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Inside the Lab Industry: AI Imaging Drives Modest Uptick in Digital Pathology Investment Flows

Since 2014, companies dedicated to developing digital pathology solutions have raised over $860 million in investment capital. However, $207 million, or almost a quarter of that total, was raised in the first few months of 2021. Those are the findings of a new report from market data firm Signify Research.

Digital Pathology Investment Trends

The increased interest of investors in digital pathology was

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FDA Watch: VALID and VITAL Bills for LDTs Regulation Are Back in Play

Reform of FDA Laboratory Developed Tests (LDTs) regulation is back on the agenda and this time it may result in actual legislation. Fired by the agency's ineffectiveness in bringing new SARS-CoV-2 tests to market rapidly during the early days of the public health emergency, Congress exhumed the VALID and VITAL Acts proposing different approaches to LDTs regulation.

The FDA's Current Regulatory "System"

Since the original *Food Drug & Cosmetics Act* legislation doesn't provide for regulation of laboratory tests, the FDA justifies its regulatory authority over LDTs, aka, in vitro clinical tests (IVCTs), as an extension of its power to regulate medical devices. Accordingly, it clears LDTs via the 510(k)

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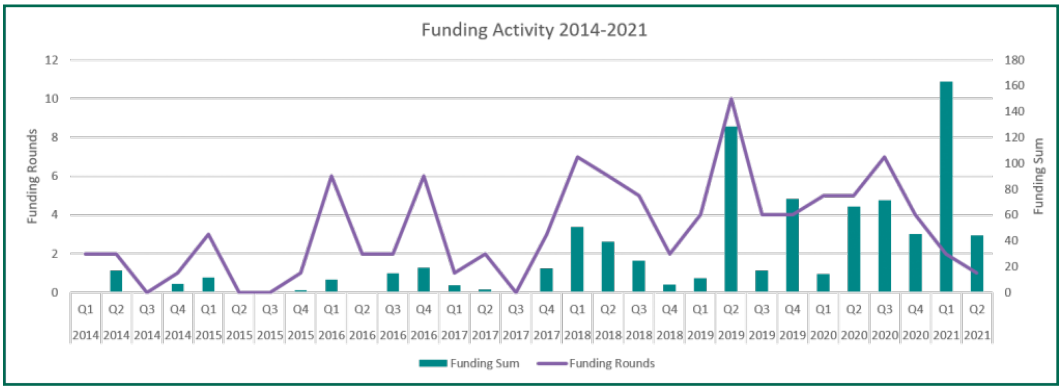
Inside the Lab Industry: AI Imaging Drives Modest Uptick in Digital Pathology Investment Flows, *from page 1*

in evidence before the COVID-19 pandemic. Thus, of the $860 million raised since 2014, 73.4 percent has come since 2019. Signify suggests that these recent increases reflect the growing recognition of global health care providers of the need to digitize their pathology departments. While US-based companies account for 68.8 percent of the funding raised, Signify reports that investment is also beginning to scale in other international markets as companies mature and seek later stage funding.



Source: Signify Research

The Growing Attraction of Pathology AI Image Analysis Solutions

Digital pathology investment is not just increasing but migrating in a new direction. In recent years, there has been what Signify calls a "notable shift" in investment from hardware/software solutions toward start-up companies focused on digital pathology AI-image analysis. In fact, AI vendors accounted for all three of the largest deals in the period, including:

- Paige.AI: $125 million Series C;
- PathAI (which just acquired Poplar Healthcare): $60 million Series B; and
- Volastra: $44 million Seed.

Companies like Volastra and Owkin that specialize in preclinical markets generally attract larger funding amounts at an earlier stage than do those focusing on clinical markets. Signify attributes this to the higher potential for return on investment and lower regulatory barriers to adoption.

Takeaway

Even though capital flows have been increasing, getting providers to shell out investment funds to modernize clinical labs remains a challenge. Thus, digital pathology still attracts far less investment than markets like medical imaging AI and AI in drug development. According to Signify, this is probably due to a combination of factors including regulation and the fragmented supply chain.

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DX Deals: Cloud-Based Platform Enlists Quest to Provide COVID-19 Molecular Test Results to Travelers

As proof of COVID-19 vaccination and/or negative molecular test results morphs into a passport for air travel and attending live events, labs with the capacity to generate rapid and reliable tests and results on an expansive geographic scale will be in growing demand. Quest Diagnostics has been quick to recognize and take advantage of this opportunity by enlisting as a test provider for TrustAssure.

The TrustAssure Platform

Created by CLX Health, a developer of cloud-based solutions owned by SiriusIQ, the TrustAssure Global Testing Platform collaborates with physicians, clinics, hospitals and other providers in 5,000 U.S. and 15,000 global locations to provide test results to travelers and meeting attendees needing COVID-19 clearance to go through with their plans. Quest will become the first national provider of molecular COVID-19 testing to participate in TrustAssure.

The newly announced Quest/CLX Health collaboration will enable individuals to use the TrustAssure platform to schedule test appointments at Quest patient centers and more than 750 retail pharmacy partner locations across the country knowing that they'll get their results within 48 hours. This way, they can secure the "passport" they need to fly or attend the event in advance.

It's an ideal strategic collaboration: CLX Health secures Quest's massive molecular testing capabilities to bolster its solution; in turn, Quest gets to leverage the TrustAssure platform, which integrates the IBM Digital Health Pass, to reach the air travel and live events markets.

"COVID-19 testing is a powerful tool for providing insights that can foster safer environments," noted Cathy Doherty, Quest senior VP and group executive, clinical franchise solutions and marketing. "As COVID-19 restrictions are lifted around the country and world, our collaboration with TrustAssure will allow us to facilitate high-quality testing for individuals looking to get back to recreation and travel."

This is hardly Quest's first venture into consumer empowerment over lab test results. The company was among the first diagnostic information services provider to offer free online access to test results. The lab giant also offers the MyQuest mobile app and patient portal enabling consumers to access and track their test results, as well as the QuestDirect service providing tests for various health conditions, illnesses and infections.

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DX Deals: Cloud-Based Platform Enlists Quest to Provide COVID-19 Molecular Test Results to Travelers, *from page 3*

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Oncimmune Holdings	Dana-Farber Cancer Institute	• Objective: Use Oncimmune's SeroTag biomarker discovery engine in Institute's cancer chemotherapy clinical trials • Dynamic: Institute to use SeroTag to identify cancer-linked antigens predictive of therapeutic response or resistance
Ibex Medical Analytics	Unilabs	• Objective: Implement Ibex's AI-based Galen platform in Europe • Dynamic: Unilabs to deploy platform in pathology labs in 16 countries, starting with Sweden
Pacific Biosciences	Invitae	• Objective: Develop a production-scale HiFi sequencing platform • Dynamic: Expand current collaboration to incorporate into the platform advance cancer detection technology developed by Omniome, a firm recently acquired by Pac Bio
Quest Diagnostics	CLX Health	• Objective: Provide COVID-19 molecular testing for international travelers and live events attendees • Dynamic: Enable individuals to use using CLX's TrustAssure Global Testing Platform to schedule test appointments at Quest patient centers, with results provided 48 hours before travel or event date
Illumina	Sanigen	• Objective: Develop next-generation sequencing panels for food safety testing • Dynamic: Sanigen to also distribute Illumina's sequencing technology in South Korea
Roche	Hyrax Biosciences	• Objective: Comarket Hyrax's Exatype automated DNA analysis platform with Roche's research-use-only KAPA HyperCap SARS-CoV-2 panel • Dynamic: Combine technologies into a single workflow to improve reliability of sequencing-based viral genotyping

Partner 1	Partner(s) 2+	Deal Summary
Roche	Mimetas	• Objective: Develop human disease models to characterize novel drug compounds in inflammatory bowel disease (IBD) and hepatitis B virus (HBV) infections • Dynamic: Mimetas, which will be eligible for unspecified upfront and milestone payments, responsible for developing tissue-based disease models and assays in its OrganoPlate organ-on-a-chip platform • Roche gets access to technology, the disease models and resulting data, plus an option to exclusively license specific disease models and assays for use in drug discovery
Mission Bio	Sequanta Technologies	• Objective: Provide single-cell sequencing services in mainland China • Dynamic: Sequanta to provide access to Mission Bio's Tapestri single-cell platform on fee-for-service basis
GE Healthcare	SOPHiA GENETICS	• Objective: Develop new AI-driven analytics and workflow solutions for clinical and biopharma markets • Dynamic: Solutions to combine GE Healthcare's medical imaging and monitoring expertise and Edison data aggregation platform with SOPHiA's DDMTM analytics platform
Thermo Fisher Scientific	Ortho Clinical Diagnostics	• Objective: Distribute Thermo Fisher quality control and quality assurance products for use with Ortho's Vitros analyzers • Dynamic: Ortho customers to have access to Thermo Fisher's MAS third-party quality controls and LabLink xL web-based quality assurance program
Nonacus	University of Birmingham (UK)	• Objective: Develop noninvasive liquid biopsy assay for bladder cancer detection • Dynamic: Assay to use Nonacus' liquid biopsy platform and panel of biomarkers validated by the University
Qiagen	Sysmex	• Objective: Develop and commercialize cancer companion diagnostics using Sysmex's Plasma-Safe-SeqS next-generation sequencing technology • Dynamic: Forge collaborations with pharmaceutical companies to develop cancer therapies and promote the early clinical adoption of ultra-sensitive liquid biopsy companion diagnostics

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DX Deals: Cloud-Based Platform Enlists Quest to Provide COVID-19 Molecular Test Results to Travelers, *from page 5*

Partner 1	Partner(s) 2+	Deal Summary
Qiagen	Verogen	• Objective: Offer labs next-generation sequencing-based human identification workflows support • Dynamic: Qiagen gets rights to globally distribute Verogen products • Firms to also work together to commercialize Verogen's NGS workflows with Qiagen's sample prep automation to provide full sample-to-ID workflows for human ID labs
Bio-Rad Laboratories	Seegene	• Objective: Develop and commercialize multiplex molecular diagnostic tests for infectious diseases for US market • Dynamic: Seegene to provide multiplex assays for Bio-Rad's CFX96 Dx Real-Time PCR System
BGI Americas	Advaite	• Objective: Market BGI's PCR-based SARS-CoV-2 detection kit with Advaite's RapCov COVID-19 immunoassay • Dynamic: Combined offering to provide more SARS-CoV-2 options to customers with both central lab and point-of-care CLIA-waived testing
SpeeDx	MolGen	• Objective: Create supply and distribution partnership in Europe and Asia-Pacific region • Dynamic: Combine MolGen's liquid handling and purpose-built automation with SpeeDx's COVID-19 diagnostic solutions to offer a full workflow to pathology labs

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
PixCell Medical	Gamidor Diagnostics	• Products: PixCell's HemoScreen hematology analyzer • Territory: Israel • Exclusive
Fosun Pharma	Todos Medical	• Products: GenScript Biotech's cPass SARS-CoV-2 Neutralizing Antibody Detection Kit, which Todos is automating at its Provista Diagnostics CLIA-certified lab • Territory: Undisclosed
SQI Diagnostics	Azova	• Products: SQI's COVID-19 Home Antibody Test • Territory: US • Azova to sell and distribute Canada-based SQI's test to airline industry, wholesale clubs, retail pharmacies, grocery chains, state governments, school districts, universities and consumers
Natera	TomaLab	• Products: 3 of Natera's cell-free DNA tests • Territory: Italy

Product Owner	Distributor	Deal Summary
Microbix Biosystems	Thomas Scientific	• Products: Microbix's quality assessment products (QAPs) • Territory: US
Shoreline Biome	AH Diagnostics	• Products: Shoreline Biome's microbiome research products • Territory: Denmark, Iceland, Sweden, Finland, Norway • Exclusive
Specific Diagnostics	BioMérieux	• Products: Specific Diagnostics' Specific Reveal Rapid AST antibiotic susceptibility testing platform • Territory: Europe

LICENSES

Licensor	Licensee	Deal Summary
IBM Research	NanoDx	NanoDx licenses metal-oxide semi-conductive compatible nanoscale sensors to expand rapid testing for COVID-19, traumatic brain injury, sepsis and stroke
ERS Genomics	Japan SLC	Japanese biotech company gets nonexclusive access to ERS' CRISPR-Cas9 patents to expand its animal model offerings
ERS Genomics	Nippon Gene	Japanese biotech company gets nonexclusive access to ERS' CRISPR-Cas9 patents to develop, manufacture and sell research reagents

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

GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
LightDeck Diagnostics	US Departments of Defense and Health and Human Services	$35.1 million contract to increase manufacturing capacity for LightDeck's upcoming COVID-19 Ultra-Rapid Antigen and Total Antibody tests

M&A Report: Biden Orders Feds to Target Health Care Consolidation but Deals Continue

This month's big stories in M&A deal making come not just from the market but the regulatory front.

New Biden Executive Order Targets Health Care Consolidation

Consolidation in the health care market has been a major concern, particularly in the past two years when hospitals, health networks and corporate equity funds began swallowing up independent physicians' practices at accelerated rates. Against this backdrop, as well as a new report from the Physicians Advocacy Institute (PAI) finding that only 30 percent of all physicians in the U.S. are practicing medicine independently, President Biden issued a new Executive Order (EO) on July 9 calling on the Department of Justice (DOJ), Federal Trade Commission (FTC) and other federal government agencies to vigorously enforce the antitrust laws across all markets, including health care.

The EO identifies four segments of health care as priority areas for enforcement:

- Hospital consolidation;
- Prescription drugs;
- Health insurance consolidation; and
- Hearing aids.

The EO stresses that hospital mergers can be harmful to patients, especially in rural areas left underserved by consolidation. Thanks to "unchecked mergers," the 10 largest healthcare systems now control a quarter of the market, the EO notes, adding that 138 rural hospitals have shuttered since 2010, including a high of 19 last year, in the middle of a healthcare crisis. Research shows that hospitals in consolidated markets charge far higher prices than hospitals in markets with several competitors. The EO thus recommends that the DOJ and FTC review and revise their merger guidelines and directs HHS to support existing hospital price transparency rules and finish implementing bipartisan federal legislation to address surprise hospital billing.

Mologic Becomes a Social Enterprise and PerkinElmer Makes a Big Play

Meanwhile, M&A deals did come down during July, including a pair of blockbusters. The first, which was announced on July 19, represents a kind of counterpoint to the consolidation-is-bad message of the new Biden EO issued just nine days earlier. Instead of greedy insurance executives and Wall Street corporate raiders, financing for the acquisition of rapid diagnostic test maker Mologic and its sister firm Global Access Diagnostics (GAD) by the Soros Economic Development Fund is coming from the Bill & Melinda Gates Foundation. Mologic and GAD will become part of

Global Access Health, a social enterprise dedicated to expanding access to affordable medical technology in underserved low- and middle-income countries around the world.

Teeming with COVID-19 testing cash, PerkinElmer announced that it has agreed to plunk down $5.25 billion in cash and stock to acquire antibodies and reagents provider BioLegend, a firm with over 700 employees and expected 2022 revenues of $380 million. The acquisition, the largest in company history, positions PerkinElmer to enter new segments of the life sciences research market. San Diego-based BioLegend will become PerkinElmer's global center of excellence for research reagent content development. The combined company will become a "true powerhouse that will have the skill to be able to accelerate scientific advancement and new product innovation across the company and around the world," according to the statement of PerkinElmer CEO Prahlad Singh.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
PerkinElmer	BioLegend	• Price: $5.25 billion in cash and stock • Status: Expected to close in 2021 • PerkinElmer moves into new segments of life science via acquisition of producer of antibodies and reagents for cytometry, proteogenomics, multiplex assays, recombinant proteins, magnetic cell separation and bioprocessing with expected $380 million in 2022 revenues • PerkinElmer said. The deal will expand PerkinElmer's presence into new life sciences segments
Pacific Biosciences	Omniome	• Price: Up to $800 million, including 9.4 million shares of Pac Bio's common stock + $300 million cash + $200 million in contingent, milestones-based cash and stock • Status: Expected to close by end of Q2 • Merger enables Pac Bio to combine its long-read portfolio with Omniome's short-read sequencing technology
PathAI	Poplar Healthcare	• Price: Undisclosed • Status: Closed • Acquisition of provider of specialized lab testing services for gastrointestinal pathology, dermatology, oncology, urology and women's health

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M&A Report: Biden Orders Feds to Target Health Care Consolidation but Deals Continue,

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Acquiring Company	Target(s)	Deal Summary
Becton Dickinson	Velano Vascular	• Price: Undisclosed • Status: Closed • BD acquires developer of technology enabling blood draws from peripheral intravenous catheter lines
Meridian Bioscience	Otsuka America Pharmaceutical	• Price: $20 million cash • Status: Expected to close in Q4 • Meridian acquires Otsuka's BreathTek, a urea breath test for detection of Helicobacter pylori
Sapphiros	Biocrucible	• Price: Undisclosed • Status: No closing date announced • Newly formed company formed by investment firm KKR acquires UK startup developer of point-of-care molecular diagnostics
XPhyto Therapeutics	3a-diagnostics	• Price: €3.9 million ($4.6 million), including €400,000 up front and €3.5 million on closing • Status: Expected to close at end of October • Acquiring all outstanding shares of 3a, its exclusive diagnostics development partner, enables XPhyto to expand into point-of-care biosensor diagnostics
BioIVT	Tissue Solutions	• Price: Undisclosed • Status: Closed • Acquisition of UK-based virtual biobank
Kiromic BioPharma.	InSilico Solutions	• Price: Swap stock deal at undisclosed price • Status: Closed • Acquisition of developer of custom bioinformatics applications to help researchers extract meaning from genomic datasets boosts Kiromic's bioinformatics capacity
Soros Economic Development Fund with support of Bill & Melinda Gates Foundation	Mologic + Global Access Diagnostics	• Price: Undisclosed • Status: Closed • Both companies to be integrated under Global Access Health (GAH), a social enterprise dedicated to expanding access to affordable medical technology in low- and middle-income countries • GAH to invest at least $41 million in deal

Acquiring Company	Target(s)	Deal Summary
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: Expected to close July 31 • Genetic Technologies to acquire all websites, brand identities, lab testing and distribution agreements associated with General Genetics Corporation, which trades as EasyDNA
Inotiv	MilliporeSigma	• Price: Undisclosed • Status: Closed • MilliporeSigma sells off genetic toxicology assets of its BioReliance portfolio after deciding to discontinue its genetic toxicology operations
Nephros	GenArraytion	• Price: Undisclosed • Status: Closed • Nephros acquires substantially all assets of infectious disease monitoring firm which will be integrated into its Nephros Pathogen Detection Systems platform
ACT Genomics	MC Diagnostics	• Price: Undisclosed • Status: Closed • Taiwanese molecular diagnostic firm to develop fusion gene chips on ALDAS, MC Diagnostics' automated low density array platform
Ro	Kit	• Price: Undisclosed • Status: Closed • Telehealth firm acquires at-home diagnostic testing company
Q^2 Solutions	Myriad Genetics	• Price: Undisclosed • Status: Closed • Myriad continues restructuring by selling off Myriad RBM unit which provides contract research services for pharmaceutical industry after selling Vectra to LabCorp
Sebia	Orgentec Diagnostika	• Price: Undisclosed • Status: Expected to close in Q3 • Acquisition of German diagnostics firm expands Sebia's capabilities in autoimmunity, infectious diseases and clinical trials

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M&A Report: Biden Orders Feds to Target Health Care Consolidation but Deals Continue, *from page 11*

Acquiring Company	Target(s)	Deal Summary
Twist Bioscience	iGenomX	• Price: $35 million • Status: Closed • Acquisition of developer of multiplex library preparation tools for next-generation sequencing workflows boosts Twist's capacity to support multiplex sequencing preparations across multiple markets
DCN Dx	IVD Vision	• Price: Undisclosed • Status: Closed • Acquisition of developer of custom diagnostic instruments and software comes on heels of DCN Dx's acquisition of PortaScience, a point-of-care diagnostics company focused on dry chemistry technology
GenesisCare	PreludeDx	• Price: Undisclosed • Status: Closed • GenesisCare acquires minority stake in PreludeDx as part of partnership to offer latter's DCISionRT precision medicine breast cancer test in Australia

FDA Watch: VALID and VITAL Bills for LDTs Regulation Are Back in Play, *from page 1*

premarket review pathway. Rather than following the notice of rulemaking process designed to ensure transparency and public input into new federal regulation, the agency regulates LDTs via informal guidance that it posts on its website. Adding to the arbitrariness is the "enforcement discretion" the agency exercises by deferring regulation of most LDTs to the Centers for Medicare and Medicaid Services (CMS) under the *Clinical Laboratory Improvement Amendments* (CLIA) law.

Fixing this mess has been an almost decade-long endeavor. On the legislative front, a bill called the *Diagnostic Accuracy and Innovation Act* (DAIA) would have removed diagnostic tests from the definition of a

medical device and thus placed it outside the scope of the 510(k) pathway. Rather than totally stripping the FDA of regulatory authority over IVCTs, a 2018 bill called the *Verifying Accurate, Leading-edge IVCT Development* (VALID) proposed to limit it by establishing IVCTs as a new product category consisting of LDTs and test kits. The bill didn't get far; nor did an updated version of it proposed in March 2020.

The VALID Act of 2021

The VALID Act of 2021 would create a risk-based framework for IVCT regulation:

High-Risk Tests: High-risk tests, like novel assays, would have to go through premarket review to verify analytical and clinical validity.

Lower-Risk Tests: VALID would establish a separate technological certification program for lower-risk tests, as well as a new system allowing hospitals and labs to submit their tests electronically.

Emergency Use Tests: To eliminate the EUA bottlenecks and delays that became apparent during the pandemic, validated tests would be authorized to use for emergency purposes pending review of their EUA clearance.

Grandfathered Tests: Qualifying LDTs offered for clinical use before enactment of the legislation would receive "grandfathered" status and not require premarket review, provided that they carry a disclaimer on the label and are neither modified nor flagged by the FDA as posing a special concern.

Transitional Tests: IVCTs first offered between the date VALID is enacted and 90 days after it takes effect would be allowed to remain on the market as "transitional" IVCTs, provided that the test maker submits a timely marketing application to the FDA.

Other key features of the 2021 version of VALID:

- Establishment of test design and quality requirements for IVCTs, equivalent to the current Quality Systems requirements for medical devices;
- Creation of a new process that the FDA can use to request information from an otherwise exempt IVCT, such as a transitional or grandfathered test, in certain situations;
- Authority of FDA to participate in collaborative communities for purposes of "facilitating community solutions and decision-making" for IVCTs;

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FDA Watch: VALID and VITAL Bills for LDTs Regulation Are Back in Play, *from page 13*

- A requirement that FDA create and maintain an IVCTs database that is more extensive than the current device registration and listing database; and
- New IVCT adulteration, misbranding and postmarket surveillance requirements mirroring current rules that apply to medical devices.

The VITAL Act

VALID isn't the only LDTs regulation bill on the table. First introduced by Senator Rand Paul (R-KY) in March 2020, the newly reintroduced *Verified Innovative Testing in American Laboratories Act* (VITAL) would transfer the FDA's regulatory powers over LDTs to the U.S. Department of Health and Human Services (HHS). Supporters of the bill believe that the FDA's slow response in expanding access to SARS-CoV-2 virus tests during the pandemic reaffirms the need for stripping the agency of power to regulate LDTs. "When we face a health emergency, government should trust academic, community and public health labs to do what they are already trained and certified to do," noted Senator Paul in a press release. "With all of the debates about how government should respond, here's one thing it can stop doing: piling counter-productive bureaucratic hurdles in the way of our medical professionals."

Subsequent FDA management of the EUA process seemed to vindicate and strengthen the drive to get the agency out of the business of regulating LDTs. In August 2020, HHS issued a determination stating that the FDA can't require premarket review of LDTs without notice and comment rulemaking. While not eliminating FDA regulatory authority over LDTs, the HHS determination barred the agency from its traditional—and to most in the industry—infuriating practice of exercising that authority via website guidelines and other informal pronouncements serving as shortcuts around the burdensome notice and comment rulemaking protocols.

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

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Promega	Clearance to use OncoMate MSI Dx Analysis System to screen colorectal cancer patients for Lynch syndrome
Ortho-Clinical Diagnostics	EUA for Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators

Manufacturer(s)	Product
Becton Dickinson	EUA for sodium citrate collection tubes
AnchorDx	Breakthrough device designation for UriFind urine DNA methylation early bladder cancer detection test
First Light Diagnostics	Marketing clearance for SensiTox C. difficile Toxin Test
First Light Diagnostics	Marketing clearance for MultiPath Analyzer
GenBody	EUA for COVID-19 Ag point-of-care antigen test
Ortho-Clinical Diagnostics	EUA for Vitros Anti-SARS-CoV-2 IgG Quantitative test
Thermo Fisher Scientific	EUA for TaqPath COVID-19 RNase P Combo Kit 2.0
Ellume	EUA for COVID Antigen Test by CLIA labs
Exact Sciences	EUA for COVID-Flu Multiplex Assay
BioGx	EUA for Xfree COVID-19 Direct RT-PCR assay
Bio-Rad	EUA for BioPlex 2200 SARS-CoV-2 IgG assay
Foundation Medicine	Clearance for tissue-based FoundationOne Liquid CDx as companion diagnostic to identify patients eligible for treatment with capmatinib (Novartis' Tabrecta)
Foundation Medicine	Clearance for FoundationOne CDx test as companion diagnostic for Takeda's FDA-approved non-small cell lung cancer treatment brigatinib (Alunbrig)
Access Bio	EUA for CareStart EZ COVID-19 IgM/IgG, point-of-care version of firm's SARS-CoV-2 antibody assay
Inova Diagnostics	510(k) clearance for Aptiva System
Inova Diagnostics	510(k) clearance for Aptiva Celiac Disease IgA Assay

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Scope Fluidics	Fully automated PCR One SARS-CoV-2 panel
MeMed	MeMed COVID-19 Severity COVID-19 management tool
PathogenDx	DetectX-Rv assay for COVID-19
Agilent Technologies	Expanded use of PD-L1 IHC 22C3 pharmDx as companion diagnostic to identify non-small cell lung cancer patients eligible for treatment with cemiplimab (Regeneron Pharmaceuticals and Sanofi's Libtayo)
Hologic	Use of Aptima SARS-CoV-2 molecular assay on saliva samples
Bio-Rad Laboratories	Reliance SARS-CoV-2/FluA/FluB RT-PCR Kit
Genetron Health	One-Step Seq eight-gene lung cancer sequencing assay
BioLytical Laboratories	Insti HCV Antibody Test
Quidel	Respiratory viral panel test for use with Savanna multiplex molecular analyzer

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FDA Watch: VALID and VITAL Bills for LDTs Regulation Are Back in Play, *from page 15*

Manufacturer(s)	Product(s)
QuantumDx	Rapid PCR, point-of-care diagnostic system along with assay to detect SARS-CoV-2
Qiagen	NeuMoDx HAdV Quant Assay for identification and quantification of human adenovirus DNA
Genome Diagnostics	NGSgo-MX11-3 human leukocyte antigen typing product for organ and stem cell transplantation testing
LumiraDx	SARS-CoV-2 RNA STAR Complete assay
Attana	Attana Cell 250 analyzer instrument

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Cue Health	India	Cue COVID-19 Test Kit
Amoy Diagnostics + Precision Medicine Asia	Japan	AmoyDx Pan Lung Cancer PCR Panel