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# LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

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## HIGHLIGHTS



## Upcoming Events



## Industry Buzz: Lab Companies Scramble to Bring Coronavirus Detection Tests to Market

Along with an urgent public health challenge, the outbreak of the novel 2019-nCoV coronavirus in Wuhan, China, first reported on Dec. 31, has created a strategic opportunity for makers of lab tests. Lab and diagnostic companies around the globe scrambling to develop and commercialize products capable of rapid and effective 2019-nCoV detection. Here's a look at the current situation and who might be poised to win the race to market.

### The CDC Test

Because the 2019-nCoV virus is so new, there are no FDA-approved commercial products for it in the US. As it has in responding to previous infectious disease outbreaks, the FDA has called on test makers to seek expedited clearance

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## FDA Watch: Agency to Use EUA Pathway to Clear New Coronavirus Detection Tests

There are no FDA-cleared tests to detect the new 2019-nCoV Wuhan coronavirus. But on Jan. 28, the agency unveiled its strategy to promote the rapid development and availability of safe and effective investigational medical products "to address this urgent public health situation."

As with previous infectious disease outbreaks like Zika, the FDA will clear new 2019-nCoV tests and treatment products on an expedited basis via the Emergency Use Authorization (EUA) pathway. The FDA is calling on diagnostic test sponsors interested in potential EUA for detection tests to contact the Center for Devices and Radiological Health (CDRH) (CDRH-EUA-Templates@fda.hhs.gov) for information and templates.

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Lab Companies Scramble to Bring Coronavirus Detection Tests to Market, *from page 1*

of investigational products via the Emergency Use Authorization (EUA) pathway.

In the meantime, the only test for 2019-nCoV available in the US is the reverse transcriptase real-time PCR (rRT-PCR) assay developed assay Centers for Disease Control and Prevention for respiratory and blood serum samples. On Jan. 27, the CDC published the test formula and announced that it's using the assay to create kits for distribution to state health departments and public health labs in the next few weeks. Meanwhile, CDC labs are testing all reported US cases in accordance with agency protocol. The hope is that these temporary measures will hold down the fort until the expected stream of EUA tests hit the market.

## Commercial Coronavirus Tests

Not surprisingly, labs and diagnostic companies in Asia, where the virus originated, are making progress on the commercialization front.

## Veredus Laboratories

On Jan. 24, Singapore biotech firm Veredus Laboratories announced plans for a Feb. 1 commercial launch of a kit capable of detecting the coronavirus with "high specificity and sensitivity." The VereCoV kit is based on lab-on-chip technology which integrates two molecular biological applications, polymerase chain reaction and microarray. It's the same application that Veredus, which is currently owned by Japanese plastics giant Sekisui Chemicals, has used to create kits for detecting the Mers, Zika, Dengue and H1N1 viruses. The company claims the new kit can detect, differentiate and identify all three coronaviruses in a single test in about two hours.

## Meridian Bioscience

On Jan. 27, Meridian Bioscience announced that its Lyo-Ready 1-Step RT q-PCR mix is actually being used to deal with the coronavirus outbreak. According to Meridian, labs in China are using the reagent to develop "fast and accurate" screening assay. The ready-to-use reagent is designed to improve assay accuracy, since they can be "set up and freeze-dried, so that they are highly stable, just requiring the patient sample to be added and the assay run," noted **Liang Zhang**, Meridian's general manager in China. The announcement spurred a single-day 21% increase in Meridian stock.

## BGI

A day after the Meridian announcement, BGI and its MGI Tech subsidiary revealed that they have received emergency clearance from China's National Medical Products Administration (NMPA) for a pair of coronavirus products, including:

- MGI Tech's DNBSEQ-T7 sequencer and analysis software for use in future epidemic control and prevention;

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Barbara Manning Grimm, Managing Editor

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Andrea Stowe, Business Development

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- PMseq metagenomics sequencing kit, which uses BGI's combinatorial probe-anchor synthesis sequencing technology to rapidly detect viral sequences to identify and diagnose 2019-nCoV while running on the DNBSEQ-T7 platform; and
- BGI's real-time fluorescent RT-PCR kit for specific testing of 2019-nCoV.

In addition to scaling up production of the assay, BGI has donated 20,000 kits to support 2019-nCoV response efforts in Wuhan and Hubei Province. BGI also said that China's National Health Commission has authorized it as the third-party collaborator to detect 2019-nCoV in the country.

### Other Potential Players

Other companies that have developed products or technologies for rapid and accurate virus screening that can potentially applied to 2019-nCoV include Oxford Nanopore and Co-Diagnostics.

## Diagnostic Deals: Lab Corp & Quest to Continue Targeting Small and Independent Labs for Acquisition

PAMA price cuts were supposed to drive consolidation in the lab market. The expectation was that price pressures would make it impossible for smaller labs to remain independent, rendering them juicy targets for the likes of lab giants Quest and LabCorp. And that's largely what happened in 2018. But it didn't continue in 2019. While PAMA did drive smaller and independent labs out of business, the volume of M&A deals during the year was much less than expected. During the recent J.P. Morgan Healthcare Conference, we got some clues about what happened and what to expect in 2020.

### M&A Deals Are Getting Harder to Make

What we learned is that LabCorp and Quest wanted to do the deals but they couldn't. At least that's how new LabCorp CEO **Adam Schechter** explained things during his presentation at the J.P. Morgan event. Simply stated, M&A deals are becoming harder to close. "It's surprising to me on how long it takes," Schechter said. "It's a lot of discussions, hospital by hospital and department by department. Trying to get people to move fast has been harder than I would have anticipated." Schechter said. Apparently, Quest encountered similar frustrations.

But LabCorp and Quest are not giving up. On the contrary, both companies revealed during the Conference that acquisition of local and hospital labs remains a key element of their respective post-PAMA growth strategies. Schechter acknowledged that LabCorp has "a long list of

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Diagnostic Deals: Lab Corp & Quest to Continue Targeting Small and Independent Labs for Acquisition, *from page 3*

potential" targets. These acquisitions "make a lot of sense and I would do as many of them as I could," Schechter explained. "We can be accretive in the first year. We can return our cost of capital within two years, typically."

Schechter's Quest counterpart, CEO **Steve Rusckowski** echoed similar sentiments. "It's still a very fragmented marketplace and there's plenty of opportunity for us to consolidate it," he noted during the conference.

## Signs of an M&A Thaw?

Both CEOs also suggested that continued PAMA pricing pressures and hospital consolidation will make acquisitions of independent labs easier in the coming year. Schechter said his team is already "starting to see people consider" selling to LabCorp rather than continuing as independent labs.

Quest, too, seems to be encountering less resistance and has already announced its first independent lab acquisition of 2020, namely, the outreach lab division of Memorial Hermann Health Systems consisting of 21 hospital labs in the Houston area.

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Here's a summary of the key M&A and other strategic diagnostic deals announced during January:

### MERGERS, ACQUISITIONS & ASSET SALES

| Acquiring Company | Target(s) | Deal Summary |
|---|---|---|
| Masimo | NantHealth | • Price: $47.3 million cash<br>• Status: Expected to close by end of Q1<br>• Masimo to buy NantHealth's medical device interoperability assets including DCX device connectivity system, VCX patient vitals software, HBox connectivity hub + Shuttle interoperability cable |
| Clayton, Dubilier & Rice investment funds | Cynosure (owned by Hologic) | • Price: $205 million cash (of which Hologic will net $138 million)<br>• Status: Expected to close before end of 2019 pending regulatory approval<br>• Hologic sells off medical aesthetics business it acquired for $1.6 billion in 2017 after $732 million value write down<br>• Sale enables Hologic to concentrate breast health and molecular diagnostics core businesses |
| Quest Diagnostics | Blueprint Genetics | • Price: Undisclosed (all cash)<br>• Status: Closed<br>• Acquisition of genetic testing firm enhances Quest's capacity to serve pediatric + academic hospitals + other providers specializing in rare diseases + neurology |
| Definitive Healthcare | PatientFinder | • Price: Undisclosed<br>• Status: Closed<br>• Definitive secures foothold in genomics market by acquiring producer of technology to identify patients groups who might benefit from various drugs, medical devices + services |

| Acquiring Company | Target(s) | Deal Summary |
|---|---|---|
| OncoCyte | Insight Genetics | • Price: $7 million cash + $5 million OncoCyte common shares + 10-year revenue share of up to 10% net collected revenues for current IG pharma service offerings + tiered revenue share percentage of net collected revenues through end of lifecycle of new cancer tests developed using IG's technology + contingent consideration of up to $6 million cash and/or common shares<br>• Status: No closing date announced<br>• OncoCyte acquires IG lung cancer immunotherapy test in development + access to IG's existing pharma services infrastructure, including a CLIA-certified + CAP-accredited lab + menu of single-gene tests for various biomarkers |
| NeoGenomics | Human Longevity | • Price: $37 million cash<br>• Status: Closed<br>• NeoGenomics acquires Human Longevity's oncology division which performs NGs services for pharmaceutical customers + had about $10 million in revenue in 2019 |
| Calibre Scientific | Qiagen | • Price: Undisclosed<br>• Status: Closed<br>• Acquisition of Qiagen's NeXtal Biotechnologies structural biology products line |
| Todos Medical | Provista Diagnostics | • Price: Undisclosed<br>• Status: No closing date announced<br>• Todos Medical gets exclusive option to acquire company developing Videssa blood test for breast cancer |
| NuProbe Global (spinout from Harvard University's Wyss Institute) | CarrierGene Biotech | • Price: Undisclosed<br>• Status: Closed<br>• Merger with new entity to continue operating as NuProbe in the US + offer target enrichment assays for NGS-based tests based on toehold probes<br>• Newly merged entity partners with Illumina to develop molecular diagnostic kits for nucleic acid extraction + library construction for use on Illumina's sequencing platform |
| Psomagen-Macrogen Consortium | uBiome | • Price: $7.05 million<br>• Status: Closed<br>• Psomagen acquires all key assets of microbiomics company that declared for bankruptcy in 2019 |
| Algimed Trade | Novacyt | • Price: €400,000 ($446,000) +10% royalty on sales in certain markets<br>• Status: Closed<br>• Novacyt sells off Novaprep business to focus on core Primerdesign and Lab21 reagent development + manufacturing business |
| Abcam | Expedeon | • Price: €120 million ($130 million) cash<br>• Status: Expedeon shareholders approve deal<br>• Abcam to acquire Expedeon's core proteomics business + immunology-focused subsidiaries (Innova Biosciences + TGR Biosciences)<br>• Expedeon plans to change its name + focus on genomics operations<br>• Expedeon to keep its San Diego-based operations |

*Continued on page 6*

Diagnostic Deals, *from page 5*

## STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

| Partner 1 | Partner(s) 2+ | Deal Summary |
|---|---|---|
| Illumina | Roche | • Objective: Increase use of NGS assays for oncology<br>• Dynamic: 15-year, non-exclusive gives Roche rights to develop + distribute in vitro diagnostic tests on Illumina NextSeq 550Dx System + future Dx-branded sequencing systems, including forthcoming NovaSeqDx<br>• Roche to collaborate with Illumina to expand claims for Illumina's comprehensive pan-cancer assay TruSight Oncology 500 (TSO 500) |
| Illumina | Archer DX | • Objective: Broaden access to NGS oncology testing<br>• Dynamic: Develop ArcherDX tests for therapeutic selection, personalized monitoring + new recurrence surveillance<br>• Co-market new tests, starting with the ArcherDX Stratafide companion diagnostic, alongside Illumina's NextSeq 550Dx + MiSeq Dx instruments<br>• Deal is latest in series of co-development agreements between companies |
| Illumina | Genomics England | • Objective: Sequence up to 300,000 genomes over 5 years<br>• Dynamic: Illumina to deliver up to 300,000 "whole genome equivalents"<br>• Illumina Laboratory Services to perform sequencing using NovaSeq 6000 sequencer |
| Roche | Inotrem | • Objective: Commercialize mechanism-based companion diagnostic test using soluble plasma protein sTREM-1 to identify patients likely to respond to Inotrem's treatment, nangibotide, a TREM-1 inhibitor<br>• Dynamic: Worldwide license building on current collaboration to develop test for measuring sTREM-1 in plasma samples of septic shock patients |
| Evotec | Indivumed | • Objective: Form drug discovery + development alliance focused on non-small cell lung cancer<br>• Dynamic: Use Evotec's bioinformatics analysis platform + drug discovery technologies + Indivumed's IndivuType database, which integrates patients' clinical information with genomic, transcriptomic, proteomic + digital histopathology data from biospecimens |
| Dolomite Bio | S2 Genomics | • Objective: Automate library preparation of tissue samples for single-cell RNA sequencing<br>• Dynamic: Combine S2 Genomics' Singulator instrument for automated solid tissue preparation with Dolomite Bio's Nadia single-cell sample prep platform |
| Amgen | Qiagen | • Objective: Develop tissue-based companion diagnostics for Amgen's investigational treatment AMG 510 for non-small cell lung cancer (NSCLC)<br>• Dynamic: Therascreen CDx test will use real-time PCR to identify cancer patients that have the KRAS G12C mutation<br>• Qiagen to seek FDA premarket + global regulatory approvals |
| Amgen | Guardant Health | • Objective: Develop + commercialize global blood-based companion diagnostic test for AMG 510 investigational oral therapy<br>• Dynamic: Guardant to seek FDA + global approval of its Guardant360 CDx assay as companion diagnostic to AMG 510 in metastatic NSCLC patients with the KRAS G12C mutation |
| LabCorp | SpeeDx | • Objective: Codevelop new molecular tests<br>• Dynamic: Leverage SpeeDx's technology to create tests starting with assays for women's health + infectious diseases |

| Partner 1 | Partner(s) 2+ | Deal Summary |
|---|---|---|
| Personal Genome Diagnostics | Eisai | • Objective: Develop a liquid biopsy biomarker discovery tool<br>• Dynamic: Create kitted NGS technology enabling researchers + biopharma companies to do biomarker discovery work on patient blood samples collected during clinical trials |
| Personal Genome Diagnostics | Mayo Clinic | • Objective: Improve clinical diagnostic oncology solutions<br>• Dynamic: Combine Mayo Clinic's clinical knowledge + expertise in oncology with PGDx's genomic technology experience |
| Telo Genomics | Mayo Clinic | • Objective: Evaluate + validate Telo's telomere analytics as prognostic solution for multiple myeloma<br>• Dynamic: Conduct studies using Telo's telomere analytics to predict progression of multiple myeloma precursors to full stage multiple myeloma + predict patient responses to first-line therapy at the point of diagnosis |
| Genomic Testing Cooperative | C2i Genomics | • Objective: Develop liquid biopsy tests for solid tumor staging + monitoring<br>• Dynamic: GTC to sequence samples + help with technical + clinical validation<br>• C2I responsible for AI-based analysis of data, recruitment of samples + clinical trial activities<br>• Initial focus on lung, colon + breast cancer + melanoma |
| Swift Biosciences | MGI Tech (subsidiary of BGI Group) | • Objective: Jointly market Swift's library prep products in Europe + Asia Pacific<br>• Dynamic: Partnership to make Swift's library prep kits compatible with MGI's DNBSEQ sequencers, starting with 2S Turbo DNA kit for whole-genome and targeted sequencing + Rapid RNA + Methyl-Seq DNA Library kits |
| Horizon Discovery | Mammoth Biosciences | • Objective: Develop new generation of genetically engineered CHO cells for production of biotherapeutics<br>• Dynamic: License agreement giving Horizon access to Mammoth's CRISPR platform<br>• Companies to collaborate on optimizing certain CRISPR tools to rapidly develop proprietary CHO cell lines in which selected genes will be knocked out to improve performance parameters like productivity or purification |
| Veravas | Tymora Analytical Operations | • Objective: "Explore the integration of their respective technologies"<br>• Dynamic: Use those respective technologies to enrich + measure circulating biomarkers for use in Alzheimer's disease diagnostics |
| Adaptive Biotechnologies | Genentech (subsidiary of Roche) | • Objective: Use Adaptive's ClonoSeq assay to assess minimal residual disease (MRD) in patients in Phase III clinical trial<br>• Dynamic: Genentech to use ClonoSeq assay to assess MRD in response to venetoclax treatment for patients newly diagnosed with chronic lymphocytic leukemia (CLL)<br>• Agreement also covers use of ClonoSeq in future venetoclax studies for CLL |
| Biocartis | AstraZeneca | • Objective: Demonstrate capacities of Biocartis' Idylla platform in reducing complexity + turnaround time of biomarker testing for lung cancer patients<br>• Dynamic: Widen current tissue-based lung cancer study to additional countries + develop companion diagnostic covering any type of indication or biomarker<br>• Launch new project to evaluate if liquid biopsy testing using Idylla ctEGFR mutation assay may offer further benefits to tissue-based EGFR molecular testing |
| Veracyte | Acerta Pharma | • Objective: Support Acerta's development of oncology therapeutics<br>• Dynamic: Veracyte to provide genomic information to hematology research + development arm of AstraZeneca |

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Diagnostic Deals, *from page 7*

| Partner 1 | Partner(s) 2+ | Deal Summary |
|---|---|---|
| Sebia | Sanofi | • Objective: Develop diagnostic test to mitigate potential interference from Sanofi's investigational antibody, isatuximab, in patients with multiple myeloma<br>• Dynamic: Agreement covers development of Hydrashift 2/4 isatuximab IVD kit to be used in conjunction with Sebia's Hydragel immunofixation electrophoresis assay |
| Bio-Techne | Fresenius Kabi + Wilson Wolf | • Objective: Provide support for researchers + biopharm companies in field of cell + gene therapy<br>• Dynamic: Create joint venture company to provide scalable manufacturing technologies + processes for developing + commercializing new cell + gene therapies |
| Genialis | Oncologie | • Objective: Evaluate biomarkers for gastric cancer<br>• Dynamic: Use Genialis' Expressions software to model gene expression signatures that might predict potential treatments for gastric cancer |

## DISTRIBUTION, SALES & MARKETING AGREEMENTS

| Product Owner | Distributor | Deal Summary |
|---|---|---|
| Exosomics | LCM Genect | • Products: Exosomics' SelectEV-DNA and SortEV-RNA kits<br>• Territory: Italy |
| PredictImmune | Cambridge Clinical Laboratories | • Products: PredictImmune's PredictSure IBD test<br>• Territory: UK, Ireland, Middle East, Balkans<br>• CCL to oversee PredictSure IBD order fulfillment, + receive and process test samples, on a nonexclusive basis in UK + Ireland + exclusively in Middle East + Balkans |
| Osteolabs | Eurofins LifeCodexx | • Products: Osteolabs' osteoporosis early detection test<br>• Territory: Germany |
| Osteolabs | BioGen Medical | • Products: Osteolabs' osteoporosis early detection test<br>• Territory: Turkey |
| Ark Diagnostics | Siemens Healthineers | • Products: Ark Diagnostics' ARK Fentanyl Assay<br>• Territory: Undisclosed but assay has been cleared in both US and Europe |
| SphingoTec | Sysmex Suisse (Sysmex subsidiary) | • Products: SphingoTec's Nexus IB10 point-of-care immunoassay platform<br>• Territory: Switzerland<br>• Exclusive |
| SphingoTec | Hitado (Sysmex subsidiary) | • Products: SphingoTec's Nexus IB10 point-of-care immunoassay platform<br>• Territory: Germany<br>• Exclusive |
| Celsee | Kindstar Global | • Products: Celsee's Genesis single-cell isolation platform<br>• Territory: China |
| T2 Biosystems | Undisclosed | • Products: T2 Resistance, T2Bacteria, and T2Candida panels<br>• Territory: Israel<br>• Exclusive |
| Euformatics | Alliance Global | • Products: Euformatics' bioinformatics software<br>• Territory: Middle East, Asia, Africa<br>• Exclusive |

| Product Owner | Distributor | Deal Summary |
|---|---|---|
| IncellDx | Biolidics | • Products: IncellDx bioINK PD-L1 CTC Core Kit along with Biolidics' ClearCell FX1 system<br>• Territory: Undisclosed |

## LICENSES

| Licensor | Licensee | Deal Summary |
|---|---|---|
| RNAssist | Quality Control for Molecular Diagnostics | • QCMD gets right to use VivoPhix biomolecule stabilization technology to develop new reagents for use with its own molecular infectious disease proficiency testing solutions |
| Rutgers University | Horizon Discovery | • Horizon exercises option to exclusively license novel base editing technology for therapeutic, diagnostic and service purposes |
| ERS Genomics | Daiichi Sankyo | • Japanese pharmaceutical company gets access to ERS' CRISPR-Cas9 genome editing technology patents to support its own R&D initiatives addressing areas of unmet medical need |
| ERS Genomics | New England Biolabs | • NEB gets rights to sell CRISPR-Cas9 tools + reagents from ERS' CRISPR IP portfolio to researchers |
| Codexis | Roche | • Roche gets worldwide rights to include Codexis' EvoT4 DNA ligase in its own nucleic acid kits, sequencing products + workflows |
| MilliporeSigma | Promega | • Promega gets right to use CRISPR genome editing technology to create new research products for investigating endogenous biology, including for drug development |

## NEW CLINICAL STUDIES

| DX Partner | Other Partner(s) | Description of Study |
|---|---|---|
| Natera | -- | • BESPOKE CRC nationwide multi-center prospective registry study to measure clinical impact of serial testing with its Signatera cell-free DNA blood test in colorectal in patients with stage II or stage III colorectal cancer |
| Interpace Diagnostics (subsidiary of Interpace Bioscience) | University of North Carolina | • UNC to evaluate effectiveness of Interpace's BarreGen test in Barrett's esophagus patients undergoing radiofrequency ablation (RFA) in predicting resistance or relapse after RFA |

# The DX Pipeline: OraSure Subsidiary's DNA Test Sample Collection Kit Gets FDA Greenlight

On Jan 22, Ottawa-based DNA Genotek announced that it has obtained FDA 510(k) clearance for its Oragene Dx kits for collecting saliva samples for DNA testing. According to the company, Oragene Dx is now the first and only device with general clearance for collection and stabilization of DNA from saliva for use in genetic testing of human germline DNA, "including prescription or over-the-counter, direct-to-consumer use."

The DX Pipeline: OraSure Subsidiary's DNA Test Sample Collection Kit Gets FDA Greenlight, *from page 5*

Collected samples The kits also allow for long-term storage of samples at room temperature. DNA Genotek is a wholly-owned subsidiary of OraSure Technologies since being acquired by the latter for $50.6 million in 2011.

## Other New DX Product Launches

Here's a rundown of the other key product launches announced from late December through late January.

### NEWLY LAUNCHED PRODUCTS & SERVICES

| Company(ies) | Product(s)/Service(s) |
|---|---|
| MGI | One Million Genomes Total Solution, software + hardware solution combining sample preparation, high-throughput sequencing + data analysis for large-scale population genome sequencing projects |
| Oxford Nanopore Technologies | Flow cells using the R10.3 nanopore chemistry |
| Congenica | Congenica Neuro, new module for firm's clinical decision support platform to help physicians characterize epilepsy + neurodevelopmental disorders |
| Biocept | Target Selector liquid biopsy assays detecting circulating tumor cells + biomarkers in cerebrospinal fluid of patients with breast or lung cancer suspected of brain or central nervous system metastases |
| Oxford Gene Technology | SureSeq CLL + CNV Panel for cancer research |
| Genome Diagnostics | New version of NGSengine human leukocyte antigen typing software |
| Bio-Rad Laboratories | SEQuoia Complete Stranded RNA Library Prep Kit for RNA-Seq library preparation |
| OncoCyte | DetermaRx test for identifying early-stage lung cancer patients who may benefit from adjuvant chemotherapy after surgical resection |
| Illumina | New sequencing platforms NextSeq 1000 + NextSeq 2000 |
| Qiagen | QiaSymphony PowerFecal Pro DNA Kit for isolating microbial genomic DNA from stool + soil using QiaSymphony automation platform |
| Pillar Biosciences | Pillar Onco/Reveal Solid Tumor Panel, a 47-gene enrichment assay for research use |
| Personalis | NeXT Dx Test, NGS panel to help oncologists identify potential therapies + clinical trial options for cancer patients |
| Viracor Eurofins | Viracor TRAC donor-derived, cell-free DNA assay for diagnosing kidney transplant rejection |
| PreventionGenetics | Rapid PGxome whole-exome sequencing test |
| Sysmex | Japanese launch of Ipsogen JAK2 DX reagent |
| AMS Biotechnology | cfPure Max kit for circulating cell-free DNA purification |

| Company(ies) | Product(s)/Service(s) |
|---|---|
| Lucid Diagnostics (PAVmed subsidiary) | subsidiary has launched its EsoGuard Esophageal DNA Test as |
| SpeeDx | European launch of ResistancePlus MG FleXible for GeneXpert System |
| Caris Life Sciences | MI GPS (Genomic Profiling Similarity) Score, AI product generating tumor type biology similarity score |

FDA Watch: Agency to Use EUA Pathway to Clear New Coronavirus Detection Tests, *from page 1*

The FDA has also created a landing page to keep product developers and the public informed about the outbreak and the FDA's response measures.

## New FDA Approvals

Key new product approvals announced from late December 2019 through late-January 2020:

**NEW FDA APPROVALS**

| Manufacturer(s) | Product(s) |
|---|---|
| DNA Genotek (subsidiary of OraSure Technologies) | 510(k) clearance for Oragene Dx sample collection kits |
| Geneoscopy | Breakthrough device designation for colorectal cancer screening test based on extraction of stool-derived eukaryotic RNA transcripts |
| **Manufacturer(s)** | **Product(s)** |
| KDx Diagnostics | Breakthrough device designation for URO17 Bladder Cancer Recurrence Test |
| Luminex | Clearance for NxTag Respiratory Pathogen Panel qualitative test run on firm's Magpix instrument to simultaneously detect and identify nucleic acids from multiple respiratory viruses and bacteria |
| Microgenics | Clearance for Cedia Benzodiazepine Assay, a homogeneous enzyme immunoassay to detect benzodiazepines in human urine at cutoff concentration of 200 ng/mL |
| Sentinel Diagnostics | Clearance for Albumin BCP assay measuring albumin in human serum or plasma |
| i-Sens | Clearance for ReliOn Premier Classic Blood Glucose Monitoring System measuring glucose in fresh capillary whole-blood samples drawn from fingertips, forearm, palm, thigh or calf |
| Promisemed Hangzhou Meditech | Clearance for Promisemed Heel Blood Lancet for collection of capillary blood from heels of newborn or premature babies |

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FDA Watch: Agency to Use EUA Pathway to Clear New Coronavirus Detection Tests, *from page 11*

| Manufacturer(s) | Product(s) |
|---|---|
| Immunotech Vit Oburka | Clearance for Active Free Testosterone RIA test radioimmunoassay used to measure free testosterone in human serum |
| Applied BioCode | 510(k) clearance for BioCode Respiratory Pathogen Panel (RPP) for use on BioCode MDx-3000 system |
| Qiagen | Clearance for Therascreen PIK3CA RGQ PCR Kit as companion diagnostic to identify advanced breast cancer patients with PIK3CA mutations likely to respond to Novartis' Piqray (alpelisib) |
| Applied BioCode | 510(k) clearance for BioCode respiratory pathogen panel diagnostic test used with firm's MDx-3000 system for detecting common respiratory viruses and bacteria |
| AstraZeneca + Merck | Expanded indication for olaparib (Lynparza) as a maintenance treatment for metastatic pancreatic cancer patients identified via a companion diagnostic |
| Curetis | Clearance for Unyvero LRT lower respiratory tract application cartridge |

To read the rest of this story go to https://www.g2intelligence.com/fda-watch-agency-to-use-eua-pathway-to-clear-new-coronavirus-detection-tests/

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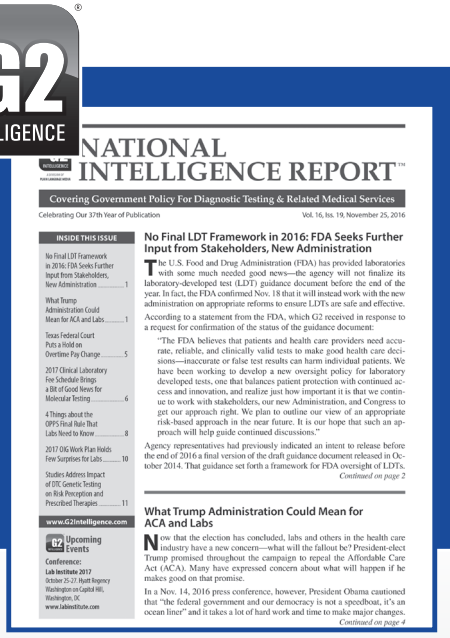
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Upcoming Events

Conferences:
Lab Institute 2017
October 25-27, Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

**No Final LDT Framework in 2016: FDA Seeks Further Input from Stakeholders, New Administration**

The U.S. Food and Drug Administration (FDA) has provided laboratories with some much needed good news—the agency will not finalize its laboratory-developed test (LDT) guidance document before the end of the year. In fact, the FDA confirmed Nov. 18 that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

> "The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions—inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right. We plan to outline our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide continued discussions."

Agency representatives had previously indicated an intent to release before the end of 2016 a final version of the draft guidance document released in October 2014. That guidance set forth a framework for FDA oversight of LDTs.

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**What Trump Administration Could Mean for ACA and Labs**

Now that the election has concluded, labs and others in the health care industry have a new concern—what will the fallout be? President-elect Trump promised throughout the campaign to repeal the Affordable Care Act (ACA). Many have expressed concern about what will happen if he makes good on that promise.

In a Nov. 14, 2016 press conference, however, President Obama cautioned that "the federal government and our democracy is not a speedboat, it's an ocean liner" and it takes a lot of hard work and time to make major changes.

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DIAGNOSTIC TESTING & Emerging Technologies

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November 2016

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Upcoming Conferences

Lab Institute 2017
October 25-27
Hyatt Regency Washington DC on Capitol Hill
www.labinstitute.com

**FDA Oversight of LDTs Delayed for Consultation with New Administration, Stakeholders**

The U.S. Food and Drug Administration (FDA) has provided laboratories with some much needed good news—the agency will not finalize its laboratory-developed test (LDT) guidance document before the end of the year. In fact, the FDA confirmed Friday that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

> "The FDA believes that patients and health care providers need accu-
> rate, reliable, and clinically valid tests to make good health ca
> sions—inaccurate or false test results can harm individu
> have been working to develop a new oversight policy
> developed tests, one that balances patient protectio
> cess and innovation, and realize just how important it
> ue to work with stakeholders, our new Administrati
> get our approach right. We plan to outline our vie
> risk-based approach in the near future. It is our hope
> proach will help guide continued discussions."

Agency representatives had previously indicated an intent to re
the end of 2016 a final version of the draft guidance document
tober 2014. That guidance set forth a framework for FDA oversight o

*Continued on*

**DTC Test Results Don't Lead to Dramatic Changes in Health Care Use**

The U.S. Food and Drug Administration (FDA) has frequently expressed concern about direct-to-consumer (DTC) marketing of genetic testing. For example, the FDA required pre-market approval for 23andMe's Personal Genome Service. One of the FDA's stated concerns is that in the case of DTC genetic tests no physician is involved to provide consumers guidance in utilizing these results and there is a danger that consumers will make their own decisions about treatment or use of prescription medicines that can create risks to their health. Recent studies provide some insight regarding consumers' perceptions of these genetic test results.

*Continued on page 8*



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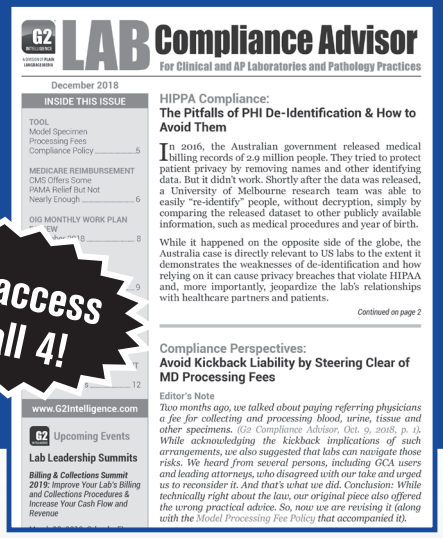
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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

December 2018

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Upcoming Events

Lab Leadership Summits

*Billing & Collections Summit 2019: Improve Your Lab's Billing and Collections Procedures & Increase Your Cash Flow and Revenue*

**HIPPA Compliance:**
**The Pitfalls of PHI De-Identification & How to Avoid Them**

In 2016, the Australian government released medical billing records of 2.9 million people. They tried to protect patient privacy by removing names and other identifying data. But it didn't work. Shortly after the data was released, a University of Melbourne research team was able to easily "re-identify" people, without decryption, simply by comparing the released dataset to other publicly available information, such as medical procedures and year of birth.

While it happened on the opposite side of the globe, the Australia case is directly relevant to US labs to the extent it demonstrates the weaknesses of de-identification and how relying on it can cause privacy breaches that violate HIPAA and, more importantly, jeopardize the lab's relationships with healthcare partners and patients.

*Continued on page 2*

**Compliance Perspectives:**
**Avoid Kickback Liability by Steering Clear of MD Processing Fees**

Editor's Note

*Two months ago, we talked about paying referring physicians a fee for collecting and processing blood, urine, tissue and other specimens. (G2 Compliance Advisor, Oct. 9, 2018, p. 1). While acknowledging the kickback implications of such arrangements, we also suggested that labs can navigate those risks. We heard from several persons, including GCA users and leading attorneys, who disagreed with our take and urged us to reconsider it. And that's what we did. Conclusion: While technically right about the law, our original piece also offered the wrong practical advice. So, now we are revising it (along with the Model Processing Fee Policy that accompanied it).*

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