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HIGHLIGHTS

Investment Trends: Dx/Tools Venture Capital Keeps Flowing Despite Decline in Early-Stage Investment

Continuing a four-year trend, total U.S. venture capital investment in health care surged in 2018, reaching a new all-time high of $9.6 billion, according to Silicon Valley Bank's (SVB) *Trends in Healthcare Investments and Exits* annual report. While the largest gains were in biopharma, the diagnostics and tools sector (Dx/Tools) also had a strong year with slight growth in investments, with strength in later-stage company investments offsetting slight declines in Series A investment.

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Diagnostic Deals: A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month

A government shutdown, ongoing tensions with China and concerns about continued economic growth have marked the beginning of 2019. Against this backdrop, diagnostic deals continue to move forward. Here's a quick overview of the past month's activity.

M&A

The biggest M&A deal for the period involved Luminex, which has completed its previously announced acquisition of MilliporeSigma's flow cytometry portfolio. Valued at $75 million in stock, assets, and inventory, it gives Luminex access to Amnis imaging flow cytometry products for cell-based analysis, as well as the Guava portfolio of products, which leverage microcapillary technology and are also used for cell-based analysis. These additions complement Luminex's offerings and enhance its current flow-based systems—and expand the number of the company's installed systems to more than 5,000.

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Dx/Tools Venture Capital Keeps Flowing Despite Decline in Early-Stage Investment, *from page 1*

Dx/Tools By the Numbers

In 2018, Dx/Tools venture capital flows were $4.8 billion (spread over 211 deals), up from $4.3 billion in 2017 and representing roughly half of the $9.6 billion total generated by the entire health care industry. SVB breaks down the Dx/Tools sector into three primary categories:

Dx/Tools 2018 U.S. Venture Capital Flows by Category

Category	Total 2018 Investment	Number of Deals
R&D tools companies	$2.4 billion	95
Diagnostic test companies (yes/no diagnostic tests)	$1.28 billion	64
Diagnostic tools and analytics companies (actionable data analytics)	$1.11 billion	51

Slight Decline in Dx/Tools Series A Investment

The strong growth in overall fundraising within Dx/Tools belies the year-over-year decline in the number of Series A deals, i.e., first-round from institutional or corporate venture investments of at least $2 million, from 70 to 64. There was a corresponding decrease in Series A investment dollar totals, from $845 million to $621 million. "Following multiple large Series A investments over the past two years, it is not surprising to see a slowdown in early-stage investment as investors wait for things to play out," wrote report author **Jonathan Norris**, managing director of SVB's Life Science and Healthcare Practice."

Even so, median Series A round size remained stable at $6 million. There were also eight Series A raises in Dx/Tools sector in 2018 of over $20 million, including by:

- Glympse Bio (Cambridge, MA);
- Paige.AI (NY, NY);
- Shine (Janesville, WI);
- Celsius Therapeutics (Cambridge, MA);
- ArcherDx (Boulder, CO);
- Now Diagnostics (Springdale, AR);
- Mammoth Biosciences (SF, CA); and
- Alveo Technologies (Alameda, CA).

Later-Stage Investments Pick Up the Slack

The flip side of investors' wait-and-see attitude was that 85% of Dx/Tools sector investments in 2018 went to later-stage companies. Overall, there were 25 raises of over $50 million during the year, including eight rounds of over $100 million by:

- Tempus (Chicago, IL);
- Helix (San Carlos, CA);
- HeartFlow (Redwood City, CA);
- Synthego (Redwood City, CA);
- Twist Bioscience (SF, CA);
- Grail (Menlo Park, CA);

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- 10x Genomics (Pleasanton, CA); and
- Zymergen (Emeryville, CA).

Billion-Dollar Companies

Six private Dx/Tools companies were valued at more than $1 billion in the last two years, the largest number of any sector, SVB says, including the aforementioned Grail, 10x Genomics and Tempus, as well as:

- 23andMe (Mountain View, CA);
- Human Longevity (SD, CA); and
- Ginkgo Bioworks (Boston, MA).

M&A and IPOs

After a slow 2017 in which there was just one IPO and no mergers and acquisitions in Dx/Tools, activity in the sector rebounded in 2018 with strong with two successful IPOs in 2018 (by Guardant Health (Redwood City, CA) and Twist Biosciences), and 10 acquisitions.

M&A deal value, led by $1.9 billion in upfront M&A payments, set a six-year high but still substantially trailed biopharma and other health care sectors. Among the 10 M&A deals in Dx/Tools, four were between diagnostic test companies (three of them commercial) and six involved R&D tools companies. Three of the four diagnostic companies were commercial. "Nine of 10 deals were at a commercial stage and acquired by traditional lab instrument, research and diagnostic companies," writes Norris. "We are surprised to see no new acquirers, especially tech players, emerge."

Of the companies with exits, the median years to exit was 9.1, the highest reported in the past six years.

Geographical Breakdown

Geographically, California remained the center of the Dx/Tools deals universe in 2018 with 82 deals valued at $2.371 billion, including:

- 65 deals valued at $2.09 billion in Northern California; and
- 17 deals valued at $362 million in Southern California.

Massachusetts had 31 deals in 2018 valued at $579 million. Other key deal venues included New York (11 deals valued at $148 million) and Pennsylvania (7 deals valued at $36 million).

What to Expect in 2019

So, what's in store for the coming year? SVB predicts that overall investment in the life science and health care space will continue at a "healthy pace." overall. Predictions for the Dx/Tools sector in 2019:

- Series A deals will "likely climb" even though overall investment dollars could shrink following the multiple larger financings of 2017 and 2018;
- Tech acquirers will likely scoop up a few diagnostic test, tools and analytics companies, which could drive an uptick in M&A deal value; and
- There could be two to four IPOs among revenue-generating, R&D tools companies

The DX Pipeline: A roundup of the month's key new product launches

Late December through January was fairly slow for new product launches in terms of both volume and impactful-ness. Here's a rundown of the new offerings that did emerge from the pipeline:

NEWLY LAUNCHED PRODUCTS & SERVICES	
Company(ies)	**Product(s)/Service(s)**
Oxford Nanopore Technologies	PromethION 24 and PromethION 48 sequencing platforms now available for users to order
Oxford Nanopore Technologies	Field Sequencing Kit for sequencing library preparation from genomic DNA without refrigeration
Intermountain Healthcare Precision Genomics	ICG100 Myeloid Malignancies Panel for classification and diagnosis of multiple blood cancer types
AusDiagnostics	New *in vitro* diagnostic kit that detects dermatophytes and other fungi
Horizon Discovery	Expansion of CRISPR Screening Service to include ex vivo T lymphocytes
XIFIN	VisualStrata precision medicine informatics platform
HTG Molecular	HTG EdgeSeq Reveal software
NRGene + Macrogen	ArrayMagic joint sequencing-based genotyping service providing ultra-high-density SNP genotying
TATAA Biocenter	TATAA ALU-60 and TATAA ALU-187 ultra-sensitive qPCR assays targeting human-specific Alu repeats
Asuragen	AmplideX PCR/CE HTT kit detecting CAG trinucleotide repeats within the HTT gene linked to development of Huntington disease
Yourgene Health	Sage 32 plex test, high-throughput noninvasive prenatal testing and analysis solution
Twist Bioscience	Service to synthesize genes up to five kilobases in length for $0.15 per base pair with turnaround time of 15 to 25 days
PreventionGenetics	Addition of Patient Plus feature to its PGxome whole-exome sequencing tests

Inside the Lab Industry: 5.1% Growth Expected to Lift Lab Automation Market to $5 Billion by 2022

Projected compound annual growth of 5.1% will take the lab automation market from its current $4.06 billion (2017) to $5.20 billion by 2022.

The Study

This is the finding of a new study on the lab automation market from leading B2B research company, MarketsandMarkets.

Objective: The goals of the new study include defining, describing and forecasting the lab automation market by equipment and software, application, end user and region and identifying the major factors driving growth and opportunities they present.

Methodology: The report analyzes lab automation, by equipment and software,

in six primary categories, including: Automated workstations; Off-the-shelf automated workcells; Robotic systems; Automated storage & retrieval systems; Other equipment; and Software. It also looks at the lab automation market by application, including: Drug discovery; Clinical diagnostics; Genomics solutions; Proteomics solutions; Microbiology; and Other applications.

Findings

Here's a summary of the report's key findings.

Current Market Share: The automated workstations segment currently accounts for the largest share of the lab automation market, according to MarketsandMarkets. The firm cites high demand for automation in liquid handling as the key factor driving market growth in this segment. It notes that automated workstations offer advantages such as enhanced accuracy, and reduced time and cost.

Projected Growth: Based on applications, the genomics solutions segment is expected to grow at the highest compound annual growth rate during the forecast period. The firm finds that use of automation is on the rise in genomics for high-throughput requirements, providing greater reproducibility and throughput as compared to manual methods.

Source of Growth: North America currently commands the largest share of the global lab automation market. MarketsandMarkets cites:

- Increasing adoption of lab automation systems;
- Implementation of the *Affordable Care Act* (ACA) in 2010; and
- Economic stimulus programs such as increased funding for the National Institutes of Health (NIH) and National Science Foundation (NSF); and
- Increased R&D activities by biotechnology and pharmaceutical companies as drivers of market growth in North America.

Key Market Players: Companies serving as major players in the lab automation market include:

- Tecan Group (Switzerland);
- PerkinElmer (US);
- Danaher (Beckman Coulter & Molecular Devices) (US);
- Thermo Fisher (US);
- Agilent Technologies (US);
- Hamilton Robotics (US);
- Abbott Diagnostics (US);
- Eppendorf (Germany);
- QIAGEN (Netherlands);
- Roche Diagnostics (Switzerland); and
- Siemens Healthcare (Germany).

Diagnostic Deals: A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month, *from page 1*

Other deals that closed this period include two involving OraSure Technologies, and the acquisition of Connective Tissue Gene Tests by Health Network Laboratories. Details for these and other M&As are provided in the chart below.

Strategic Alliances

Among new strategic alliances is a partnership between population genomics technology company Color and NorthShore University HealthSystem. Together, they have launched an initiative called DNA10K, which will provide genetic testing to 10,000 patients as part of their annual exam with their primary care practitioner. The program is aimed at helping patients learn about their genetic makeup, including risk factors for certain disease types such as common hereditary cancers and heart diseases, so that NorthShore may then personalize care for each patient to support improved outcomes, prevention, and overall health. The initiative is the largest known primary-care based genomics program in the United States.

Other U.S. agreements include three involving Personal Genome Diagnostics (PGDx), all of which are detailed in the chart below.

Product integration and deals are likewise hot in Asia this month, especially in China, where, as in the U.S., the focus is often on genomics and/or cancer.

Key Diagnostic Deals

Here's a summary of key diagnostic deals from late December through January:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Luminex	MilliporeSigma	• Price: $75 million including $69.9 million under a stock and asset purchase agreement and $5.1 million in inventory purchases • Status: Closed • Acquisition of MilliporeSigma's flow cytometry portfolio, including Amnis imaging flow cytometry products for cell-based analysis and Guava portfolio enhances Luminex's flow-based detection systems line
OraSure Technologies	CoreBiome	• Price: Undisclosed upfront payment + contingent performance-based future payments • Status: Closed • Acquisition of privately held provider of microbiome research services for customers for pharmaceutical, agricultural and research markets
OraSure Technologies	Novosanis	• Price: Undisclosed upfront payment + contingent performance-based future payments • Status: Closed • Acquisition of privately held urine sample collection device developer
Health Network Laboratories	Connective Tissue Gene Tests	• Price: Undisclosed • Status: Closed • Acquisition of molecular diagnostic lab specializing in inherited genetic disorders
Qiagen	N-of-One	• Price: Undisclosed but purchase made with cash reserves • Status: Closed • Acquisition of molecular oncology decision company boost Qiagen's offerings in decision support
Chiral Technologies	Arbor Biosciences	• Price: Undisclosed • Status: Closed • Acquisition of NGS and synthetic biology products provider whose offerings include custom DNA microarrays, oligonucleotide libraries and myBaits line of targeted sequencing panels

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Neogen	Delta Genomics Centre	• Price: Undisclosed • Status: Closed • Acquisition of Canadian animal genomics lab to be renamed Neogen Canada

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Roche	Phoenix Molecular Designs	• Objective: Develop CDx for a kinase inhibitor developed for triple-negative breast cancer • Dynamic: Assay to use immunohistochemistry to detect activation of RSK2 kinase in tumors via measuring nuclear RSK2 • Roche to establish CAP/CLIA-certified protocol for assay for clinical tumor analyses
Luminex	AllerGenis	• Objective: Develop and market precision food allergy diagnostic assay • Dynamic: Leverage Luminex xMAP technology to create tests starting with AllerGenis peanut allergies test slated to launch in fall 2019
Illumina	PierianDx	• Objective: Develop cancer sequencing products • Dynamic: PierianDx to leverage Clinical Genomics Workspace platform and Clinical Genomics Knowledgebase to provide variant interpretation and reporting for Illumina TruSight Tumor 170 and TruSight Oncology 500 research assays • Non-exclusive also covers future products
Veracyte	Johnson & Johnson Innovation	• Objective: Develop Veracyte's lung cancer tests • Dynamic: Veracyte to join J&J's Lung Cancer Initiative, combine its study cohorts with J&J patient cohorts and collaborate on enrolling new cohorts
Color	NorthShore University HealthSystem	• Objective: Deliver genomic testing as part of routine primary care to population of 10,000+ • Dynamic: So-called "DNA10K" expands previous collaboration in which patients signed up for Color population health program as a part of their primary care visit • Color labs to analyze blood samples provided by NorthShore patients who elect to participate in program
Personal Genome Diagnostics (PGDx)	PathGroup	• Objective: Get US regulatory approval for PGDx Elio tissue complete assay • Dynamic: Co-development agreement collaboration integrating PGDx's scientific, development, and regulatory expertise with PathGroup's NGS experience
Personal Genome Diagnostics (PGDx)	Merck	• Objective: Use Elio tissue complete assay to assess TMB during enrollment portion of Merck phase II precision oncology KeyImpact study • Dynamic: Test to study application of biomarker-based, pembrolizumab-based therapies for advanced non-small-cell lung cancer patients
Personal Genome Diagnostics (PGDx)	KingMed Diagnostics	• Objective: Commercialize PGDx's Elio tissue complete assay in China and Hong Kong • Dynamic: Establish KingMed as qualified clinical trial testing site for assay once assay gets regulatory approval
Sphere Fluidics	Peak Analysis and Automation (PAA)	• Objective: Product integration to help increase throughput in antibody discovery and cell line development • Dynamic: PAA to combine its automated microplate handling technology with Sphere Fluidics' Cyto-Mine single-cell analysis system
BC Platforms	MedEngine	• Objective: Offer "turnkey research solutions" • Dynamic: Strategic alliance under which MedEngine to integrate its research and medical knowledge into BC Platforms' analytics platform and biobank data stores
Adaptive Biotechnologies	Genentech (part of Roche)	• Objective: Enable Adaptive to develop personalized cancer therapies • Dynamic: Adaptive to use Genentech's TruTCR T-cell receptor screening platform to identify TCRs for targeting individual cancer patients' neoantigens • Genentech to use TCRs to engineer and manufacture personalized therapies and get regulatory approvals • Adaptive to get $300 million upfront + up to $2 billion in future development, regulatory and commercial milestones + royalties

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Arbor Biotechnologies	Vertex Pharmaceuticals	• Objective: Discover new proteins, including DNA endonucleases, for developing gene editing-based therapies for cystic fibrosis and other diseases • Dynamic: Combine Arbor's protein biodiscovery platform with Vertex's expertise in developing gene editing-based approaches for treating serious diseases • In addition to funding research, Vertex will pay undisclosed up-front cash payment + future milestone payments + royalties on future net sales • Vertex to also make investment in Arbor via a convertible note and get an observer seat on Arbor's board
CellMax Life	Medigen Biotech	• Objective: Clinical trial evaluating patients with stage II and III colorectal cancer • Dynamic: Integrate CellMax's CMx circulating tumor cell platform with Medigen's liquid biopsy panel to examine patient treatment selection and response
NX Prenatal	Milu Labs	• Objective: Commercialize NX Prenatal's test for preterm birth risk in Asia • Dynamic: Milu to help launch test in China and other countries as part of the new maternal fetal medicine and women's health business it's developing in Asia
LifeMap Sciences	Novogene	• Objective: Offer LifeMap Sciences' TGex clinical genomics platform in China • Dynamic: Platform to be offered through Novogene's Tianjin, China-based clinical lab
Pillar Biosciences	China Biotech Services Holdings	• Objective: Provide Pillar Bio's precision diagnostic products in Hong Kong, Macau, South Korea and Southeast Asia • Dynamic: Parties to create new joint venture • China Biotech Services to also participate in Pillar Bio's Series B financing round
Biocartis	Nichirei Bioscience	• Objective: Commercialize Biocartis' Idylla MDx oncology tests in Japan • Dynamic: Nicherei to seek regulatory approval from Japanese Ministry of Health, Labor and Welfare and serve as local distributor once tests are registered

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Gemelli Biotech	Advanced Medical German	• Products: IBS-smart, Gemelli's blood test for irritable bowel syndrome • Territory: Kuwait, United Arab Emirates, Qatar, Saudi Arabia, Egypt, Turkey
SpeeDx	AB Analitica	• Products: SpeeDx ResistancePlus and PlexPCR tests • Territory: Italy
SpeeDx	Immuno Diagnostic Oy	• Products: SpeeDx ResistancePlus and PlexPCR tests • Territory: Finland
Sienna Cancer Diagnostics	Mirax	• Products: Sienna's bladder cancer test • Territory: South Korea • Exclusive • Mirax to also seek regulatory approval for test in South Korea
Omni Life Science	Bioké	• Products: OLS' CERO benchtop 3D cell incubator and bioreactor + CASY cell counter and analyzer • Territory: Belgium, Netherlands, Luxembourg
Roche	MilliporeSigma	• Products: Roche's biochemical reagents, Kapa Biosystems portfolios and select qPCR and nucleic acid purification products • Territory: Global • Renewal of existing deal through 2025
Paragon Genomics	MGI Tech	• MGI to distribute Paragon's CleanPlex NGS panels for use with its own sequencing platforms worldwide except for the US • Paragon to distribute MGI's MGISP-100RS, MGISP-960RS and future automated sample prep systems in US and Canada • Neither deal is an exclusive

LICENSES		
Licensor	**Licensee**	**Deal Summary**
Salisbury NHS Foundation Trust	NimaGen	• Property: One-step PCR technology using reverse complement probes for use in developing NGS products • NimaGen also gets worldwide license to technology for research uses including development and sale of products for sample tracking and authentication within labs, high-throughput screening and diagnostic research
Expedeon	Cell Guidance Systems	• Property: Expedeon's Lightning-Link Rapid Biotin technology • License and supply agreement allows Cell Guidance Systems to use technology to develop its TRIFic (Time Resolved Immunofluorescence Exosome Detection Assay) immunoassays
Genfit	Covance (LabCorp drug development business)	• Property: Genfit's NIS4, non-alcoholic steatohepatitis liver diagnostic (NASH) assay • Agreement allows Covance to deploy NIS4 for clinical research space to further validate its use for better identification and characterization of patients, and to generate new biological insights on NASH disease pathogenesis

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client/User**	**Deal Summary**
Abbott	Japanese Red Cross Society	• 8-year deal making Abbott an exclusive supplier of immunoassay-based serological instrumentation, tests and consumables for blood and plasma screening in Japan
LabCorp	Texas Association of Community Health Centers (TACHC)	• Extension of existing making LabCorp exclusive preferred provider of lab services for TACHC • Parties to use data analytics to identify population health trends, enabling targeted community and individual outreach about screening, monitoring and treatment options for common health conditions
Primerdesign (molecular testing division of Novacyt)	Genesis Diagnostics	• Exclusive supply agreement with Primerdesign to develop and supply 384-well plate molecular assay panels, including respiratory, women's health, sexually transmitted diseases, wound and urinary tract infections, to Genesis to use in its Pennsylvania-based clinical service lab

FDA Watch: Agency Finalizes New Medical Device Marketing Pathway & Okays Direct Lab Reporting of PGx Test Results

On Jan. 22, the FDA issued final guidance establishing a new alternative pathway for getting medical devices to market. Under the "Safety and Performance Based Pathway" (new Pathway), new product approval will be based on consensus standards rather than direct predicate comparisons with previously approved devices.

How the New Pathway Works

The new Pathway is to be used when FDA determines that:

- The new device has indications for use and current technological characteristics that don't raise safety and effectiveness questions different from identified predicates;
- The predicate is within the scope of the list of eligible device types;
- The performance criteria align with the performance of one or more modern legally marketed devices of the same type as the new device; and
- The new device meets all FDA-identified performance criteria.

If the above criteria are met, the FDA may request and review underlying data and testing methodologies as necessary to find that a new device is substantially equivalent. If any of the criteria aren't met, the manufacturer can seek approval through the Traditional, Special or Abbreviated 510(k) pathways.

When the New Pathway Will Become Available

In its press release, the FDA outlined its implementation plans:

- Create a list of device types eligible for the new Pathway with input from industry;
- Establish criteria applicable to each device type;
- Issue new guidance listing the eligible device types and corresponding criteria;
- Hold a webinar and take other steps to educate stakeholders how to use the new Pathway.

Once the new Pathway launches, the FDA will publish the list of device types and applicable criteria on its website and review them on a periodic basis.

Discouraging Use of Older Predicates

In a separate action, the FDA issued a notice requesting comments on approaches to drive sponsors to offer patients devices with the latest improvements and advances. Specifically:

- Should the FDA publish a list of devices or manufacturers that rely on predicates that have been on the market for more than a certain number of years? If so, what number of years should that be?
- Should the FDA consider using other criteria to inform its point of reference?
- What other actions should the agency FDA take to promote use of more modern predicates?
- Should the FDA consider certain actions that might require new authority, such as making at least some older devices ineligible as predicates?

Deadline to comment: April 22.

New FDA Approvals

The other headliner from January was the agency's first ever approval for a direct-to-consumer test company (23andMe) to provide pharmacogenetic test results to customers without a doctor's order. 23andMe CEO and co-founder praised the decision for opening "the door for consumers to work with their health providers to better manage their medications," However, some experts caution that patients may be tempted to bypass their doctors and medical lab testing if they're directly informed how they metabolize medications on the basis of genetic testing.

Here's a look at the other key FDA approvals announced at the end of December through the final days of January:

NEW FDA APPROVALS	
Manufacturer(s)	**Product(s)**
Illumina	Breakthrough device designation for TruSight Oncology Comprehensive pan-cancer assay
Hologic	*de novo* clearance to market Aptima assay for *Mycoplasma genitalium* sexually-transmitted infection
Phadia AB (ThermoFisher Scientific)	Clearance for EliA RF IgM immunoassay for measuring IgM class rheumatoid factor antibodies in serum and plasma to diagnose rheumatoid arthritis operating on Phadia 2500/5000 instrument
Thermo Fisher	Clearance for Thermo Scientific QMS Plazomicin Immunoassay
PTS Diagnostics	Clearance for PreVantage medical device convenience kit for quantitative measuring percentage of glycated hemoglobin, total cholesterol, high-density lipoprotein, triglycerides and glucose in whole blood
ArcherDx	Breakthrough device designation for companion diagnostic assay
Grifols	Clearance for Erytra Eflexis, a fully automated benchtop analyzer for pretransfusion compatibility testing
DiaSorin Molecular	Clearance for Simplexa Bordetella Direct assay to detect pathogens that cause pertussis or whooping cough
Miris	Marketing authorization after *de novo* premarket review of Miris Human Milk Analyzer for measuring nutrients in breast milk
GenMark Diagnostics	510(k) clearance for ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel molecular diagnostic panel assay to detect fungal pathogens from blood cultures of patients with suspected blood stream infections run on the firm's ePlex system
BioMérieux	Approval for Vitek MS mass spectrometry system to identify microorganisms cultured from human specimens
Lin-Zhi International	Clearance for LZI Fentanyl Enzyme Immunoassay for detection of norfentanyl in human urine at cutoff of 5 ng/mL
Ark Diagnostics	Clearance for immunoassay for detection of tramadol in urine at cutoff of 100 ng/mL
Sekisui Diagnostics	Clearance for Acucy Influenza A & B test for use with Acucy system and Influenza A & B control kit
Axis-Shield Diagnostics	Clearance for Advia Centaur Calcitonin assay to diagnose and treat thyroid and parathyroid gland diseases, including carcinoma and hyperparathyroidism
YD Diagnostics	Clearance to market UriScan 10ACR urine strips run on UriScan Optima urine analyzer to measure blood, acetoacetic acid, protein, nitrite, glucose, pH, specific gravity, leucocytes, albumin and creatinine

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE	
Manufacturer(s)	**Product(s)**
NuGenerex Diagnostics	CE marking for Express II Syphilis TreponemalAssay rapid, point-of-care syphilis test
Theradiag	CE marking for Lisa Tracker drug response kit for Novartis' Cosentyx (secukinumab) treatment for psoriasis, psoriatic arthritis and ankylosing spondylitis
Chembio Diagnostics	CE marking for diagnostic test developed with AstraZeneca to detect an undisclosed biomarker using firm's DPP platform
Mobidiag	CE-IVD marking for its Novodiag CarbaR+ test for carbapenemase-producing enterobacteriaceae (CPE), a bacterium resistant to carbapenem antibiotics

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Qiagen	Canada	Health Canada approval for QuantiFeron-TB Gold Plus (QFT-Plus) test for latent tuberculosis infection
Qiagen	Japan	Japanese Pharmaceuticals and Medical Device Agency approval for Therascreen EGFR RGQ PCR kit as companion diagnostic with Pfizer's Vizimpro (dacomitinib) for EGFR mutation-positive, inoperable or recurrent non-small cell lung cancer
Foundation Medicine	Japan	Ministry of Health, Labour and Welfare approval for FoundationOne CDx genomic profiling assay