2 assay for quantitation of albumin
BioMérieux	510(k) clearance for ETest Fosfomycin manual assay for antimicrobial susceptibility
BioMérieux	510(k) clearance for BioFire COVID-19 Test 2
Becton Dickinson	510(k) clearance for Kiestra IdentifA specimen preparation system and BD Kiestra Laboratory Automation Solution
InBios International	EUA for SCoV-2 Ag Detect Rapid Self-Test, over-the-counter SARS-CoV-2 home antigen test

### New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

#### NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
LumiraDx	Point-of-care SARS-CoV-2 & Flu A/B Antigen Test
Avacta	AffIDX SARS-CoV-2 antigen assay for use as consumer self-test
Becton Dickinson	MX, a new instrument component of firm's BD Cor system
Roche	Cobas SARS-CoV-2 Qualitative test for use with saliva samples
Roche	Four molecular infectious disease tests for use on firm's new cobas 5800 instrument
Roche	Combo SARS-CoV-2 and influenza A/B rapid antigen test

Manufacturer(s)	Product(s)
Eurobio Scientific	EBX 047 test, Eurobioplex SARS-CoV-2 Fast Screening and Variants Detection (SVD)
Genedrive	Rapid point-of-care molecular COVID-19 test
Eufomatics	OmnomicsNGS variant interpretation and reporting software
Qiagen	QuantifERON SARS-CoV-2 assay
DNA Script	SYNTAX enzymatic DNA synthesis platform

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Becton Dickinson	Australia	MX, a new instrument component of firm's BD Cor system
CoSara Diagnostics	India	SARAPLEX Flu A/Flu B/COVID-19 (ABC) multiplex RT-PCR test
Chembio Diagnostics	South Africa	DPP SARS-CoV-2 Antigen test
Novacyt	UK	Genesig COVID-19 Real-Time PCR assay



## COVID Testing: Omicron Surge Creates Nationwide Shortage of COVID-19 Tests

Even before Omicron, demand for COVID-19 tests was on a major rise. The emergence of the new highly transmissible variant has now stretched testing supplies and capabilities to the breaking point. Drug stores and major retailers are sold out of rapid, point of care antigen tests. Lines for PCR tests stretch around the block in many cities across the country. While government help is on the way, especially on the rapid test front, shortages are likely to last well into the new year.

### The COVID-19 Test Shortage

It's hard to believe that a year ago at this time, vaccines were being rolled out and many manufacturers were scaling down their COVID-19 capacities to focus on normal core business. But the recent outbreaks have created the kinds of shortages and pressures on testing supplies that existed in the early months of the pandemic. And it's going to get worse before it gets better. At its peak, roughly 2.4 million COVID-19 tests were performed in the US each day, according to the Department of Health and Human Services (HHS). But, because Omicron is spreading more rapidly than

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expected, the agency estimates the need for tests to reach between 3 and 5 million tests per day by early February.

Of course, pressure on COVID-19 testing capacity is nothing new. Supply shortages have bedeviled COVID-19 testing from the moment the public health emergency (PHE) began as the pandemic exposed the fundamental flaws and lack of coordination of the national testing “system,” and produced shortages in key supplies, raw materials and, above all, health care workers.

The situation seemed to have stabilized earlier this year. As case rates fell and vaccination rates climbed, government and health leaders began to look to the future. The basic strategy: Promote widespread distribution and utilization of rapid antigen tests providing results in 15 minutes or less for preventive screening at home while reserving gold standard PCR molecular testing performed by offsite labs for symptomatic cases. But the one-two-punch of Delta and Omicron has overwhelmed the system and disrupted supplies of both kinds of tests.

#### At-Home PCR Tests Are Available but Expensive

While most COVID-19 rapid tests are antigen tests that detect the antigens secreted by antibodies the body creates to fight the virus, there are also at-home tests that use more accurate PCR molecular technology to directly detect SARS-CoV-2 RNA. But at-home molecular test kits are also more expensive. For example, Cue Health’s Cue Reader costs \$250—and that’s just for the reader. A three-pack of tests will set you back \$225. Detect offers a cheaper starter kit containing one PCR test and a reusable hub at about \$75 with additional tests selling at \$50 a pop.

#### The Federal Response

Unlike its predecessor, the Biden administration has made widespread lab testing, particularly rapid testing, a centerpiece of its COVID-19 response strategy. This September, the president outlined a broad [action plan](#) providing for accelerated development and use of rapid and at-home tests. Drawing on the federal government’s powers to mobilize private industry under the Defense Production Act (DPA), the plan included government purchase of nearly \$2 billion worth of rapid point-of-care and over-the-counter (OTC) at-home tests—280 million total tests—from multiple manufacturers.

To expand test access, the plan also promoted cooperation with private business, including major retailers Walmart, Amazon and Kroger for the sale of at-home rapid COVID-19 tests to consumers at cost for three months. In addition, the government mandated that states’ Medicaid

cover at-home tests for free and not establish “arbitrary barriers” to those seeking care.

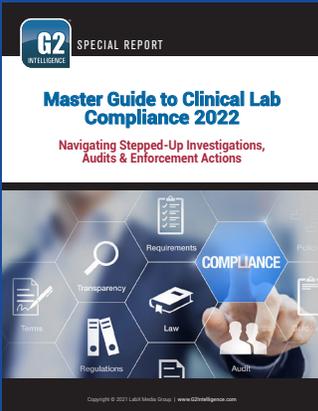
Meanwhile, the FDA has played a role by providing Emergency Use Authorization (EUA) for eight different OTC COVID-19 tests, including five since the administration published its September action plan. There were no such tests on the market when the administration took office.

### The New Private Payor Coverage Mandate for Rapid Tests

On Dec. 2, the Biden administration took additional steps to promote wider use of at-home COVID-19 testing in response to Omicron. Among other things, the new plan requires private health insurers to cover 100 percent of the cost of at-home tests purchased by plan members. Individuals who purchase OTC COVID-19 diagnostic tests will then be able to seek reimbursement from their group health plan or health insurance issuer and have insurance cover the cost for the remainder of the public health emergency. **Limitation:** Tests purchased before the policy takes effect won't be covered retroactively. HHS is expected to issue guidance on which tests should be covered and at what frequency in mid-January.

The Biden plan includes other measures designed to quadruple the number of rapid, at-home COVID-19 tests available, as compared to late summer, including by:

- ▶ Adding \$1 billion to the previous \$2 billion outlay for rapid tests;
- ▶ Making free rapid, at-home COVID-19 tests available to individuals without private insurance that can be picked up at locations like rural clinics and community health centers and then used at home; and
- ▶ Doubling its September commitment to distribute free tests to community sites from 25 million to 50 million.



## What will *your* lab compliance program look like to a Judge?

### The Master Guide to Clinical Lab Compliance

What You Need to Know and Do to Protect Your Lab against False Claims, Anti-Kickback, Stark Law and Other Fraud and Abuse Liability Risks

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Rank	Buyer	Target	Reported Price
3	Danaher	Aldevron	\$9.6 billion
4	Illumina	Grail	\$8.0 billion cash + stock
5	PerkinElmer	BioLegend	\$5.25 billion all cash
6	DiaSorin	Luminex	\$1.8 billion all cash
7	Roche	GenMark Diagnostics	\$1.8 billion all cash
8	Pacific Biosciences	Omnio	\$800 million cash + stock
9	Hologic	Mobidiag	\$795 million cash + debt assumption
10	PerkinElmer	Oxford Immunotec	\$591 million cash

### Biggest Deal (by Dollar Value): Thermo Fisher's \$17.4 Billion Acquisition of PPD

Having just narrowly failed to acquire Qiagen months before the public health emergency and massive demand for new COVID-19 tests, Thermo Fisher Scientific rebounded quite nicely by posting the year's biggest deal—the \$17.4 billion cash acquisition of PPD, which closed this month. The acquisition of the global clinical research and lab services firm whose operations in 50 different countries generated total revenues of \$4.7 billion in 2020 enriches the value that Thermo Fisher can deliver to its extensive network of pharmaceutical and biotech customers. The Massachusetts-based diagnostics powerhouse followed up with a \$591 million acquisition of molecular PCR test firm Mesa Biotech in March.

### Most Surprising Deal: Illumina's Acquisition of Grail

Illumina's move to acquire former liquid biopsy spinoff Grail for \$8 billion (including \$3.5 billion in cash and \$4.5 billion in shares of Illumina common stock) was a head scratcher from the moment it was announced in September 2020. But the real shocker was how and when it closed. While regulatory turbulence wasn't totally unexpected, the fact that it came mostly from Europe in the form of review from the European Commission (EC) Directorate-General was a stunner. Staring a \$300 million termination fee in the face while the EC dragged its feet, Illumina threw caution to the wind and closed the deal in August. It's now holding Grail as a wholly-owned company that will operate independently while it awaits word from the EU. Assuming it doesn't have to be unwound, acquiring Grail and its highly touted blood-based cancer screening Galleri test significantly strengthens Illumina's position in early cancer diagnostics.

### Most Active Company: PerkinElmer

No company was more aggressive in the diagnostics M&A space in 2021 than PerkinElmer. Awash in COVID-19 testing cash, the life sciences and genetics test giant made no fewer than four strategic deals during the year, including two of the top 10: the \$5.25 billion acquisition of BioLegend, the largest in company history (at #5) and the acquisition of tuberculosis detection test firm Oxford Immunotec for \$591 million (#10).

On May 13, PerkinElmer announced that it had reached an agreement to buy Nexcelom Bioscience for \$260 million in cash. Founded in 2003, Nexcelom produces tools and instruments for cell counting and analysis, as well as fit-for-purpose cell counting method selection and development instruments that follow ISO cell counting standards for use in development of cell, gene, and immuno-oncology therapies, virology drugs and vaccines. Four days after the Nexcelom buy, PerkinElmer made another bold move by agreeing to shell out \$155 million in cash for Immunodiagnostic Systems (IDS) to bolster its immunodiagnostics business.



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

#### MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Thermo Fisher Scientific	PPD	<ul style="list-style-type: none"> <li>Price: \$17.4 billion cash + assumption of roughly \$3.5 billion of net debt</li> <li>Status: Expected to close by end of 2021</li> <li>Acquisition of global provider of clinical research and lab services for pharmaceutical and biotech industry, which will be merged into Thermo Fisher's laboratory products and services business unit</li> </ul>
Quidel	Ortho Clinical Diagnostics	<ul style="list-style-type: none"> <li>Price: \$6 billion in cash and stock + assumption of Ortho's \$2 billion debt</li> <li>Status: Expected to close in H1 2022</li> <li>Firms anticipate combined cost synergies of \$90 million by end of year three, and revenue synergies greater than \$100 million by 2025 driven by operational efficiencies, shared administrative functions and supply chain optimization</li> </ul>

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Acquiring Company	Target(s)	Deal Summary
LabCorp	Personal Genome Diagnostics	<ul style="list-style-type: none"> <li>• Price: \$450 million in cash + \$125 million in additional payments based on performance milestones</li> <li>• Status: Expected to close in H1 2022</li> <li>• Acquisition of cancer genomics firm expands LabCorp's next-generation sequencing genomic profiling capabilities and bolsters liquid biopsy assets, allowing for offering kit-based options enabling hospitals and labs to run tests internally</li> </ul>
Roche	TIB Molbiol Group	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Roche completes share purchase agreement to acquire 100 percent of TIB Molbiol's outstanding shares</li> <li>• Acquisition of TIB Molbiol, which will operate as a diagnostics division subsidiary, expands Roche's molecular diagnostic solutions</li> </ul>
Quest Diagnostics	LabTech Diagnostics	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• Quest bolsters presence in South by acquiring provider of lab services in South Carolina, North Carolina, Georgia and Florida</li> </ul>
Hologic	Bolder Surgical	<ul style="list-style-type: none"> <li>• Price: \$160 million</li> <li>• Status: Closed</li> <li>• Hologic advances strategy to build out its surgical franchise by acquiring provider of advanced energy vessel sealing surgical devices</li> </ul>
Becton Dickinson	Scanwell Health	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• BD bolsters position in digital at-home testing for infectious diseases by acquiring provider of smartphone-based at-home tests</li> </ul>
Co-Diagnostics	Idaho Molecular and Advanced Conceptions	<ul style="list-style-type: none"> <li>• Price: Roughly \$50 million for about 4.72 million shares of newly issued common stock and 465,000 common stock warrants</li> <li>• Status: Expected to close by year's end</li> <li>• Co-Diagnostics has been collaborating with 2 private biotech firms to develop YourTest, an at-home/point-of-care diagnostic device, based on Co-Diagnostics' Eikon PCR platform</li> <li>• Co-Diagnostics acquires rights to all existing and future assets and intellectual property related to the technology as it begins principle and large-scale manufacturing of the device</li> </ul>

Acquiring Company	Target(s)	Deal Summary
Castle Biosciences	Cernostics	<ul style="list-style-type: none"> <li>• Price: \$30 million upfront (either all in cash or \$20 million in cash and \$10 million in Castle common stock) + up to \$50 million more in cash and/or common stock based on Cernostics' achievement of milestones in 2022</li> <li>• Status: Closed</li> <li>• Acquisition of company specializing in spatial biology and artificial intelligence-driven image analysis of tissue biopsies</li> </ul>
Bico	Biosero	<ul style="list-style-type: none"> <li>• Price: \$165 million, including roughly \$103.9 million in cash, \$34.7 million in consideration shares and \$26.4 million in combined cash and stock to be paid out over the next three years</li> <li>• Status: Acquisition agreement signed but no closing date announced</li> <li>• Acquisition of lab workflow software provider enables Bico to bolster its software capabilities and offer customers fully automated and connected lab workflow solutions</li> </ul>
Northwest Pathology	Avero Diagnostics (Progenity affiliate)	<ul style="list-style-type: none"> <li>• Price: \$10.9 million</li> <li>• Status: Closed</li> <li>• Progenity exits lab business and stems \$28 million in annual cash losses by selling off Avero, its diagnostics affiliate</li> </ul>
CellCarta	Biogazelle	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• Acquisition of Belgian genomic testing firm enables Canadian precision medicine lab services provider to secure clients in fields with high demand in genomic analysis, such as immunology and cell and gene therapy</li> </ul>
Eurofins Scientific	Genetic Lab	<ul style="list-style-type: none"> <li>• Price: Share purchase agreement with Genetic Lab parent firm Transgenic at undisclosed price</li> <li>• Status: No closing date announced</li> <li>• Acquisition of Japanese molecular biology-based testing provider for diagnostics, biomarker development and drug discovery</li> </ul>
Rebus Biosystems	EEL Transcriptomics	<ul style="list-style-type: none"> <li>• Price: Undisclosed</li> <li>• Status: Closed</li> <li>• Rebus acquires intellectual property related to an enhanced electric, or EEL, fluorescence <i>in situ</i> hybridization assay, which can now be run on firm's Esper platform</li> </ul>

Continued on page 16

■ M&A Report: The Top 10 Diagnostics Deals of 2021, from page 15

Acquiring Company	Target(s)	Deal Summary
Todos Medical	NLC Pharma	<ul style="list-style-type: none"> <li>Price: \$2.2 million in initial funding + \$2 million in cash over 15 months + 13.333 million ordinary shares of Todos' stock + single digit net royalties</li> <li>Status: Expected to close before year end</li> <li>Todos to acquire all 3CL protease biology-related assets from NLC Pharma and form a majority-owned subsidiary called 3CL Sciences to leverage those assets to develop diagnostics, therapeutics and dietary supplements</li> </ul>
Discovery Life Sciences	In Vitro ADMET Laboratories	<ul style="list-style-type: none"> <li>Price: Undisclosed</li> <li>Status: Closed</li> <li>Acquisition of contract research firm fortifies Discovery's position in research biospecimen and biomarker development market</li> </ul>



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- GENETIC TESTS:** New Guidelines Advise Against Using Polygenic Risk Scores for Routine Patient Management
- TESTING STRATEGY:** COVID-19 Retesting Should Be Pushed Back to 4 Weeks to Give Virus Sample Times to Shed

**Emerging Tests: COVID-19 Antigen Tests Are Ready for Mass Utilization but Antigen Test Reporting is Not**  
 It will take something on the order of 200 million COVID-19 screening tests per month, as opposed to the 25 million being performed currently, to safely reopen the U.S., estimates a new paper from Duke University. Because of their low costs, scalability and speed, antigen tests may play a crucial role in meeting this unprecedented level of demand, particularly in nursing homes, educational and workplace settings. However, if antigen testing is to be the answer, there is one significant problem that will need to be addressed: lack of reliable and consistent test data reporting.

**The Promise of Antigen Testing**  
 What the country and world need right now are point-of-care tests that can deliver accurate results at cost-effective prices that can be

**Testing Strategy: New Study Shows Saliva-Based SARS-CoV-2 Test to Be at Least as Accurate as Swab Tests**  
 Saliva-based tests could go a long way in relieving the supplies shortage that has hampered COVID-19 testing efforts. The question, though, is whether saliva samples yield results as accurate as those produced by respiratory samples obtained by nasal and nasopharyngeal (NP) swabs. The good news is that a new study suggests that at least one of these saliva-based tests is every bit as reliable as the tests based on samples obtained by swabs.

**The Diagnostic Challenge**  
 Real-time reverse transcription polymerase chain reaction (RT-PCR) testing for qualitative detection of SARS-CoV-2 nucleic

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- FDA WATCH:** FDA Pulls the Plug on EUA Review of COVID-19 LDTs
- OPINION:** CDC Cautions Down on Providers Who Don't Provide Individuals' Timely Access to PPE

**Enforcement Trends: Labs Caught Up in Massive National Telemedicine Takedown**  
 So much for the pandemic's dulling the momentum of federal fraud enforcement. Dubbed "Operation Rubber Stamp," the new nationwide enforcement action revealed by the Department of Justice (DOJ) on Sept. 29 is the largest "take-down" in Department history involving 54 federal districts, 345 defendants, including over 100 doctors, nurses and other licensed medical professionals, and \$6 billion in false claims. And, while not necessarily the primary target, medical labs have been pulled in to the "Rubber Stamp" dragnet.

**The Takedown Target**  
 Of the \$6 billion in false and federal claims submitted to federal health care programs and private insurers involved

**Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy**  
 Bottom Line on Top: Make it all about fitness for duty, rather than zero tolerance

Although it may sound good, zero tolerance may not be the best foundation on which to build a legally enforceable workplace substance abuse policy. This is especially true in states that have legalized recreational marijuana. The reason drug and alcohol use and impairment in the workplace cannot be tolerated isn't so much that it's illegal, but because it renders employees unfit to do their job. In addition to undermining the productivity you're entitled to expect from your employees, this inflexible-for-duty may pose a health and safety dangers to not only the employee who's high but others in the lab. Here are 14 things to include in your Substance Abuse and Fitness for Duty Policy, along with a Model Policy you can adapt for your own use.

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**COVERING GOVERNMENT POLICY FOR DIAGNOSTIC TESTING & RELATED MEDICAL SERVICES**

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- Special Report:** The 5 Things Labs Also Need to Know About the Biden COVID-19 Testing Plan
- Focus On:** How the Transition from Trump to Biden Will Affect Federal Regulation and Reimbursement
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- FDA Watch:** FDA to Issue Emergency Use Authorization for Multi-Analyte Respiratory Panels During the Pandemic
- Whitefield News:** California Case Shows Why Paying Specimen Collection Fees of Any Amount Are a Liability Risk
- Technology:** CMS Proposes Clarified Medicare Coverage "Reasonable and Necessary" Criteria for Breakthrough Devices

**Special Report: The 5 Things Labs Need to Know about the Biden COVID-19 Testing Plan**  
 Testing labs on the front lines of the COVID-19 battlefield are getting federal reinforcements. And it's not just money. The new administration is taking an entirely new line of attack that differs from the approach of its predecessor in almost every conceivable way. Perhaps the starkest contrast is with regard to urgency, with the new president unveiling his COVID-19 testing strategy on his very first day in office. Here's a quick overview of the five key elements of the Biden plan, aka, National Strategy for COVID-19 Response and Pandemic Preparedness.

**1. Provide More Money**  
 Let's start with money. The administration's proposed \$1.9 trillion American Rescue Plan includes \$50 billion to expand COVID-19 testing by providing funding to purchase rapid tests, expand lab capacity and support regular testing efforts of schools and local governments.

**Focus On: How the Transition from Trump to Biden Will Affect Federal Regulation and Reimbursement**  
 "Meet the new boss... same as the old boss."  
 The Who's "Won't Get Fooled Again" is a rock classic; but as far as U.S. presidents and federal regulations are concerned, the "new boss" is almost never the same as the "old boss." The typical pattern: The outgoing administration recognizes that its opportunity to impose its political agenda is running out and generates a final spasm of new regulation; the incoming

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