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# The Diagnostics Year in Review
## *Mid Year 2025*

*Editor: Mara G. Aspinall, Partner, Illumina Ventures*

August 2025

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# MegaDx Index: 2020 through June 30, 2025

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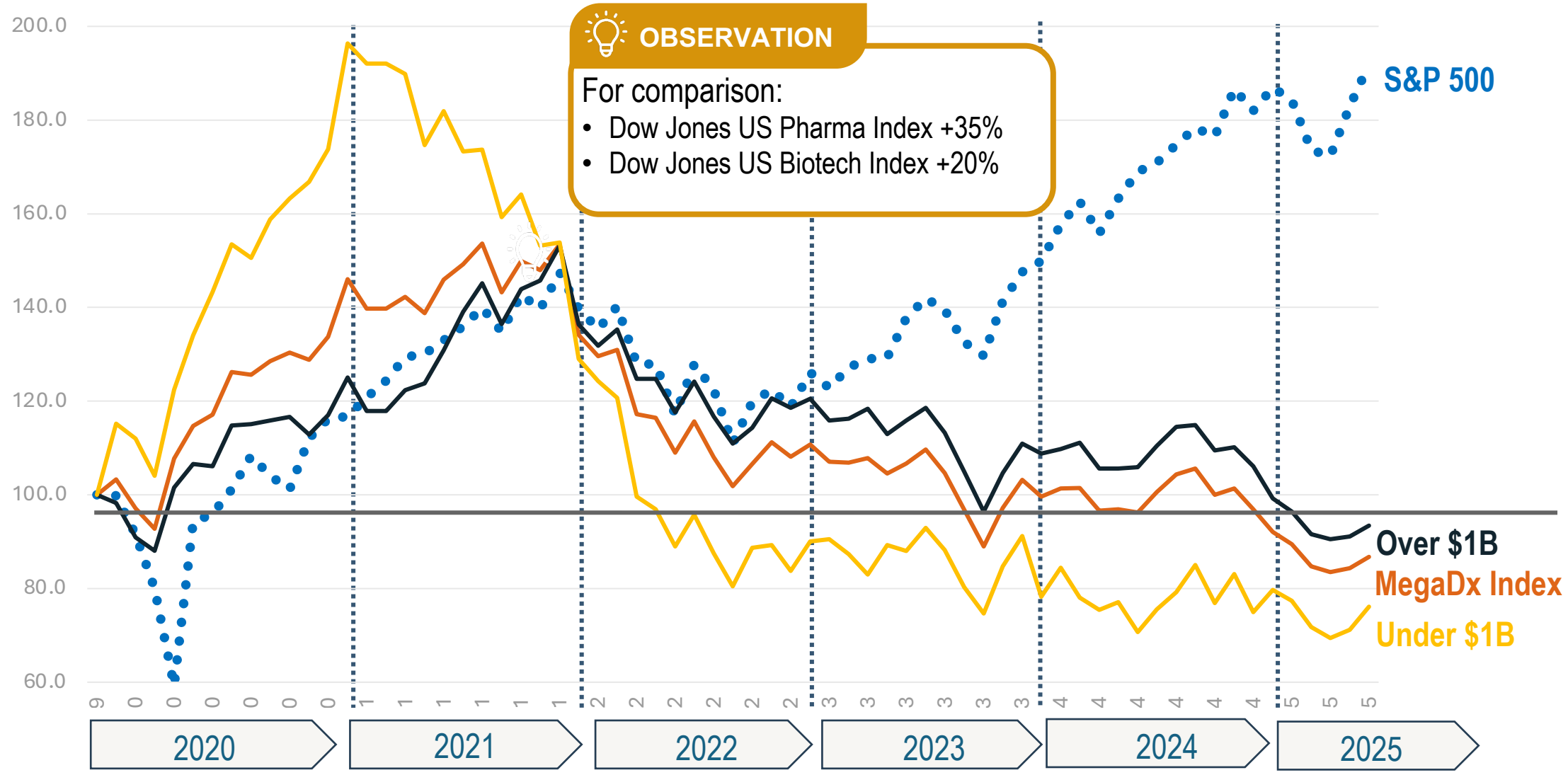

# If You Bought $1 of these Diagnostics IPOs at their IPO Initial Price …

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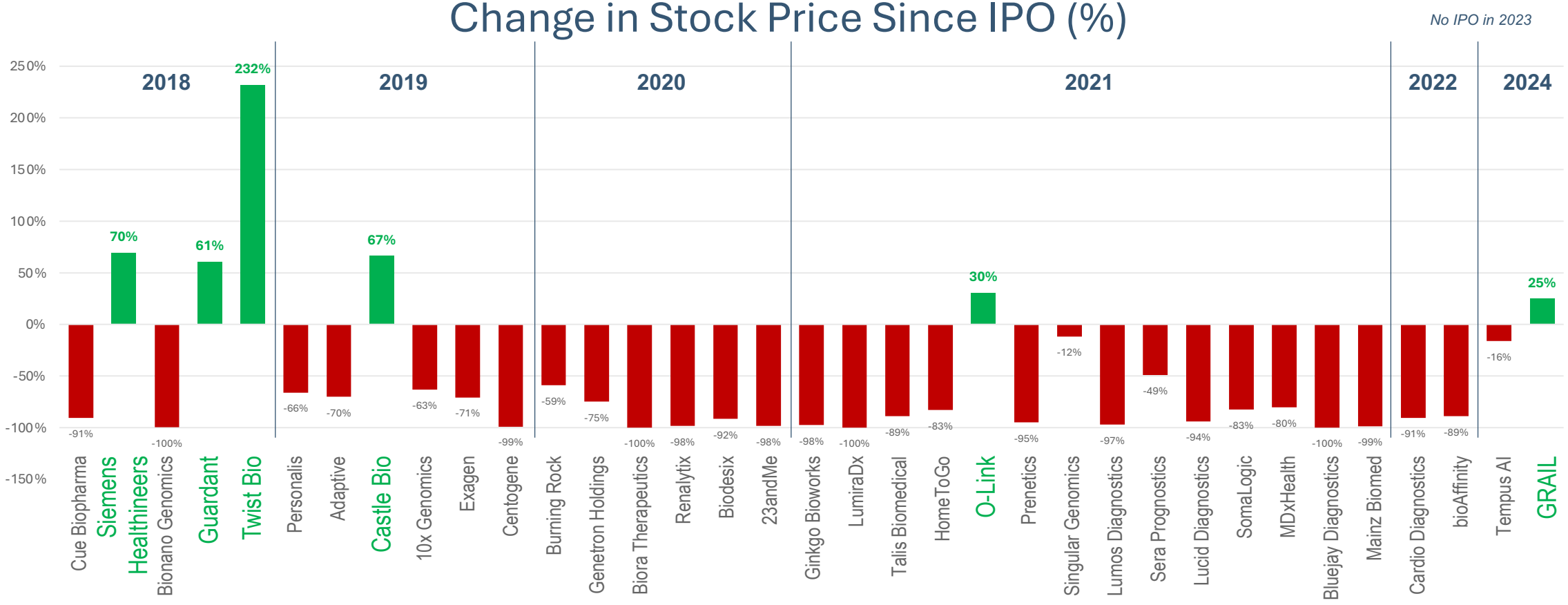
## Change in Stock Price Since IPO (%)




*Caris IPO: June 18, 2025*

Source: Dealogic - Factset as of 12/31/24.

# Diagnostics Venture Capital & Private Equity Investments through June 2025

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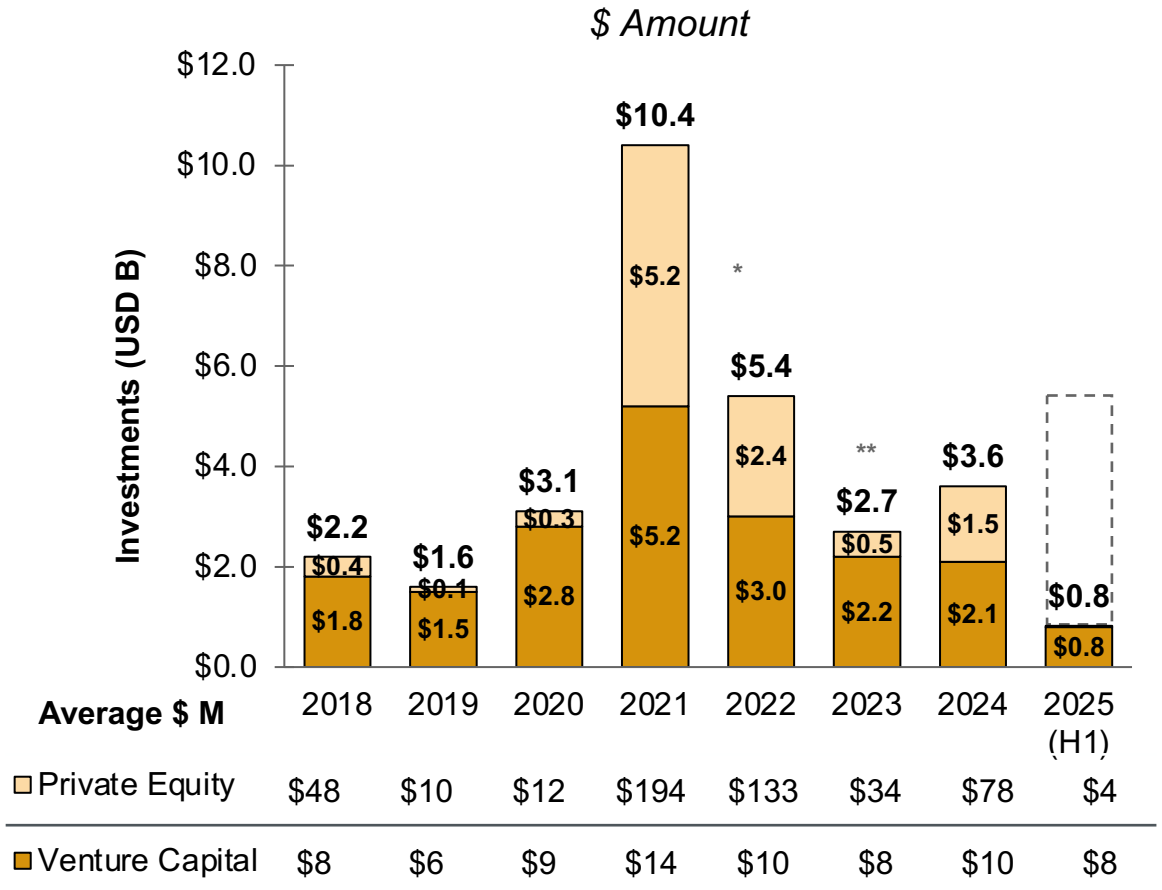
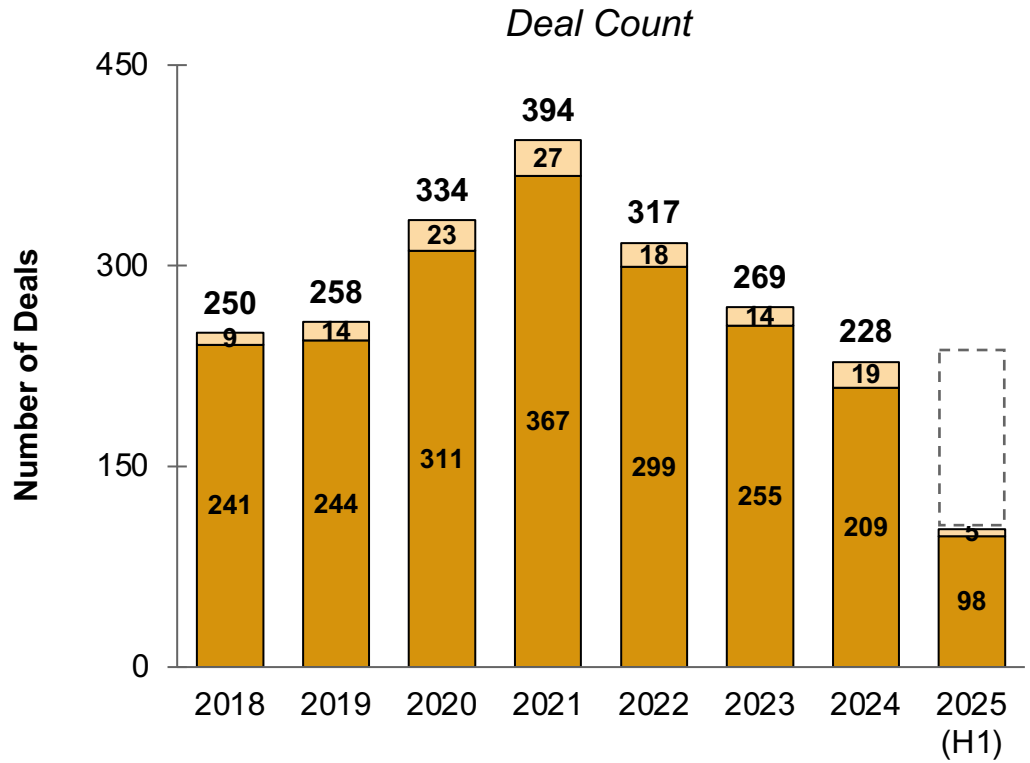
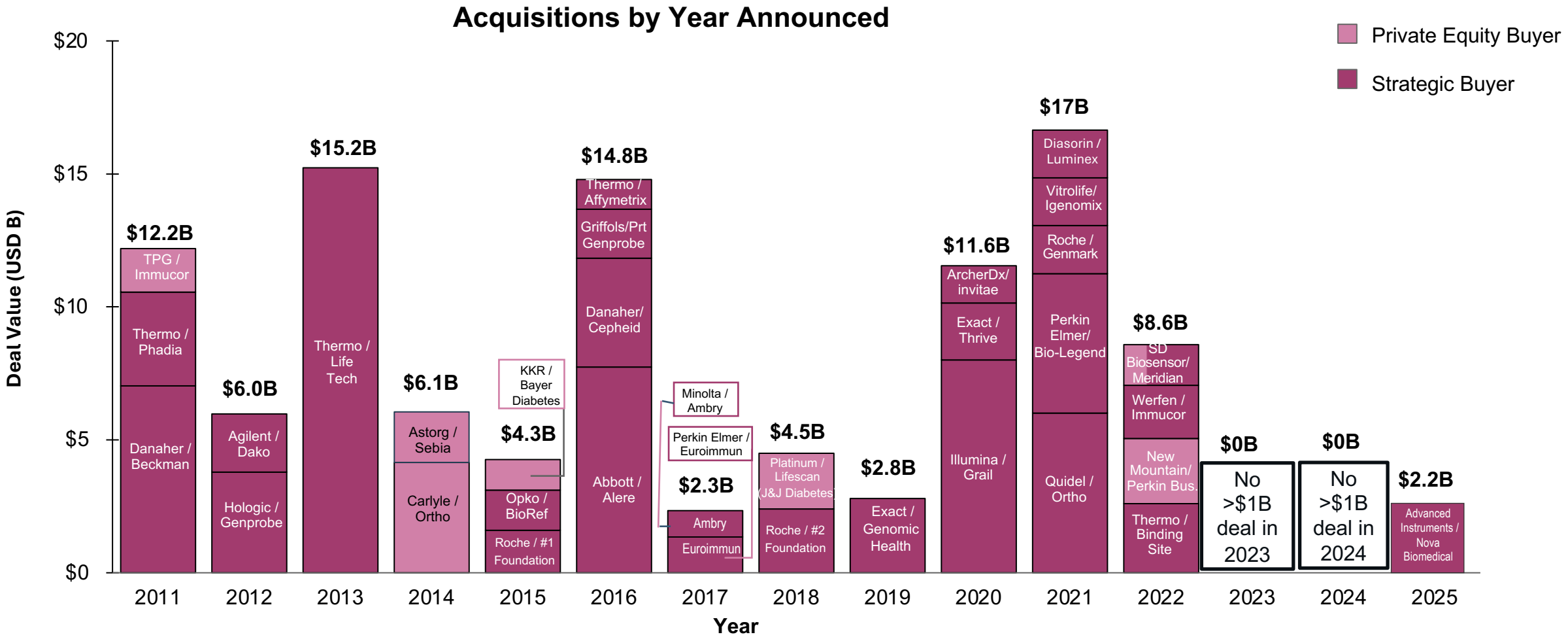



* Including Amedes Group (Buyout/LBO, $1.66B) | Groupe Inovie (Buyout/LBO, $2.3B). .
** Including Affidea (Buyout/LBO, $1.75B).
Note: VC (all VC stages), PE (Buyout/LBO, PIPE, etc.) Source: Pitchbook

# Diagnostic Industry Transforming Acquisitions (>$1 Billion) through June 2025



# Smaller Diagnostic Acquisitions (<$1 Billion) H1 2025

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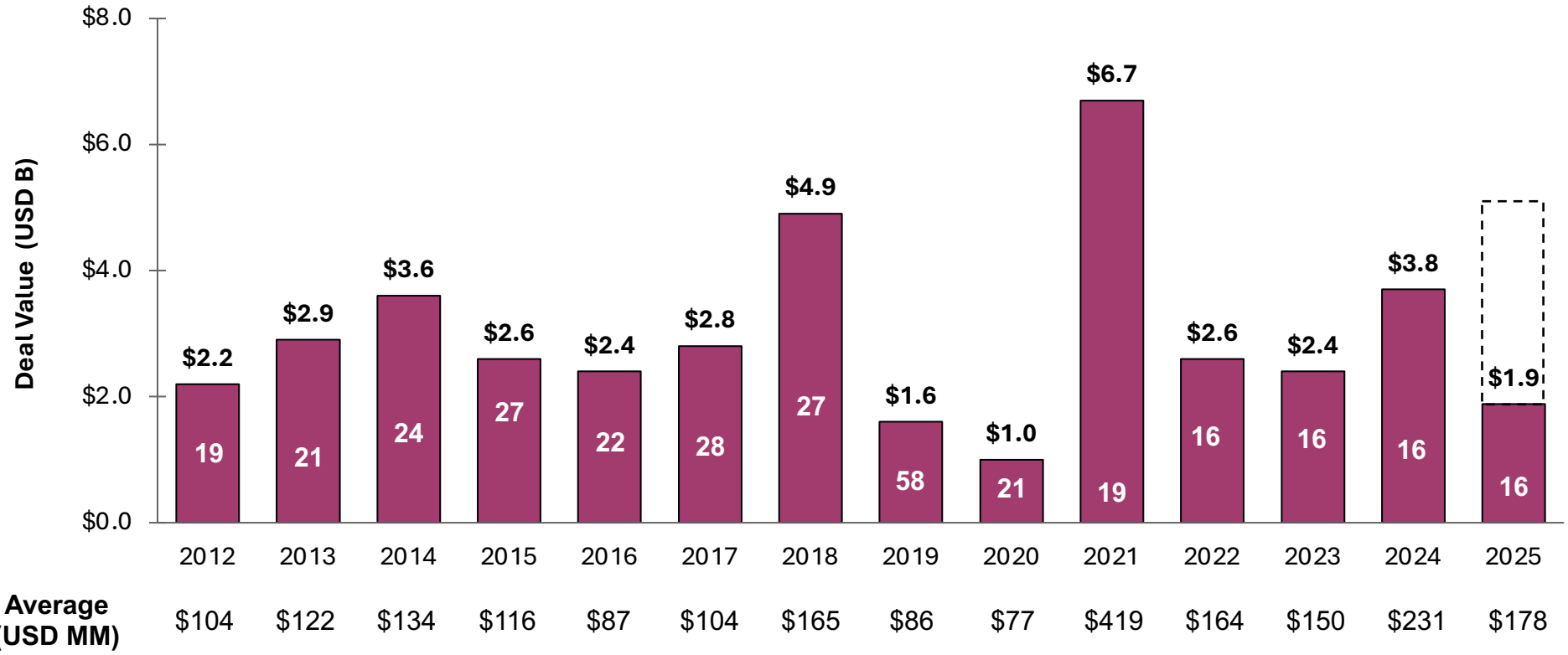
## Acquisitions by Year Announced




Note: Excludes deals with undisclosed financial terms and deals with transaction value less than $25mm; Year of transaction based on announcement date; Only includes transactions with US-based targets.

**2025 First Half Deals,** *by size*

| Acquirer | Target | Value ($M) |
|---|---|---|
| Illumina | Somalogic | $425 |
| TTAM | 23andMe | $305 |
| Bio-Rad | Stilla | $275 |
| LabCorp | BioRef Onc. | $225 |
| Takara | Curio | $191 |
| BioMérieux | SpinChip | $142 |
| QuidelOrtho | Lex Dx | $140 |
| Quanterix | Akoya | $69 |
| GeneDx | Fabric | $51 |
| Battery VC | Enzo | $37 |
| BioMérieux | Day Zero | $25 |

**Undisclosed Terms**

Castle / Previse
Labcorp / Incyte
Quest / Spectra
Bruker / Biocrates
Mapmygenome / Microbiome Insights

# Regulatory Focus: US LDT Final Rule Vacated by Federal Court – March 30, 2025

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The Rule concerning the FDA's enforcement discretion for Laboratory Developed Tests (LDT) was published on May 6, 2024.

**On March 30, 2025, the U.S. District Court (Eastern District of Texas Sherman Division) vacated the FDA LDT rule. The court stated that the FDA does not have the authority to regulate LDTs. As a result, the FDA LDT Rule and its compliance deadlines are no longer in effect.**

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# Laboratory Volumes
## (January 2020 – May 2025)

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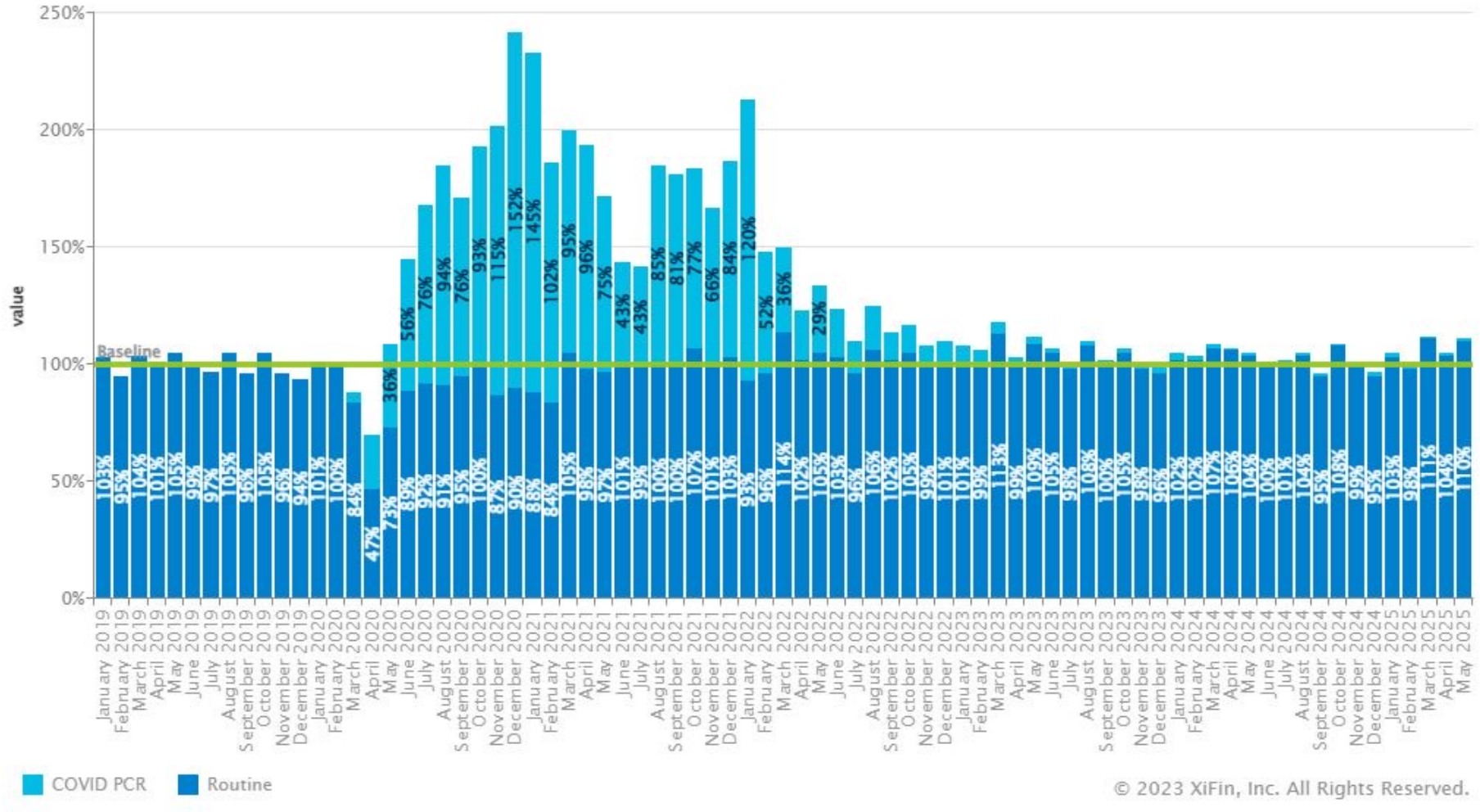
### All Routine and COVID PCR Testing

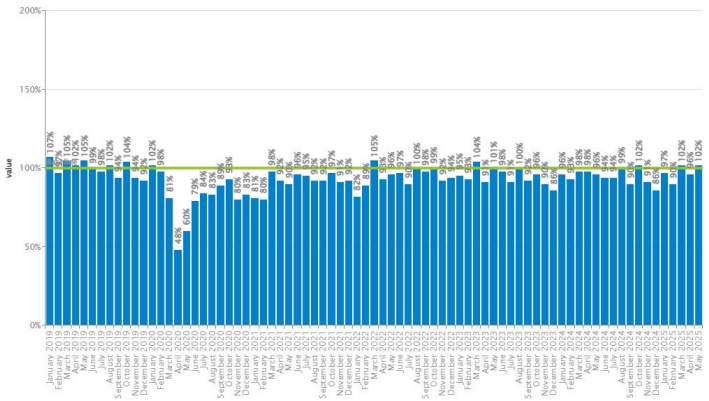



Source: Xifin Lab Volume Index. Baseline is the average monthly volume for 2019; data for January 2020 through May 2025.

# Laboratory Volumes by Testing Discipline

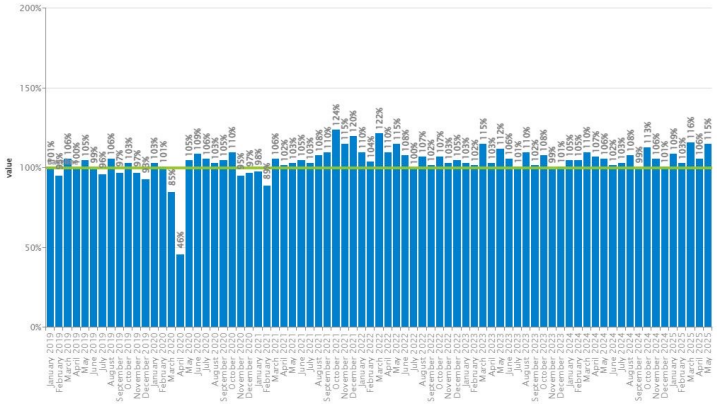
## Clinical

Significant dip in April 2020 (COVID) with slow recovery in 2020. Has since stabilized and now at or slightly below 2019 baseline.



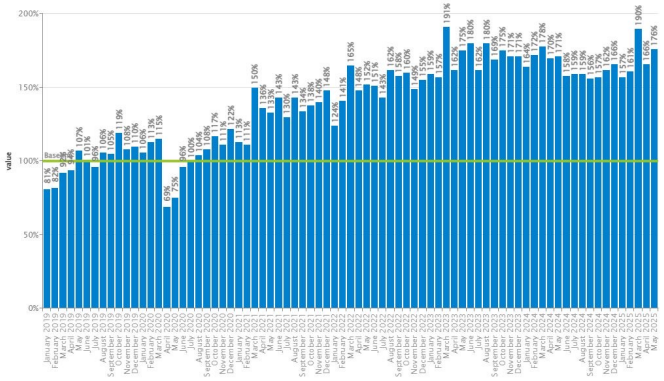
## Immunology & Microbiology

Sharp decline in April 2020 (COVID) followed by a rapid recovery in 2020. Stable with little variation and now above 2019 baseline.



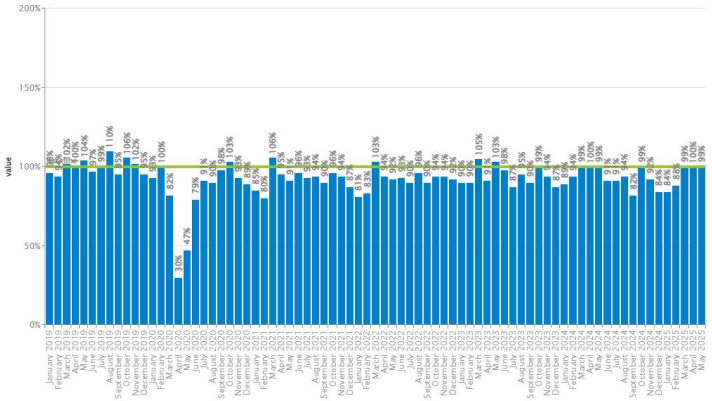
## Molecular & Genetic

**Consistent upward trend – 2025 is 70% above 2019** baseline. Tests: PCR, FISH, WES, WGS, CNV, MLPA



## Pathology

Huge decline in April 2020 (COVID) with gradual recovery and now at 2019 baseline.



Note: Baseline is the average monthly volume for 2019; January 2020 through May 2025.
Source: Xifin Lab Volume Index

# FDA Approvals: H1 2025 Breakthrough Designation Diagnostics

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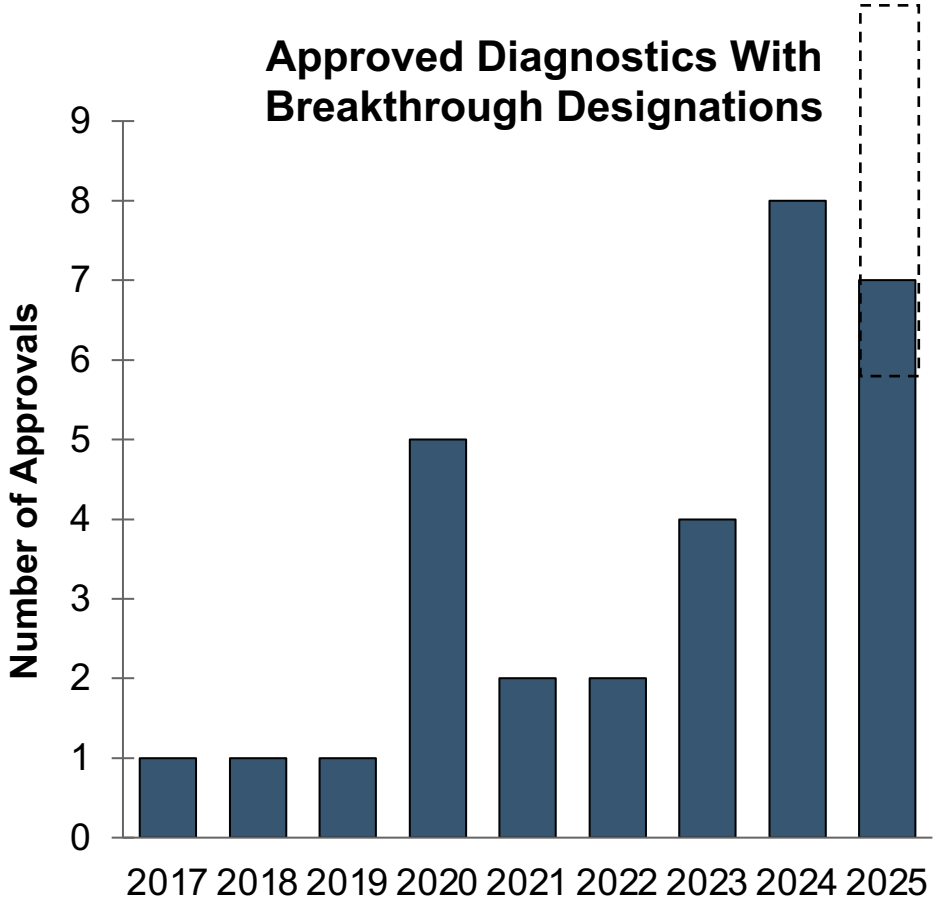
**Principles of Breakthrough Device Program Benefits**
*(From Finalized Guidance)*

1. Interactive and Timely Communication
2. Pre/Post market Balance of Data Collection
3. Efficient and Flexible Clinical Study Design
4. Review Team Support
5. Senior Management Engagement
6. Priority Review
7. Breakthrough Device Sprint Discussion
8. Data Development Plan
9. Clinical Protocol Agreement

**Approved Diagnostics With Breakthrough Designations**




**7 tests granted Breakthrough Designation in First Half 2025**

1. DAMO PANDA: AI driven model to detect pancreatic cancer
2. EvoLiver: Blood test for early detection of liver cancer
3. Paige PanCancer Detect: First AI application to identify regions suspicious for cancer
4. PMcardio STEMI AI ECG Model: Detects acute ST-elevation myocardial Infarction
5. Shield MCD Test: Blood test for screening for multiple cancers
6. TOBY Test: Urine test for routine noninvasive detection of early cancers
7. Ventana TROP2 (EPR20043) RxDx Device: AI-driven companion diagnostic for non-small cell lung cancer

Source: Health Advances and Illumina Ventures analysis, FDA, company websites.

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# FDA Approvals: Machine Learning Enabled Devices

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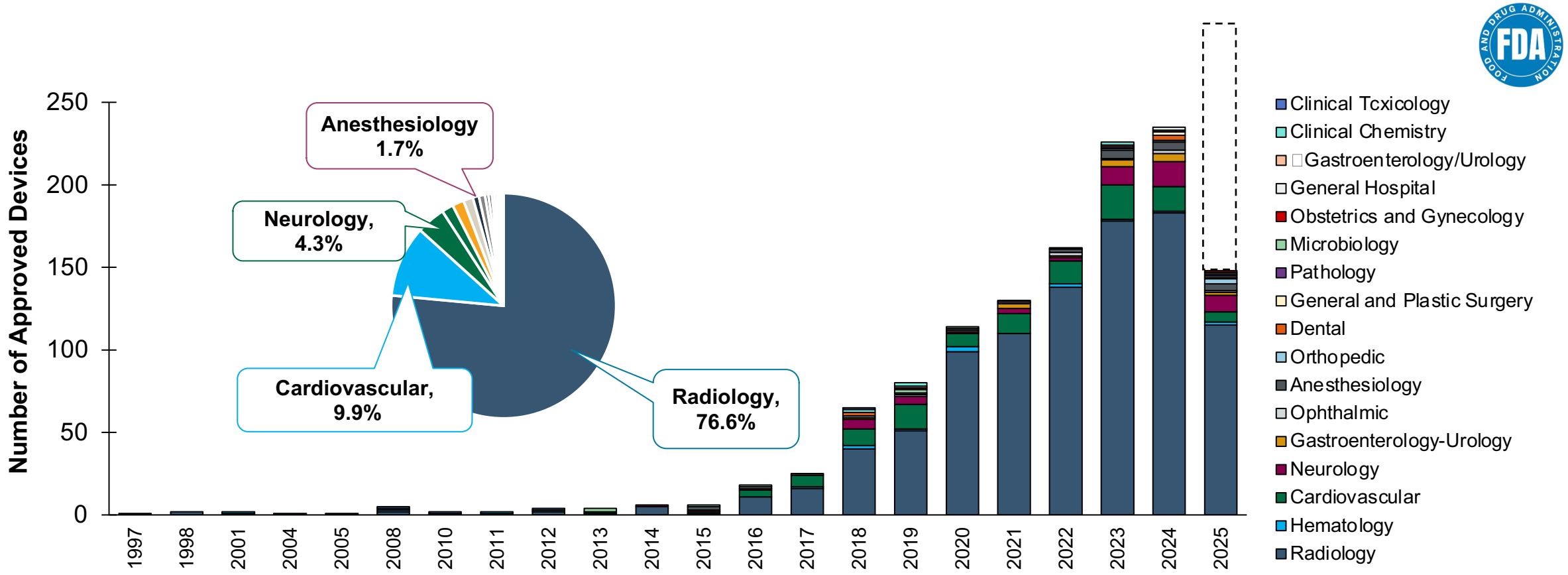
**Cumulative 1995 to 2025**




Note: FDA publishes new approvals in May each year so 2025 is only half year of data.
2025 has had 158 approvals through May 30, 2025

# FDA Approvals: Companion Diagnostics (CDx) Biomarkers: H1 2025

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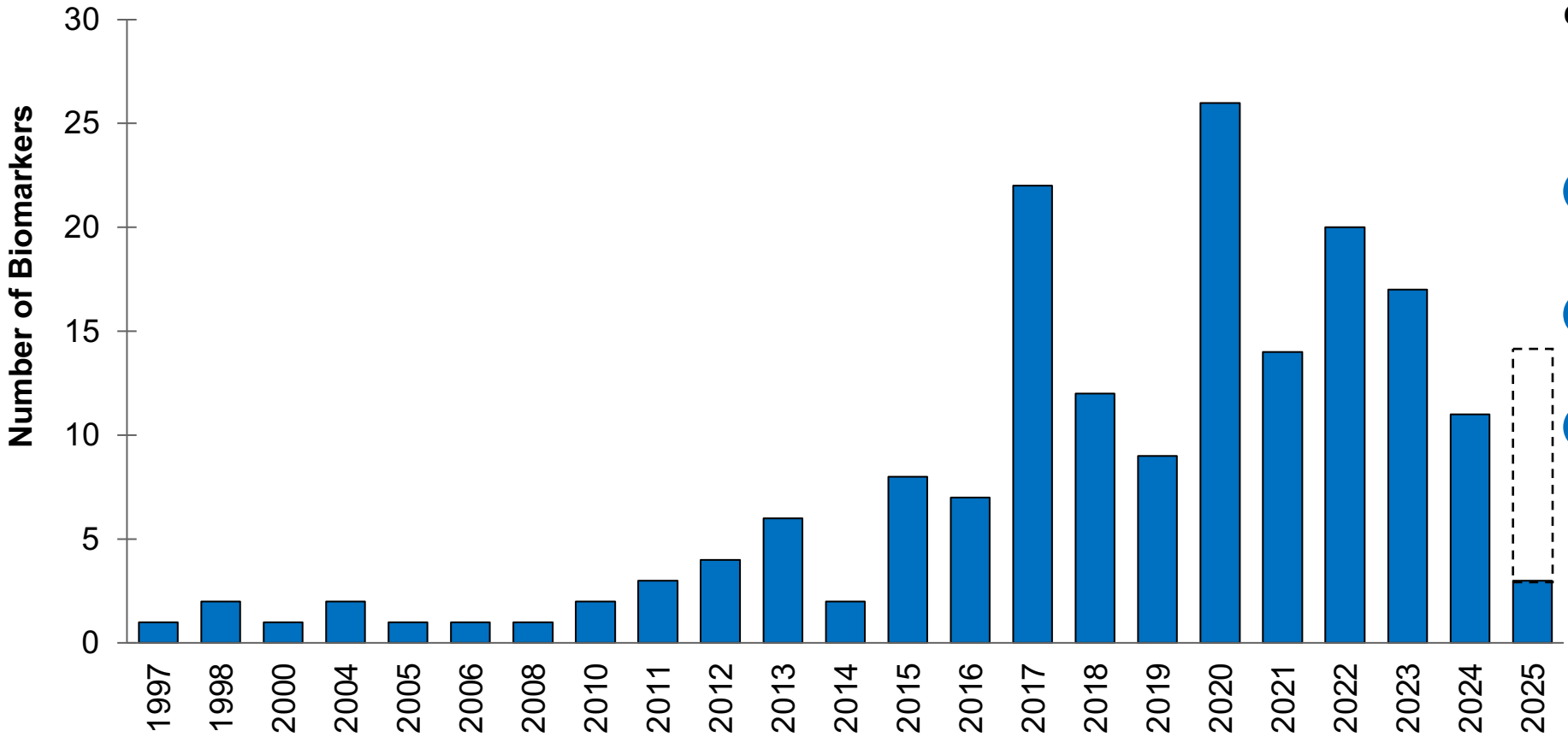
**Companion Diagnostics (CDx) Biomarkers by Approval Type**
175 Cumulative (1997 to *2025)




**Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) for Q1 & Q2 of 2025**

1. therascreen® KRAS RGQ PCR Kit
2. FoundationOne CDx
3. PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody

Source: FDA, Samantha Burg analysis.

* Current through July 10, 2025

# Biomarker Access Legislation Expanding
# 22 states passed bills & 12 in process

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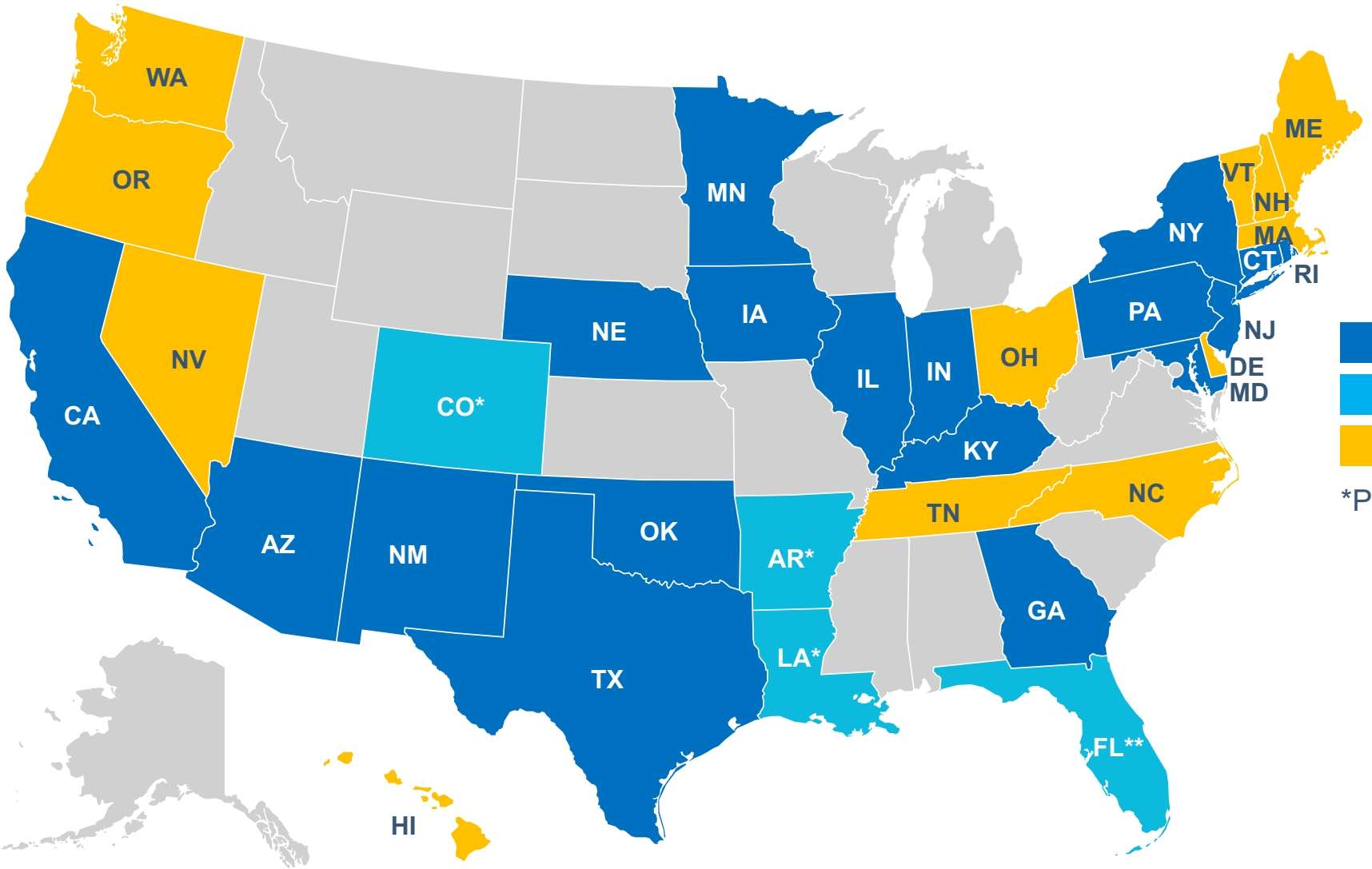


Law Passed

Narrow Law Passed

Legislation Introduced in 2025

*Private Plans Only ** Public Plans Only

American Cancer Society
Updated June 2025

Source: American Cancer Society Action Network (ACS CAN)

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# Healthcare Shifting to Home: Primary Drivers

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## Decentralization of Care to Lower Cost Settings

- Home care and Point of Care cheaper than hospitals
- Private insurers driving more treatment and some testing to outpatient to limit per diem allowances
- Need to hold hospital beds for acutely and severely ill

## Technology and Business Model Advancements

- Smaller, simpler, and faster technologies with little to no sacrifice in accuracy
- Treatments with fewer doses and more convenient administration (including at home)
- Digital connectivity enables integrated solutions (e.g. physician notifications, repeat testing reminders, links to follow-up treatment)

**Ongoing Shift in Location of Testing**

## Patient Agency

- Patients want convenience, flexibility and privacy of home testing & treatment
- Patients and family caregivers comfortable with home healthcare including SC drugs
- “Hospital at Home” model is growing for chronic illness

## Limited Skilled Healthcare Labor

- Provider shortage and access issues accelerate
- Aging and declining pool of laboratory technicians
- Need to curb burnout and turnover among healthcare practitioners

Source: Health Advances and Illumina Ventures analysis.

# Good News:
# 2024 Diagnostics “Firsts” for Home Tests

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| First Home COVID / Flu Combo Tests | First Home Menstrual Blood Home Collection | First Home OTC Glucose Meters | First Home Syphilis Test |
|---|---|---|---|
| FDA authorized eight combined COVID and Flu A & Flu B sold Over-The-Counter (OTC) | FDA-cleared analyte to analyze A1C levels for diabetes monitoring | FDA approval of OTC continuous glucose meters (CGM) designed for general health and wellness, for individuals without diabetes | FDA approval for first at-home, OTC test to detect syphilis antibodies in human blood (Follow up test needed) |
|   |   |   |   |

Source: Health Advances and Illumina Ventures analysis.

# Good News:
# 2024 Diagnostics “Firsts” for POC & Lab

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| First POC Hepatitis C Test | First POC high sensitivity troponin | First Blood-based Colon Cancer Test | Blood Tests for CNS diseases |
|---|---|---|---|
| FDA approval of the first hepatitis C virus (HCV) for use at the Point of Care | FDA approval of the first high-sensitivity cardiac troponin test for use at the Point of Care | FDA approval of first blood-based test for detection of colorectal cancer | New blood tests for Alzheimer's and other neuro-degenerative disorders offer less invasive alternative to traditional methods (LDTs) |
|  |  |   |  |

Source: Health Advances and Illumina Ventures analysis.

# Diagnostics “Firsts” Launched First Half 2025

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**First Home STI Test: CT/ NG**

FDA approval of the first fully at-home test for chlamydia, gonorrhea and trichomoniasis (no follow up test needed)


**OTC Blood Pressure Monitoring Device**

FDA clearance of a wearable, cuffless, over-the-counter device for at home blood pressure monitoring in adults

**First blood test approved for Alzheimer’s**

FDA approval for blood-based test for Alzheimer’s early detection

# Acknowledgements:
# Thanks for important insights & contributions


| illumina VENTURES™ | Deloitte. | Health Advances™ | J.P.Morgan | ASU Arizona State University |
|---|---|---|---|---|
| Nick Naclerio<br>William Byrne<br>Charles White | Erich Sachse<br>Annika Swanson<br>Rachel Porsche | Donna Hochberg<br>Martha O'Neill<br>Rebecca Podolsky<br>Chris Wolfram<br>Julia Strauss | Kyle Finegan<br>Chris Pritchard<br>Christine Baker<br>Richard Meland<br>Nicole Rong<br>William Thiessen | Michael Donovan<br>Travis Schlappi<br>Michael Yudell |

Special appreciation to Arnaud Autret, Samantha Burg, Ralph Hall, Alan Hirzel, Tim Stenzel and Liz Ruark.

# Illumina Ventures: Advancing Diagnostics Innovation

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ARIMA GENOMICS

Advancing the life sciences through the power of 3D genomes

DELFI

Non-invasive early cancer detection analyzing plasma-derived cell-free DNA fragmentation patterns

HEPTA BIO

Genomics and machine learning applied to NASH / MASH detection and monitoring

LetsGetChecked

Delivering tailored at-home healthcare solutions to 5000+ organizations and transforming care for employers, health plans, providers and more

Precede Biosciences

Liquid biopsy delivering tissue transcriptional biology by harnessing the power of gene regulatory elements for precision medicine

PREDICTA BIOSCIENCES

Multiomics and AI to develop personalized diagnosis and treatment options for hematologic malignancies

Serimmune

NGS-based universal serology and mapping human immunity through antibody detection

SHERLOCK BIOSCIENCES

Engineering biology to develop molecular diagnostic products to decentralize testing to personalize healthcare

STILLA

Simple, rapid, multiplexed digital PCR creating cost effective assays for genomic markers

TAGOMICS

Disease diagnosis through comprehensive multiomic profiling multiomic biomarkers from a DNA sample using a streamlined workflow