



# The Diagnostics Year in Review 2024

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

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April 2025



- **The Financial Results**

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

- **The Deals**

- Mergers & Acquisitions
- Partnerships

- **The Regulations & Reimbursement**

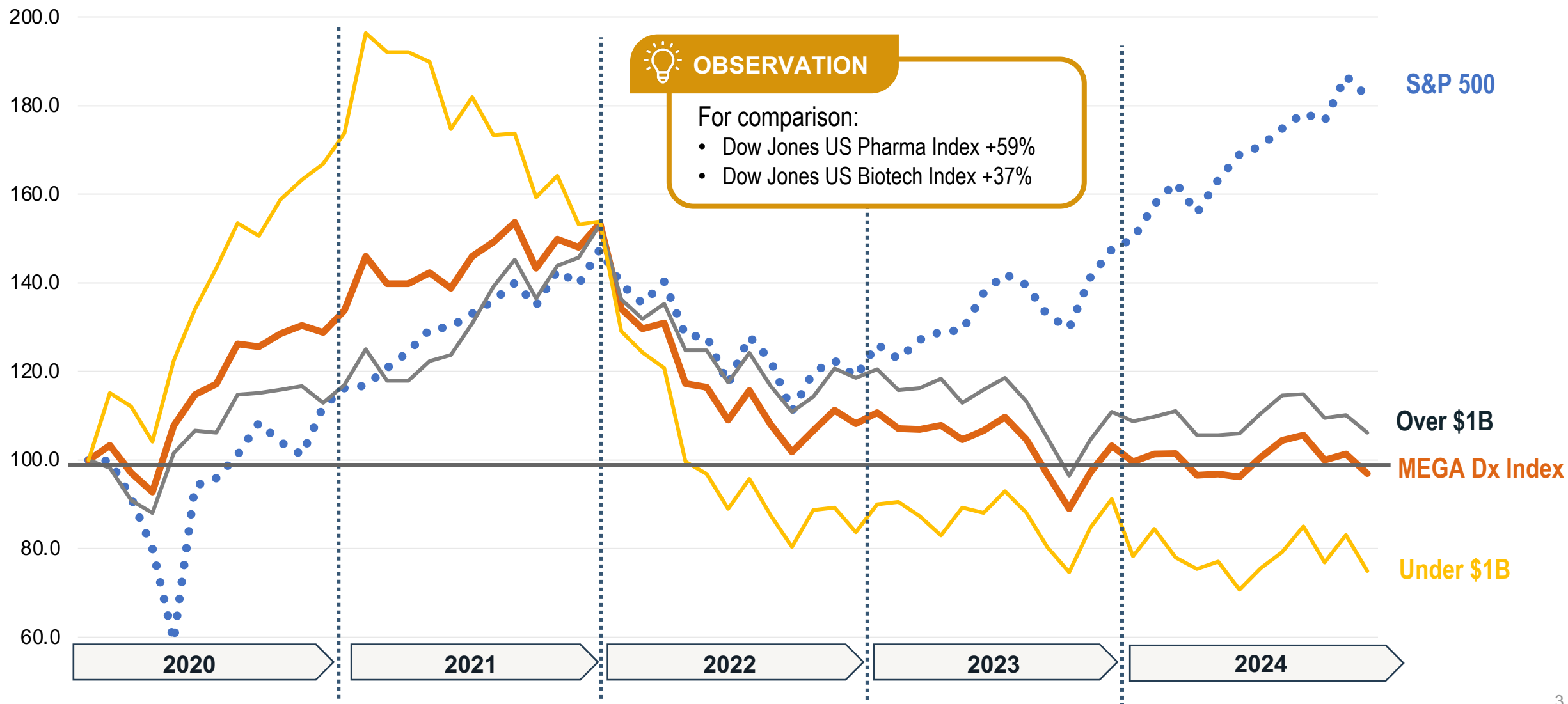
- US and Europe Regulations
- Reimbursement Focus
- Market Access Focus

- **The Numbers / The Products**

- Test Volumes
- FDA Approvals
- Focus: Companion Diagnostics
- Focus: At-Home / OTC Tests

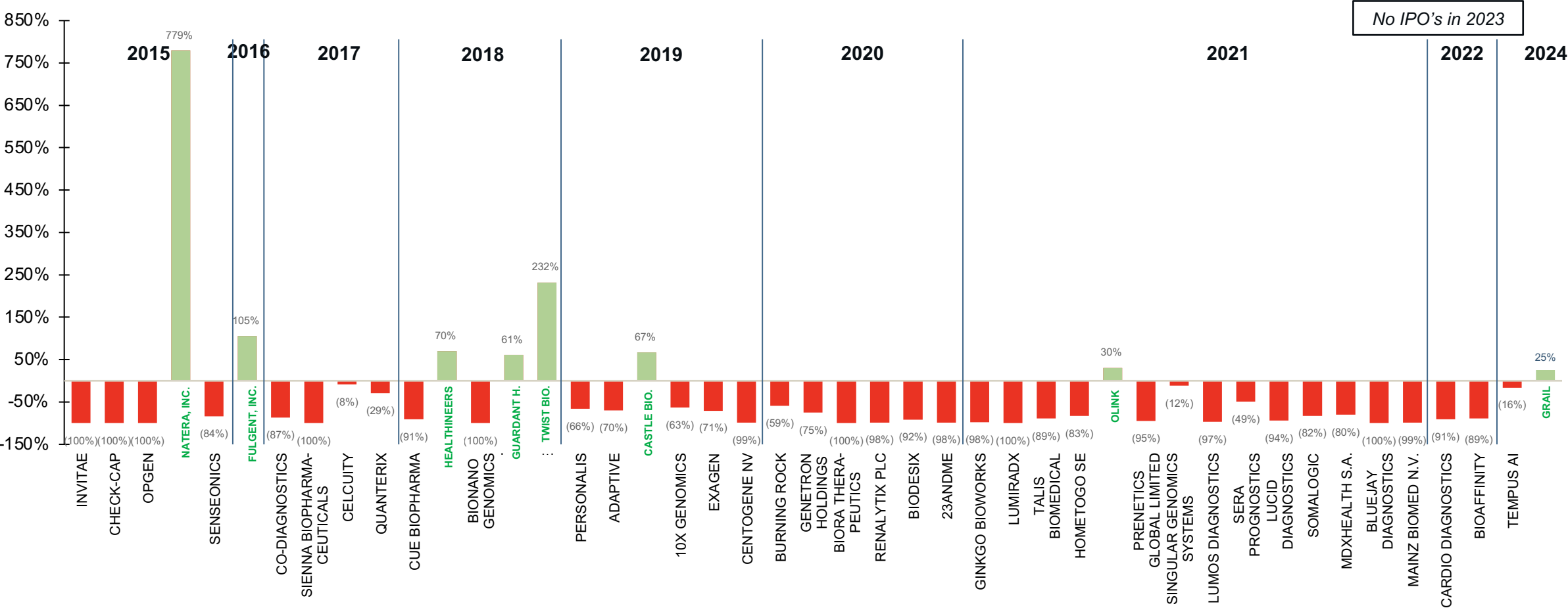
- **Addendum**

# MegaDx Stock Index 2020-2024



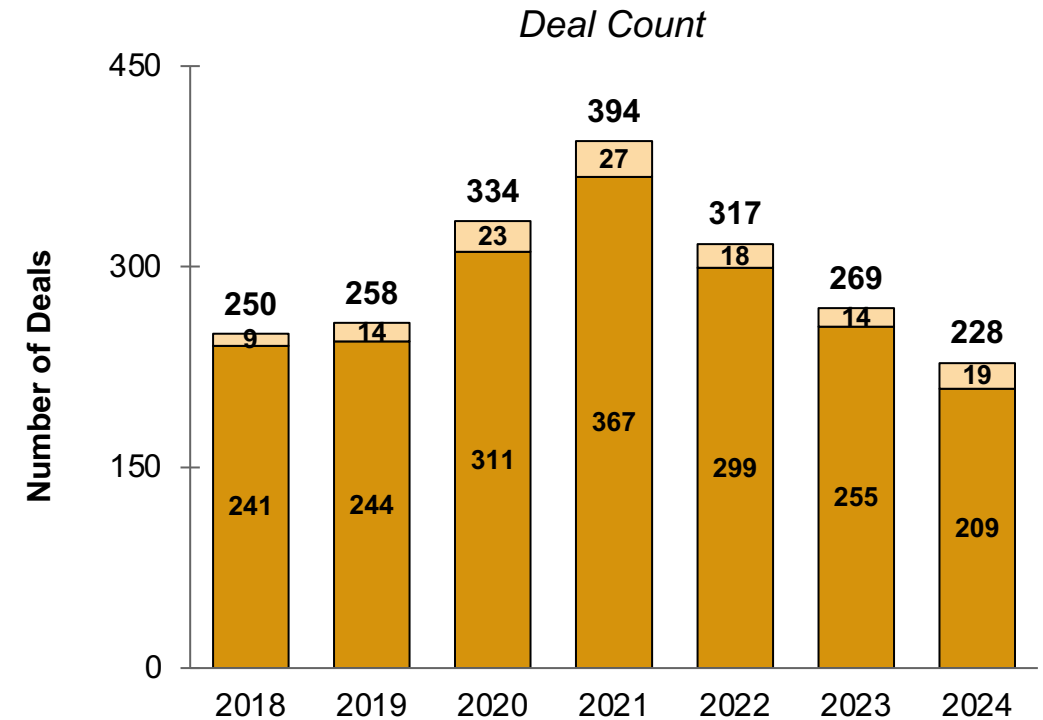
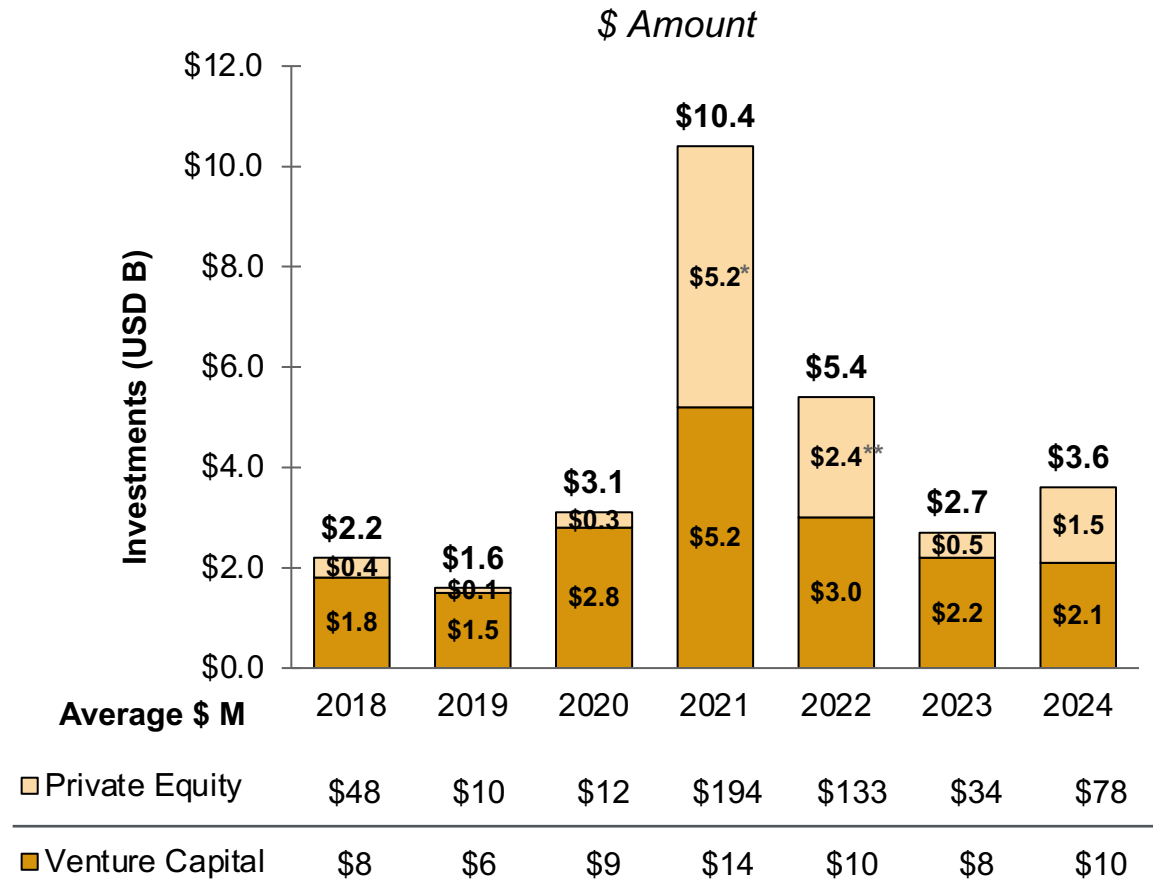
# If You Bought \$1 of these Diagnostics IPOs at their IPO Initial Price ...

Change in Stock Price since IPO (%)



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

# Diagnostics Venture Capital & Private Equity Investments



\* 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

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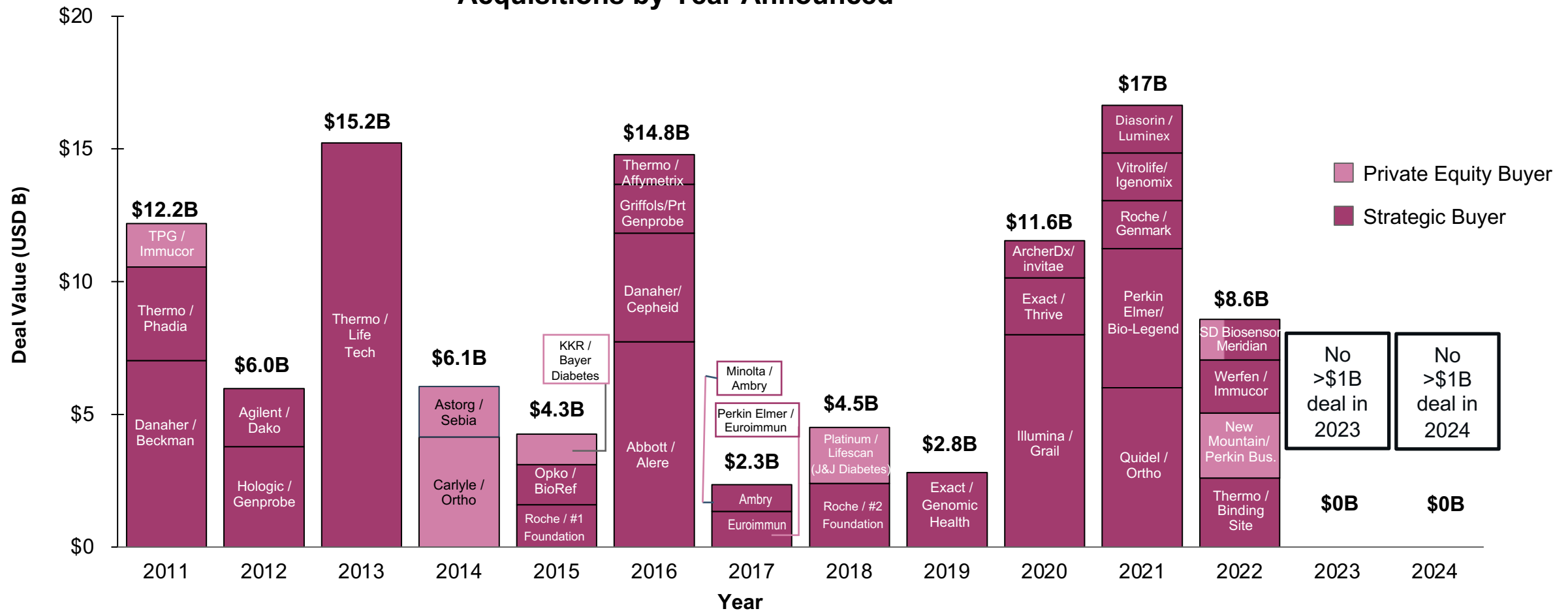
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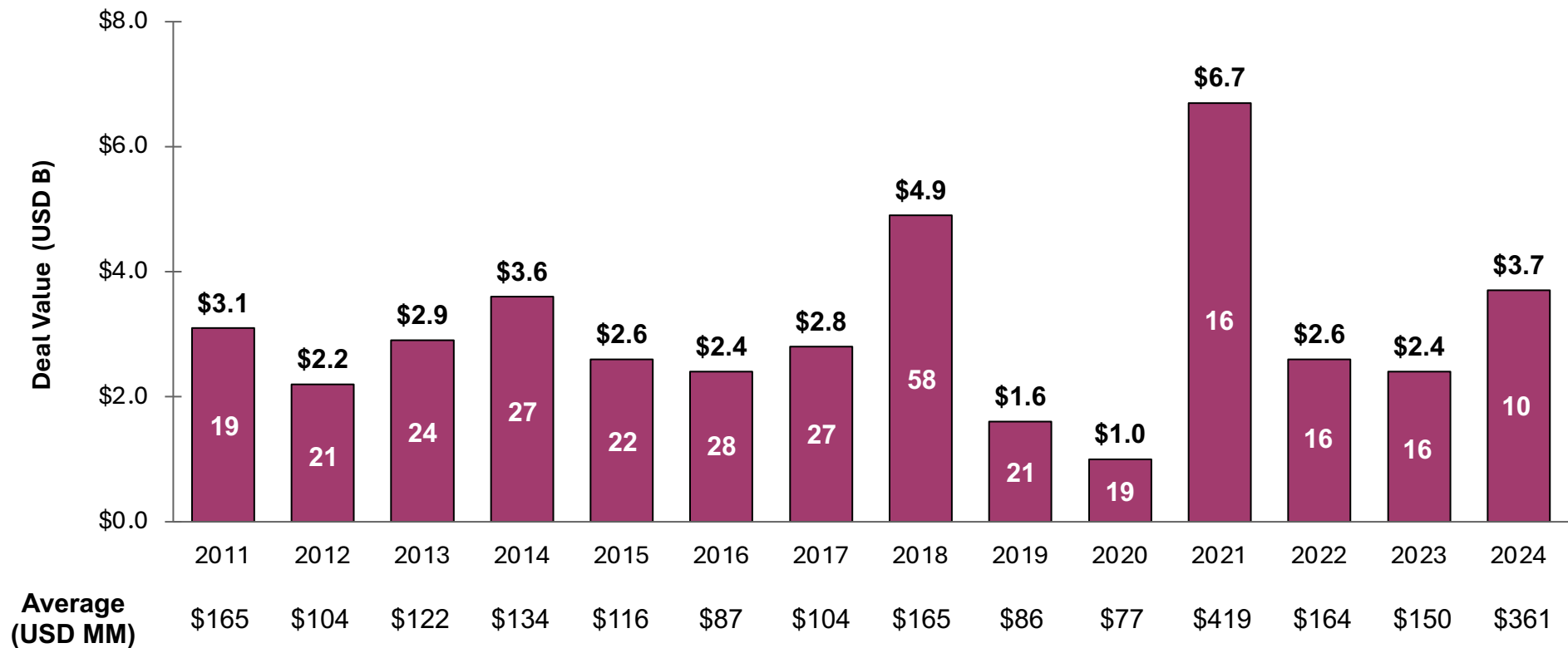
# Diagnostic Industry Transforming Acquisitions (>\$1 Billion)

Acquisitions by Year Announced



# Smaller Diagnostic Acquisitions (<\$1 Billion)

Acquisitions by Year Announced



- 2024 Deals (\$ size order)**
- Acquirer:** Quest / **Target:** LifeLabs  
**Deal value:** \$985M
  - Acquirer:** Bruker / **Target:** ELITech  
**Deal value:** \$943M
  - Acquirer:** Tempus AI / **Target:** Ambry  
**Deal value:** \$600M
  - Acquirer:** Bruker / **Target:** NanoString  
**Deal value:** \$393M
  - Acquirer:** Hologic / **Target:** Gynesonics  
**Deal value:** \$350M
  - Acquirer:** LabCorp / **Target:** Invitae  
**Deal value:** \$239M
  - Acquirer:** LabCorp / **Target:** Bioreference Health  
**Deal value:** \$237M
  - Acquirer:** Veracyte / **Target:** C2i  
**Deal value:** \$95M
  - Acquirer:** Natera / **Target:** Invitae  
**Deal value:** \$52M
  - Acquirer:** OraSure / **Target:** Sherlock  
**Deal value:** \$25M

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 with exception of ELITechGroup, LifeLabs, and Lumira Dx..  
Source: Dealogic.



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- Partnerships

- **The Regulations and Reimbursement**

- US and Europe Regulations
- Reimbursement Focus: Payments
- Market Access Focus: PLA Codes

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

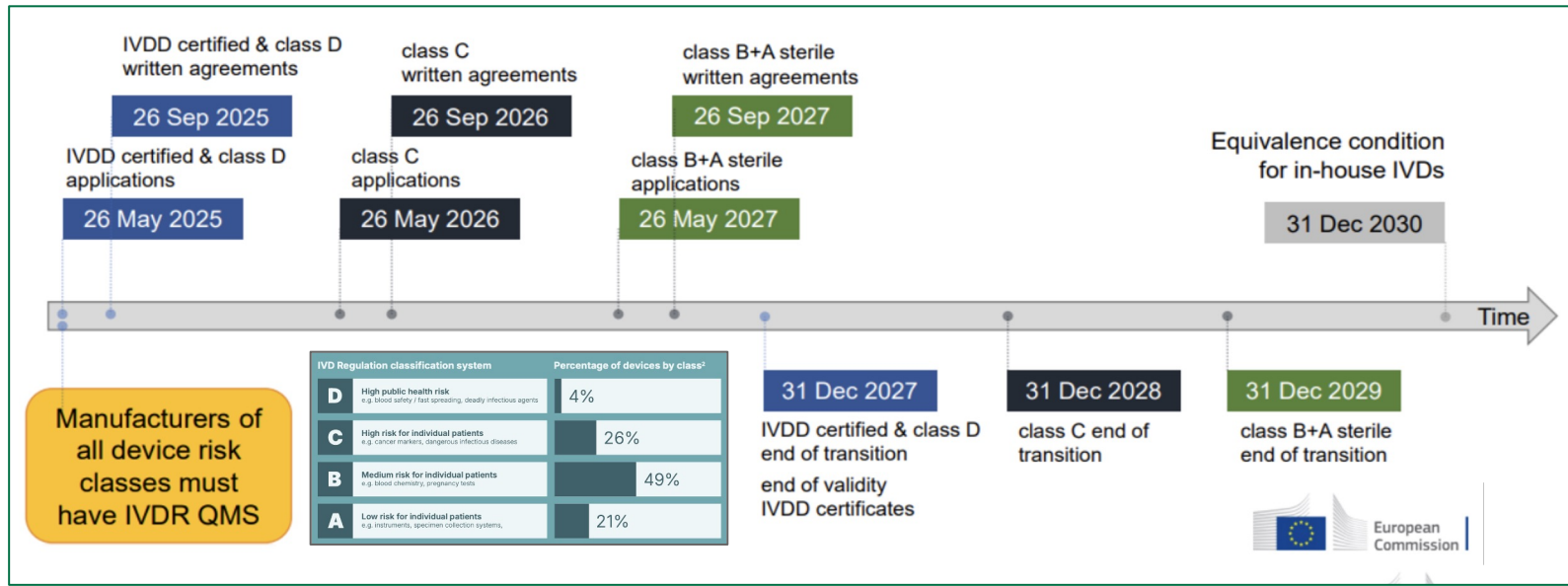


The Rule concerning the FDA's enforcement discretion for Laboratory Developed Tests (LDT) was published on May 6, 2024.

**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.**

# Regulatory Focus: European Union IVD Roll-Out

- 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



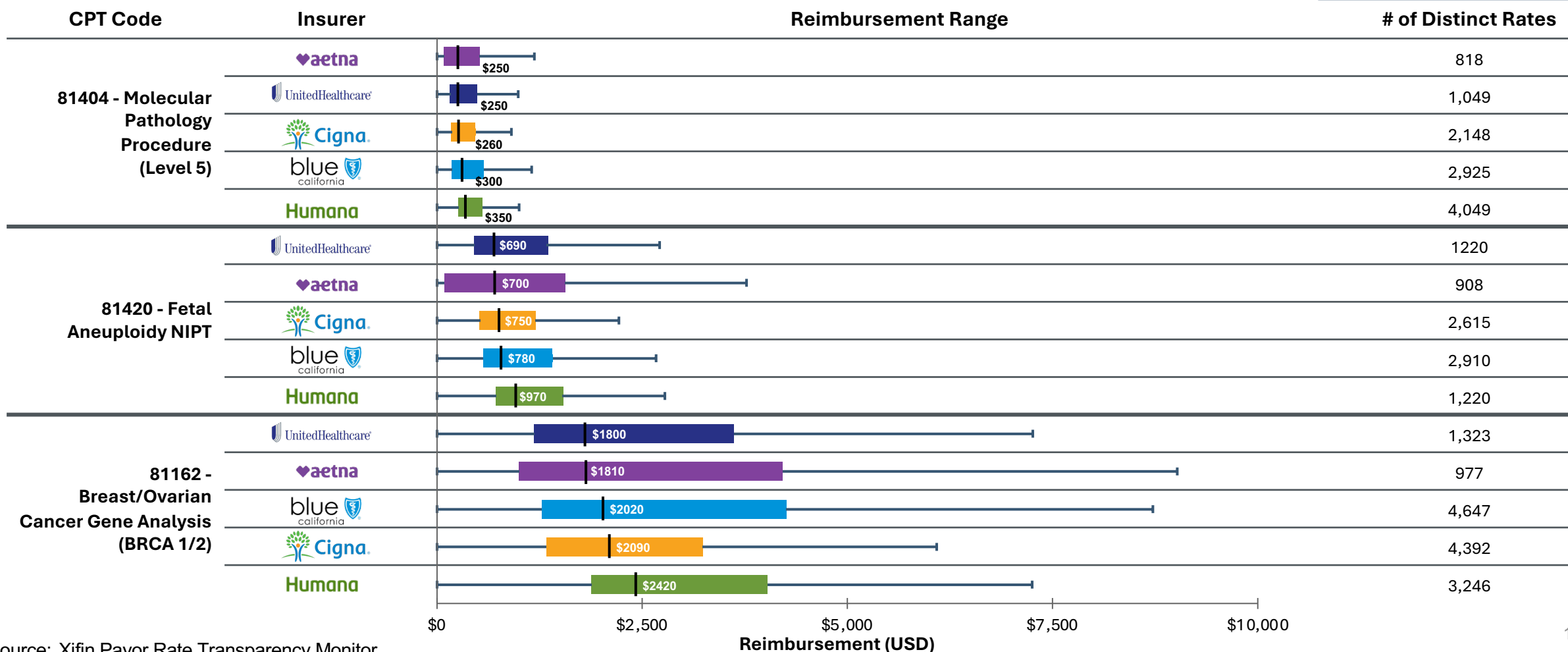
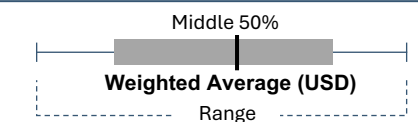
## **OBSERVATION**

This proposal provides more time both to manufacturers and the notified bodies to get the IVD devices to comply with the new European regulations

# Reimbursement Focus:

## Payer Rate Monitor - Molecular Tests

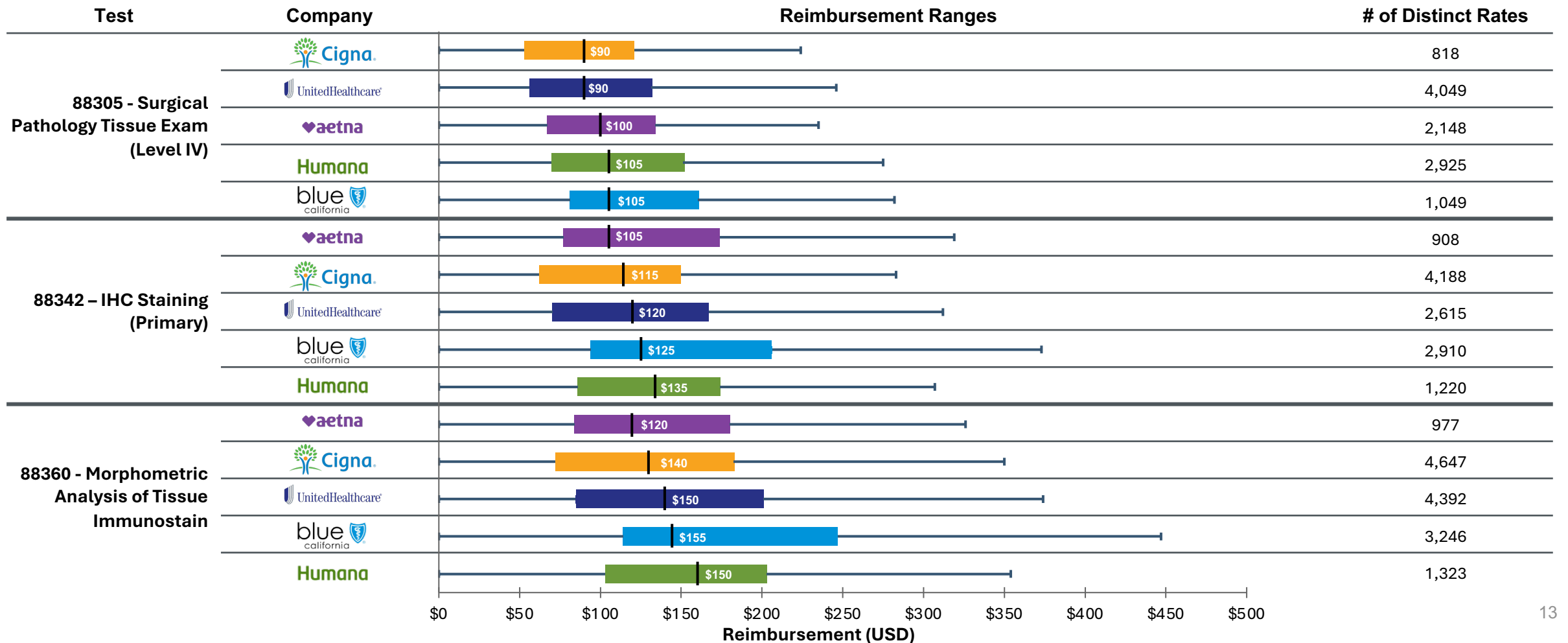
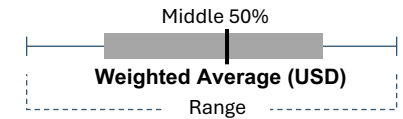
### Rate Dynamics for Representative Molecular Tests



# Reimbursement Focus:

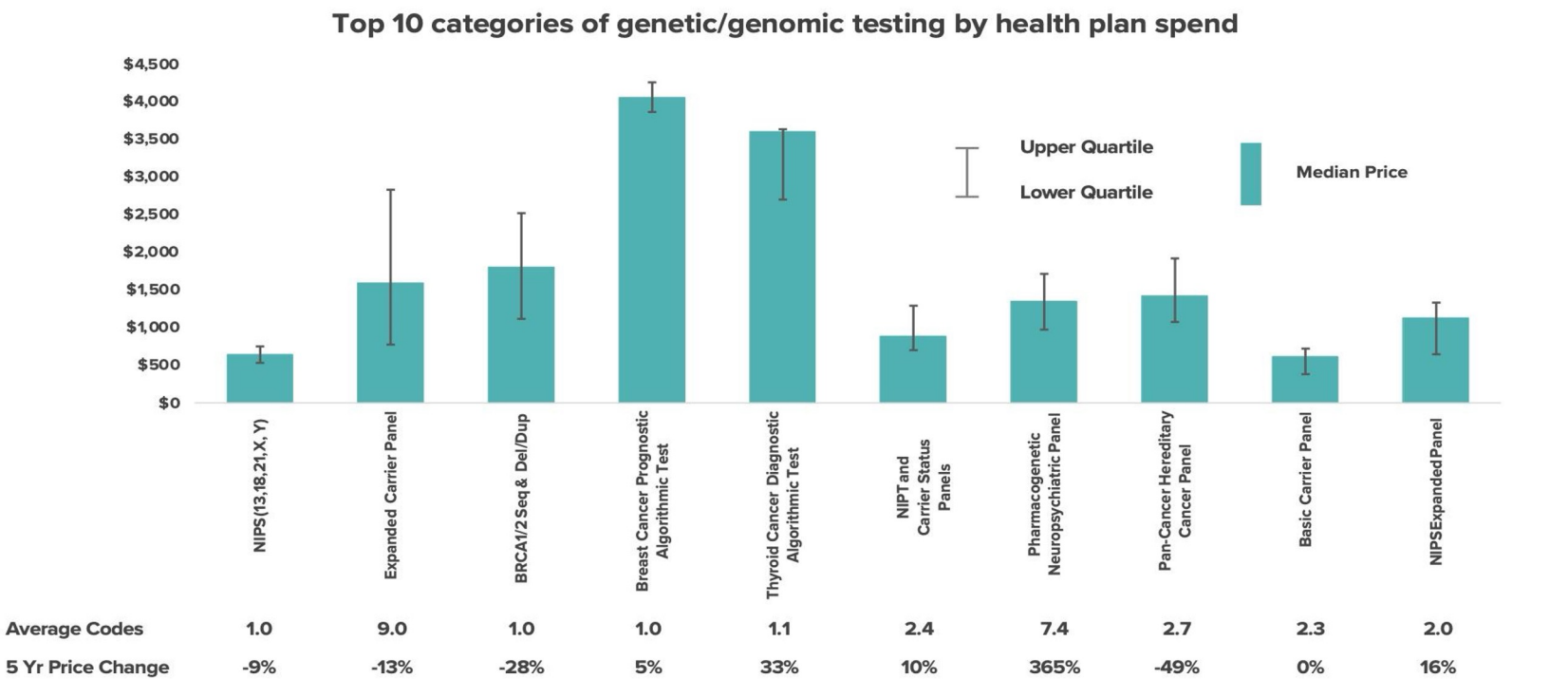
## Payer Rate Monitor - Pathology Tests

### Rate Dynamics for Representative Pathology Tests





# Reimbursement Focus: Price Variability for Genetic / Genomic Tests

**Variability in coding and pricing for genetic and genomic tests remains high, leading to inconsistent reimbursement and other access issues**



Concert Genetic Test Price Transparency Report, Nov 2023. <https://www.concert.co/resources/2023-genetic-test-price-transparency-report/>  
FIT-DNA omitted from chart because coding/price variability is relatively low. See report for details.

# Market Access Focus: The Advent and Role of PLA Codes

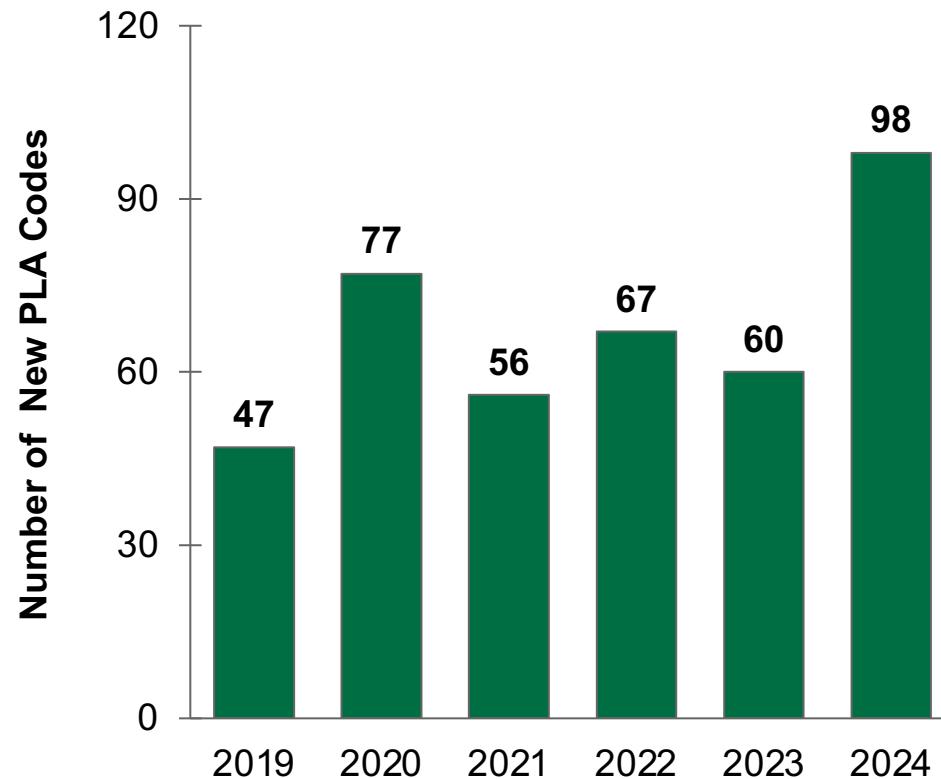
	Class I CPT	Proprietary Laboratory Analyses (PLA)*
<b>Definition</b>	Used by providers, healthcare facilities, and manufacturers to report medical procedures and professional services delivered in ambulatory and outpatient settings	Subsection of pathology CPT codes used unique to represent <b><u>a single test</u></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>	12-24 months 	6-12 months 
<b>Review Times (per Year)</b>		
<b>Additional Requirements</b>	Strong advocacy support from relevant medical society	None

- 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.

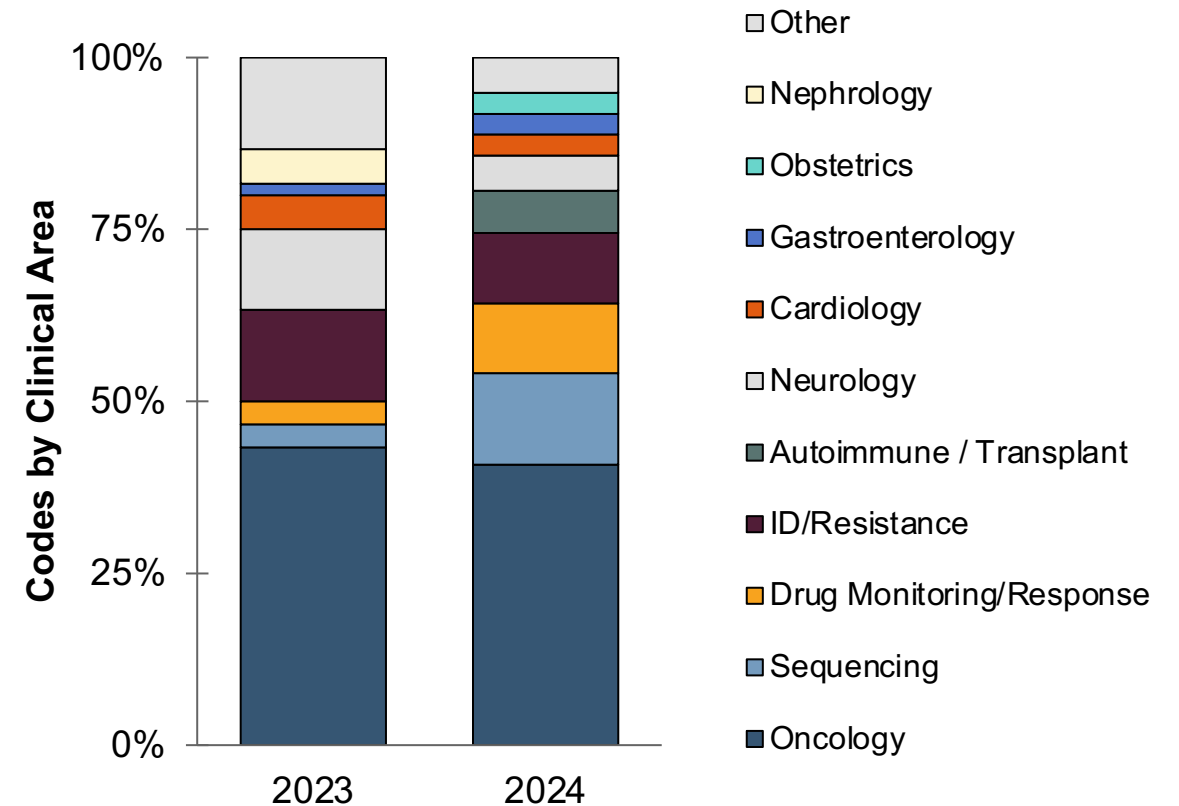
# Market Access Focus: PLA Code Numbers

## New PLA Code Introductions...

### ...by Year



### ...by Clinical Area





# Market Access Focus: PLA Code Use



## OBSERVATION

### Significant increases in:

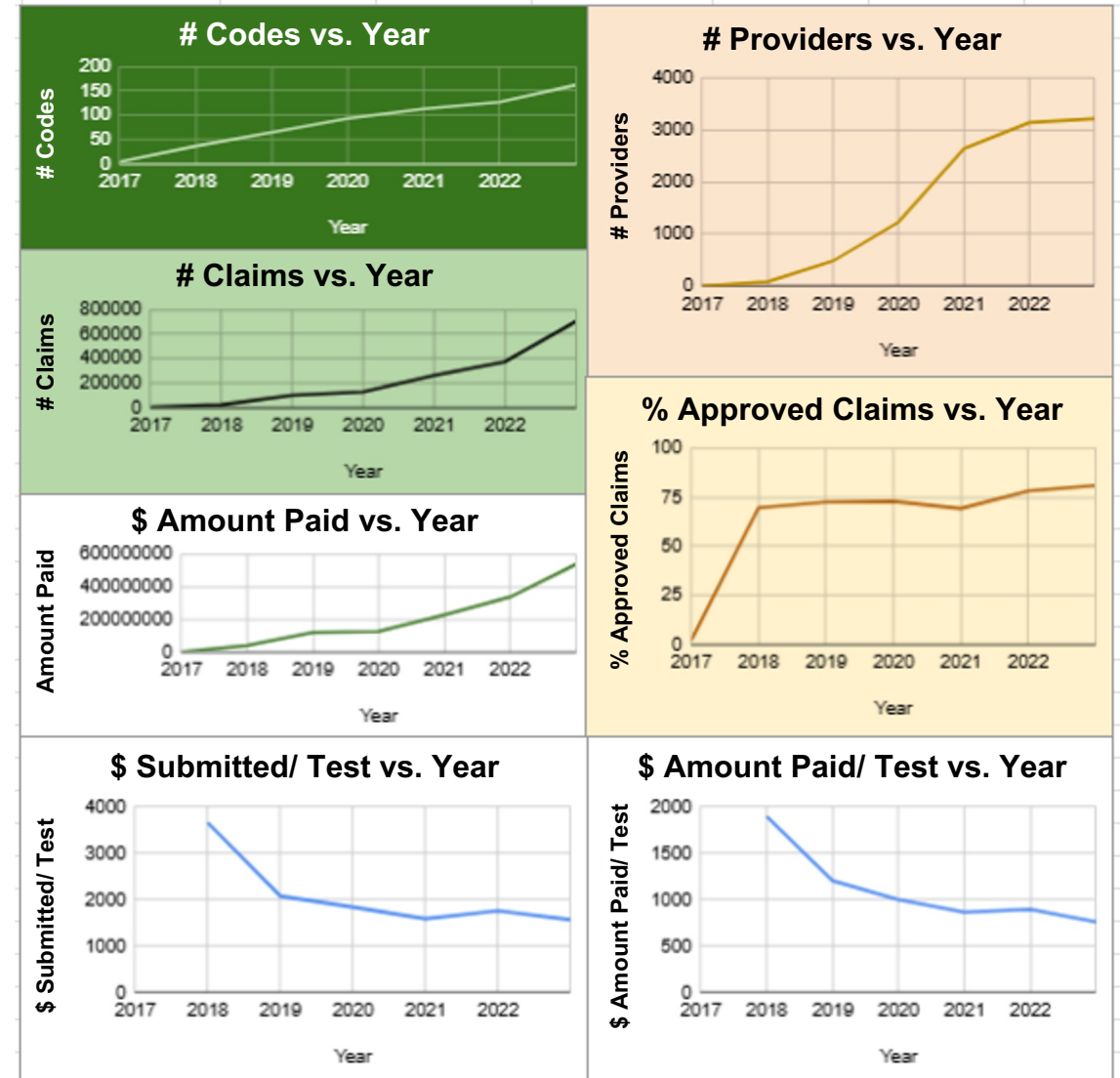
- Available PLA codes
- PLA code claims to Medicare
- Total Revenue for proprietary laboratories

### 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



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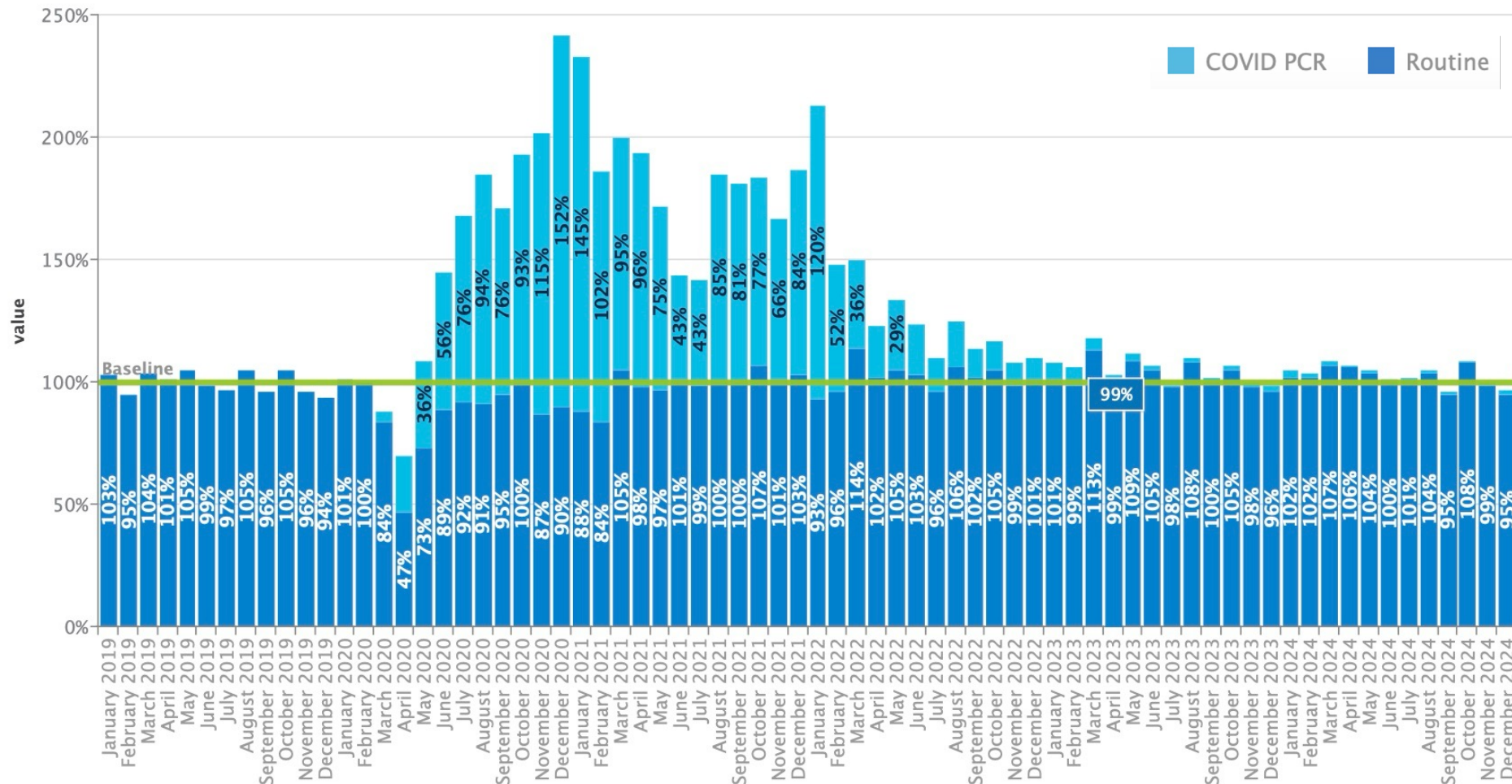
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# Laboratory Volumes 2019 to 2024

## All Routine and COVID PCR Testing

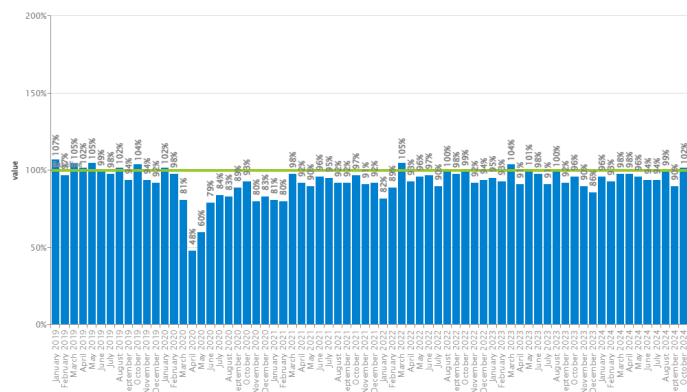


Source: Xifin Lab Volume Index. Baseline is the average monthly volume for 2019; January 2020 through December 2024

# Laboratory Volumes 2019 to 2024 by Testing Discipline

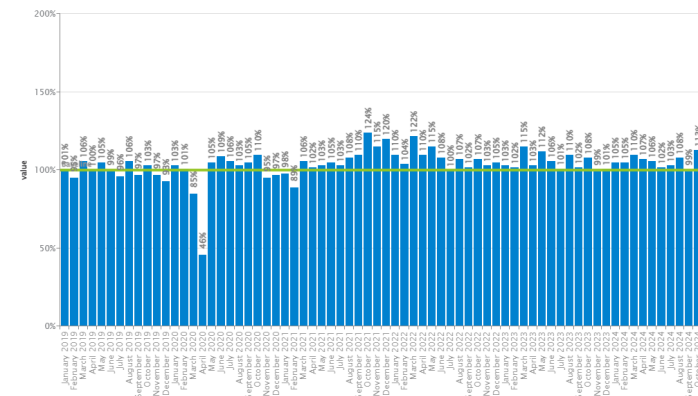
## Clinical

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



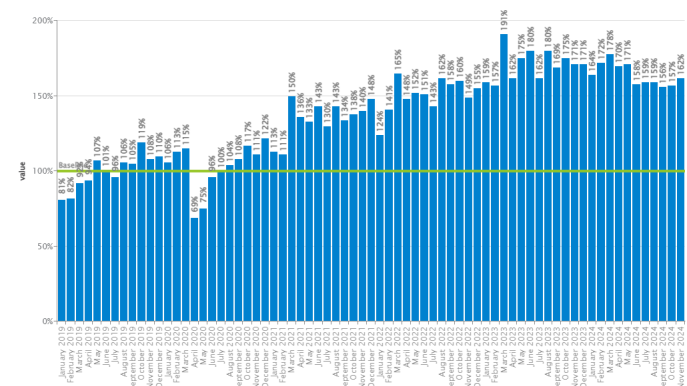
## Immunology & Microbiology

Sharp decline in April 2020 (COVID) followed by a rapid recovery in 2020. Stable with little variation since then.



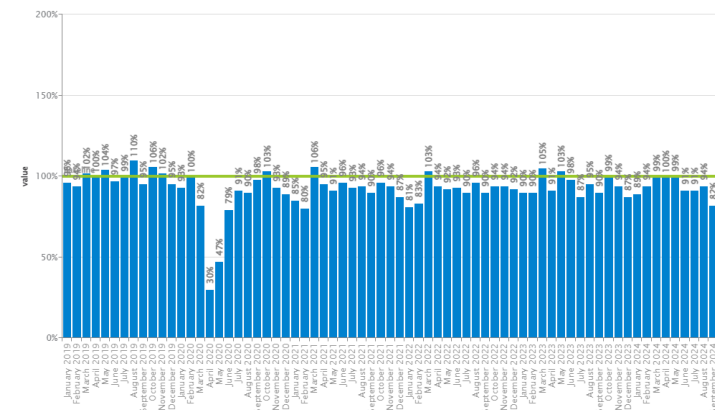
## Molecular & Genetic

Consistent upward trend – 2024 is 50% above 2019 baseline. Tests: PCR, FISH, WES, WGS, CNV, MLPA



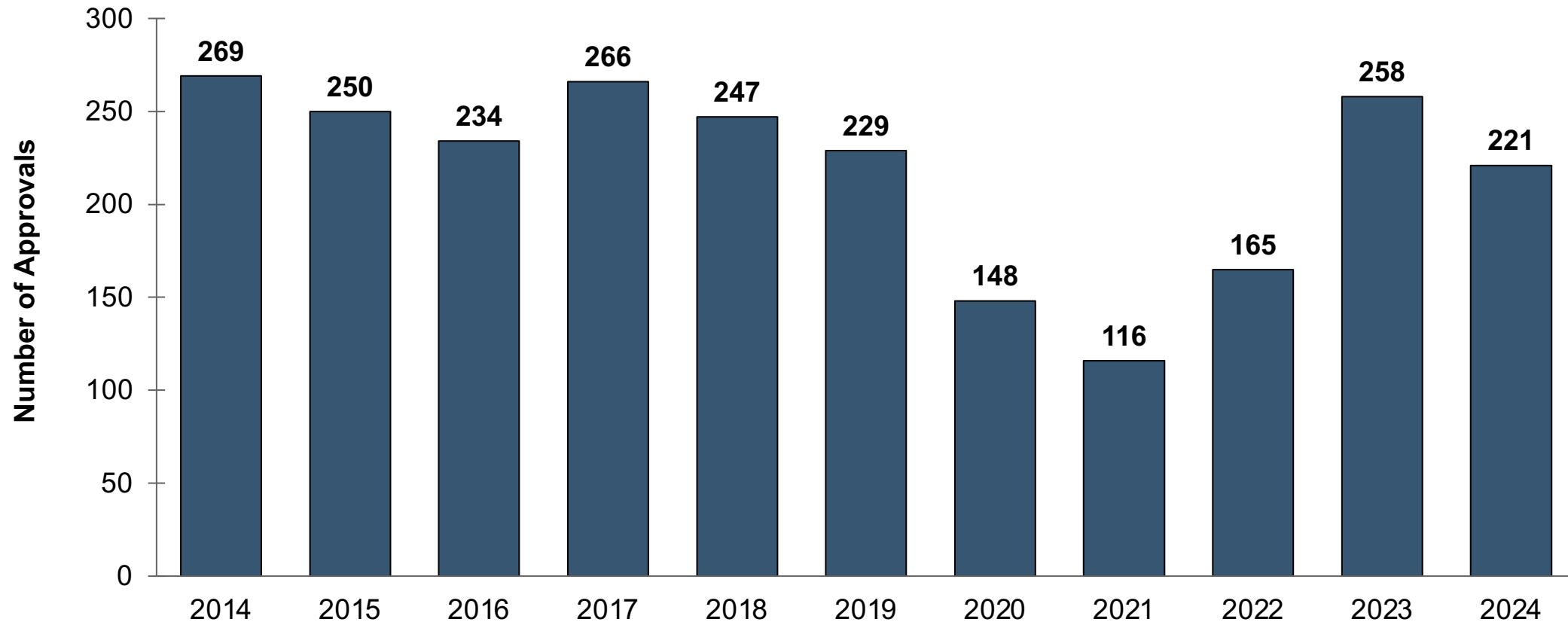
## Pathology

Huge decline in April 2020 (COVID) with gradual recovery but still at or slightly below 2019 baseline.



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

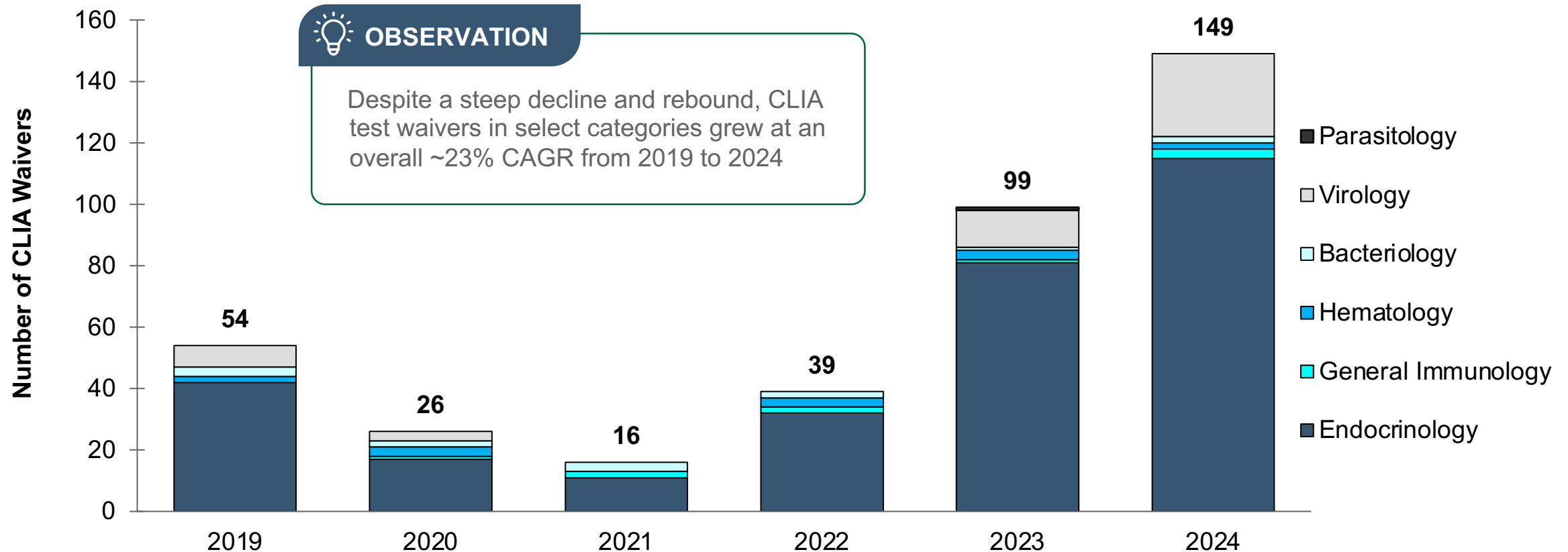
## Diagnostics 510(k) Approvals by Year



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

# FDA Approvals: CLIA Waivers -Increases Post COVID

## CLIA Test Waivers in Select Analyte Groups



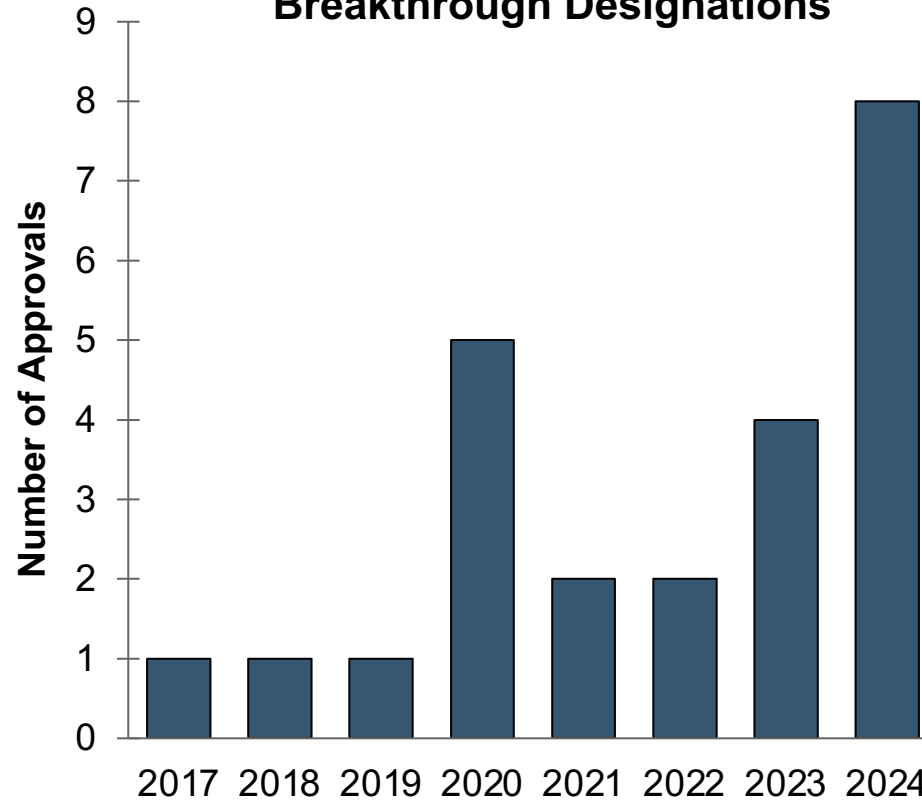
Note: An additional ~800 waivers were granted between 2019 and 2024 for analytes in urinalysis, toxicology, and general chemistry.  
Source: Health Advances analysis, FDA.

# FDA Approvals: Diagnostics with Breakthrough Designation









## 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

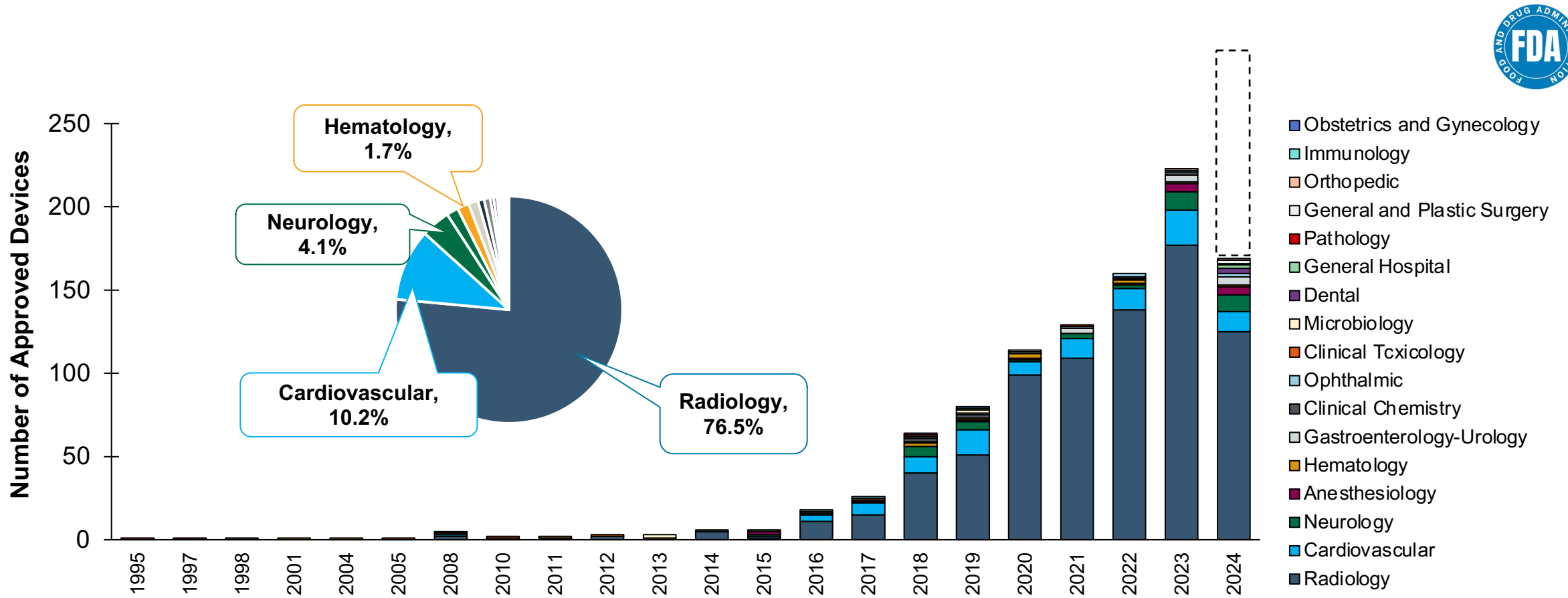


## 8 Diagnostics Approved in 2024 via Breakthrough Designation

- 1  **Q-LINEA** **ASTar:** Fully automated system for rapid AST
- 2  **Geneoscopy** **ColoSense:** Multi-target stool RNA test for colorectal cancer screening
- 3  **PRELUDE Dx** **DCISionRT:** Risk assessment for breast cancer patients
- 4  **INSTAN SIS** **InstaStrip Fentanyl:** OTC dipstick test for detection of Fentanyl at low concentration
- 5  **Abbott** **i-STAT TBI:** Blood-based test for traumatic brain injury
- 6  **Selux Dx** **PBC Separator:** Automatic preparation of positive blood culture for rapid AST
- 7  **deepull** **UIICORE:** Bloodstream Infection (BSI) Test
- 8  **BIO-MERIEUX** **VITEK REVEAL:** Rapid AST for bloodstream infections

# FDA Approvals: Machine Learning Enabled Devices

Cumulative 1995 to 2024



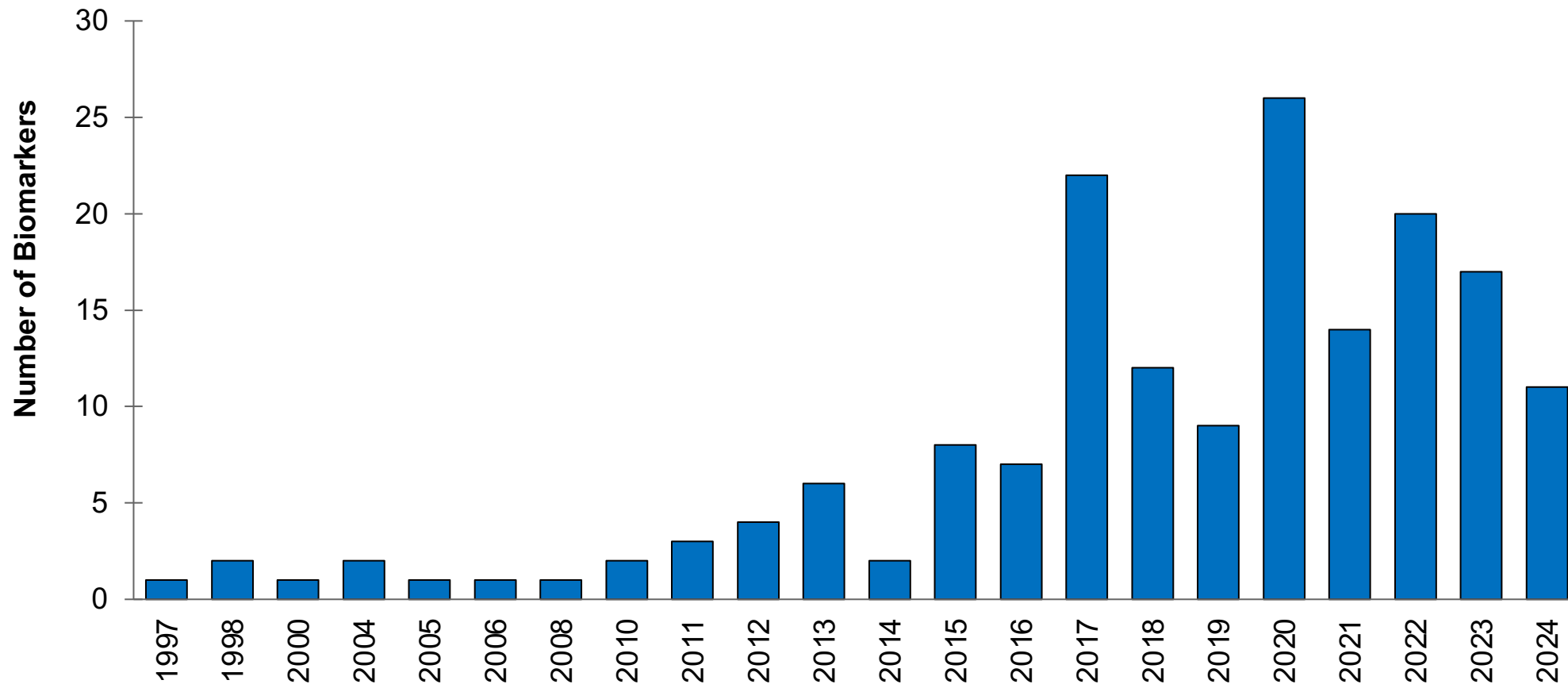
Note: FDA publishes new approvals in June each year so 2024 is only half year of data.

Source: FDA



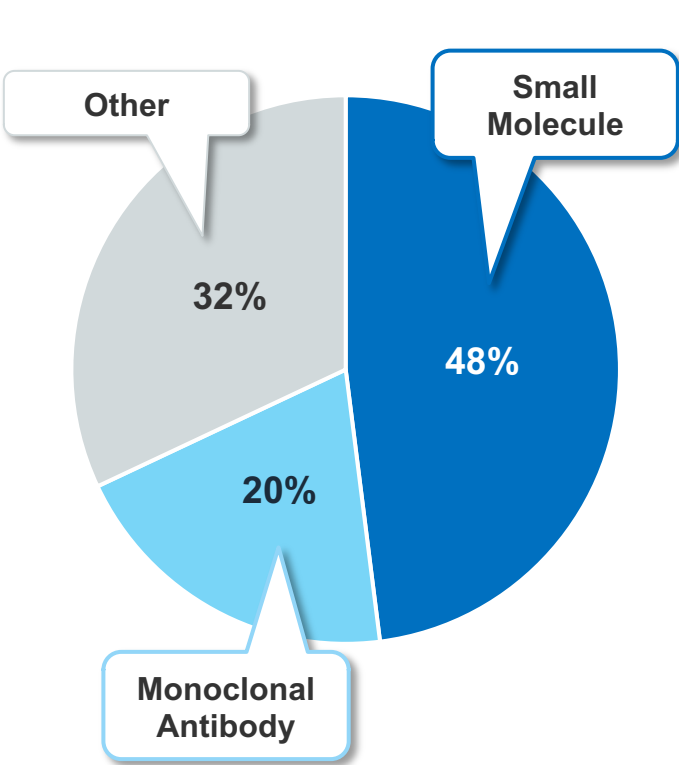
# FDA Approvals: Companion Diagnostics (CDx) Biomarkers

Companion Diagnostics (CDx) Biomarkers by Approval Type  
172 Cumulative (1997 to 2024)

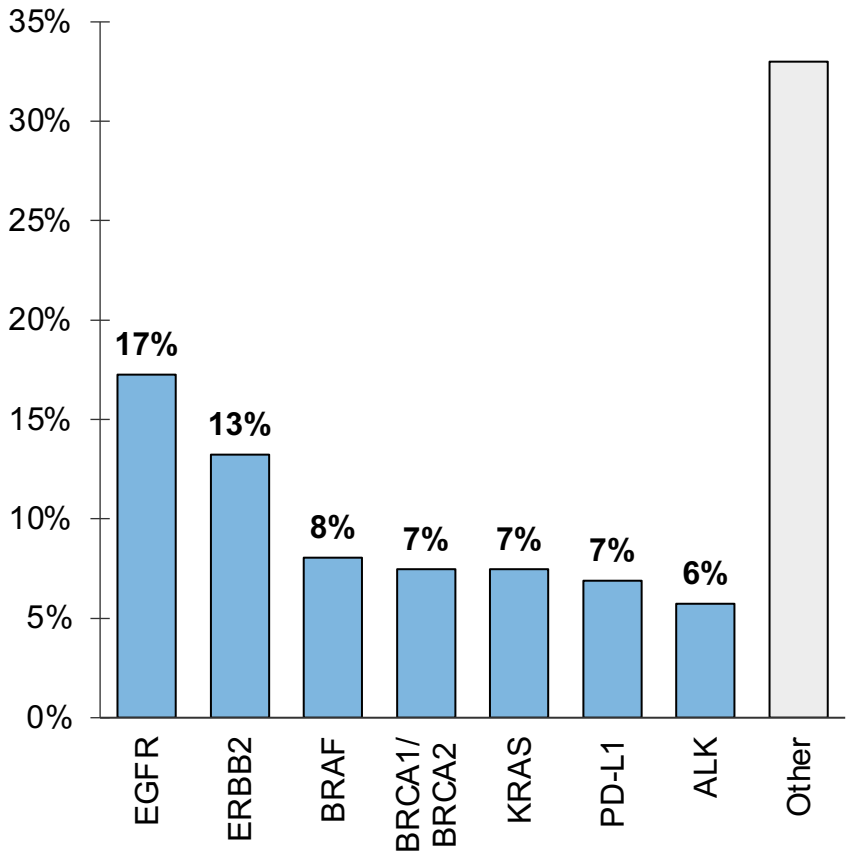


# FDA Approvals: Companion Diagnostics (CDx) Summary

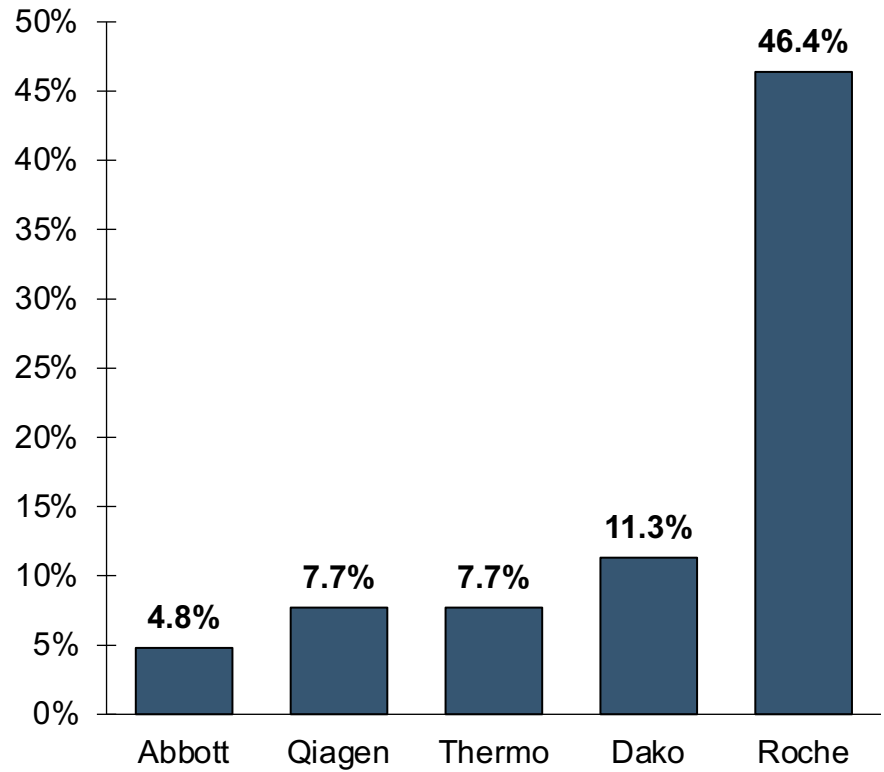
**172 CDx** associated with **64 unique therapies** from 2010 through 2024



**65%** of CDx approvals are for **7 biomarkers**



**75%** of CDx approvals are held by **5 companies**



FMI / Fdn - 26%  
Ventana - 11%  
Molecular - 9%

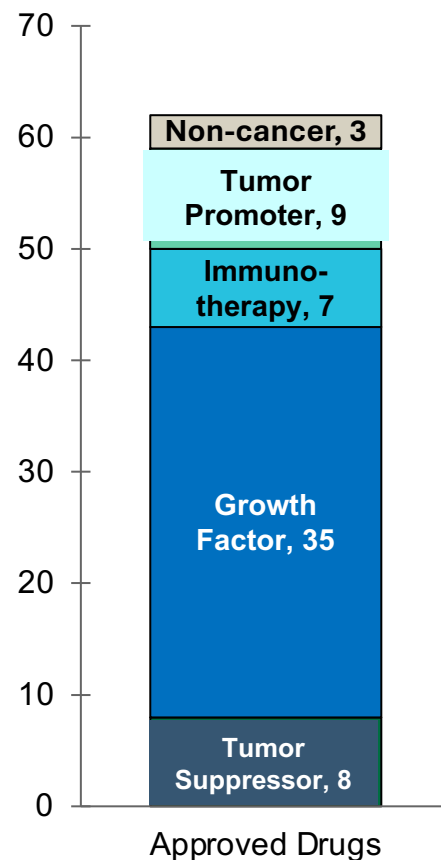
Source: FDA, Samantha Burg analysis.

# CDx Biomarker Targeted Therapies

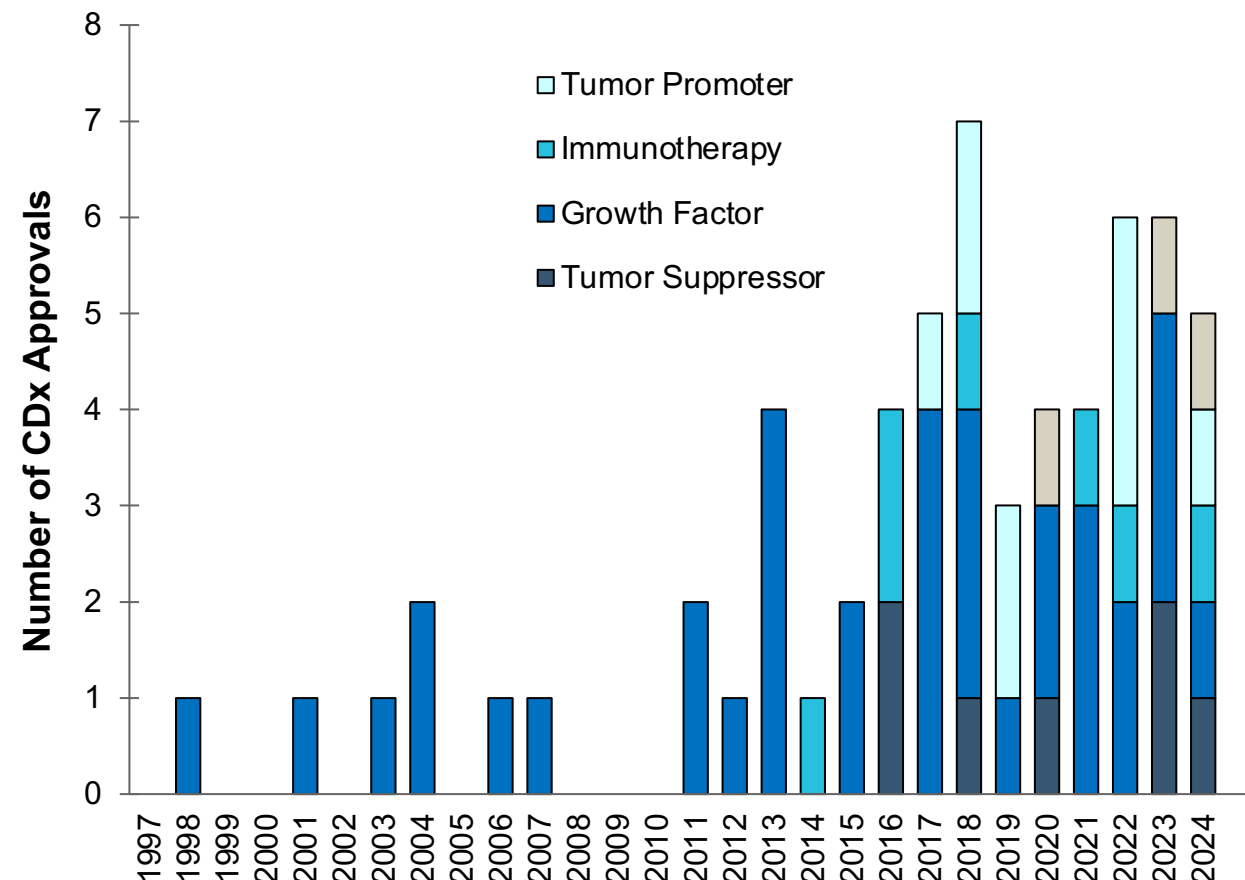
## OBSERVATION

- 64 unique CDx Biomarker Targeted treatments
- 34 unique cancer indications have CDx Targeted drug therapy
  - Lung Cancers: ~27% of approved intended uses
  - Breast cancers: ~11% of approved intended uses
- Non-Cancer CDx treatments for:
  - Hemophilia B (Labcorp & Pfizer) 2024
  - Hemophilia A (ARUP & BioMarin) 2023
  - Obesity (Rhythm & Exact) 2020

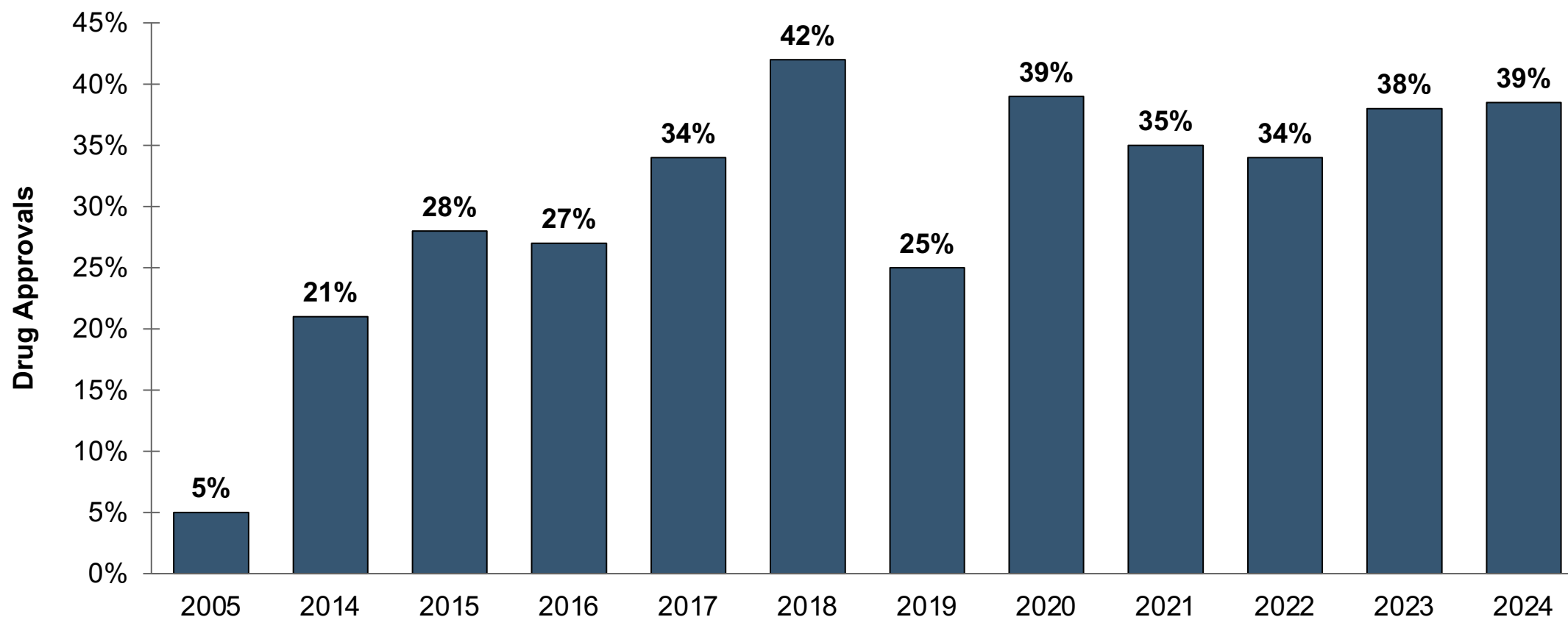
**Number of Approved Drugs**



**Number of Biomarker Approved Targeted Therapies**  
(by Biomarker Function and Year)



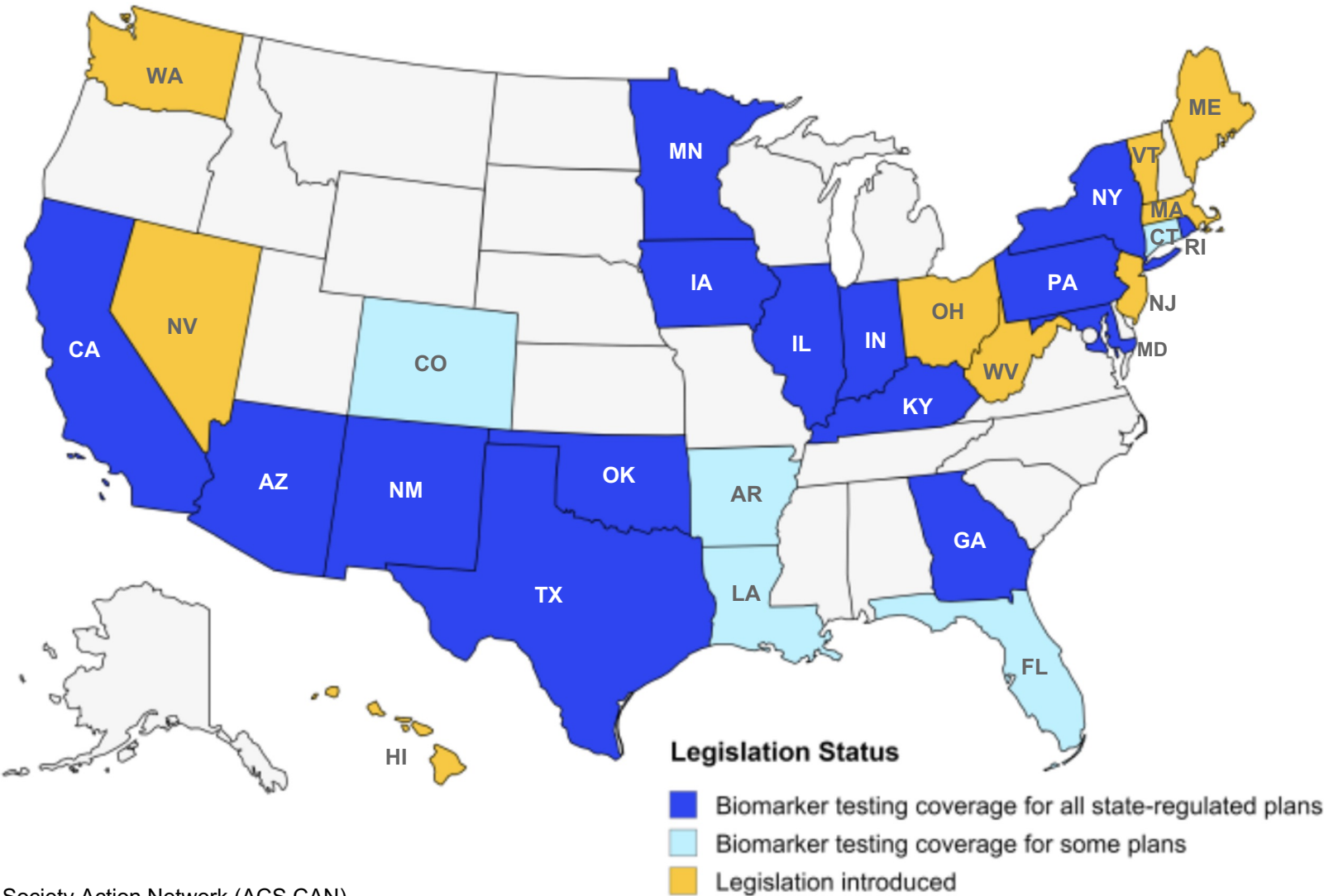
# Biomarker-Dependent Drug Approvals as % of all Drug Approvals



Source: Personalized Medicine Coalition: Personalized Medicine at FDA: The Scope and Significance of Progress

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.

# Biomarker Access: State Legislation Expanding

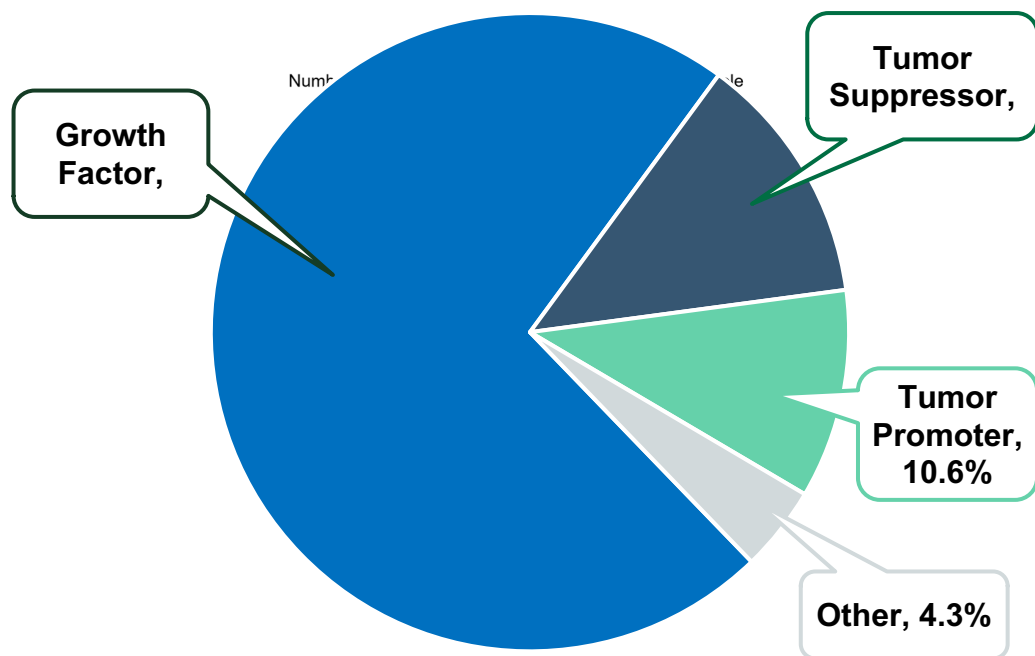


# Patient Impact of CDx: Targeted Drug Treatment

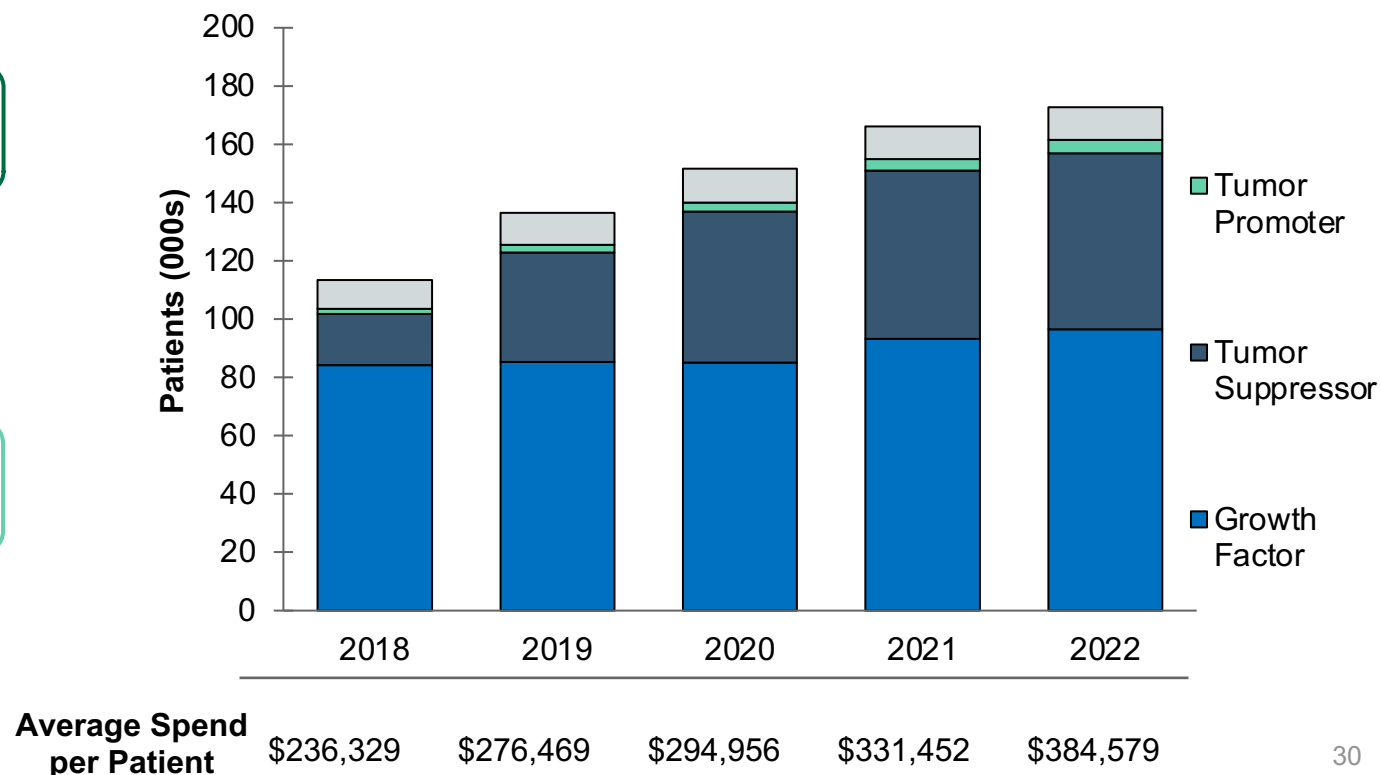
## OBSERVATION

>53% increase in Number of Patients on CDx Biomarker Targeted treatments from 2018 to 2022  
>500,000 Patients on CDx Biomarker Targeted treatments over the 5 years

Number of Therapies Approved by  
Biomarker Cancer Role



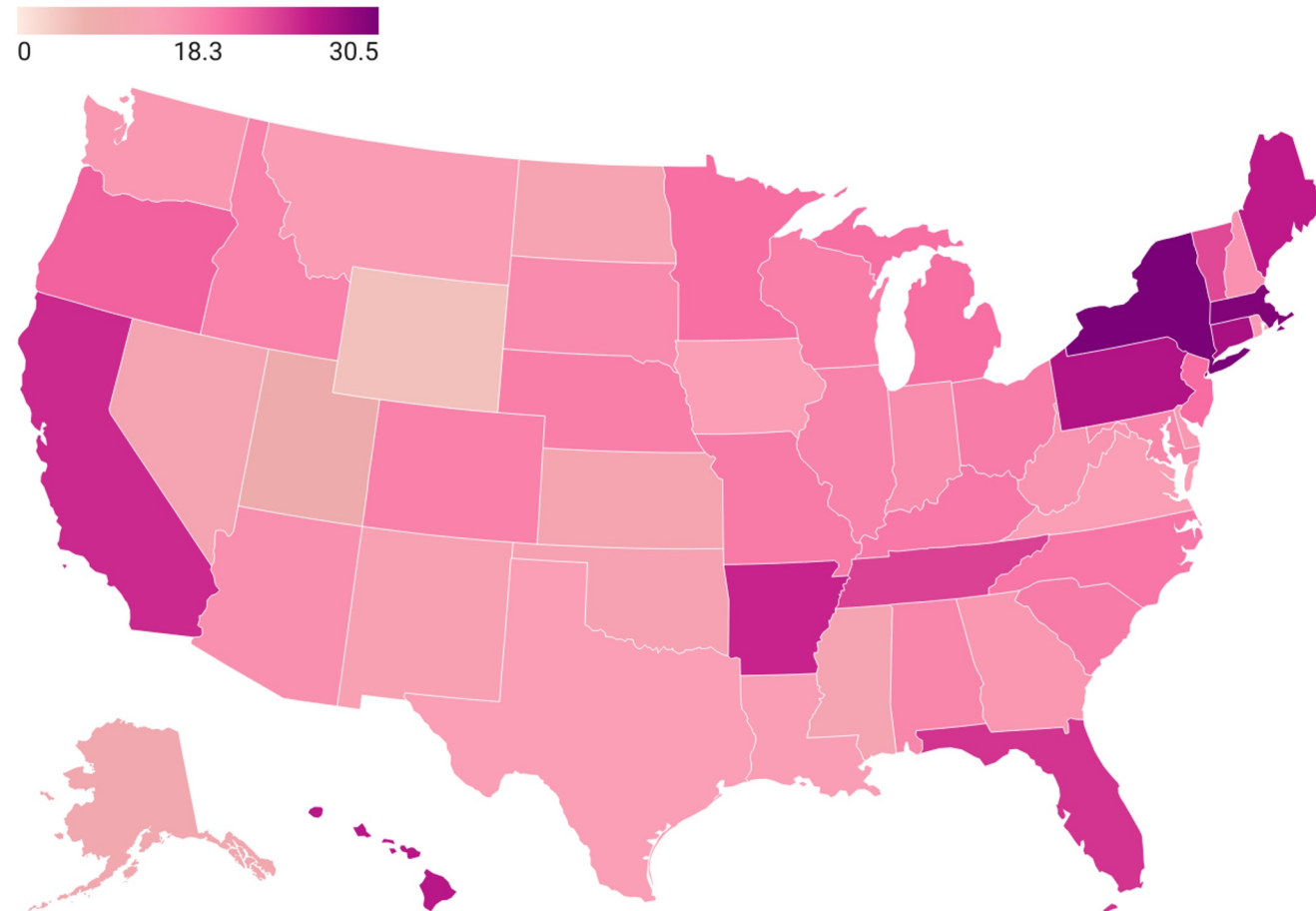
CDx Biomarker Targeted Treatment Usage  
*Medicare Part D 2018-2022*



# Biomarker Access: Patients per Capita by State

## 2022 Patients per 100,000 on CDx Approved Cancer Therapies

Medicare Part D Prescribers by Geography and Drug 2022 Normalized to State Population



# Healthcare Shifting to Home: Primary Drivers



## 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



## 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



## 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)



## 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

**Ongoing Shift in  
Location of Testing**



# Healthcare Shifting to Home: Drugs



**Hormone Injections**  
(InVitro Fertilization)  
1978



**Insulin Pen**  
1985



**Plaque Psoriasis Injection**  
(Cosentyx, Taltz, Stelara)  
2009



**Crohn's /  
Ulcerative Colitis Pen**  
(Simponi, Zymfentra)  
2009



**Neutropenia  
On-Body Injector**  
Neulasta Onpro  
2014



**GLP-1 Pen**  
(Wegovy, Ozempic,  
Mounjaro)  
2015



**Inhibitor of Type 2  
Inflammation Pen**  
Monoclonal Antibody  
(Dupixent)  
2017



**Arthritis Pen** (Enbrel,  
Humira, Simponi,  
Cimzio, Kineret)  
2018



**Migraine Prevention  
Calcitonin gene-related  
peptide (CGRP)**  
(Aimovig, Ajovy, Emgality)  
2018



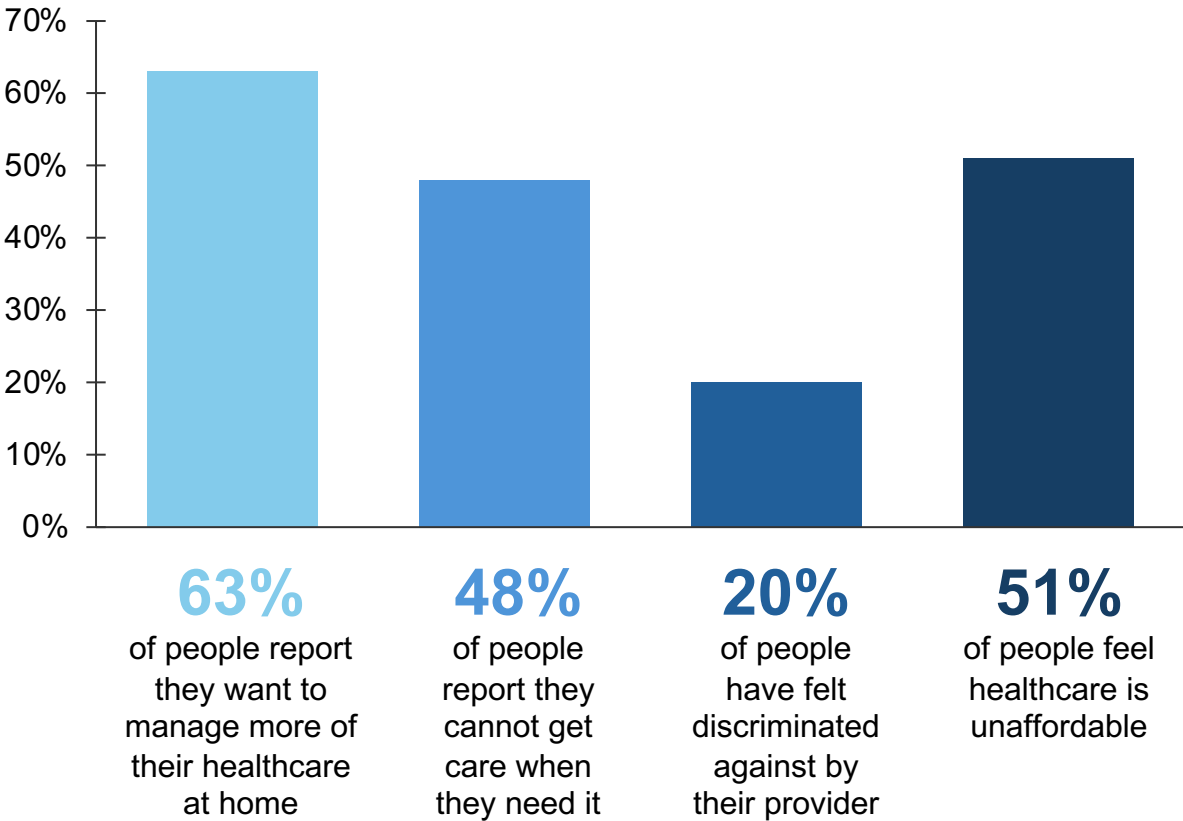
**Plaque Psoriasis  
On-Body Injector**  
(Skyrizi)  
2019



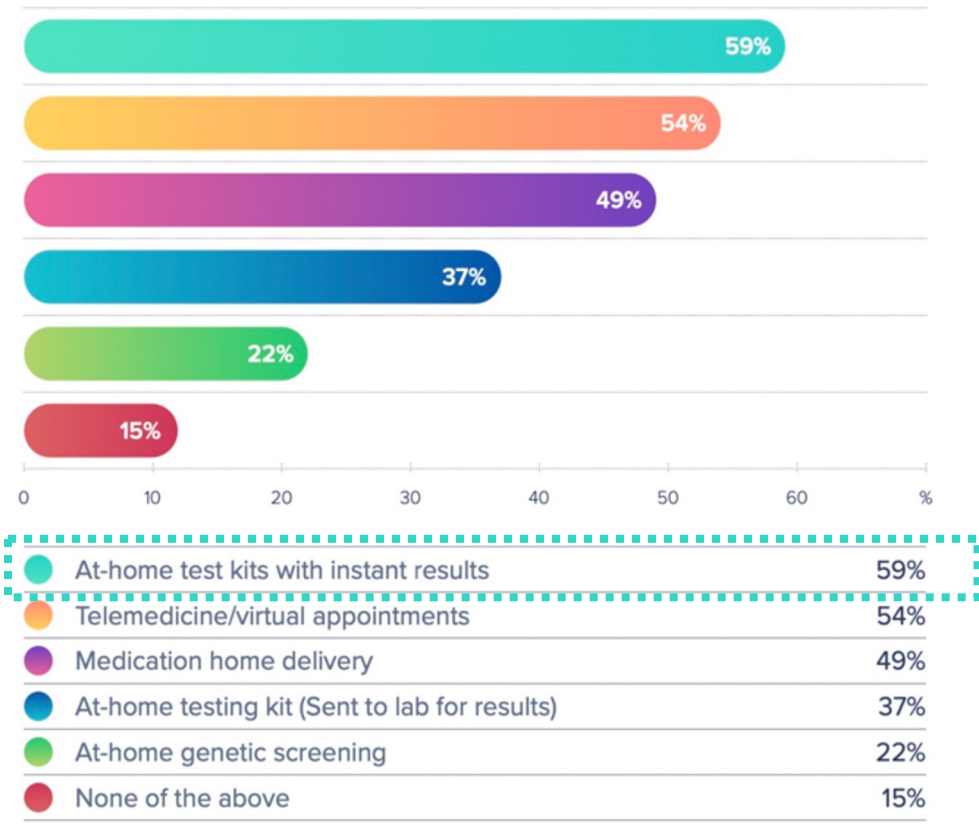
**Asthma Pen**  
(Tezspire, Fasenra)  
2019

# Healthcare Shifting to Home: Consumer Perceptions

How do you perceive your healthcare?



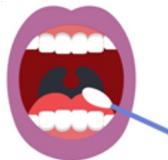
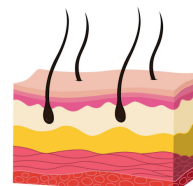





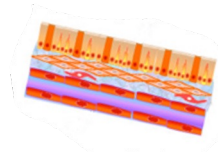










Which healthcare services are you most comfortable with at home?



Source: LetsGetChecked Health Equity Report 2024.

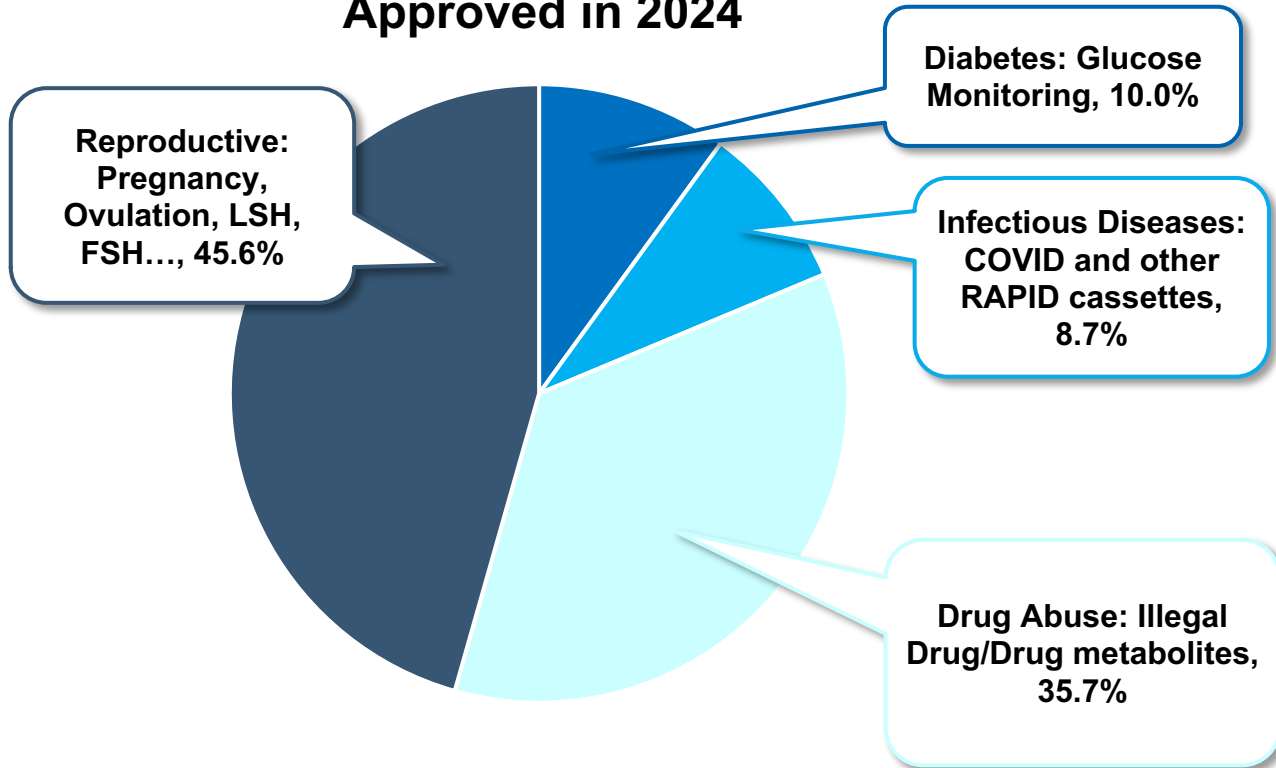
# Healthcare Shifting to Home: Less Invasive Samples

Established	<div>Blood</div> 	<div>Eyes</div> 	<div>Saliva</div> 	<div>Skin</div> 	<div>Stool</div> 	<div>Sweat</div> 	<div>Urine</div> 
Emerging	<div>Breath/ Cough e.g. Asthma</div> 	<div>Gait e.g. Dementia</div> 	<div>Interstitial Fluid e.g. Hormone levels</div> 	<div>Menstrual Blood e.g. Endometriosis</div> 	<div>Seminal Fluid e.g. Male fertility</div> 	<div>Voice e.g. Parkinson's</div> 	
Experimental	<div>Hair e.g. Autism</div> 	<div>Nail Bed e.g. Anemia</div> 	<div>Nipple Aspirate Fluid e.g. Breast cancer</div> 	<div>Surgical Drain Fluid e.g. Head &amp; Neck cancer</div> 	<div>Tears e.g. Parkinson's</div> 		

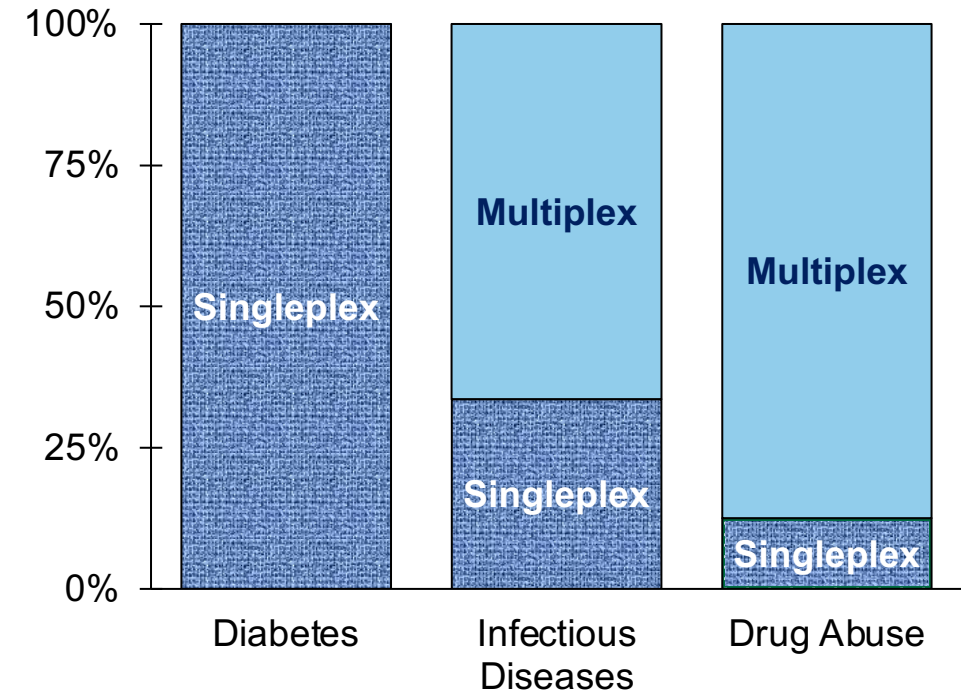
# FDA Approvals: Over-The-Counter / Home Tests



## Over the Counter Diagnostics Approved in 2024



## Singleplex vs. Multiplex



- 36 new unique analytes are approved by FDA for at-home testing in 2024
- Additionally, FDA authorized 8 COVID/flu tests for home use (EUAs)

# Good News: New Diagnostics Launched

## New Unique Diagnostics Launched in 2024

### First Home COVID / Flu Combo Tests

FDA authorized eight combined COVID and Flu A & Flu B sold Over-The-Counter (OTC)



### First Home Menstrual Blood Home Collection

FDA-cleared analyte to analyze A1C levels for diabetes monitoring



### First Home OTC Glucose Meters

FDA approval of OTC continuous glucose meters (CGM) designed for general health and wellness, for individuals without diabetes



### First Home Syphilis Test

FDA approval for first at-home, OTC test to detect syphilis antibodies in human blood (Follow up test needed)



### First POC Hepatitis C Test

FDA approval of the first hepatitis C virus (HCV) for use at the Point of Care



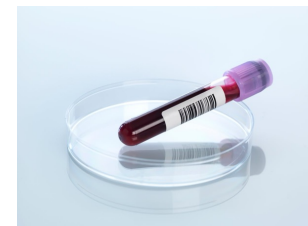
### First POC high sensitivity troponin

FDA approval of the first high-sensitivity cardiac troponin test for use at the Point of Care



### Blood Tests for CNS diseases

New blood tests for Alzheimer's and other CNS related disorders offer less invasive alternative to traditional methods





# Acknowledgements:

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# Illumina Ventures: Advancing Diagnostics Innovation



Advancing the life sciences through the power of 3D genomes



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



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



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



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



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



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



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



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



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

- **The Financial Results**

- MEGA Dx Stock Index
- Initial Public Offerings
- Capital: VC and PE investments

- **The Deals**

- Mergers & Acquisitions
- Partnerships

- **The Regulations**

- US and Europe
- Market Access

- **The Numbers / The Products**

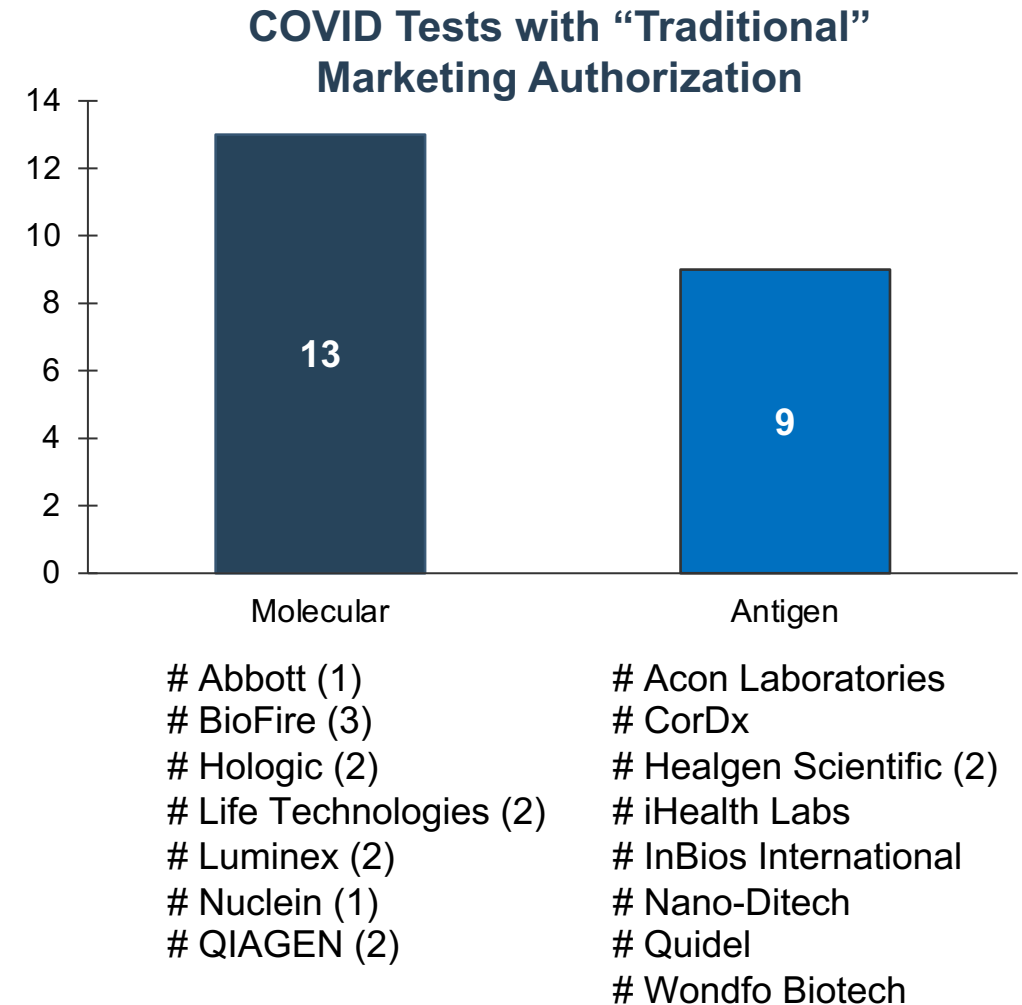
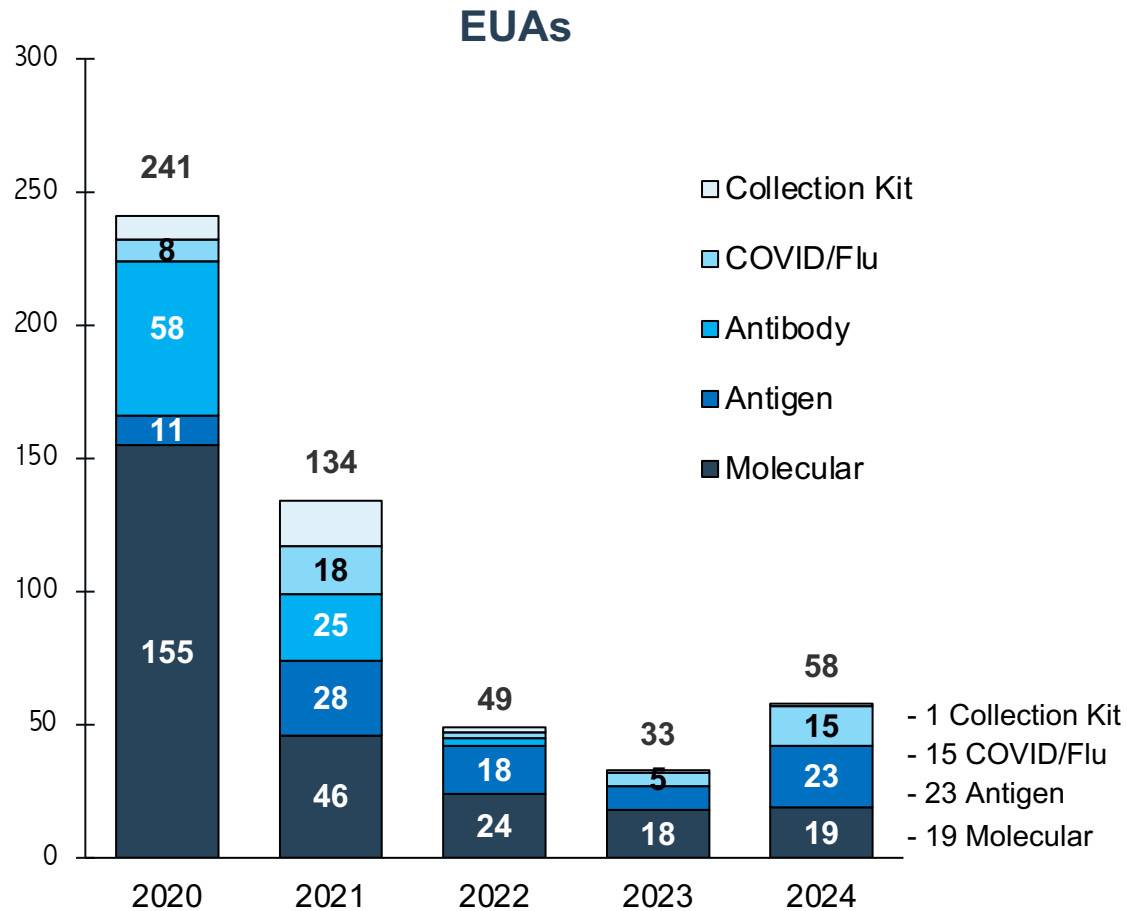
- Test Volumes
- FDA Approvals
- Focus: Companion Diagnostics
- Focus: At-Home / OTC Tests

- **Addendum**

- COVID and Respiratory Tests
- MegaDx Index



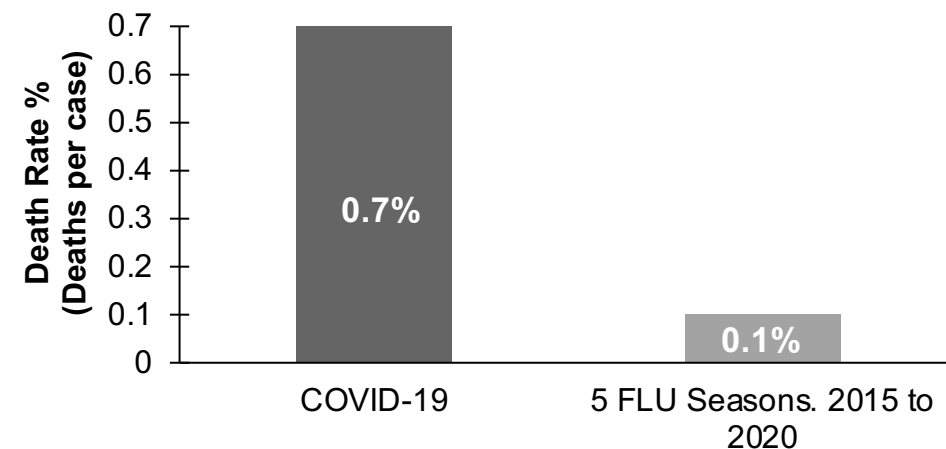
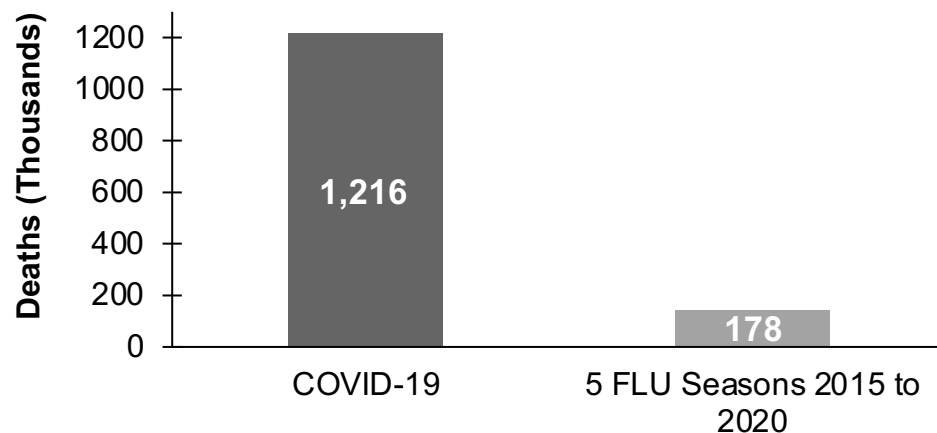
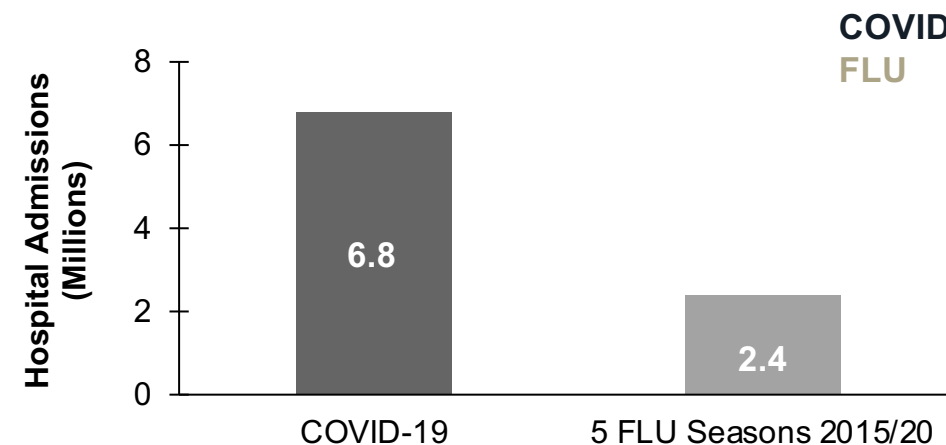
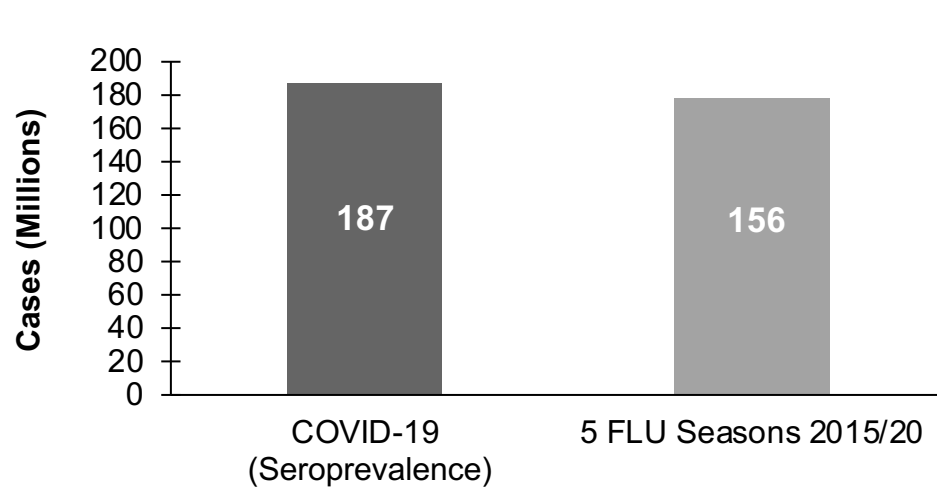
# FDA Approvals and Authorizations: COVID Tests



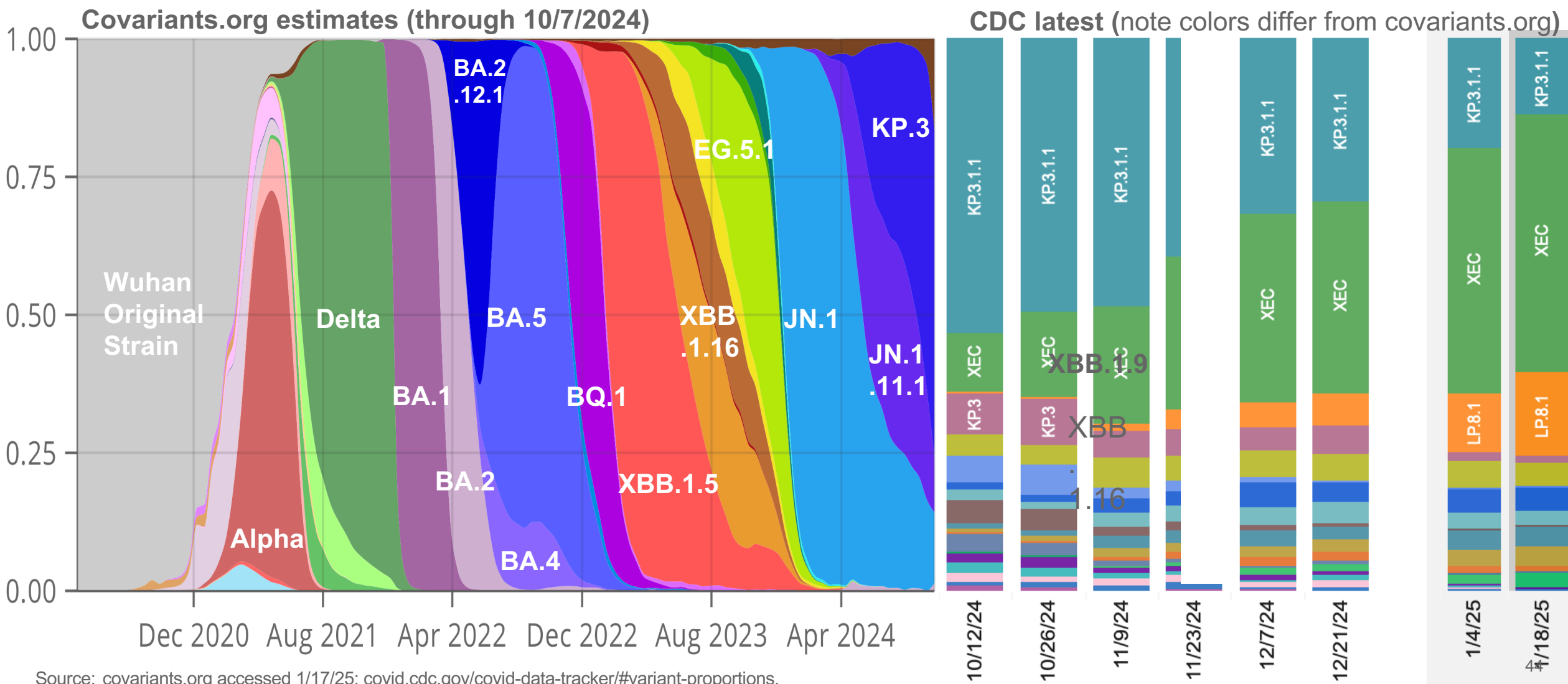
# COVID-19 / Flu Combo Antigen Tests 2024

Company	Test	Date of EUA	Home / OTC / Self?
SEKISUI	OSOM Flu SARS-CoV-2 Combo Home Test	2/29/24	Yes
SEKISUI	OSOM Flu SARS-CoV-2 Combo Test	2/29/24	No
CorDx	CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test	3/21/24	Yes
OSANG	OHC COVID-19/Flu Antigen Test Pro	3/21/24	No
OSANG	QuickFinder COVID-19/Flu Antigen Self Test	4/3/24	Yes
CorDX	CorDxTyFast FluA/B & COVID-19 At Home Multiplex Rapid Test	4/5/24	Yes
Wondfo	WELLlife COVID-19 / Influenza A&B Test	4/19/24	No
Wondfo	WELLlife COVID-19 / Influenza A&B Home Test	4/30/24	Yes
iHealth	iHealth COVID-19/Flu A&B Rapid Test	5/7/24	Yes
Watmind	Speedy Swab Rapid COVID-19 + Flu A&B Antigen Test	5/8/24	No
Watmind	Speedy Swab Rapid COVID-19 + Flu Antigen Self-Test	5/24/24	Yes
iHealth	iHealth COVID-19/Flu A&B Rapid Test Pro	5/31/24	No
Healgen	Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette	6/10/24	Yes
Nano-Ditech	Nano-Check Influenza+COVID-19 Dual Test	7/8/24	No
ACON	Flowflex Plus COVID-19 and Flu A/B Home Test	7/23/24	Yes

# Cumulative COVID-19 vs. 5 Years of Influenza



# COVID Variant History of the US: All Omicron after 2022



- MegaDx Index is a database and an associated index of changes in the market value of the most inclusive collection of public companies that participate in the clinical in-vitro diagnostic industry worldwide:
  - 130 public companies tracked during 2024: 77 on US exchanges, 24 in China, and 29 elsewhere
  - Bias toward inclusion: many large Dx participants have most of their revenues outside clinical diagnostics.
    - The MegaDx index includes the proportion of their market value based on the proportion of diagnostics revenues to total revenues (e.g. 24% of Roche; 21% of Agilent). It does not value segments independently (due to circularity).
    - Companies are included for entire year if they were public for any month of that year (value introduced or revised for all public/private events: IPOs added (just one in 2024, none in 2023); mergers and acquisitions; bankruptcy; etc.
- Companies included in MegaDx index; diagnostic revenue proportion; and currency rates are revised at the beginning of each calendar year and held fixed for the full year.

# MegaDx Index:

## Companies Included in Index 2024

### More than \$1 billion diagnostic revenue

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

### Less than \$1 billion diagnostic revenue

10x Genomics  
23andMe  
Accelerate Dx  
Adaptive Biotechnologies  
Adicon Holdings Ltd  
Amoy dx  
Angle PLC  
Autobio Dx  
Beijing Strong Biotechnologies  
BGI Genomics Co Ltd  
Bio-Techne  
Bioaffinity Technolgies  
Biocartis  
Biodesix, Inc.  
Biomerica inc  
BioNano Diagnostics  
BioSino Biotechnology and Science  
BioSynex  
Biovica  
BluJay Diagnostics  
Burning Rock Biotech Ltd  
Cardio Diagnostics  
CareDx Inc  
Castle Biosciences  
Cellavision AB  
Centogene

CoDiagnostics  
Cue  
Da An Gene  
DermTech  
Diaceutics PLC  
Dirui Industrial  
Dr Lal PathLabs  
EKF Diagnostics Holding PLC (UK)  
Enzo Biochem  
EuroBio Scientific  
Exagen  
Fulgent Genetics  
GeneDx  
Genetic Signatures  
Genetic Technologies Ltd (Australia)  
Getein Biotech  
Ginkgo  
Grifols  
Guardant  
Hybri Biotech Co Ltd  
Immunovia  
Inoviq  
IntegraGen  
Interpace Diagnostics  
Invitae  
Kindstar Global Gene Technology

Leadman Biochemistry Co Ltd  
Lucid Diagnostics  
Lumos Diagnostics  
Maccura Biotechnology  
Mainz Biomed  
MDX Health SA  
MedicalSystem Biotechnology  
Medmira  
Myriad Genetics  
Nanostring  
Nautilus  
Navidea Biopharmaceuticals, Inc  
NeoGenomics  
OncoCyte  
OpGen, Inc  
Opko Health  
OraSure Technologies  
Oxford BioDynamics  
Oxford Nanopore  
Pacific Biosciences  
Pacific Edge  
Personalis  
Precipio  
Prenetics  
ProMIS Neurosciences  
ProPhase Labs

Proteomics International Laboratories  
Psychemedics Corp  
Quanterix  
Renalytix AI  
Runda Medical Technology Co Ltd  
SD BioSensor  
Senseonics  
Sera Prognostics  
Shanghai Kehua Bioengineering  
Singular Genomic Systems, Inc  
Sinocare  
Snibe  
SurModics Inc.  
T2 Biosystems  
Talis Biomedical  
Tellgen  
Tempus AI  
Thalys Medical Technology Inc.  
Trinity Biotech Plc (Ireland)  
Universal Biosensors  
Veracyte  
VolitionRX Ltd  
Wondfo Biotech  
YHLO Biotech