



# The Diagnostics Year in Review 2025

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

February 2026

# What a Difference a Year Makes: From Recovery to Renaissance



## New Ecosystem

*(macro sociopolitical, regulatory, & economic)*



## New Technologies

*(e.g. multimodal / disciplinary, AI integration)*



## New Markets

*(e.g. at-home, prevention)*



## New Leaders

*(e.g. profitable companies, consolidation)*



## New & Renewed Pharma Interest

*(e.g. large biomarker and data partnerships)*



## Still Room for Improvement



**Diagnostics Renaissance**

- **The Financial Results**

- Diagnostics MegaDx Index
- Initial Public Offerings
- VC and PE investments

- **The Clinical Impact**

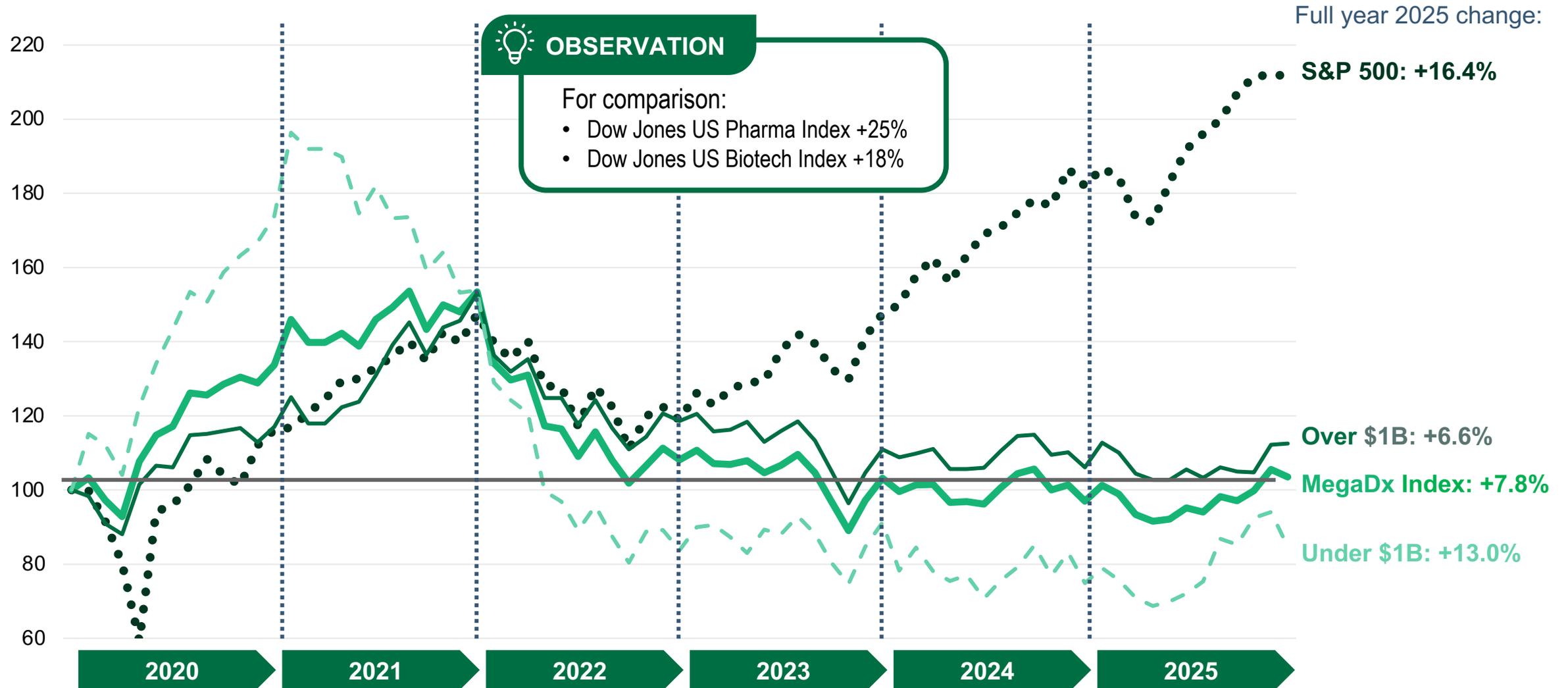
- **The Deals**

- **The Future**

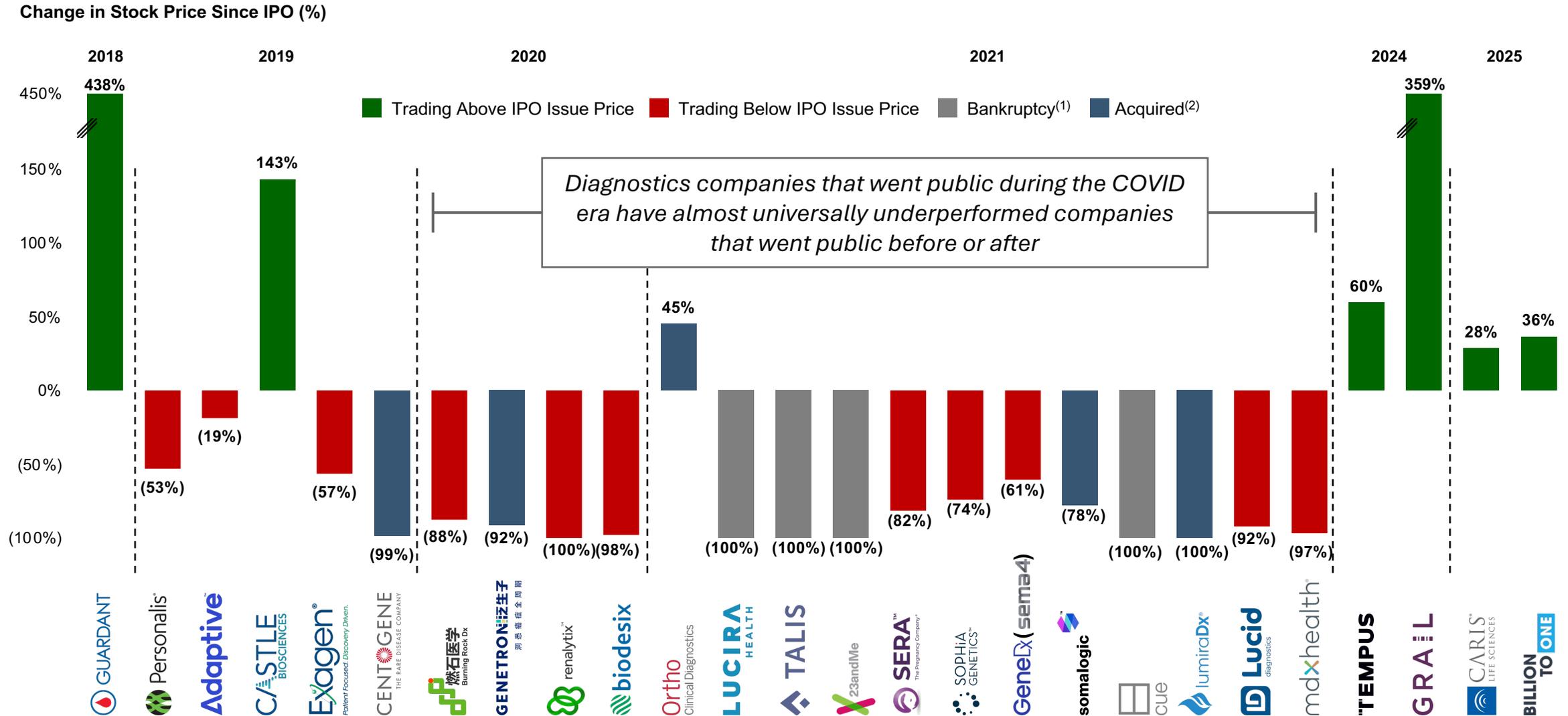
- **The Access to the Markets**

- **The Addendum**

# The Diagnostics MegaDx Index 2020-2025



# If You Bought These Stocks at Their Initial IPO Price...

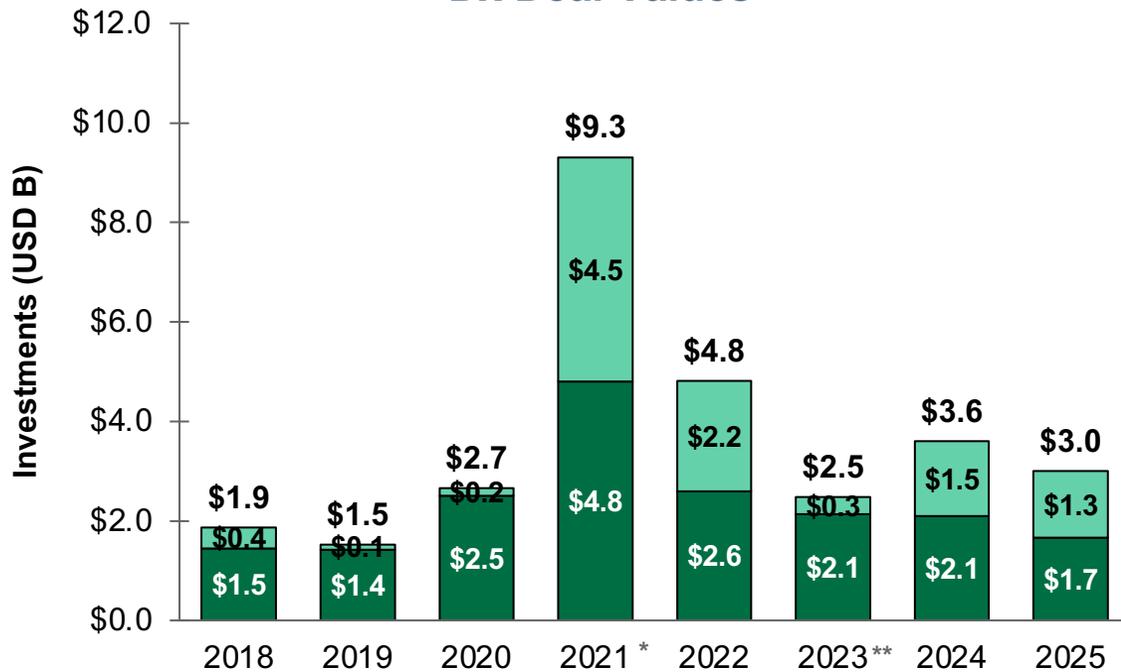


Source: Capital IQ and press releases as of December 31, 2025. (1): Assumes illustrative current price of \$0/share for bankrupt companies. (2): Implied return of acquired companies based on acquisition price at announcement.

# VC & PE Investors Don't Yet See the Upside in Diagnostics



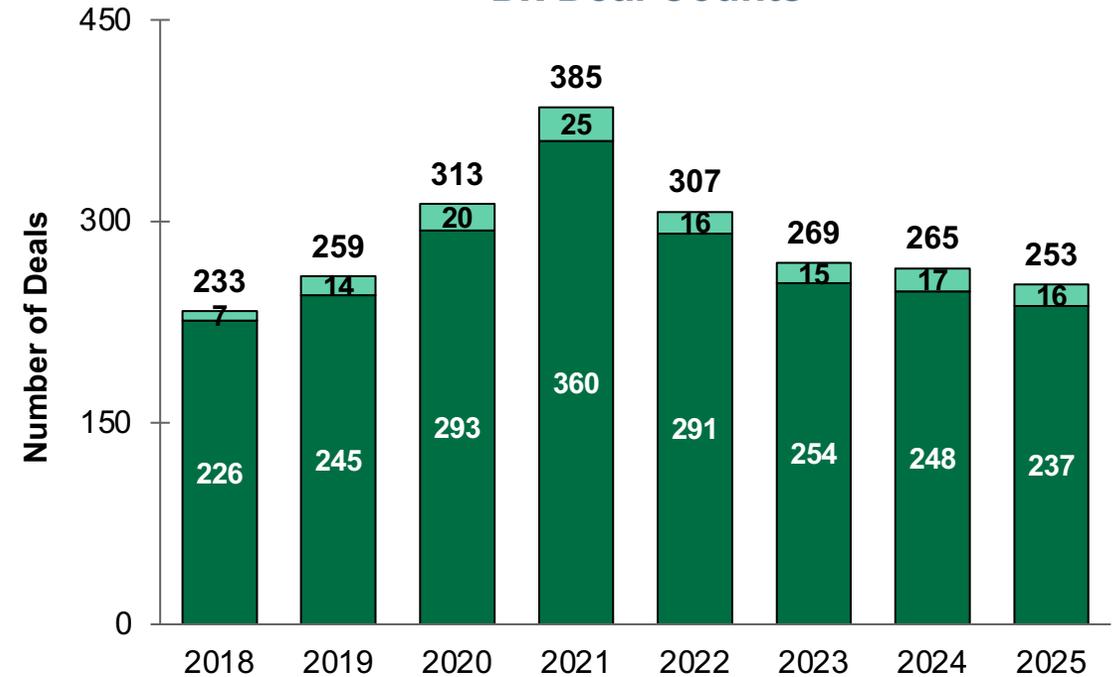
### Dx Deal Values



#### Average \$ M

	2018	2019	2020	2021*	2022	2023**	2024	2025
Private Equity	\$60	\$8	\$8	\$180	\$139	\$23	\$88	\$83
Venture Capital	\$6	\$6	\$9	\$13	\$9	\$8	\$8	\$7

### Dx Deal Counts



\* 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

# The Street Sees Upside in a New Set of Industry Leaders: The Terrific Ten: Sequencing-Forward Companies



**Adaptive™**

\$19.86 (Avg. PT)  
 22% Upside  
 \$16.24 (Current Price)

**7/8**  
 Analysts with a Buy Rating

 **GUARDANT**

\$113.57 (Avg. PT)  
 11% Upside  
 \$102.14 (Current Price)

**21/22**  
 Analysts with a Buy Rating

**BILLION TO ONE**

\$137.83 (Avg. PT)  
 68% Upside  
 \$81.84 (Current Price)

**5/7**  
 Analysts with a Buy Rating

 **natera®**

\$246.70 (Avg. PT)  
 8% Upside  
 \$229.09 (Current Price)

**18/20**  
 Analysts with a Buy Rating

 **CARIS®**  
 LIFE SCIENCES

\$38.30 (Avg. PT)  
 42% Upside  
 \$26.98 (Current Price)

**9/10**  
 Analysts with a Buy Rating

 **Personalis®**

\$11.00 (Avg. PT)  
 38% Upside  
 \$7.96 (Current Price)

**6/7**  
 Analysts with a Buy Rating

**GeneDx**

\$170.89 (Avg. PT)  
 31% Upside  
 \$130.06 (Current Price)

**8/9**  
 Analysts with a Buy Rating

**"TEMPUS**

\$88.92 (Avg. PT)  
 51% Upside  
 \$59.05 (Current Price)

**7/14**  
 Analysts with a Buy Rating

**GRAIL**

\$105.00 (Avg. PT)  
 23% Upside  
 \$85.59 (Current Price)

**2/4**  
 Analysts with a Buy Rating

 **veracyte™**

\$48.36 (Avg. PT)  
 15% Upside  
 \$42.10 (Current Price)

**10/13**  
 Analysts with a Buy Rating

Source: Bloomberg, company websites, and Capital IQ as of December 31, 2025. Note: Analyst price targets and ratings based on available research.

# The Terrific Ten & Other Leaders Bring Strength & Checkbooks



New Leaders

	Company	Market Cap	LTM Change in Market Cap	2025E Revenue <sup>1</sup>	LTM Operating Cash Flow	2025E EV / Revenue	Illustrative M&A Firepower <sup>2</sup>
The Terrific Ten	natera	\$31,688	52%	\$2,221	\$194	13.84x	\$7,380
	GUARDANT	13,160	249%	968	(223)	13.74x	3,945
	<b>TEMPUS</b>	10,505	98%	1,265	(221)	8.69x	2,861
	CARIS LIFE SCIENCES	7,612	29% <sup>(3)</sup>	725	(1)	9.98x	2,278
	GeneRx	3,759	78%	427	33	8.56x	1,151
	BILLION TO ONE	3,746	37% <sup>(3)</sup>	296	5	11.22x	1,660
	GRAIL	3,336	456%	146	(329)	16.10x	1,649
	veracyte	3,328	8%	508	108	5.83x	1,693
	Adaptive	2,479	180%	264	(61)	9.06x	713
	Personalis	707	72%	70	(60)	7.93x	292
Established Leaders	Abbott	217,859	11%	44,664	9,119	5.51x	70,251
	ThermoFisher SCIENTIFIC	217,704	9%	44,304	7,651	5.64x	60,753
	danaher	161,698	(2%)	24,506	6,318	7.22x	49,056
	labcorp	20,798	8%	13,992	1,804	1.87x	7,117
	Quest Diagnostics	19,304	15%	10,983	1,885	2.24x	7,614
	QIAGEN	9,751	(1%)	2,078	658	5.26x	5,783



Source: Company filings, Wall Street research, and Capital IQ as of December 31, 2025. (1): 2025E Revenue per median analyst estimates. (2): Illustrative M&A firepower calculated as the sum of current cash balance, 20% of current market cap, and incremental debt capacity assuming 4.0x maximum net debt / EBITDA leverage ratio. (3): Change in market cap calculated based on market cap at CAI and BLLN IPO pricing on June 17, 2025 and November 5, 2025, respectively.

# Defining Successful Characteristics of The Terrific Ten

1

**Proprietary, LDT products in large high value applications**

- All are Laboratory Developed Tests (LDT) at launch and most have stayed LDTs
- All are branded tests (often PLA and ADLT) in fields of oncology, reproductive health, and genetic disease



2

**High impact on clinical decisions, with potential to improve outcomes**

- Products solve difficult, relevant problems for providers & patients (ex: cancer therapy choice, recurrence monitoring, minimal residual disease)
- Focus shifting to syndromes vs. individual diseases



3

**Leveraging NGS and other multi-omics platforms**

- Products based on using NGS and other multi-omics platforms
- None of the companies rely on traditional diagnostics companies for their assay platforms
- Strong commitment to R&D and improving tech



4

**Strategic focus on market access and reimbursement**

- Early focused strategy on how to maximize reimbursement
- Well-developed commercialization engines, often with both in-house salesforces & commercial partnerships



5

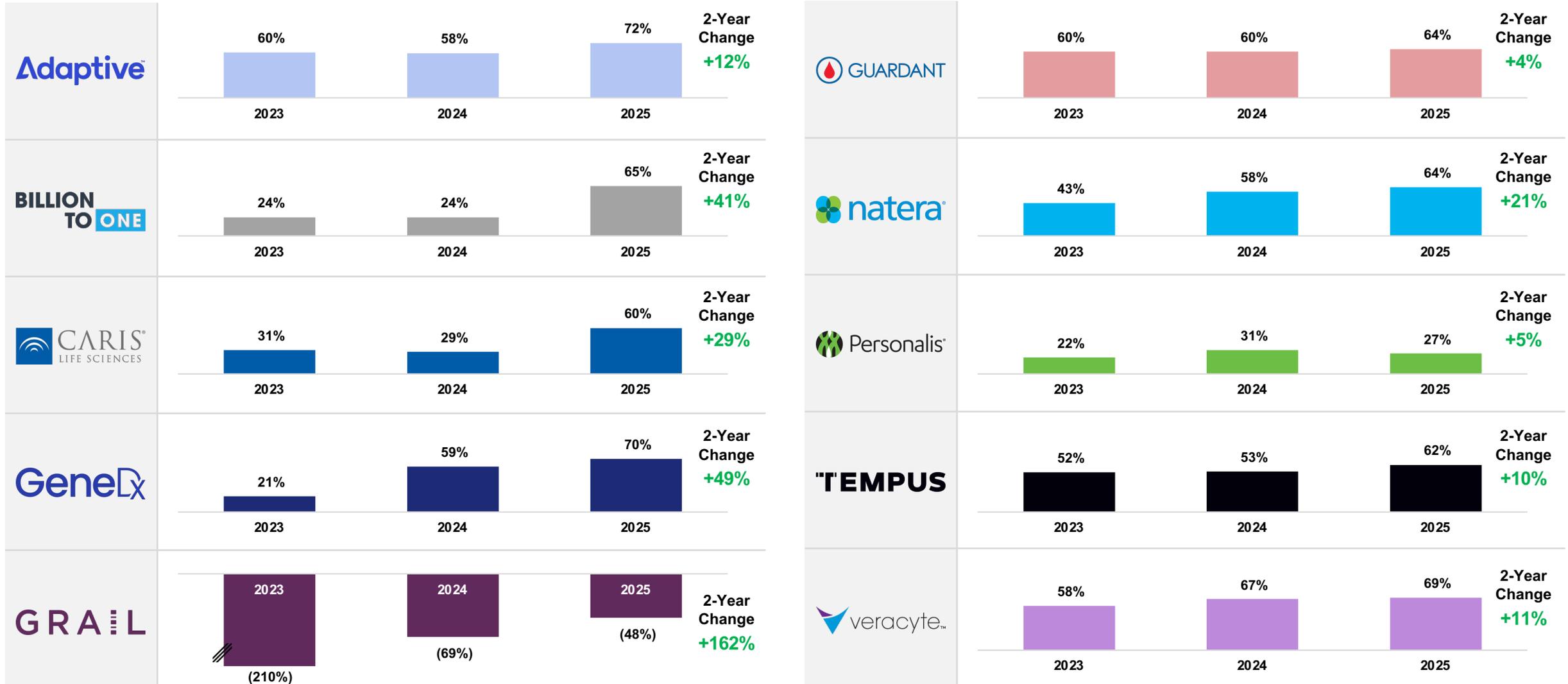
**AI & Data Forward with tech enabled processes**

- All are capturing rich information and leveraging AI models that can be monetized with biopharma
- AI and data build competitive moats



**The Terrific Ten are changing the definition of diagnostics. They are not just selling “tests” — they are data-driven clinical decision platforms with recurring economics and long expansion runways.**

# Improving Gross Margins are a Hallmark of The Terrific Ten



Source: Company filings, Wall Street research as of December 31, 2025

- **The Financial Results**

- **The Clinical Impact**

- **The Deals**

- Mergers & Acquisitions
- Partnerships

- **The Future**

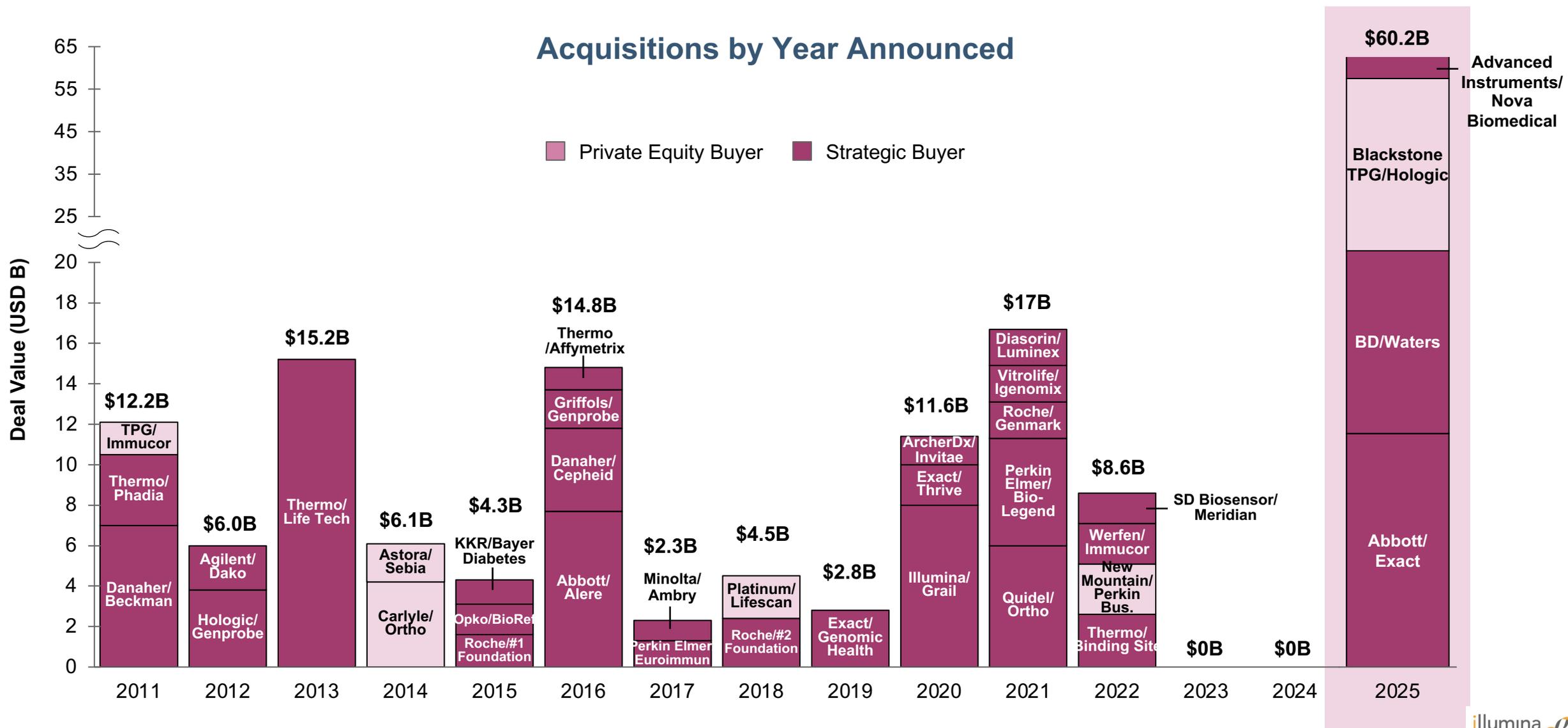
- **The Access to the Markets**

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# M&A: Industry Transforming Acquisitions (>\$1 Billion): Our Biggest Year Ever



New  
Leaders

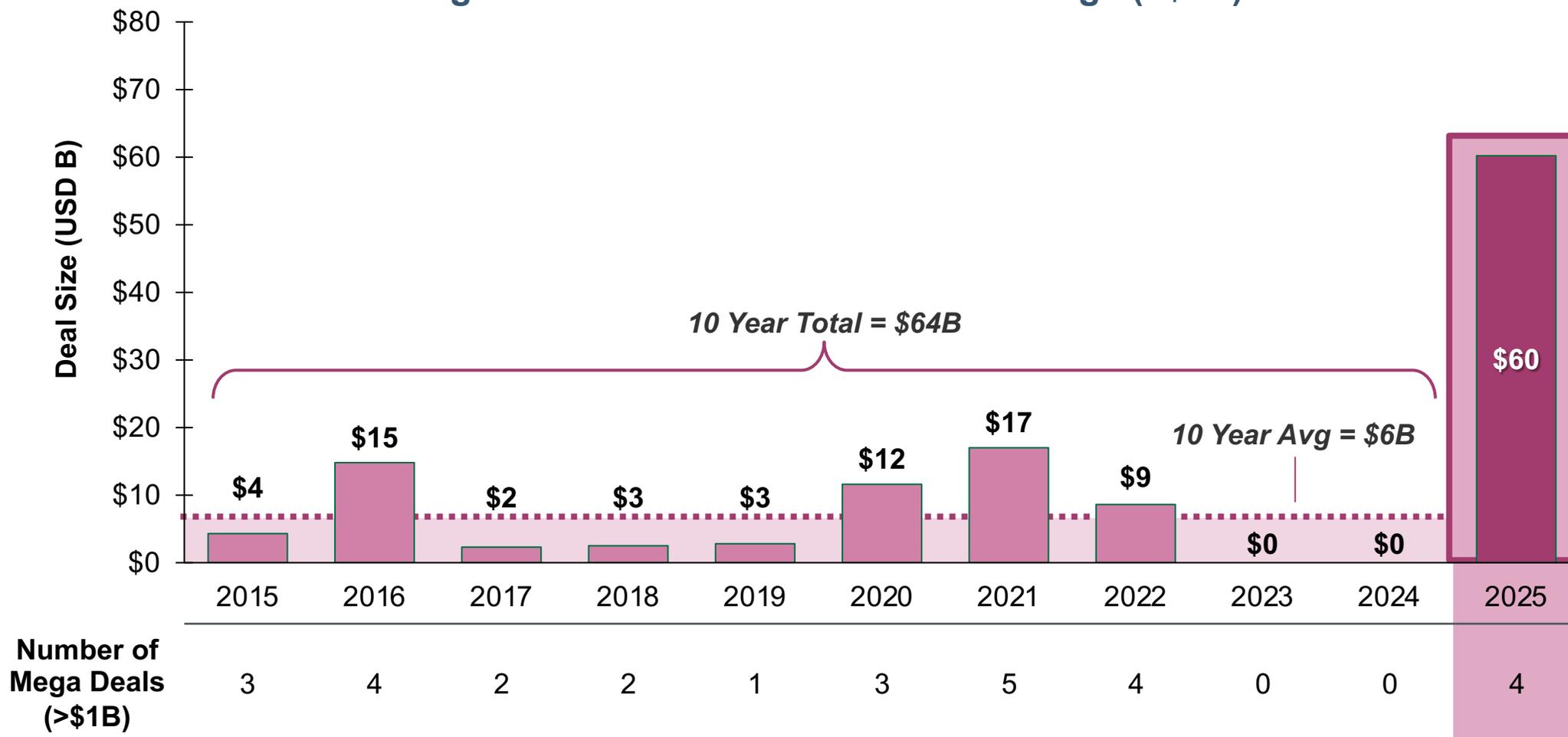


# M&A: Industry-Transforming Acquisitions (>\$1 Billion): 2025 almost as large as the last decade *combined*



New  
Leaders

## Diagnostics and Precision Medicine Mega (>\$1B) Deals



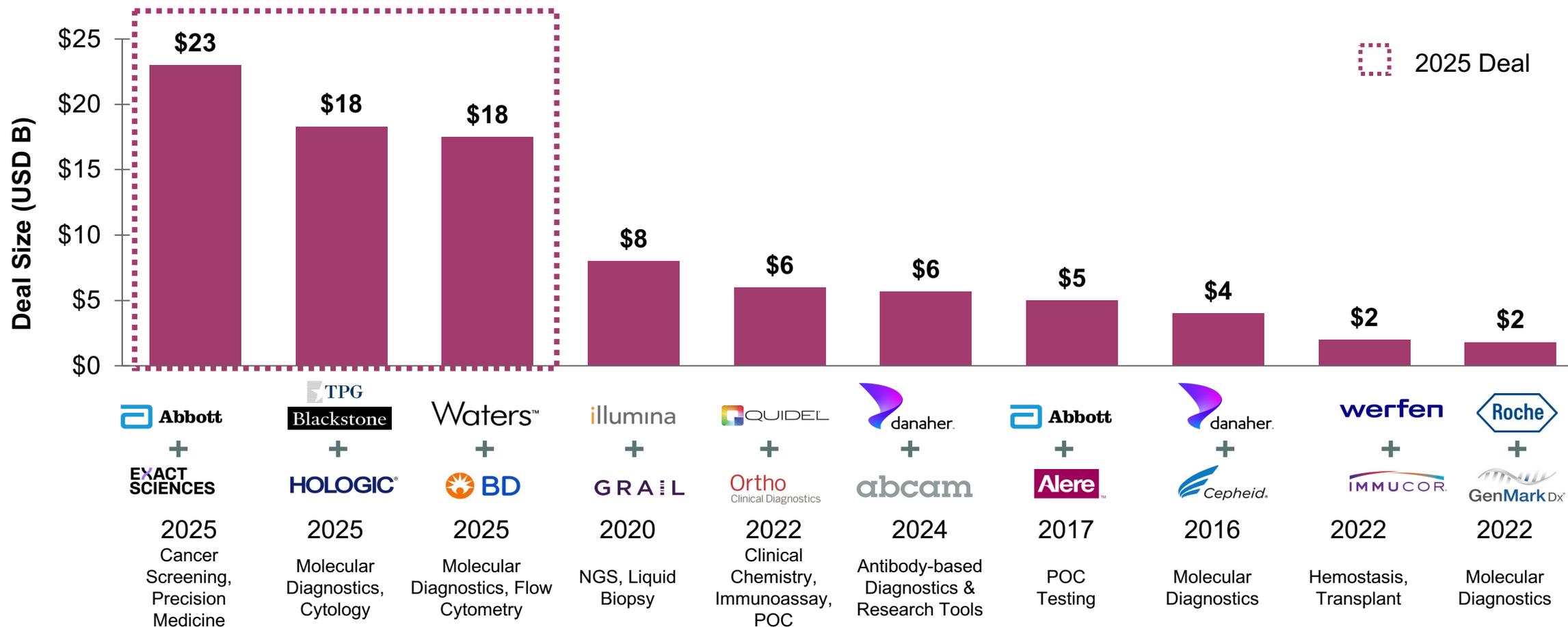
Source: Health Advances analysis, press releases and other company information.

# M&A: Industry-Transforming Acquisitions (>\$1 Billion): Top 3 Deals Ever



New  
Leaders

## Largest Deals of the Past 10 Years *Diagnostics and Precision Medicine*



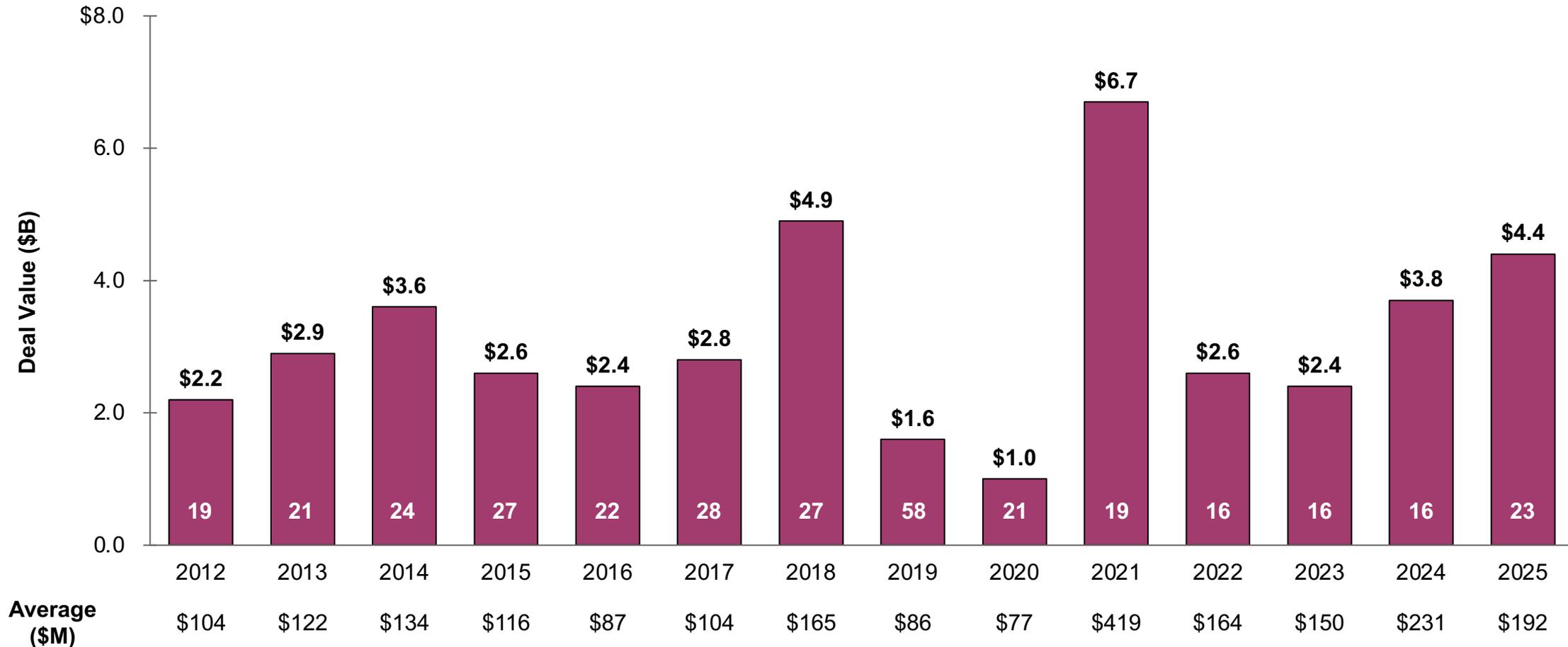
Source: Health Advances analysis, press releases and other company information.

# M&A: Smaller Acquisitions (<\$1 Billion)



New  
Leaders

## Acquisitions by Year Announced



Note: Excludes deals with undisclosed financial terms and deals with transaction value less than \$25M and greater than \$1B. Year of transaction based on announcement date. Only includes transactions with US-based targets through December 31, 2025.

# M&A: Smaller (<\$1B) Acquisitions with Disclosed Terms



New Leaders

Ann. Date	Target	Acquiror	Total Transaction Value (USD MM)
12/22/25	 (Select Assets)		\$56
12/5/25			\$450
8/22/25		<b>TEMPUS</b>	\$81
7/22/25	 (Ambulatory Lab Services)		\$195
7/14/25			\$79
6/18/25			\$72
6/16/25			\$25
6/13/25		<b>TTAM Research Institute</b>	\$305

Ann. Date	Target	Acquiror	Transaction Value (USD MM)
6/3/25			\$140
5/12/25			\$80
4/16/25			\$51
4/16/25			\$94
3/11/25		<b>TEMPUS</b>	\$17
3/11/25			\$225
1/27/25			\$131
1/13/25			\$141

Source: Capital IQ, company filings, and press releases as of December 31, 2025. Includes diagnostics transactions with announced transaction value over \$15M. Assumes private target transactions to be cash-free, debt-free, unless otherwise disclosed. Transaction value includes contingent consideration.

# Emerging Companies Turn to Strategic Equity Investments Tied to Partnerships



Partnerships  
and Pharma  
Interest

  
+  
 / 

**\$105M Series C**  
+ Partnership  
January 2025

 TRUVETA  
+  
REGENERON / illumina

**\$320M Investment**  
+ Partnership  
January 2025

  
+  


**Undisclosed Investment**  
+ Partnership  
May 2025

  
+  
illumina

**\$35M Investment**  
+ Partnership  
May 2025

  
+  
EXACT  
SCIENCES

**\$50M Investment**  
+ Partnership  
August 2025

GRAIL  
+  
SAMSUNG

**\$110M PIPE**  
+ Partnership  
October 2025

  
+  


**\$75M Investment**  
+ Partnership  
November 2025

  
+  


**Undisclosed Investment**  
+ Partnership  
December 2025

- The Financial Results

- The Clinical Impact

- The Deals

- The Future

- The Access to the Markets
  - US & EU Regulatory Updates
  - Reimbursement
    - PLA
    - ADLT
    - PAMA

- The Addendum



### **LDT Rule Vacated**

On March 30, 2025, U.S. District Court (Eastern District of Texas Sherman Division) vacated the FDA LDT Rule (published May 6, 2024). The court stated that the FDA does not have the authority to regulate LDTs.



#### **OBSERVATION**

The FDA's final LDT rule was vacated, removing a major overhang for labs and restoring confidence in the LDT pathway—the fastest and most flexible route for launching innovative diagnostics.

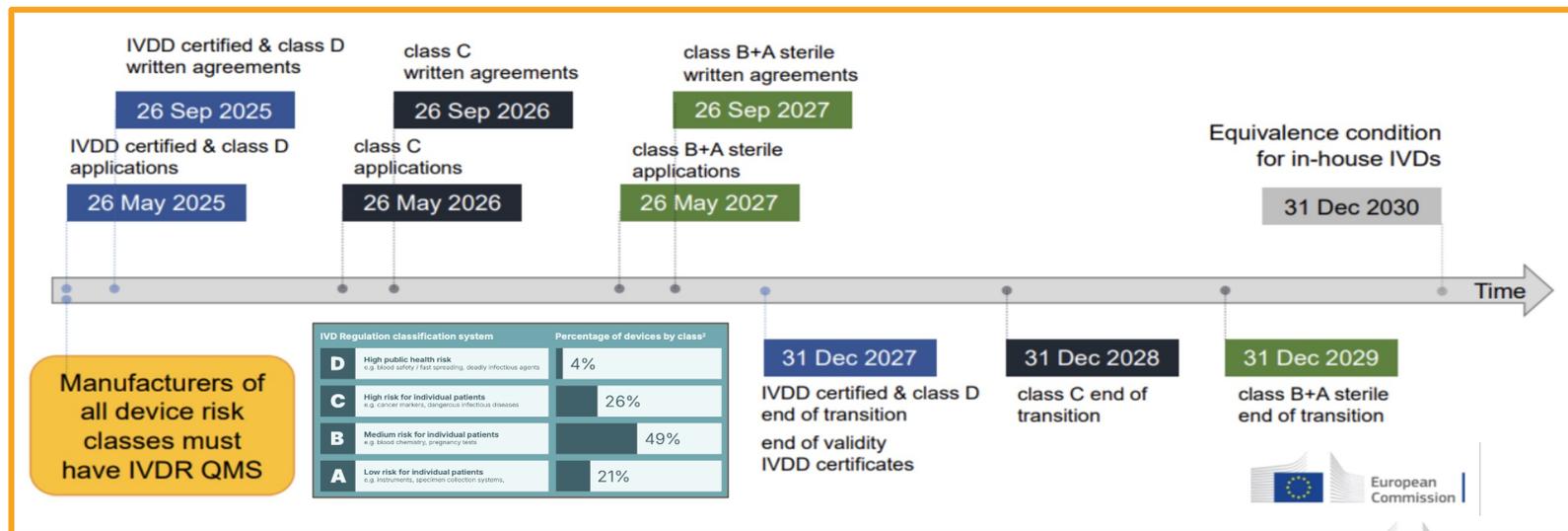
### **FDA proposes that some Class 3 companion diagnostics be regulated as Class 2 devices**

FDA proposed a reclassification of companion diagnostics (primarily molecular tests used in oncology) — from Class III devices (PMA) to Class II devices.

# EU Regulatory Update

## Little change to IVDR Roll-Out plan

- The European Commission has extended the transition periods for certain In Vitro Diagnostic (IVD) devices (January 2024)
- The key elements are as follows:
  - **Extended Transition Periods:** The transition period to the new rules for legacy IVD devices covered by a certificate or a declaration of conformity issued before May 26, 2022, is extended from May 26, 2024, to December 31, 2027, 2028, and 2029 depending on the risk class
  - **Gradual Roll-Out of EUDAMED:** Speeding up the launch of some parts of the European Database on Medical Devices – EUDAMED, to improve transparency
  - **Amendments Proposed:** As of December 2025, a proposal to amend IVDR with the goal of simplifying rules and reducing burden has been submitted



**OBSERVATION**

This proposed amendments provide more time both to manufacturers and the notified bodies to get the IVD devices to comply with the new European regulations

# Reimbursement Focus: The Advent and Role of PLA Codes

- **Proprietary Laboratory Analyses (PLA)** codes are a special category of CPT codes created by the AMA in 2019 to **uniquely identify laboratory tests that are proprietary to a single lab or manufacturer**
- PLA codes are **identification codes only** (not payment categories) and **can apply to many types of tests**, including molecular, genomic, proteomic, and algorithm-based assays
- Having a PLA code **allows a test to be distinctly tracked and billed** rather than grouped with generic CPT codes, but **reimbursement is still determined separately by CMS** through crosswalk or gap-fill unless the test also qualifies as an ADLT

## PLA Application Criteria



### Commercially Available

- The test must be commercially available in the United States for use on human specimens by the time the application is submitted



### Lab Must Request the Code

- The CLIA-certified or accredited clinical laboratory performing the PLA test or the manufacturer offering an FDA-approved, cleared, or classified in vitro diagnostic (IVD) test must request the code



### Sole-Source Laboratory Analysis

- All aspects of the analysis must be performed by a single (“sole-source,” including the same or different locations, owned and operated by the same entity) laboratory or licensed or marketed to multiple providing laboratories (e.g., cleared or approved by the Food and Drug Administration [FDA])



### Algorithm-Only Analyses

- Algorithm-only analyses of existing test results, without accompanying biomarker analysis, do not meet eligibility criteria for a PLA code

# Reimbursement Focus: The Advent and Role of PLA Codes



	Class I CPT	Proprietary Laboratory Analyses (PLA)
<b>Definition</b>	Used by providers, healthcare facilities, and manufacturers to report medical procedures and professional services delivered in ambulatory and outpatient settings	Subsection of pathology CPT codes unique to <b><i>a single test</i></b> <ul style="list-style-type: none"> <li>Can only be applied for and used by the lab performing the test or the manufacture producing the test reagents and instrumentation</li> <li>Can not be used by other labs or applied to similar distributed test kits</li> <li>Takes precedence over applicable Class I codes</li> </ul>
<b>Regulatory Requirements</b>	FDA IVD status	<b>Single site/labs:</b> LDT or FDA IVD status <b>Products (distributed to multiple labs):</b> FDA IVD Status
<b>Additional Data Requirements</b>	<ul style="list-style-type: none"> <li>Clinical efficacy must be well established and documented in US peer-reviewed literature</li> <li>Must demonstrate the service is performed by many physicians across the US</li> </ul>	None
<b>Time From Application to Decision</b>	<b>12-24 months</b>	<b>6-12 months</b>
<b>Review Times (per Year)</b>		
<b>Additional Requirements</b>	Strong advocacy support from relevant medical society	None

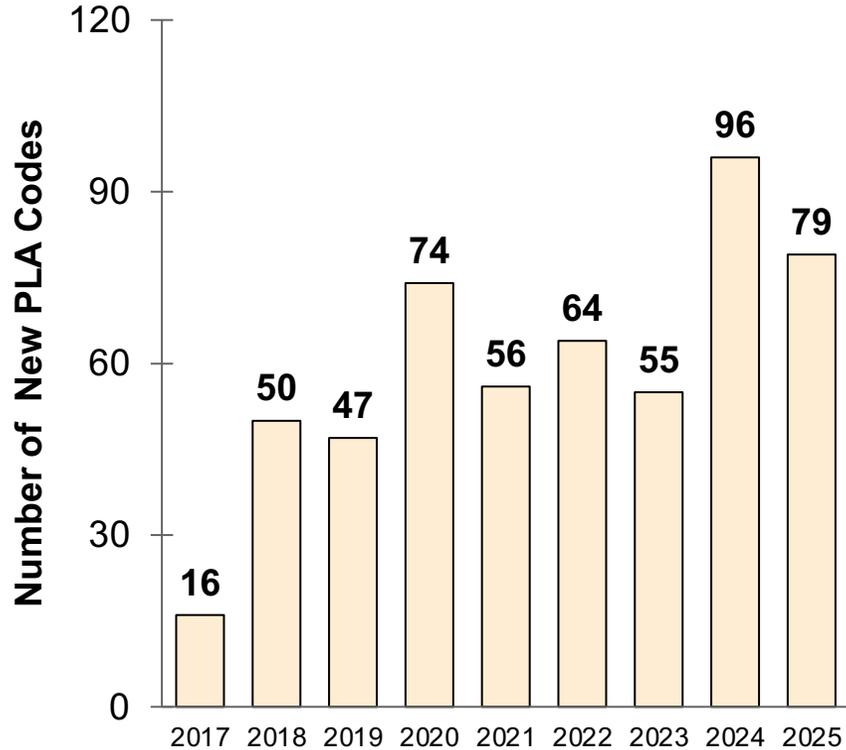
- PLA introduced by AMA and CMS as a result of Protecting Access to Medicare Act of 2014 (PAMA).
  - PAMA sought to unify lab testing fees for Medicare. The 2017 report found that undercounting of independent labs, hospital outreach labs, and physician office labs lead to a nearly \$4 billion cut to Medicare services which lead to industry backlash.
  - As part of a response to the backlash, the AMA introduced PLA codes to allow advanced independent labs and product companies to better represent their contributions in Medicare reporting data
- PLA Codes can be applied to/may be standard Clinical Diagnostics Laboratory Tests (CDLTs), Advanced Diagnostics Laboratory Tests (ADLT), Multianalyte Assays with Algorithmic Analyses (MAAA), Genomic Sequencing Procedures (GSP), and other categories as defined by PAMA.

# Reimbursement Focus: PLA Code Numbers

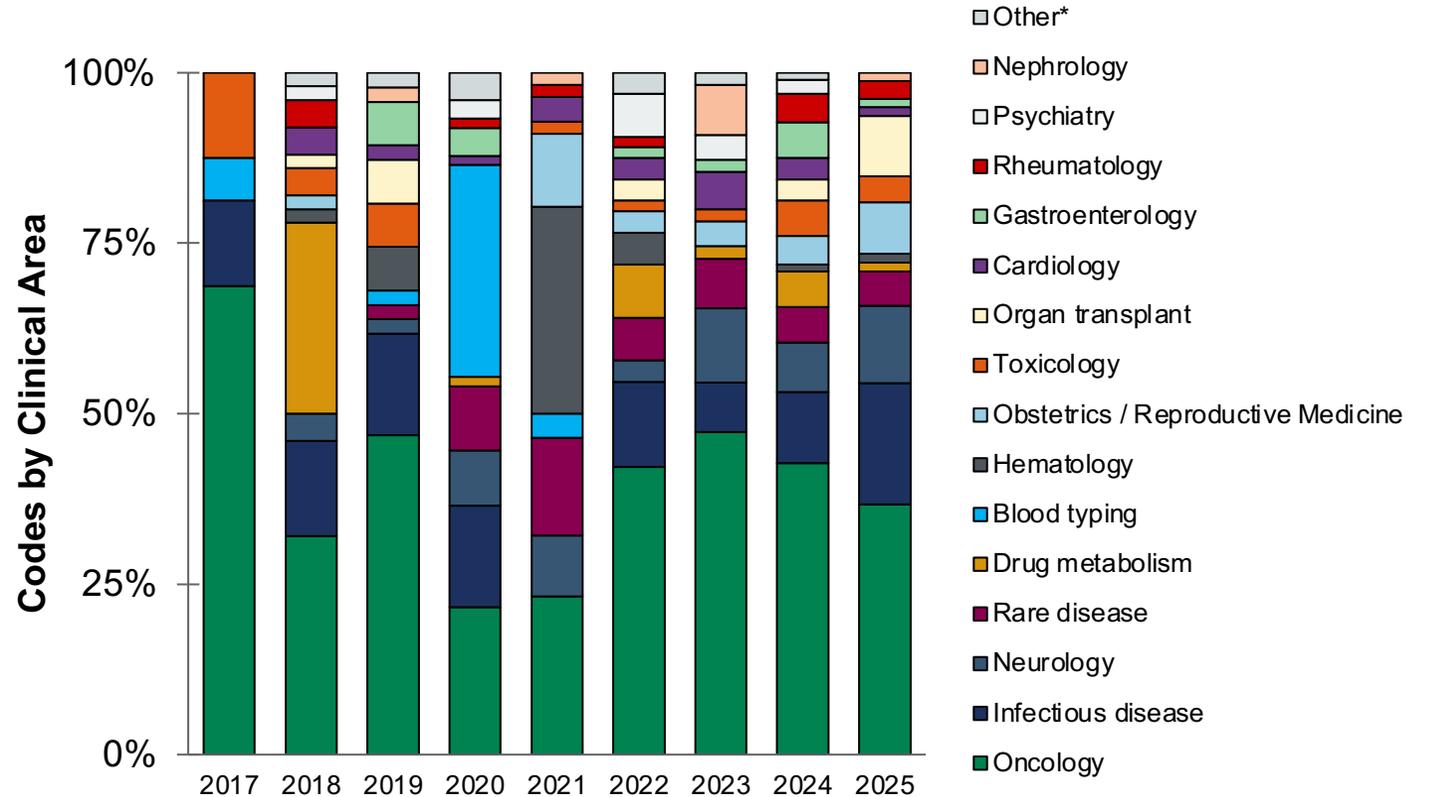


## New PLA Code Introductions...

...by Year



...by Clinical Area



\* Includes pain management, allergology, sleep medicine, ophthalmology, nutrition, longevity, and endocrinology.  
Source: Health Advances analysis, CodeMap.

# Reimbursement Focus: PLA Code Use



## OBSERVATION

### Significant increases in:

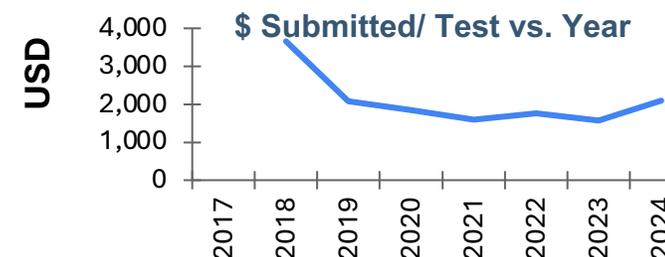
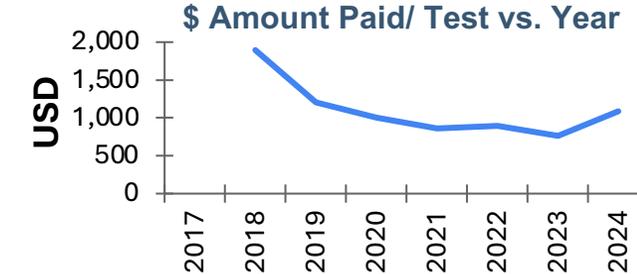
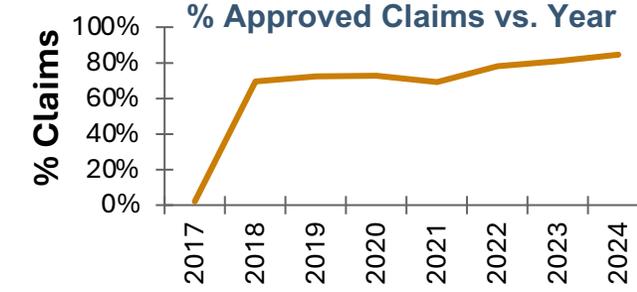
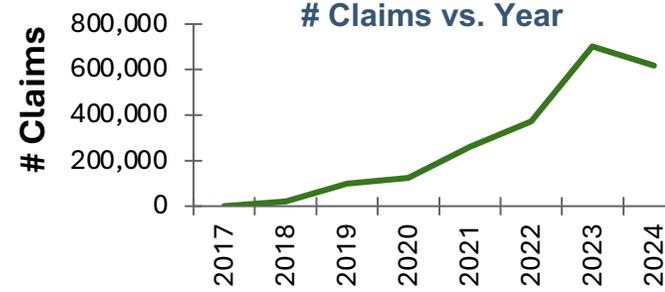
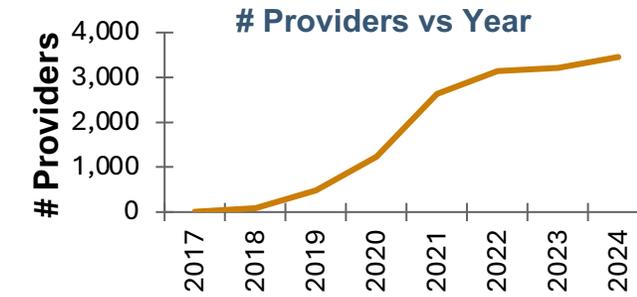
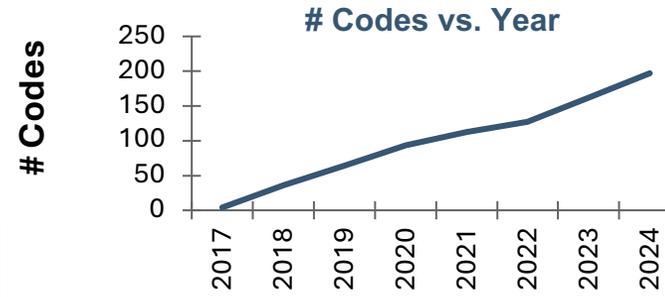
- Available PLA codes
- PLA code claims to Medicare
- Total Revenue for proprietary laboratories

### Plateau in:

- Adoption of PLA tests by providers (~3000 providers)
- Rate of claim approvals (~80%)

### Reductions in:

- Both the submitted and allowed reimbursement rates per test - fallen by 60% since 2017
- Average reimbursement for PLAs tests has more than halved in last 5 years with new codes being added



# Reimbursement Focus: The Advent and Role of ADLT



- **Advanced Diagnostic Laboratory Test (ADLT)** is a subclassification of Clinical Diagnostic Laboratory Test (CDLT) established under PAMA in 2014 with distinct pricing and reimbursement rules **aimed at encouraging innovation in clinical diagnostics**.
- ADLTs are **unique, proprietary tests** offered by a single laboratory and can include tests with **any type of code** (MAAA, PLA, GSP, etc.).
- The initial **reimbursement rate** for a new ADLT is **based on the test's actual list price for an initial period of three calendar quarters**, after which Medicare rates are adjusted annually based on private payor data median rates. This **bypasses crosswalk/gap-fill** process.

## ADLT Application Criteria



### Meet Definition of ADLT

- Test must either:

- (A) Be a clinically unique test with multiple DNA, RNA, and/or protein markers, combined with an empirically defined algorithm to predict development of a condition or response to treatment
- Or (B) be FDA approved



### Detail Uniqueness of Test

- To prove (A), detail the test description, purpose, and compare to tests with similar intended use or biomarkers to highlight new diagnostic information not obtainable with current tests



### Verify Single Lab Status

- Clearly outline all laboratory components and certify no other labs are conducting test



### Prove Unique Coding

- Provide CPT/PLA code, MoIDx Z-codes, and current payment rates



### Prove Previous Payment

- Provide evidence of at least one single payment by a MAC on a reasonable and necessary determination for a test



### Provide Pricing Data

- Provide list price, charged amount on launch date, and lowest publicly available charged amount

# Reimbursement Focus: PAMA History and Impact of RESULTS Act



- In 2014, Congress passed the Protecting Access to Medicare Act (PAMA) with the intent to tie Medicare reimbursement to private market rates
- PAMA implementation under-sampled hospital and outreach program laboratories leading to steeper cuts anchored to rates from the largest commercial labs
- Since PAMA's enactment, 72% of clinical lab tests have faced reimbursement cuts

Example Test	CPT Code	2017 Reimb. Rate	2020-2025 Reimb. Rate	Rate Cut So Far	Median Value	Total Potential Rate Cut
HIV Molecular Quantitative	87536	\$117	\$85	-27%	\$74	-36%
Her-2 Oncoprotein	83950	\$88	\$64	-27%	\$52	-41%
PSA	84153	\$25	\$18	-28%	\$16	-34%
Thyroid Stimulating Hormone	84443	\$23	\$17	-27%	\$15	-35%
Complete Metabolic Panel	80053	\$15	\$11	-27%	\$9	-37%

## RESULTS Act

- In Sept 2025, the RESULTS Act was introduced which, if passed, would freeze Medicare CLFS rates through 2028 and overhaul the way that future rates are calculated
- RESULTS Act will:
  - Increase comprehensiveness and representativeness of data
  - Reduce the data reporting burden on labs and agencies
  - Cap any individual year's reductions at 5%
- The RESULTS Act will be determined by January 31st, 2026

- **The Financial Results**

- MegaDx Stock Index
- Initial Public Offerings
- VC and PE investments

- **The Clinical Impact**

- Test Volumes
- FDA Approvals
- Focus: Companion Diagnostics / Biomarkers
- Focus: Digital Pathology

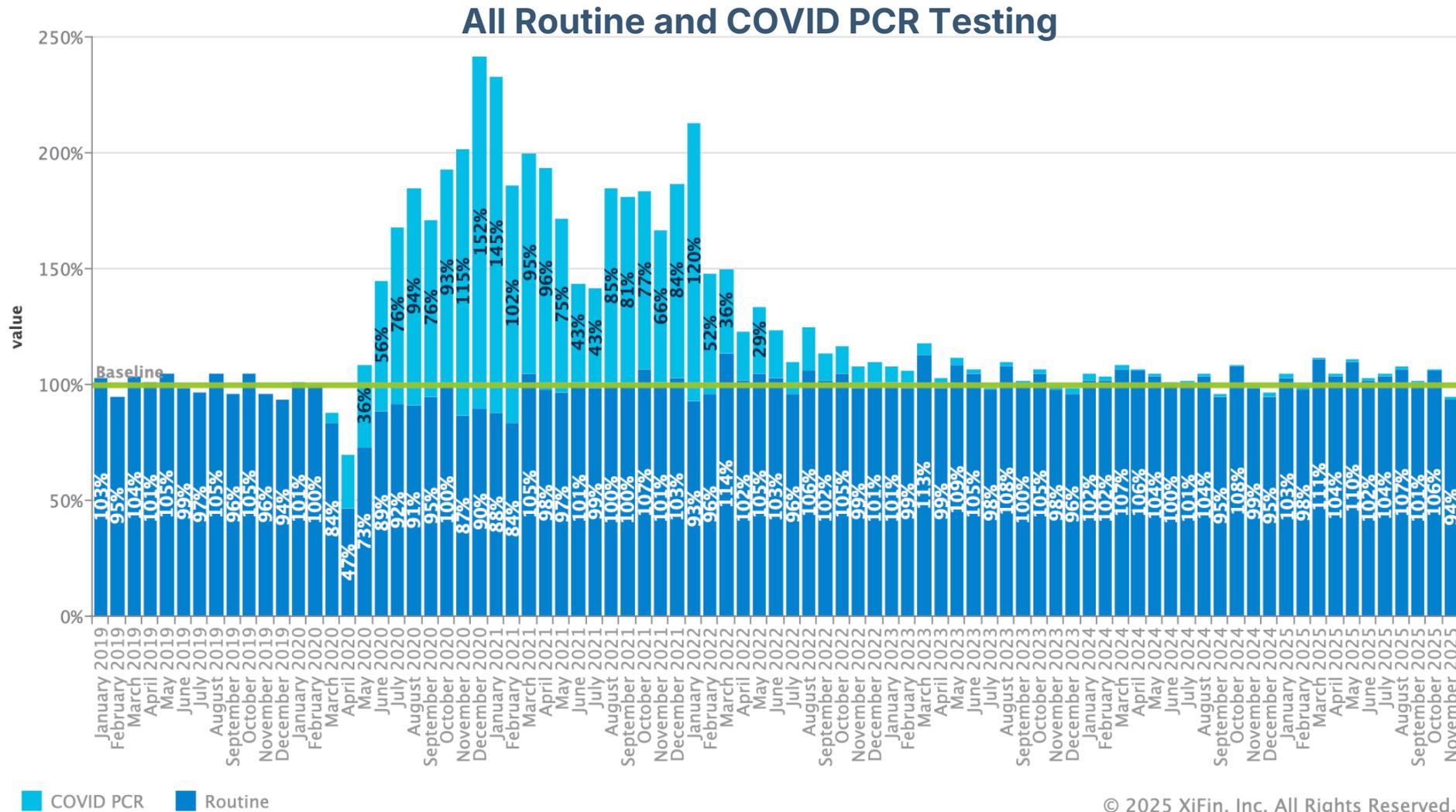
- **The Deals**

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# Laboratory Test Volumes by Discipline



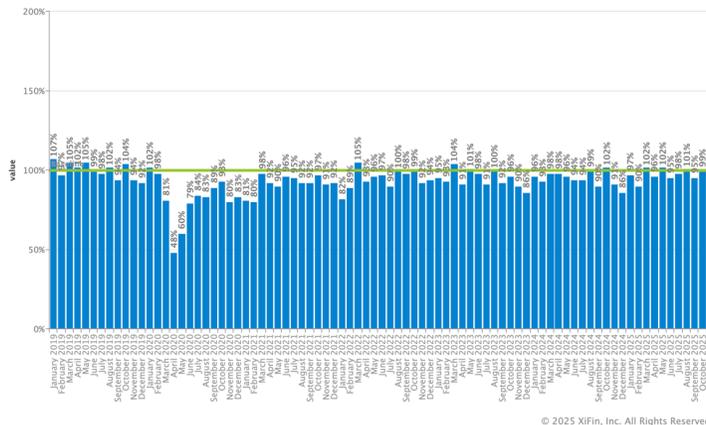
Note: Baseline is the average monthly volume for 2019; January 2019 to November 30, 2025.  
 Source: Xifin Lab Volume Index.

# Laboratory Test Volumes by Discipline



## Clinical

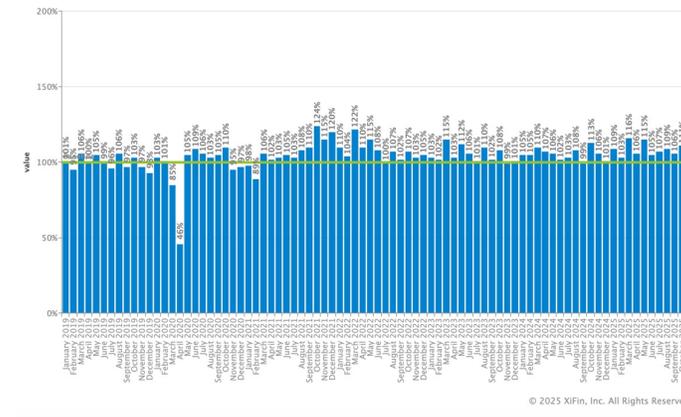
Large decline in April 2020 (COVID) with slow recovery. Now stabilized and slightly below 2019 baseline.



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## Immunology & Microbiology

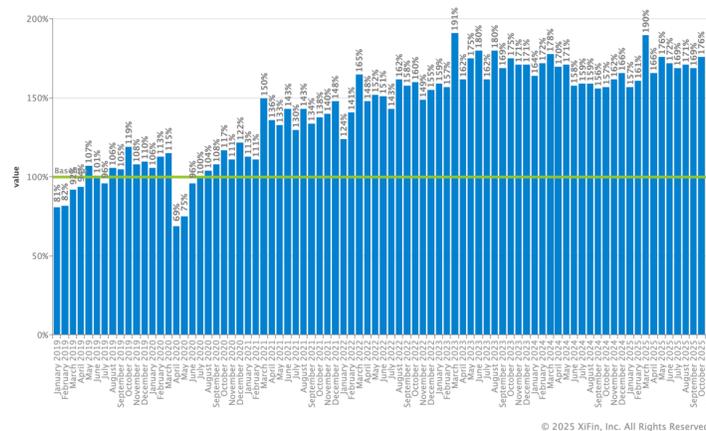
Decline in April 2020 (COVID) followed by rapid recovery. Stable and now above 2019 baseline.



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## Molecular & Genetic

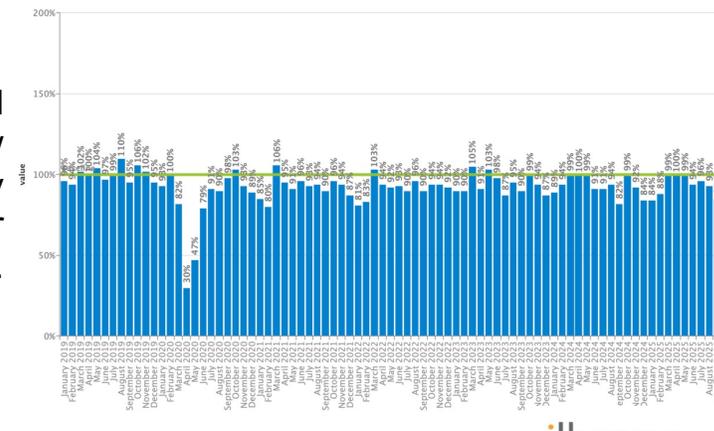
Consistent upward trend – 2025 is 70% above 2019 baseline. Tests: PCR, FISH, WES, WGS, CNV, MLPA



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## Pathology

Sharp decline in April 2020 (COVID) with slow recovery and but mostly below 2019 baseline for past 3 years.

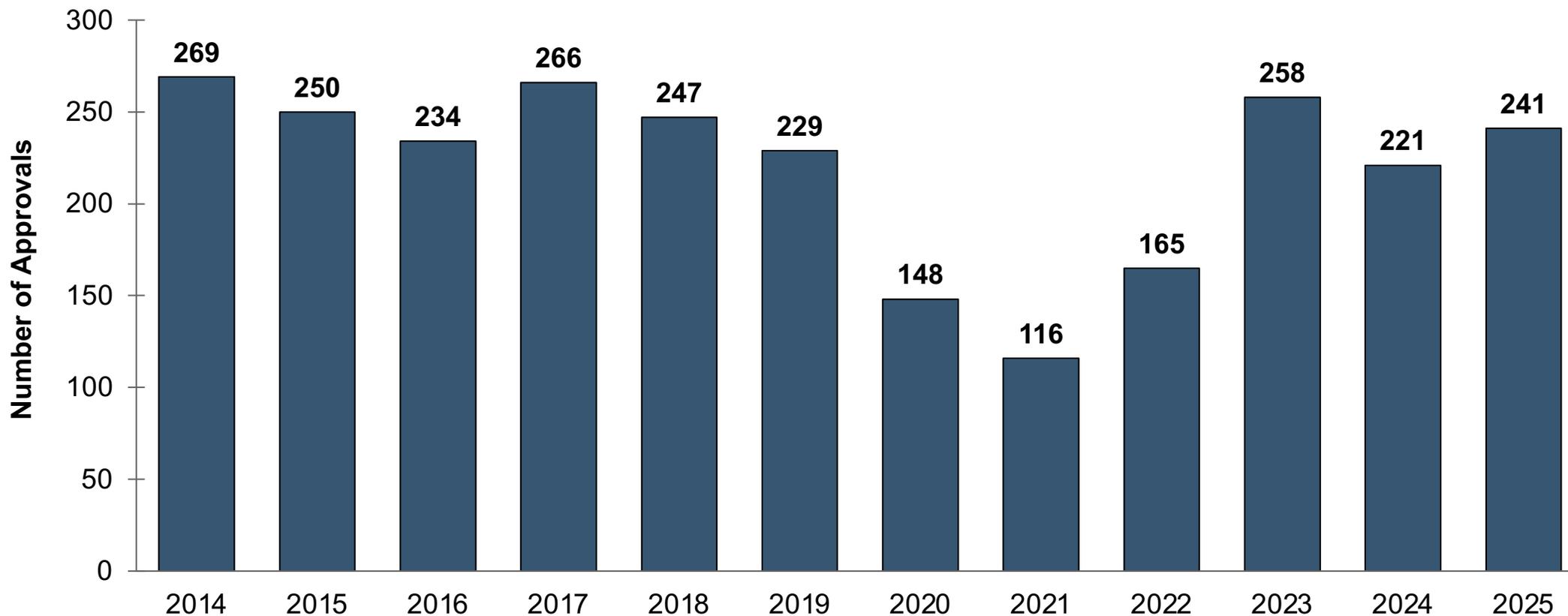


Note: Baseline is the average monthly volume for 2019; January 2020 to November 30, 2025. Source: Xifin Lab Volume Index.

# FDA Approvals: 510(k) - Approaching Pre-COVID Baseline



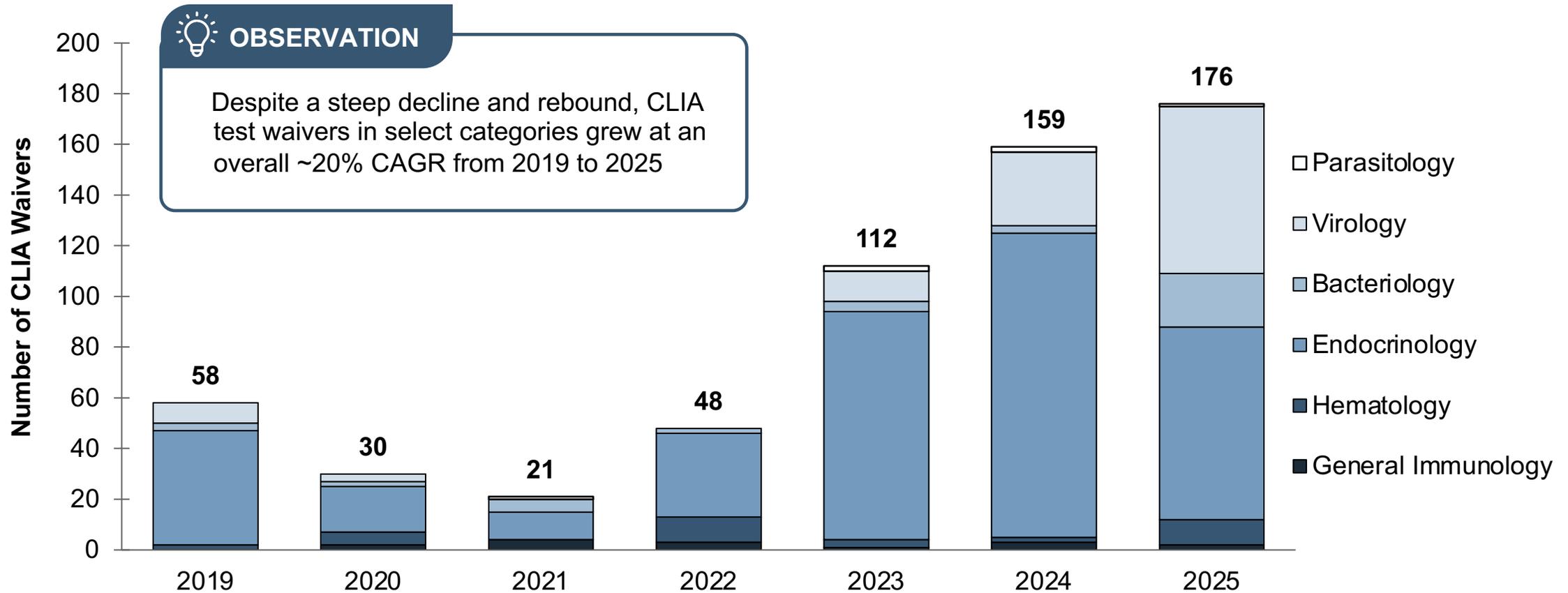
## Diagnostics 510(k) Approvals by Year



Note: Includes repeat 510Ks for products with an update.  
Source: Health Advances analysis, FDA.

# FDA Approvals: CLIA Waivers – Significant Increases Post COVID

## CLIA Test Waivers in Select Analyte Groups



Note: An additional ~8000 waivers were granted between 2019 and 2025 for analytes in urinalysis, toxicology, and general chemistry.  
Source: Health Advances analysis, FDA.

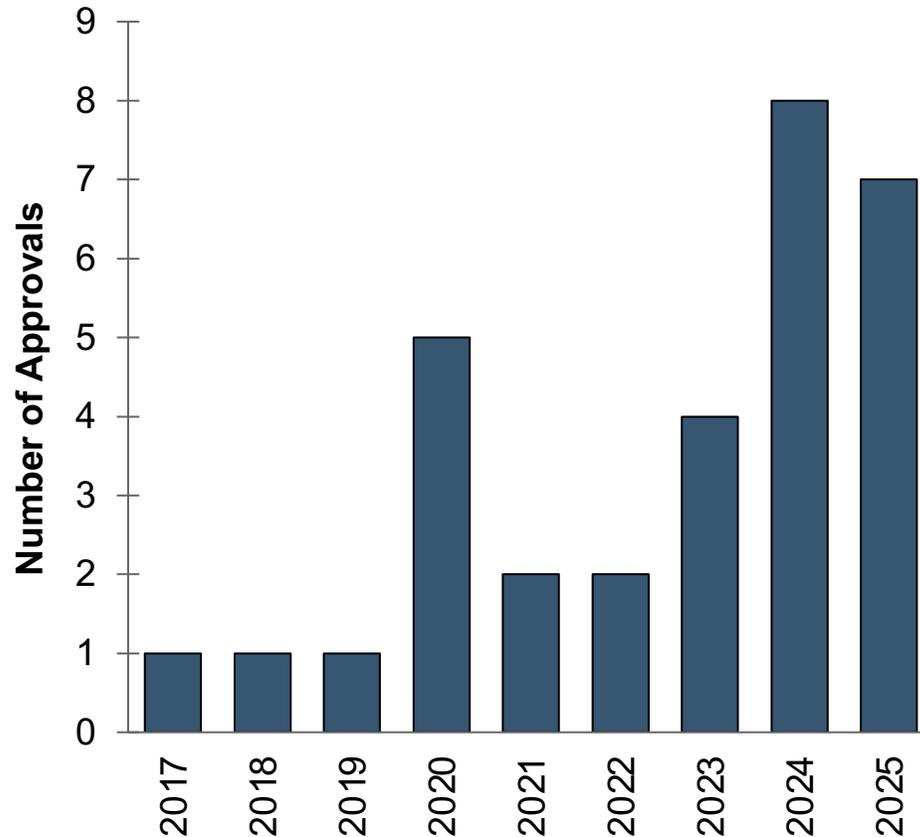
# FDA Approvals: Breakthrough Designation Diagnostics

## 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

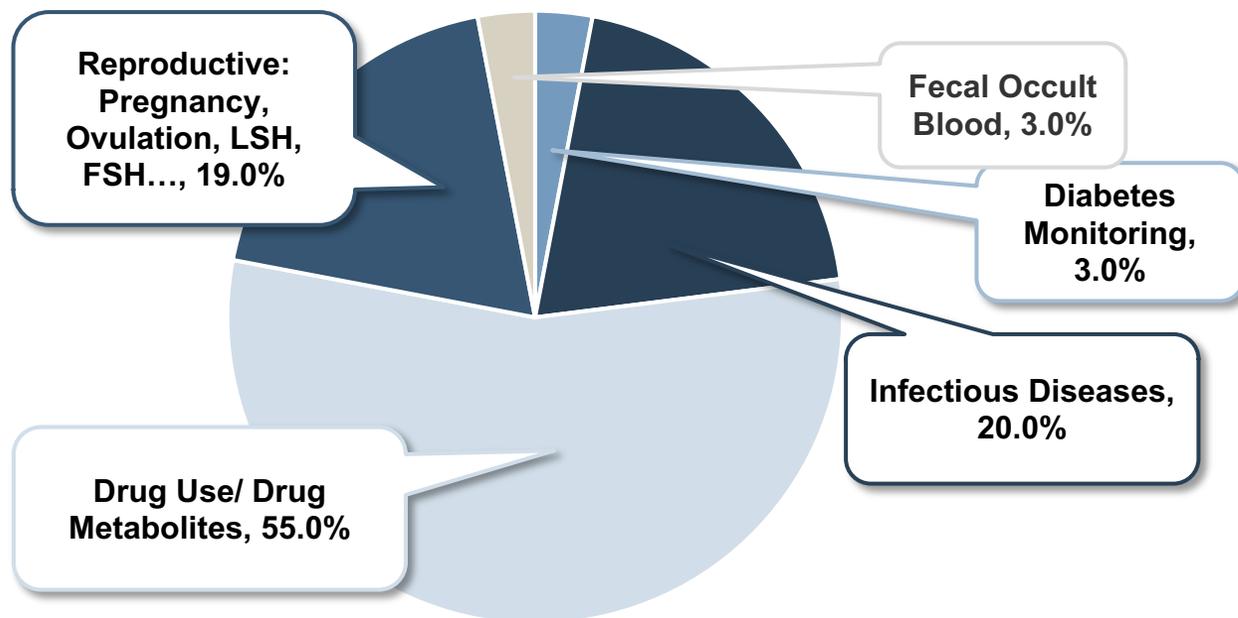


## Seven Diagnostics Approved in 2025 via Breakthrough Designation

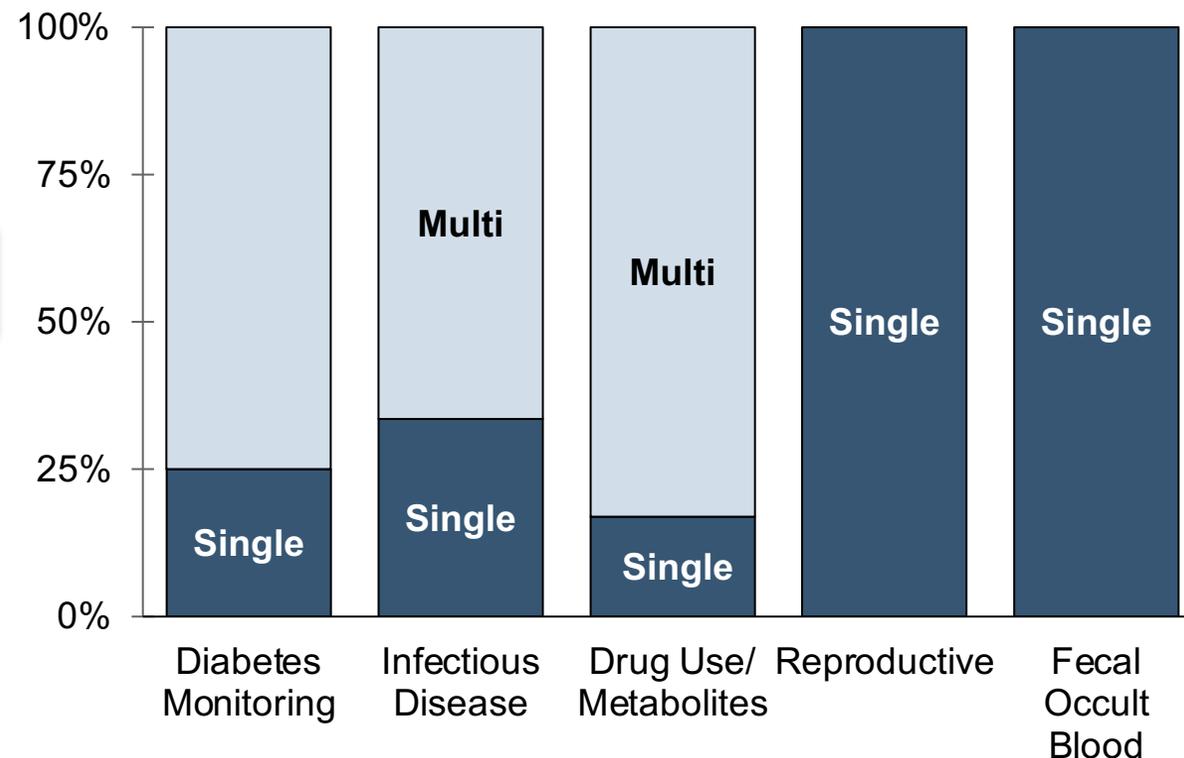
- 1 **Artera AI Prostate:** Assists with risk-based decisions for localized prostate cancer
- 2 **Beckman Coulter Alzheimer's Test:** Blood test measuring two key biomarkers implicated in Alzheimer's
- 3 **Fujirebio Lumipulse:** Plasma test to identify amyloid plaques in patients being evaluated for AD
- 4 **Teal Health Wand:** Self-collection of vaginal specimens for HPV testing
- 5 **Roche Elecsys:** Immunoassays to aid in the diagnosis of preeclampsia
- 6 **Galen Second Read:** Software-only device to analyze scanned histopathology whole slide images from prostate core needle biopsies
- 7 **Inflammatix Triverity:** Test to aid in identifying bacterial vs. viral infections

# FDA 2025 Approvals: Over-The-Counter / Home Tests

## Over the Counter Diagnostics Approved in 2025



## Singleplex vs. Multiplex

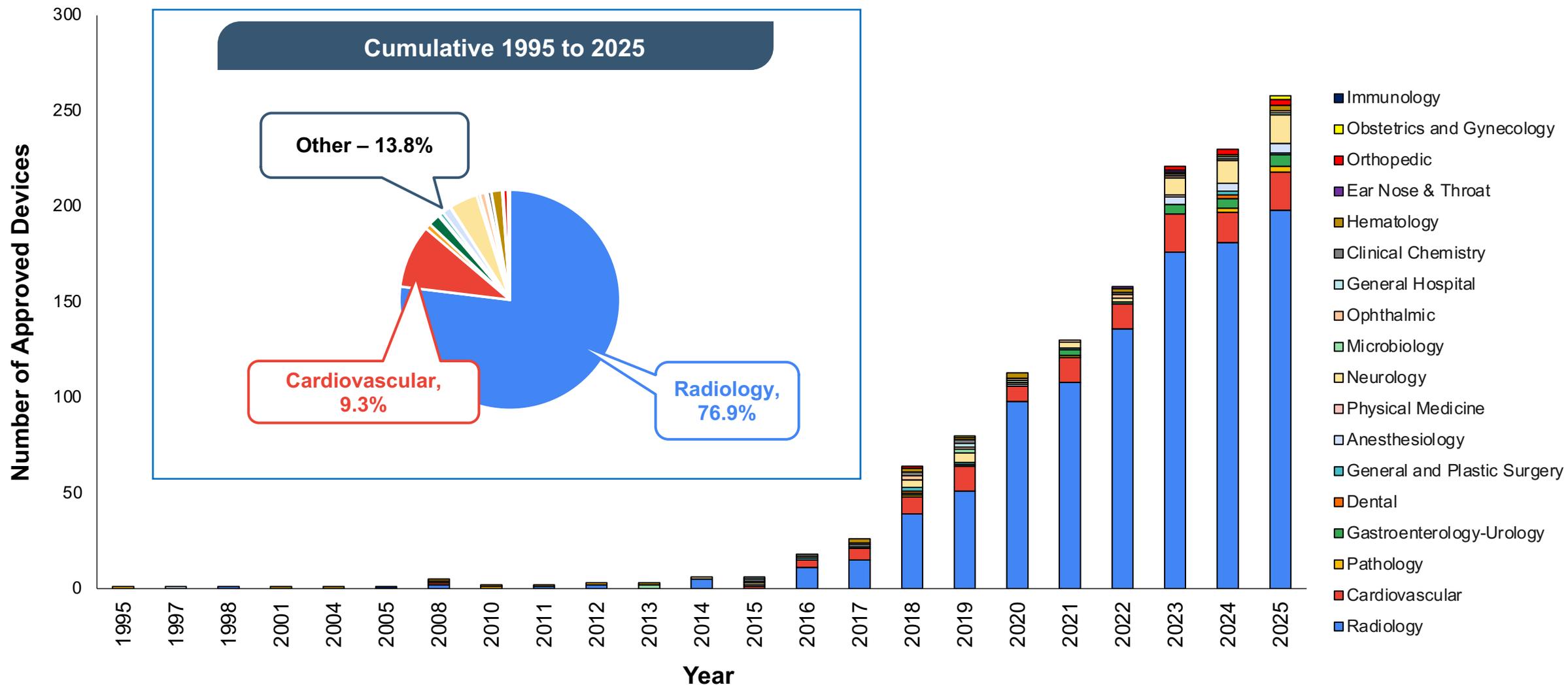


2X+ as many unique 2025 OTC approvals vs 2024

- First FDA-cleared OTC celiac genetic risk test
- 13 COVID OTC tests, 7 of which also include flu testing

Note: Assumes that each approval is unique even if for a multiple products.  
Source: FDA databases.

# FDA Approvals: Machine Learning Enabled Devices



Note: FDA published data through December 5, 2025. 2025 has had 258 approvals through December 5, 2025.  
Source: FDA databases.

# FDA Diagnostic Device Approval “Firsts” in 2025

## First blood test approved for Alzheimer’s

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



## 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)



## First OTC Blood Pressure Monitoring Device

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



## First DTC Celiac Risk Test

FDA clearance of a direct-to-consumer genetic test to predict risk of Celiac disease



## First CLIA Moderate-Complexity Mass Spec

FDA approval for first moderate-complexity mass spectrometry-based test



## First At Home Self-Collection HPV Device

First FDA-cleared device for at-home HPV self-collection for use with lab-based primary HPV



## First Multi-modal POC Instrument

FDA 510(k) for POC instrument which integrates clinical chemistry, immunoassay, and hematology assays



# The Terrific Ten “Firsts” and More LDT Achievements



## BILLION TO ONE



- MolDx/Medicare coverage for **Northstar Select**
- Published/announced validation for **Northstar Response** in a peer-reviewed study, supporting broader clinical adoption



- Positive data for **Caris Assure**, a blood-based assay leveraging whole-exome / whole-transcriptome signals for multiple use cases, including therapy selection, minimal residual disease (MRD), and early detection

## EXACT SCIENCES



- Launch of **Cologuard Plus**
- Launch of **Oncodetect MRD**, a ctDNA test for solid tumors
- Launch of **CancerGuard**, a multi-cancer early detection (MCED) blood test with broad access via Quest's patient network



## BEACONS

- Launch of **ultraRapid** whole genome sequencing, providing as soon as 48-hour results to inform care for NICU/PICU patients
- Launch of **BEACONS**, the first multi-state newborn genomic screening initiative backed by NIH

## GRAIL



- Positive topline results in Pathfinder 2 registrational study for **Galleri MCED** blood test
- FDA PMA application submitted for **Galleri MCED**, supported by Pathfinder 2 study and the NHS-Galleri trial



- **Shield**, a CRC blood screening test, received ADLT status
- Collaboration with Quest to commercialize **Shield** through ~2,200 patient access points
- Expanded **Reveal** to include therapy response monitoring



## Signatera™ Residual disease test (MRD)

- Broad clinical launch of **Signatera Genome**, a genome-based ultra-sensitive MRD test
- Unveiled **tissue-free MRD roadmap** (methylation-based capability); shared clinical data for **Latitude tissue-free MRD assay** in CRC



## NeXT Personal®

- Medicare coverage for **NeXT Personal** ultra-sensitive MRD testing in breast cancer – reimbursement rates for MRD test and Single Plasma test are \$4,266 and \$1,164, respectively

## "TEMPUS



- National launch of FDA-approved **xT CDx** (solid tumor CGP) for nationwide clinical ordering
- Introduced **xM** for treatment response monitoring (TRM) in advanced cancers



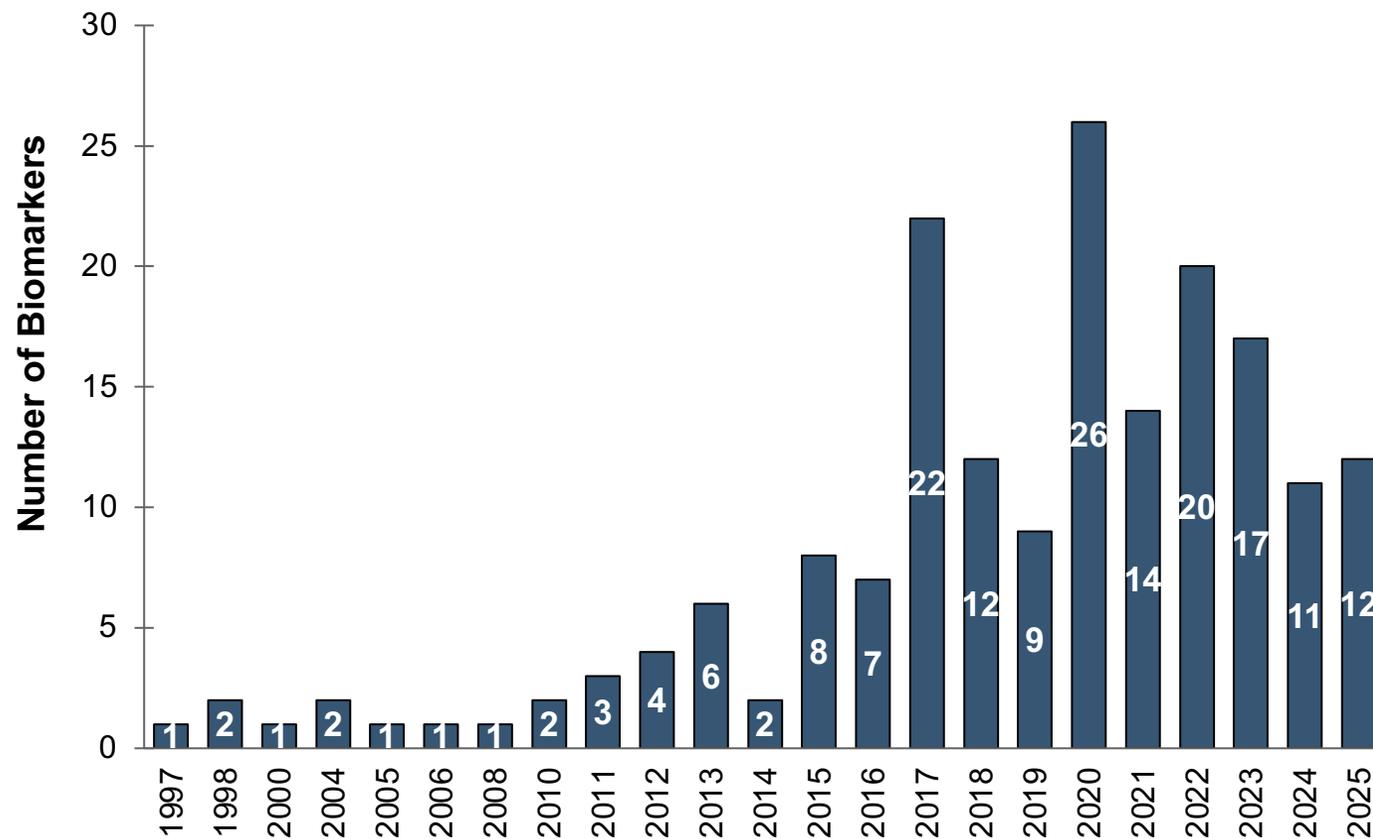
## Afirma.

- Launch of **Afirma v2 transcriptome platform** to improve efficiency of Afirma testing business and providing platform for future product launches

# Companion Diagnostics (CDx): FDA Approvals 1997 - 2025



## Companion Diagnostics (CDx) Biomarkers 184 Cumulative (1997 to 2025)



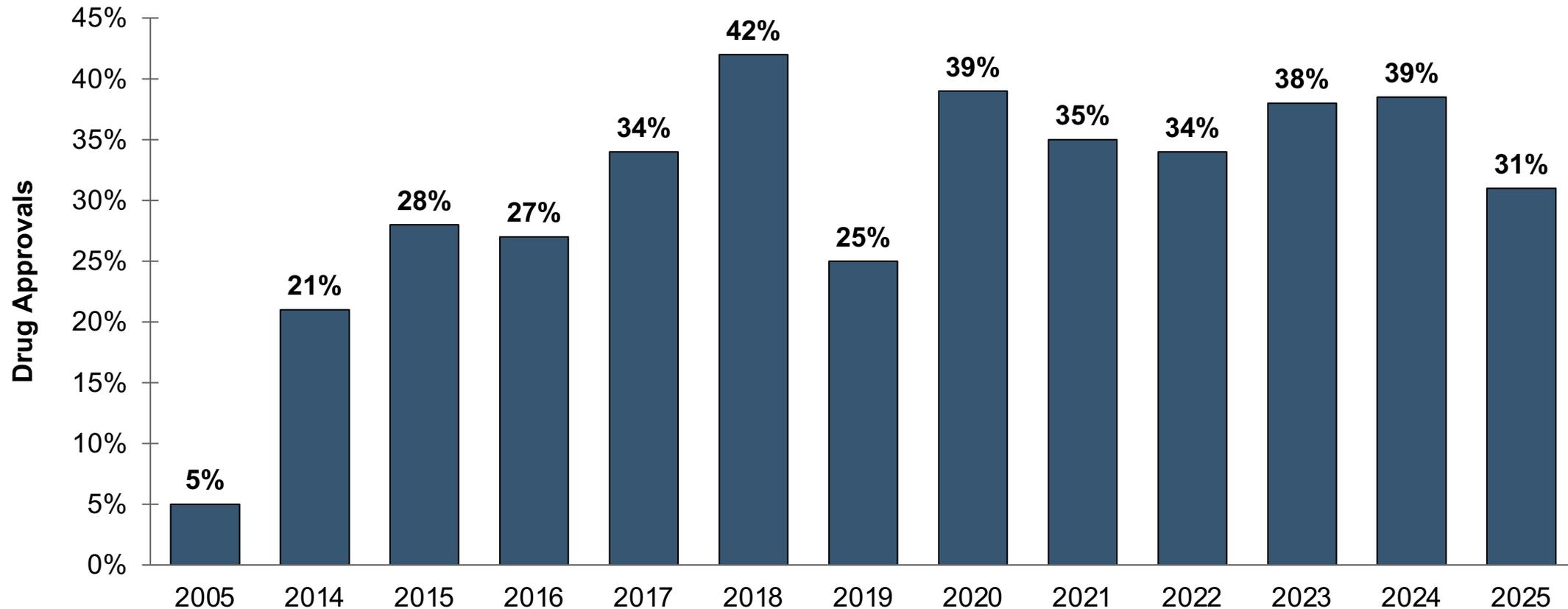
### Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)

CDx Test(s)	Biomarker
1. FoundationOne CDx	BRAF
2. theascreen® KRAS RGQ PCR Kit	KRAS
3. Monoclonal Primary Antibody and Oncomine Dx Target Test	ERBB2 (HER2)
4. INNOVANCE Antithrombin	Antithrombin III
5. VENTANA MET (SP44) RxDx IHC	MET
6. Randox ConcizuTrace ELISA	Concizumab concentration
7. Oncomine Dx Express	EGFR
8. Quest Diagnostics AAVrh74 Antibody ELISA CDx	AAVrh74
9. Vysis ALK Break Apart FISH Probe Kit	ALK
10. Idylla CDx MSI Test and MMR IHC Panel pharmDx	dMMR
11. Guardant360 CDx	ESR1
12. Ion Torrent Oncomine Dx Target Test	HER2/ERBB2 TKD

# Biomarker-Dependent New Drug Approvals as % of all Drug Approvals

## Why 2025 change:

- Biomarker dependency is heavily driven by oncology volume, and 2025 was not an oncology-heavy year
- Many 2025 approvals were vaccines, antibiotics, and broad chronic disease treatments that do not require biomarkers (
- Companies appear to be launching with broader initial labels, rather than ultra-narrow biomarker-specific indications unless required
- FDA staffing disruption and leadership turnover may have contributed to a preference for lower-risk, broader approvals

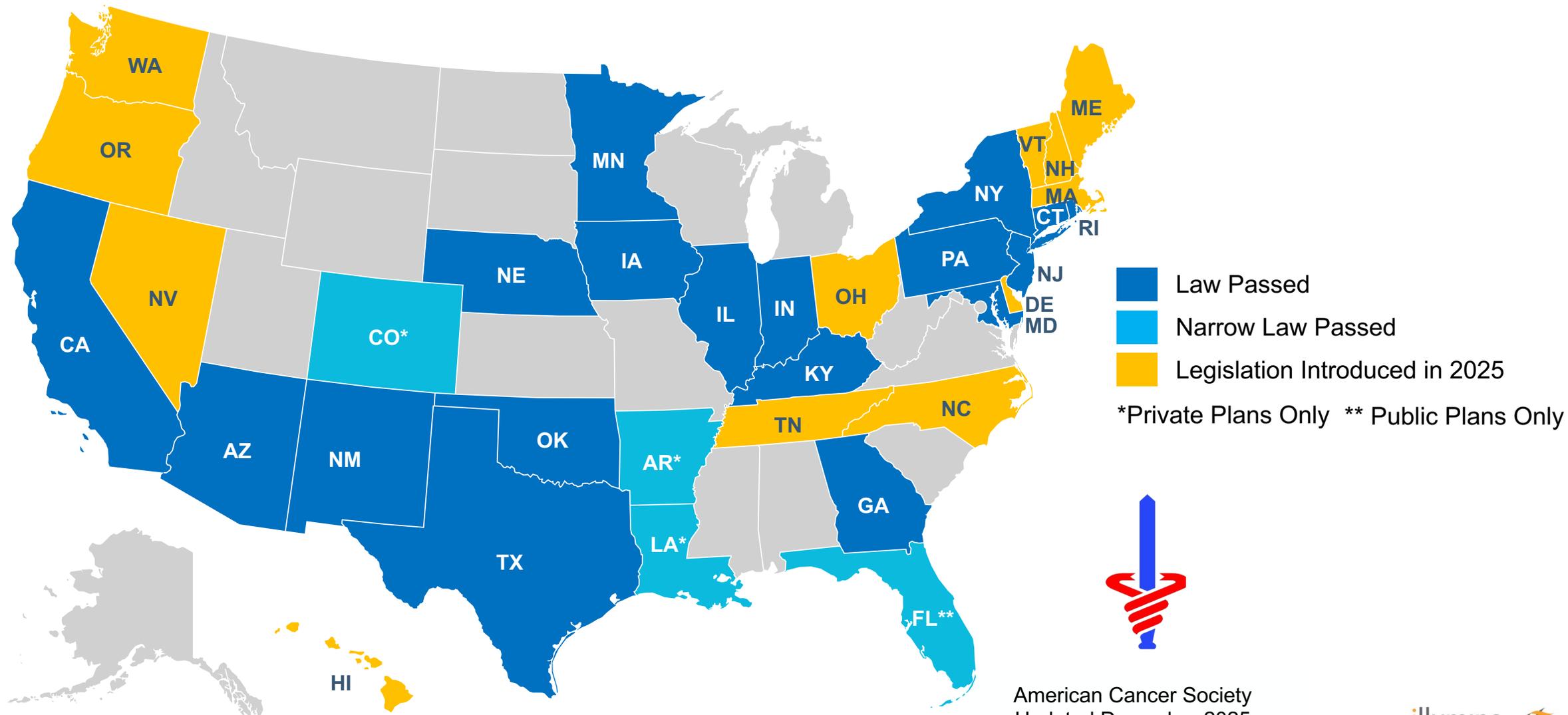


Methodology: When evaluating NMEs, PMC categorizes personalized medicines as those therapeutic products for which the label includes reference to specific biological markers, often identified by diagnostic tools, that help guide decisions and/or procedures for their use in individual patients.

Source: Personalized Medicine at FDA: The Scope and Significance of Progress in 2023, Personalized Medicine Coalition 2024, Fierce Pharma 2025.

# Biomarker Access Legislation Expanding

## 22 states passed bills & 12 in process



American Cancer Society  
Updated December 2025

Source: American Cancer Society Action Network (ACS CAN).



- The Financial Results

- The Clinical Impact

- The Deals

- The Future
  - Reasons for Optimism
  - Room for Improvement

- The Access to the Markets

- The Addendum

# What a Difference a Year Makes: From Recovery to Renaissance



## New Ecosystem

*(macro sociopolitical, regulatory, & economic)*



## New Technologies

*(e.g. multimodal / disciplinary, AI integration)*



## New Markets

*(e.g. at-home, prevention)*



## New Leaders

*(e.g. profitable companies, consolidation)*



## New & Renewed Pharma Interest

*(e.g. large biomarker and data partnerships)*



## Still Room for Improvement



**Diagnostics Renaissance**

# 2025 was great with more good news to come



## CNS Test Use and Development Continues to Grow Rapidly

- CNS drug trials broadly using biomarkers for patient inclusion and monitoring
- Success in Alzheimer's testing leading to investment in diagnostics for other CNS conditions, even before drugs are available
- Next generation of neurodegenerative tests



## Continued Growth in Liquid Biopsy Tests

- Liquid biopsies with their less-invasive samples (e.g. blood) enable easier, cheaper & faster tests with use by non-specialists for a broader population
- Growing acceptance of LBx for early detection and minimal residual disease testing create strong data sets for disease natural history
- Payers (including CMS) issuing positive coverage decisions for range of LBx products



## Big Deals & Strategic Investments Paying Off

- Abbott / Exact impact: proving big deals at high multiples are possible
- The Terrific Ten create new opportunities for acquisitions for smaller companies
- Strong margins across industry leaders create investor confidence which fuels more investment



## Advances in Automation, DTC Testing, and Wearables

- FDA approves more home tests and eases regulations for wearables
- Consumer test ordering increasingly popular with direct and indirect providers
- Improved technology enhances the ability for DTC tests and wearables to communicate with MD's (but few use it yet)



## Expansion of CDx Opportunities

- Reduced barriers to CDx development likely with FDA's new FDA proposed reclassification (Class 3 to Class 2)
- Pharma and Big Dx' real interest in CDx partnerships early in drugs' development
- Groundbreaking deals (e.g., Roche/AZ CDx) and approvals resulting from the change



## Large Volume Commodity Tests still under Price Pressure

- Payment rates for large volume commodity tests are under price pressure from government and private payors as coverage policies are tightening. LDT and ADLT rates remain steady.
- Volume base procurement (VBP) & tariff strengthening China-based companies leading to declining China revenues for multinationals



## Biomarker use way up but still less than it should be

- 50% of active cancer patients are offered biomarker tests... up from <5% in 2000 and < 10% in 2010
- 60% of cancer clinical trials include biomarkers... up from <10% in 2000 and < 15% in 2010



## Medical Community still playing catch up

- MDs diagnostics knowledge gap still exists. Few medical school teach the fundamentals of diagnostics and personalized medicine. More continuing medical education still necessary.
- Today, education provided by diagnostic companies directly.

# Summary: 2025 was a landmark year



## **Multi-Omics and Genomics combine to make better and more effective tests**

Integrated genomics, gene expression, RNA abundance and proteomics are opening new horizons from foundations in cancer, in neurology and soon, immunology



## **Less-invasive techniques (mostly liquid biopsy) open new clinical horizons**

2025 was an exciting inflection point: New markets and primary care (early diagnosis – CNS disease and oncology), new leaders (The Terrific Ten) combine to create the Diagnostic Renaissance, new technology (multi-omic integration with AI).



## **US regulatory restraint permitted existing and innovative LDTs to flourish**

Regulatory uncertainty eased with the FDA's final rule on LDTs being vacated. This removed a major overhang and enabled labs to embrace and accelerate LDT test launches in high value and large TAM markets.



## **AI and proprietary clinical (training) data the foundation for new-high value tests**

The top companies operate at the intersection of wet-lab biology and dry-lab AI, building proprietary foundational models and monetizing data through clinical care and drug development partnerships.



## **Dx investment interest rekindled: M&A Deals reach new high pinnacle**

Strategic consolidation accelerated. 2025 featured multiple mega-deals totally more than \$60B which is nearly as much as all of the last decade combined. A higher pace of smaller acquisitions and strategic partnerships to enter the “platform + data” as the dominant endgame.

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  - **MegaDx Index Data**

# The Diagnostics MegaDx Index Explained

- **The Diagnostics MegaDx Index is compiled from an evergreen database of month end market value of the most inclusive collection of public companies that participate in the clinical in-vitro diagnostic industry worldwide:**
  - 129 public companies tracked during 2025: 74 on US exchanges, 25 in China, 30 elsewhere
  - Bias toward inclusion: many large Dx participants have most of their revenues outside clinical diagnostics (e.g. Illumina in Life Science Tools, Roche in pharmaceuticals etc.).
  - The MegaDx index weights market value by estimated diagnostics out of total revenues (e.g. 24% of Roche; 21% of Agilent). It does not attempt to assign value to segments individually (due to circularity).
  - Companies are included for entire year if they were public for any month of that year (value introduced, revised or removed for public stock events: stock splits, IPOs; mergers and acquisitions; bankruptcy; etc.
  - Currency rates are revised at the beginning of each calendar year and held fixed for that full year.

# MegaDx Index 2025:

## Companies included in Index ranked by 2024 Dx Revenue

### Over \$1 billion Diagnostics revenue – Listed by revenue (descending)

Roche  
Quest  
LabCorp  
Danaher (Cepheid, Beckman, Leica, Radiometer)  
Abbott  
Eurofins Scientific  
Thermo Fisher  
Sonic Healthcare  
Beckton Dickinson  
Runda Medical Technology  
Healthineers Siemens AG  
Dexcom  
BioMerieux  
Exact Sciences  
QuidelOrtho  
Sysmex  
Illumina  
Mindray Medical International  
Hologic  
Dian diagnostics group  
Bio-Rad  
HU Group/Miraca Holdings/Fujirebio  
Revvity (pka Perkin Elmer)  
Agilent  
DiaSorin  
Natera

### Under \$1 billion Diagnostics revenue – Listed by revenue (descending)

Myriad	Hybri Biotech	Quanterix	BioSino	Universal Bio
Qiagen	Bio-Techne	Grail	BioNano	OpGen
Grifols	Thalys Med/Tech	BioSynex	Enzo Biochem	Lucid Dx
Caris	Fulgent Genetics	Tellgen	Suraksha Dx	Angle
Tempus	MedicalSystem Bio	Osang	SurModics Inc.	Talis Bio
Autobio	YHLO Biotech	Pacific Bio	Diaceutics PLC	Proteomics Lab
Diagnostyka	CareDx	Burning Rock	Senseonics	Inoviq/Sienna
NeoGenomics	Prenetics	Personalis	MIRXES-B	Insight MDx/ Mainz Biomed
Guardant	BGI Genomics	Trinity Biotech	Psychemedics	VolitionRX
Snibe	Dr Lal PathLabs	MDX Health	Pacific Edge	Biovica
Da An Gene	23andMe	EKF Diagnostics	IntegraGen	Medmira
SD BioSensor	Beijing Strong Bio	Biocartis	Precipio	Bioaffinity Tech
Adicon	Castle Biosciences	Sophia Genetics	Accelerate	Sera Prognostics
Maccura	Dirui Industrial	Leadman Bio	Genetic Signatures	BluJay Dx
Sinocare	Getein Biotech	Cellavision	Anbio Bio	Cardio Dx
Wondfo Bio	GeneDx	Ginkgo	T2	Immunovia
Opko/BioRef	Kindstar Global Gene	Exagen	CoDiagnostics	Nautilus/Arya
OraSure	Adaptive Bio	Biodesix	ABL Diagnostics S.A.	ProMIS Neuro
Veracyte	EuroBio/Diaxonhit	Centogene	3billion inc.	
Kehua	Amoy dx	ProPhase Labs	Biomerica inc	
10x Genomics	Oxford Nanopore	Interpace Dx	Lumos Diagnostics	