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Industry Buzz: Antitrust Regulators Derail Plans for Illumina-Grail Cancer Genomics Powerhouse

You could almost hear the gasp that emanated from the cancer genomics market when Illumina announced plans to shell out $8 billion--$3.5 billion in cash and $4.5 billion in common shares—to re-acquire Grail, the liquid biopsy firm it spun off in 2016. Acquiring Grail's suite of multi-cancer early detection (MCED) tests, including the highly touted blood-based screening test called Galleri that uses methylation sequencing for ultra early detection of over 50 different types of cancers scheduled to launch in 2021, would significantly

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DX Deals: Eurofins Teams with Uber for Home Delivery of COVID-19 Test Kits

At-home COVID-19 testing and sample collection is becoming so big that it's drawing players from outside the lab testing market. And it's not just the Walgreens, Walmarts, Amazons and other retailers that have been established in the direct-to-consumer (DTC) diagnostics market well before the pandemic began. Among the most recent of the new arrivals to the DTC at-home COVID testing space is Uber. On April 26, the health care arm of the omnipresent rideshare company announced that it's teaming up with Clinical Enterprise, Inc. d/b/a empowerDX, a US subsidiary of Luxembourg-based Eurofins Clinical Diagnostics, to provide on-demand delivery service of at-home COVID-19 testing kits to consumers.

The empowerDX-Uber Collaboration

empowerDX is an online shop affiliated with CLIA-certified

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bolster Illumina's position in multi-cancer diagnostics. And for that very reason, the deal is now in serious jeopardy.

FTC Sues to Block Illumina's Grail Acquisition

At the end of March, the US Federal Trade Commission (FTC) said that it planned to go to court seeking a temporary restraining order to stop the deal pending an administrative trial to determine whether it's kosher under antitrust laws. The FTC claims that the acquisition will suppress MCED innovation in the US and make Illumina's next-generation sequencing (NGS) platforms the only viable option for such tests. According to the agency, this would put Illumina in the position to raise prices charged to Grail competitors for NGS instruments and consumables thereby also impede their research and development efforts.

Regulatory Obstacles in Europe

Apparently, the FTC isn't the only with such concerns. On its face, Illumina's acquisition of Grail is a US affair with only indirect effects on non-US markets. But on April 20, even as the US administrative trial was scheduled to begin, a new regulatory obstacle unexpectedly emerged from the EU. Specifically, the European Commission's Directorate-General of Competition announced that it plans to review the deal under its controversial new guidance that allows the Commission to demand notification of a deal even when the member states involved don't.

"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. Responding in a statement of its own, Illumina CEO Francis deSouza expressed the company's belief that the European authorities lack jurisdiction to review the acquisition.

Takeaway

Illumina remains defiant and determined to go through with the Grail acquisition, which has been approved by the board of directors of both companies. The company denies the charges of throttling competition, insists that the deal is in the best interest of patients and promises to vigorously defend it in court.

But Illumina has been down this road before. In January 2020, regulatory opposition from the FTC and authorities in UK forced the San Diego-based sequencing company to drop its planned $1.2 billion acquisition of Pacific Biosciences. So, it's hardly surprising that investors and analysts remain skeptical over the likelihood that the Grail deal will encounter a similar fate.

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M&A Report: Thermo Fisher, Siemens Healthineers and DiaSorin Headline a Super Dynamic Month in Deal Making

After a prolonged pandemic-induced lull, M&A deal making in the diagnostics market continued its resurgence in April. Here's a review of what was clearly the most dynamic month in M&A since the COVID-19 crisis began last winter.

Thermo Fisher Scientific to Acquire PPD for $17.4 Billion

In 2020, Thermo Fisher Scientific was one of the most significant players in the clinical lab M&A space, most notably in its ultimately failed attempt to acquire Qiagen. But on April 15, Thermo Fisher reclaimed the headlines by announcing its agreement to acquire clinical research services provider PPD. In addition to shelling out $17.4 billion in cash, i.e., $47.50 per share of PPD common stock, Thermo Fisher will assume approximately $3.5 billion of the firm's net debt.

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 will bolster the value that Thermo Fisher can deliver to its extensive network of pharmaceutical and biotech customers. Thermo Fisher plans to absorb PPD into its lab products and services business unit after the deal closes, which is expected to happen by the end of the year.

Siemens Healthineers Acquires Varian for $16.4 Billion

Dollar value-wise, the second biggest deal in April was the closing of Siemens Healthineers' $16.4 billion acquisition of artificial intelligence (AI) firm Varian Medical Systems on April 15. The deal, which was announced last August, creates what the companies claim will be the diagnostics industry's most comprehensive cancer care portfolio. The acquisition advances the companies' ongoing EnVision strategic partnership that aims to create a digital, diagnostic and therapeutic ecosystem that includes treatment management. Siemens and Varian say they'll use AI-assisted analytics to advance data-driven precision care while redefining cancer diagnosis, care delivery and post-treatment survivorship.

DiaSorin to Acquire Luminex for $1.8 Billion

After months of speculation and rumor, Luminex has finally found its strategic suitor. On April 12, DiaSorin announced that it has agreed to acquire Luminex for $1.8 billion in cash, $37 per common share. The acquisition of Luminex and its expansive portfolio of molecular tests, including assays for infectious diseases, respiratory infections, gastroenterology infections and women's health will take Italy-based DiaSorin to a significantly higher level in the molecular testing and

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multiplexing technology marketing and, just as importantly, broaden its presence in the US.

Other Key M&A Developments

While the trio of billion-dollar deals were the headliners, there were a number of other significant M&A stories of April, including:

- News that the US Federal Trade Commission and European regulatory authorities would seek to stop Illumina from acquiring Grail on antitrust grounds (see the related story on page 1);
- Hologic's agreement to acquire Finnish molecular diagnostics maker Mobidiag, whose offerings include COVID-19 testing products cleared in the US and EU, for approximately $795 million; and
- Quest Diagnostics' divestment of its minority share in lab services firm Q2 Solutions to joint venture partner Iqvia for $760 million in cash.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
DiaSorin	Luminex	• Price: Roughly $1.8 billion in cash or $37 per share of Luminex stock • Status: Expected to close in Q3 • Acquisition of Luminex's multiplexing technology and molecular testing products bolsters DiaSorin's position in molecular diagnostics • DiaSorin to merge Luminex with its newly formed US subsidiary
Thermo Fisher Scientific	PPD	• Price: $17.4 billion cash + assumption of roughly $3.5 billion of net debt • Status: Expected to close by end of 2021 • Acquisition of global provider of clinical research and lab services for pharmaceutical and biotech industry to services which will be merged into Thermo Fisher's laboratory products and services business unit
Agilent Technologies	Resolution Bioscience	• Price: $550 million cash up front + up to $145 million more if performance milestones reached • Status: Closed • Agilent moves into liquid biopsy market via acquisition of Revolution Bioscience's NGS-based noninvasive liquid biopsy test platform designed for both centralized CLIA test services and distributable kits

Acquiring Company	Target(s)	Deal Summary
Exact Sciences	Ashion Analytics	• Price: Undisclosed • Status: Closed • Acquisition of CLIA-certified and CAP-accredited sequencing lab from Translational Genomics Research Institute (TGen) boosts Exact Sciences' efforts to develop precision oncology products, including minimal residual disease (MRD) and other sequencing-based tests
Siemens Healthineers	Varian Medical Systems	• Price: $16.4 billion all-cash merger deal for all of Varian's outstanding shares for $177.50 per share, a roughly 42% premium over Varian's 30-day volume-weighted average closing share price on July 31 • Status: Closed • Acquisition of Varian's artificial intelligence, machine learning and data analytics enable merged firm to provide services across cancer-care continuum, including screening, diagnosis, care delivery and post-treatment
Hologic	Mobidiag	• Price: Approximately $795 million, including $714 million cash + $81 million net debt • Status: Expected to close in Q4 • Acquisition of Finland-based developer of molecular tests and instruments for infectious illnesses is Hologic's third recent strategic acquisition in molecular diagnostics space
Invitae	Genosity	• Price: $200 million, including $120 million in cash + $80 million in shares of Invitae common stock • Status: Expected to close in Q2 • Invitae to leverage Genosity's software and lab solutions to accelerate development and decentralized market launch of somatic and germline oncology tests
Cancer Genetics	StemoniX	• Price: All-equity merger equity transaction in which Cancer Genetics obtains 100% of StemoniX's shares in exchange for 78% of Cancer Genetics' shares • Status: Closed • StemoniX, which develops high-density, at-scale human induced pluripotent stem cell-derived neural and cardiac screening platforms for drug discovery to keep its name and become wholly-owned sub of Cancer Genetics, which has been renamed Vyant Bio
Charles River Laboratories	Retrogenix	• Price: Undisclosed • Status: Closed • Charles River acquires early-stage contract research organization that uses proprietary cell microarray technology to provide bioanalytical services

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M&A Report, *from page 5*

Acquiring Company	Target(s)	Deal Summary
Iqvia	Quest Diagnostics	• Price: $760 million cash • Status: Closed • Quest sells off its 40% share in Q2 Solutions, a lab services firm Q2 Solutions (previously called Quintiles Research) that it owned as a joint venture with Iqvia holding the other 60%
Bio-Techne	Asuragen	• Price: $215 million in cash up front + up to $105 million if Asuragen meets future milestones • Status: Closed • Bio-Techne uses cash on hand and its own revolving fund to acquire developer of genetic carrier screening and oncology testing kits using proprietary chemistries for testing platforms that are widely available
Immunai	Dropprint Genomics	• Price: Undisclosed • Status: Closed • Acquisition of single-cell genomics software company

DTC: Big Retail Chains Set to Roll Out Over-the-Counter COVID-19 Tests

DIY at-home COVID-19 testing using over-the-counter (OTC) test kits that don't require a prescription is likely to become the new norm. With that clearly in mind, three of the country's largest pharmacy chains announced plans to start selling COVID-19 tests that can be performed at home.

CVS Gets the Jump

CVS Health Corp. was one of the first out of the gate when it began selling OTC COVID-19 tests in mid-April. Initially available to residents of Rhode Island and Massachusetts for in-store purchase, CVS says that tests will be available in all CVS stores nationwide by the end of May. Specifically, it plans to sell the:

- Ellume COVID-19 Home Test (costing $30 per test);
- Abbott BinaxNOW COVID-19 Antigen Self Test ($23.99 per test); and
- Pixel by Labcorp PCR Test Home Collection Kit ($119 per test).
- The pharmacy giant also plans to sell these OTC kits online.

Walgreens and Walmart Join the Fun

Separately, both Walgreens' Boots Alliance Inc and Walmart Inc. announced that they, too, plan to begin selling OTC COVID-19 tests, specifically the Abbott BinaxNOW antigen test, in stores and online.

■ DX Deals: Eurofins Teams with Uber for Home Delivery of COVID-19 Test Kits, *from page 1*

clinical labs in the US that offers at-home testing for men's and women's health, sexual health and general wellness. It's owner, Eurofins, was one of the many DTC businesses to expand into COVID-19 in response to the pandemic. Developed by the company's Eurofins Viracor infectious disease testing lab, the empowerDX At-Home COVID-19 PCR Test Kit received Emergency Use Authorization (EUA) from the FDA on Oct. 15 for home collection and maintenance of nasal swab specimens to detect RNA from the SARS-CoV-2 virus. Four months later, the agency expanded the kit's EUA to include DTC use and screening.

The company claims that as of December 2020, the assay offers one of the best sensitivity rates of the 117 labs that submitted results to the FDA's SARS-CoV-2 Reference Panel. The empowerDX at-home test kit, which is 100 percent covered by most insurance carriers, includes step-by-step instructions, a shallow nasal swab, test tube and a pre-paid FedEx package for easy sample returns. Consumers need to activate their kits online before taking the test. Test results are delivered to a secure patient portal within an average of 24 to 48hours from sample receipt at the company's CLIA-certified lab.

Starting in May, consumers in more than two dozen US cities, including Houston, Austin, Seattle, Denver, Phoenix, Minneapolis, Tampa and Fort Lauderdale, will be able to order the kit directly from empowerDX website without a prescription. Uber will make the kit available for delivery, hopefully in as little as one hour, from Monday through Friday between 8 AM and 4 PM. If the project proves successful, the companies plan to expand it to additional cities in the coming weeks.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Illumina	Kartos Therapeutics	• Objective: Develop next generation sequencing-based (NGS) TP53 companion diagnostic based on Illumina's TruSight Oncology 500 (TSO 500) pan-cancer comprehensive genomic profiling assay • Dynamic: Initial focus to be developing companion diagnostic for Kartos' MDM2 inhibitor, KRT-232
Biocartis	SkylineDx	• Objective: Develop SkylineDx's Merlin assay to predict melanoma patient risk of nodal metastasis on Biocartis Idylla platform • Dynamic: SkylineDx to lead assay development and Biocartis to use its Idylla network to commercialize assay in Europe
Prevencio	Atlas Genomics	• Objective: Commercialize Prevencio's artificial intelligence-based HART cardiac blood tests • Dynamic: Seattle-based CLIA lab Atlas Genomics to commercially launch HART tests for patient use on Microsoft secure cloud
Siemens Healthineers	Biognosy	• Objective: Discover and develop protein biomarkers • Dynamic: Use Biognosys' mass spectrometry technology to discover novel biomarkers, which they will then validate for potential clinical applications • Project to be run out of Siemens Healthineers' California clinical lab
Amgen	NeoGenomics	• Objective: Expand biomarker testing access to all advanced or metastatic non-small cell lung cancer (NSCLC) patients • Dynamic: Launch new Biomarker Assist project consisting of 2 parts: i. Next-Generation Sequencing Affordability Program under which Amgen to cover costs of comprehensive biomarker panels to advanced NSCLC patients; and ii. KRAS Single Gene Test Program under which Amgen to cover cost of NeoGenomics' single-gene tests for KRAS G12C driver mutation for all advanced or metastatic NSCLC patients

Partner 1	Partner(s) 2+	Deal Summary
OncoDNA	Institut Curie (France)	• Objective: Evaluate liquid biopsy-based treatment monitoring for head and neck cancer patients • Dynamic: Integrate OncoDNA's OncoFollow blood-based NGS test into Institut Curie's ongoing prospective biobanking SCANDARE study
Antelope Dx	In The Pocket + Extra Horizon	• Objective: Develop an app and cloud-based services for Antelope's self-tests • Dynamic: In The Pocket to develop the app, which will guide user through self-test process, provide test result, and propose "useful next steps" • Extra Horizon to develop cloud-based component of app to ensure safe management of data and regulatory compliance
Centogene	Takeda Pharmaceutical Company	• Objective: Diagnose patients with certain genetic disorders • Dynamic: 2-year renewal of existing global partnership made in 2015
Invitae	PTC Therapeutics	• Objective: Offer free genetic testing to US patients with symptoms or a diagnosis of cerebral palsy and no evidence of brain injury • Dynamic: Under newly launched PTC Pinpoint Direct-CP Spectrum program Genome Medical to provide genetic counseling and administration and Invitae to do the genetic testing
Twist Bioscience	Pure Biologics (Poland)	• Objective: Discover, validate and optimize new antibody candidates against useful targets for immunoncology applications • Dynamic: Twist's biopharma division to give Pure Biologics access to select synthetic antibody phage display libraries • Pure Biologics tp pay Twist annual technology access fees and future payments for preclinical, clinical and commercial milestones on any antibodies resulting from collaboration
Agena Biosciences	Ethos Laboratories	• Objective: Use Agena's MassArray MALDI-TOF platform for high-throughput detection of SARS-CoV-2 variants • Dynamic: Ethos to use Agena platform to simultaneously detect, identify and report variants in as little as 6 hours at lower cost and higher throughput than NGS methods

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DX Deals: Eurofins Teams with Uber for Home Delivery of COVID-19 Test Kits, *from page 9*

Partner 1	Partner(s) 2+	Deal Summary
Genomenon	Limbus Medical Technologies	• Objective: Integrate Genomenon's Mastermind genomics literature search engine into Limbus' Varvis genomics-based clinical diagnostics decision support system • Dynamic: Current integration allows Varvis users to preview published articles relevant to their search but requires that they click over to Mastermind to read them • Firms to create a deeper link with Mastermind's application programming interface to make full text available within Varvis
Abcam	MEDx Translational Medicine (China)	• Objective: Develop new cancer diagnostics for China market • Dynamic: Expand current alliance covering companion diagnostic and in vitro diagnostic reagents and kits for cancer genes pan-NTRK and dMMR to products for other indications
Trapelo Health	Magellan Rx Management (pharmacy benefits management arm of Magellan Health)	• Objective: Build platform to support value-based precision oncology care • Dynamic: Bundle Trapelo's clinical decision support system for utilization of molecular testing with Magellan's oncology management services helping payors with prior authorization, customized formulary management, personalized dosing, patient care management and post-service claim edits
Proscia	Unilabs	• Objective: Accelerate use of artificial intelligence in routine pathology practice • Dynamic: Unilabs to validate efficacy of Proscia's computational pathology applications and deploy them into its high-throughput pathology workflows • Partners also to create de-identified datasets, while adhering to data protection regulations
Concentric by Ginkgo (part of Ginkgo Bioworks)	Dascena Labs	• Objective: Offer scalable pooled COVID-19 testing for K-12 schools • Dynamic: Perform pooled classroom testing, combining samples from all consenting people in a classroom and running them as a single test to increase testing capacity and cut costs • Cocentric by Ginkgo also announced similar pooled school testing partnerships with Olive Labs and CQuentia

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
PixCell Medical	Axonlab	• Products: PixCell's HemoScreen point-of-care hematology analyzer • Territory: Switzerland, Austria, Netherlands, Czech Republic
GenScript BioTech BV	IES Diagnostics	• Products: GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit • Territory: Spain, Portugal, Andorra • Exclusive
Congenica	Camtech Diagnostics	• Products: Congenica's clinical decision support platform • Territory: Singapore, Malaysia, Japan, South Korea
Avacta	Abcam	• Products: Avacta's SARS-CoV-2 ELISA spike protein Affimer research reagents • Territory: Global • Non-exclusive

LICENSES

Licensor	Licensee	Deal Summary
221b Foundation (nonprofit organization established by Sherlock Biosciences)	Cooper International	Cooper International gets non-exclusive license to SHERLOCK (Specific High Sensitivity Enzymatic Reporter unLOCKing technology), which uses CRISPR for amplicon detection for single-molecule detection of nucleic acid targets
221b Foundation	United PPE	United PPE gets non-exclusive license to SHERLOCK (Specific High Sensitivity Enzymatic Reporter unLOCKing technology), which uses CRISPR for amplicon detection for single-molecule detection of nucleic acid targets
ERS Genomics	Nuvisan	Bayer spinoff gets non-exclusive license to ERS' CRISPR-Cas9 patent portfolio Nuvisan allowing the firm access to ERS' CRISPR-Cas9 patent portfolio to help advance its clients' drug discovery and early development programs
University of Manitoba	Health Logic Interactive	Exclusive license to UAL-Chip lab-on-a-chip technology for use to develop handheld device providing rapid diagnosis of chronic kidney disease at home and at point of care

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DX Deals: Eurofins Teams with Uber for Home Delivery of COVID-19 Test Kits, *from page 11*

SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
BioReference Laboratories (part of Opko Health)	Major League Baseball	BioReference to provide on-site, rapid PCR, point-of-care COVID-19 testing using Mesa Biotech's Accula system for all 30 teams during 2021 season
Arrow Diagnostics (Italian subsidiary of Seegene)	Italian Department of Defense	$107 million contract to supply approximately 7.15 million COVID-19 diagnostic tests and extraction reagents to the Ministry's Extraordinary Commissioner for COVID-19 Emergency agency
Agilent Technologies	Oxford BioDynamics	Agilent to supply a custom-made SurePrint G3CGH Microarray for OBD's research-use-only kit, which will include OBD's 3D Genome Probes with OBD holding the kit's exclusive supply and distribution rights