

Deal trends in molecular diagnostics

Infectious disease diagnostics were prominent among mergers and acquisitions in the molecular diagnostics field, while financing flowed to companies developing liquid biopsy technology.

Beth Allan and Maureen Riordan

Dealmaking was strong among molecular diagnostics (MDx) players during 2021 despite the continuation of the pandemic, with most merger and acquisition (M&A) transactions demonstrating either a pivot in a new direction or an enhancement of current portfolios. In comparison to acquisition activity in the space in 2020, overall deal value for 2021 was lower, but deal volume tripled. Financings also saw an uptick in deal numbers as well as an increase in deal value compared to the previous year. Investors' confidence was showcased through both public and private fundraising, particularly for personalized medicine and liquid biopsy-focused companies.

Acquisition activity

In 2021, molecular diagnostics companies agreed to 24 mergers and acquisitions, which had an aggregate deal value of \$9 billion versus \$13.2 billion from only 8 transactions in 2020. Deal activity in terms of both volume and value was strongest during Q1, with nine deals together valued at \$4.5 billion (half the full-year total). There was a decrease in Q2 with seven deals together totaling \$3.4 billion, but Q3 (three deals) and Q4 (five deals) did not even reach one billion dollars, with \$300 million and \$728 million in aggregate values, respectively (Fig. 1).

The outlier in Q1 2021 in terms of deal value was Roche and its \$1.83 billion all-cash purchase of GenMark Diagnostics in a transaction that will enhance Roche's presence in the infectious disease diagnostics space (especially in respiratory and bloodstream infections) and bring the company into the syndromic testing market for the first time. GenMark's ePlex system drives lab efficiency through streamlined order-to-reporting workflow and enables better patient outcomes by rapidly diagnosing a patient's symptoms. The company's Respiratory Pathogen Panels identify the most common viral and bacterial organisms associated with upper respiratory infection, including SARS-CoV-2, complementing Roche's extensive portfolio of COVID-19 diagnostics solutions.

In a similarly high-value deal in Q2, DiaSorin paid \$1.8 billion in cash to buy Luminex and its extensive test offerings in the infectious disease, respiratory, vector-borne, hospital-acquired and gastroenterology infection markets, as well as genetics products and women's health diagnostics. Its business includes molecular tests for infectious diseases with single-analyte/low-plex real-time polymerase chain reaction (PCR) technology, as well as a solid multiplexing panel technology for pathogen identification. The life sciences segment includes the licensed technologies group, which provides the xMAP technology for performing a wide range of protein and nucleic-acid-based multiplex assays on a

single platform to more than 80 partners, and a flow cytometry business developed from its January 2019 acquisition of EMD Millipore's flow cytometry portfolio. In terms of technologies, life sciences accounted for most of Luminex's \$417 million in 2020 revenues, followed by MDx multiplexing.

For the year as a whole, just those two deals hit the billion-dollar mark, but 13 other transactions reached \$100 million or more (Table 1).

Roche was one of three companies that closed more than one acquisition. In addition to the GenMark purchase, Roche also acquired the TIB Molbiol Group, a company that specializes in ultra-rapid assay development for emerging infectious diseases, including SARS-CoV-2 variants. The two other multi-deal players included Veracyte and Hologic. Veracyte held two spots on the list of top 10 deals by value with its purchases of Decipher Biosciences (urologic cancer diagnostics) for \$600 million in cash, and HalioDx (immuno-oncology diagnostics) for \$308 million.

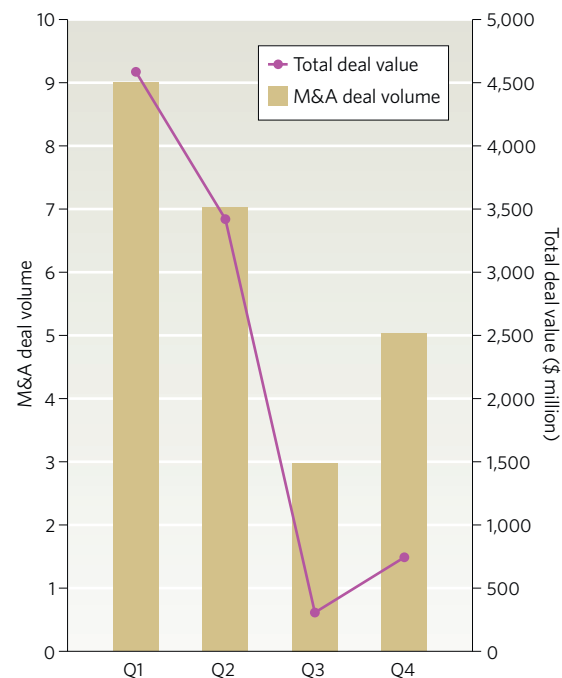


Fig. 1 | Molecular diagnostics M&A deal activity in 2021 by quarter. M&A, merger and acquisition. Source: Informa's Biomedtracker 2022.

Table 1 | Top ten molecular diagnostic M&As of 2021 by value

| Month | Acquirer | Target | Deal value (\$ million) | Deal summary |
|-----------|--------------------------|-----------------------------|-------------------------|---|
| March | Roche | GenMark Diagnostics | 1,832 | Roche purchases GenMark, a provider of multiplex molecular diagnostics to enhance Roche's presence in the infectious disease diagnostics space and bring the company into the syndromic testing market. |
| April | DiaSorin | Luminex | 1,800 | DiaSorin acquires Luminex, a global provider of molecular diagnostics specializing in multiplexing technology. |
| April | Hologic | Mobidiag | 714 | Hologic buys Mobidiag, a firm that develops and markets PCR-based tests for acute conditions including gastrointestinal and respiratory infections, and antibiotic resistance. |
| March | Agilent | Resolution Bioscience | 695 | Agilent buys Resolution Bioscience and gains next-generation sequencing-based precision oncology diagnostics to support both the biopharma services market and the clinical cancer testing market. |
| February | Veracyte | Decipher BioSciences | 600 | Veracyte acquires Decipher to further solidify its global leadership in the genomic cancer diagnostics market, gaining a portfolio of urologic cancer diagnostics that use whole-transcriptome analysis and machine-learning-based algorithms. |
| *December | LabCorp | Personal Genome Diagnostics | 575 | LabCorp agrees to acquire Personal Genome Diagnostics, a cancer genomics company with a portfolio of liquid biopsy and tissue-based products and services. |
| January | Thermo Fisher Scientific | Mesa Biotech | 550 | Thermo Fisher buys Mesa Biotech, a firm that develops and commercializes the Accula PCR-based rapid point-of-care testing platform available for detecting infectious diseases including SARS-CoV-2, influenza A and B, respiratory syncytial virus, and group A <i>Streptococcus</i> . |
| May | NeoGenomics | Inivata | 390 | NeoGenomics acquires liquid biopsy company Inivata and gains access to a platform that unlocks essential genomic information from a simple blood draw to guide and personalize cancer treatment, monitor response and detect relapse. |
| March | Bio-Techne | Asuragen | 320 | Bio-Techne buys Asuragen, which brings a portfolio of molecular diagnostic and research products, including its US FDA-cleared AmpliX Fragile X syndrome diagnostic and Carrier Screening kit as well as its Quantidex quantitative PCR (qPCR) BCR-ABL IS kit to enable the monitoring of leukemia patients for minimal residual disease. |
| June | Veracyte | HaliDx | 308 | Veracyte acquires immuno-oncology diagnostics firm HaliDx, gaining a portfolio of immune assessment solutions. |

FDA, Food and Drug Administration; M&A, merger and acquisition. *At time of publication, this deal had not yet closed. Source: Informa's Biomedtracker 2022.

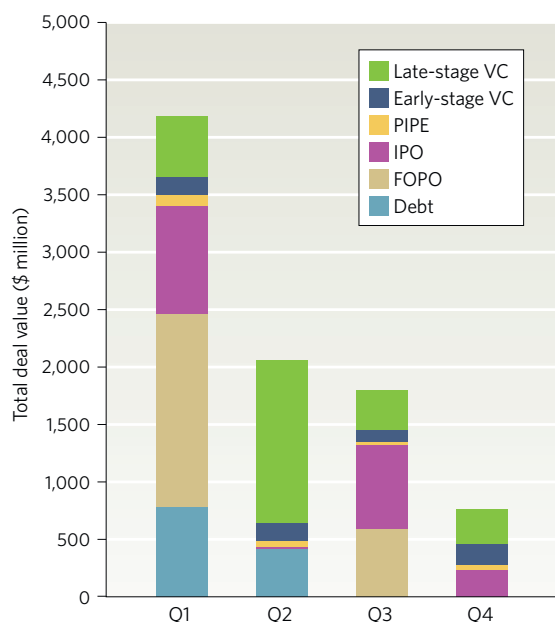


Fig. 2 | Total investment in molecular diagnostics companies in 2021, by quarter and financing type. FOPO, follow-on public offering; IPO, initial public offering; PIPE, private investment in public equities; VC, venture capital. Source: Informa's Biomedtracker 2022.

Hologic also held a top 10 spot with its \$714 million buy of PCR test developer Mobidiag, and also bought European molecular diagnostics and epigenetics firm Diagenode for \$159 million, in addition to women's health MDx company BioTheranostics for \$230 million.

Financing activity

During 2021, molecular diagnostic financings—including debt, follow-on public offerings (FOPOs), initial public offerings (IPOs), private investments in public equity (PIPEs) and venture capital (VC) funding—reached an aggregate of \$8.8 billion from 73 transactions versus \$7.6 billion in 2020 from 55 deals. The year opened strongly with 30 financings totaling \$4.2 billion in the first quarter, but deal volume was lower for the other three quarters and deal value decreased over the year, with \$2 billion in Q2 (17 deals), \$1.8 billion in Q3 (12 deals) and \$768 billion (14 deals) in Q4 (Fig. 2).

Late-stage VC rounds (series C and later) brought in most of 2021's financing dollars, with 18 transactions representing 30% of the annual aggregate and together totaling \$2.6 billion. Early-stage rounds captured just 6% of the 2021 dollars, with 13 transactions reaching a total of \$552.5 million.

Overall, there were nine MDx players raising \$100 million or more in late-stage rounds. The largest transaction in this category, and also the biggest MDx financing of the year, was achieved by Caris Life Sciences, which brought in \$830 million through a late-stage growth equity round in Q2, making up 41% of the second quarter's total financing alone. Caris is engaged in molecular

Table 2 | Venture capital investments in liquid biopsy companies during 2021

| Month | Company (products/platform) | Financing Round | Amount raised (\$ million) |
|-----------|---|------------------------|----------------------------|
| May | Caris Life Sciences (Molecular Intelligence approach uses whole exome sequencing, whole transcriptome sequencing, protein analysis, and AI models and signatures to assess genes in both DNA and RNA) | Undisclosed late-stage | 830 |
| August | InterVenn Biosciences (Dawn assay for immune checkpoint inhibitor response prediction; glycoproteomics biomarker interrogation platform uses AI and mass spectrometry) | Series C | 201 |
| February | Personal Genome Diagnostics (elio products for tissue- and liquid biopsy-based genomic testing) | Series C | 103 |
| January | Delfi Diagnostics (machine-learning approach for genome-wide fragmentation profiles of cell-free DNA) | Series A | 100 |
| September | Alamar Biosciences (leverages NGS using ultra-high sensitivity and massively parallel scale for proteomic analysis) | Series B | 80 |
| December | Exai Bio (combines oncRNA technology with machine learning and AI to decipher tumor signals) | Series A | 67 |
| April | Nucleix (Lung EpiCheck uses circulating tumor DNA methylation technology for early detection of lung cancer) | Undisclosed late-stage | 77 |
| February | Inivata (RaDaR, a highly sensitive personalized assay for detection and monitoring of MRD and recurrence) | Series C | 35 |
| June | SAGA Diagnostics (ultrasensitive SAGASign hybrid method using technologies based on digital PCR and NGS for MRD monitoring) | Series A2 | 12 |
| December | Rarecells (ISET circulating tumor cells platform applies AI algorithms to immunomorphological cellular profiles and altered genome-wide DNA characteristics) | Series A | 5 |

AI, artificial intelligence; MRD, minimal residual disease; NGS, next-generation sequencing; PCR, polymerase chain reaction. Source: Informa's Biomedtracker 2022.

profiling that assesses DNA, RNA and proteins to reveal a molecular blueprint to inform more precise and personalized treatment decisions. The funding provides the company with the capital for continued commercial expansion and investment toward delivering a first-in-class liquid biopsy platform across all cancer types.

During 2021, there were ten players overall in the liquid biopsy space raising money across both early- and late-stage vehicles (Table 2).

FOPOs were another notable deal type, with 11 transactions representing 26% (or \$2.3 billion) of the annual total. Six MDx players raised \$100 million or more through FOPOs, headed up by Natera (cell-free DNA testing) and Veracyte (cancer diagnostics powered by genomic technology and machine learning), which netted \$551.2 million and \$517 million, respectively.

During 2021, 13 companies went public in the molecular diagnostics space, accounting for \$1.9 billion (22% of the total

financing). Eight IPO transactions reached or exceeded the \$100 million mark, led by New Horizon Health, which netted \$282.5 million in its listing on the Hong Kong Exchange. Founded in 2015, New Horizon has two National Medical Products Administration of China-approved non-invasive, home-based early screening tests that target a high-risk colorectal cancer population in China. ColoClear incorporates its multi-target FIT-DNA platform, which utilizes quantitative PCR and a fecal immunochemical test (FIT) method to detect the presence of a KRAS gene mutation in stool and hemoglobin, enabling a high sensitivity for precancerous lesions. Pupu Tube is a FIT screening diagnostic to detect hemoglobin biomarkers associated with colorectal cancer in stool.

Beth Allan and Maureen Riordan are senior deals analysts at Informa Pharma Intelligence