



# HEALTH CATALYSTS DIAGNOSTICS YEAR IN REVIEW

**MARA G. ASPINALL**

CEO, Health Catalysts Group  
Managing Director, BlueStone Venture Partners

2019



# THE DIAGNOSTICS WORLD 2019:

## TABLE OF CONTENTS

### DIAGNOSTICS IN THE PUBLIC MARKETS

- 4 MEGA Index of Diagnostic Companies
- 5 Diagnostic IPO Activity

### DIAGNOSTICS TRANSACTIONS

- 6 Mergers & Acquisitions
- 8 Partnership Agreements

### FDA APPROVALS

- 9 Biomarker-Dependent Drug Approvals
- 10 Companion Diagnostics Tests
- 11 Artificial Intelligence (AI) Algorithms

### DIAGNOSTIC PRODUCTS MARKETPLACE

- 13 Genomic Tests Available
- 14 Mix of Available Genomic Tests

### 16 APPENDIX



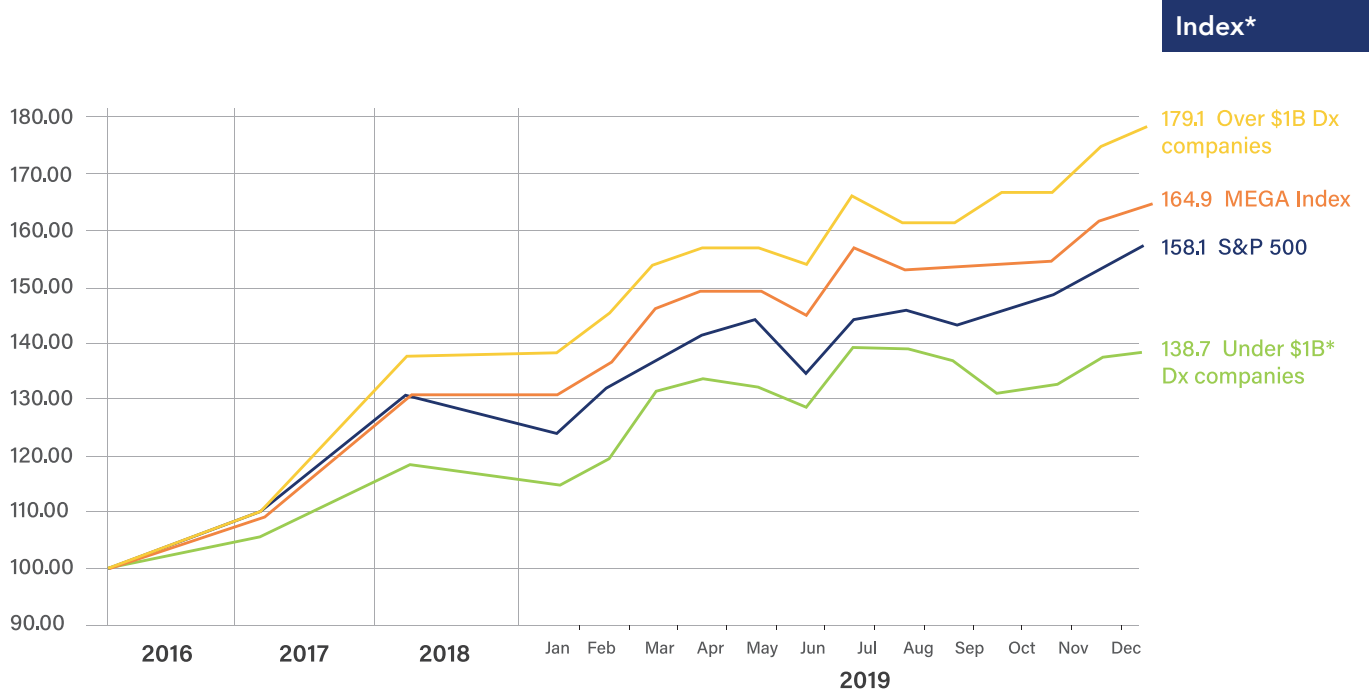


## THE MEGA INDEX EXPLAINED

Health Catalysts maintains a database and associated index of changes in the market value of the most inclusive collection of public companies that participate in the in-vitro diagnostic industry worldwide:

- 121 independent public companies tracked for 2019:
  - **70** headquartered in the US
  - **18** in China
  - **33** elsewhere
- Bias toward inclusion if the clinical Dx market is important to their future success (e.g. Illumina included)
- Many of the largest Dx participants have revenues in other industries. The MEGA index includes their market value based on proportion of Dx revenues to total revenue (e.g. 23% of Roche)
- Constant currency rates maintained throughout the year, re-calculated each January

## THE MEGA DIAGNOSTICS INDEX (2016-2019)



Source: Health Catalysts Group

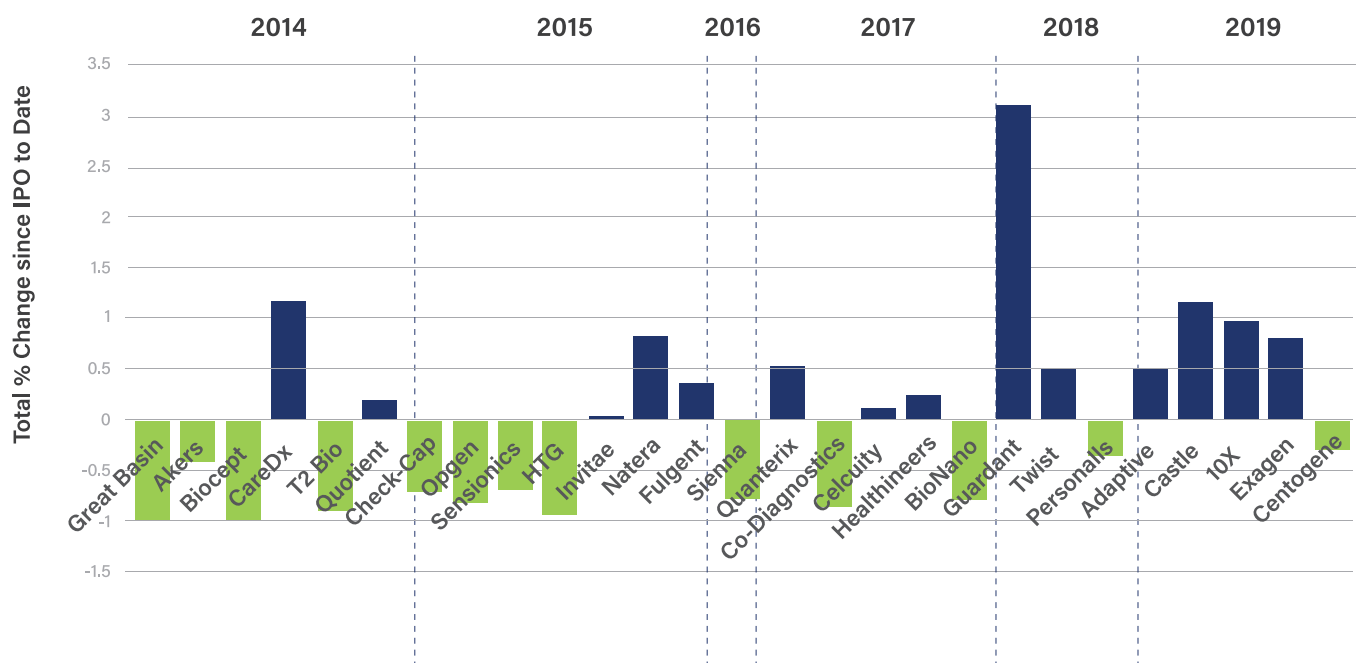
\*= Excludes BGI 2017/18 bubble

See Appendix for details.

The MEGA Index has outperformed or equaled the S&P500 in every year since we began tracking.

- The largest players in the MEGA Index have outperformed it significantly: the return on investment has been 36% above the S&P through the end of 2019
- The smaller players are more volatile: the successes have outperformed the index, but net of failures and laggards the entire group underperformed
- The big companies are a better than average equity investment at any time
- Making money with the smaller companies requires being able to pick out winners ahead of time, not an easy task absent in depth analysis and insight

# DIAGNOSTIC IPOs: PRICE PERFORMANCE FROM IPO THROUGH 2019

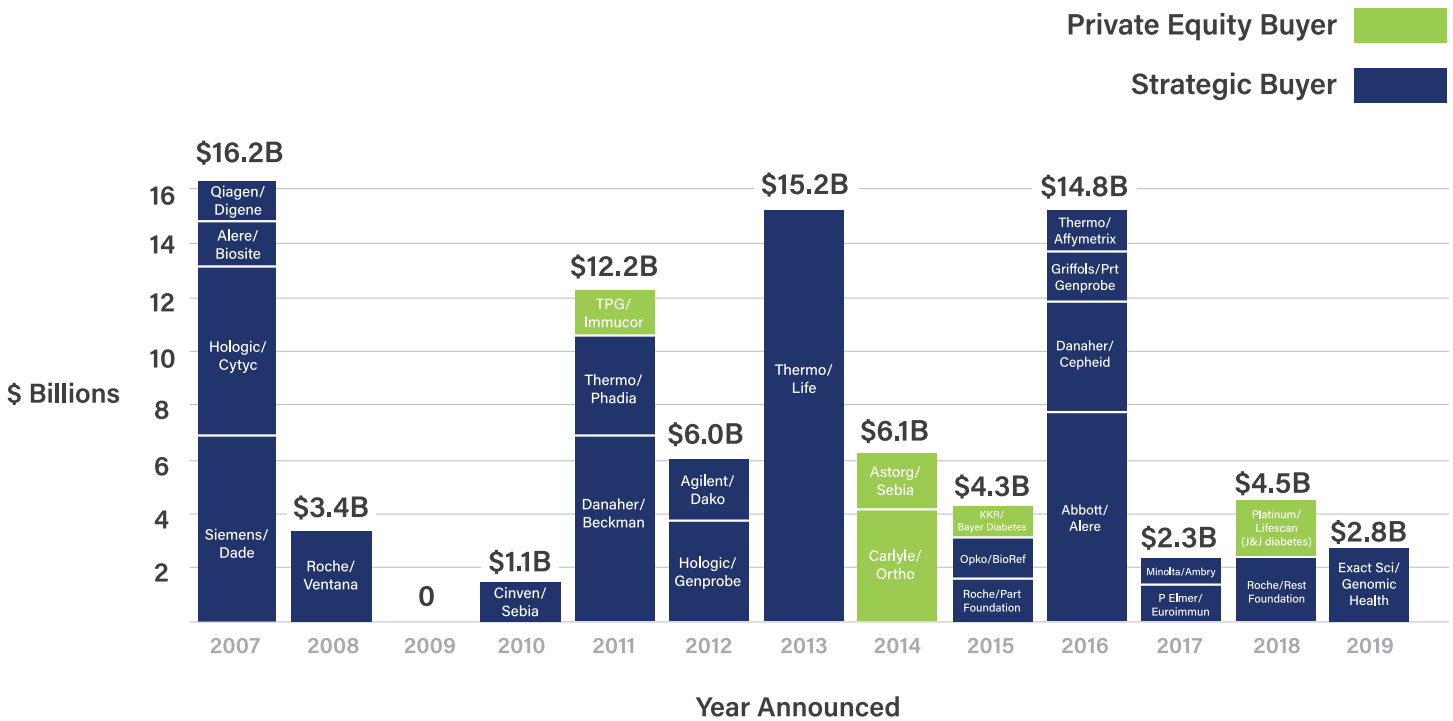


Source: Evercore

Diagnostic IPO performance has been highly variable over the last six years.

- 14 companies were trading above / 13 companies below their IPO price
- 2018's Guardant IPO has been the biggest post IPO gainer, showing the potential of less invasive testing
- 2017-19 saw several significant IPO's and a large spin-out (Healthineers), with much success through the end of 2019

# DIAGNOSTIC INDUSTRY TRANSFORMING ACQUISITIONS (>\$1 BILLION)

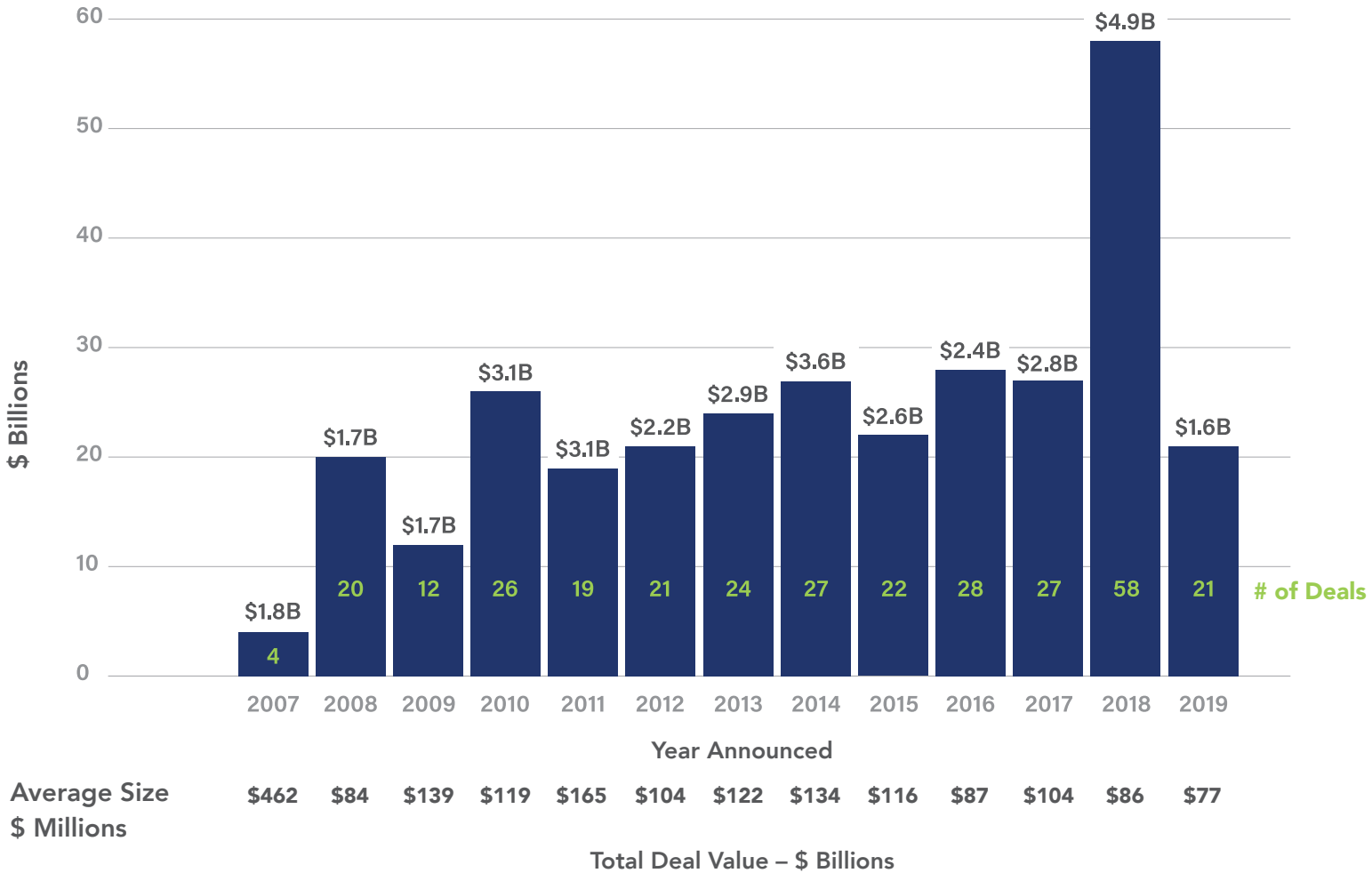


Source: Evercore

See Appendix for details.

Strategic buyers have had a large appetite for acquisitions of successful at-scale Dx companies. It is a common pattern for Dx companies to be acquired at strong multiples, and every year except 2009 saw major ownership changes. Private equity is rumored to have competed in most of these major acquisitions, but could not match the prices except in a few cases – shown in Green above.

## SMALLER DIAGNOSTIC ACQUISITIONS (<\$1 BILLION)



Source: Evercore

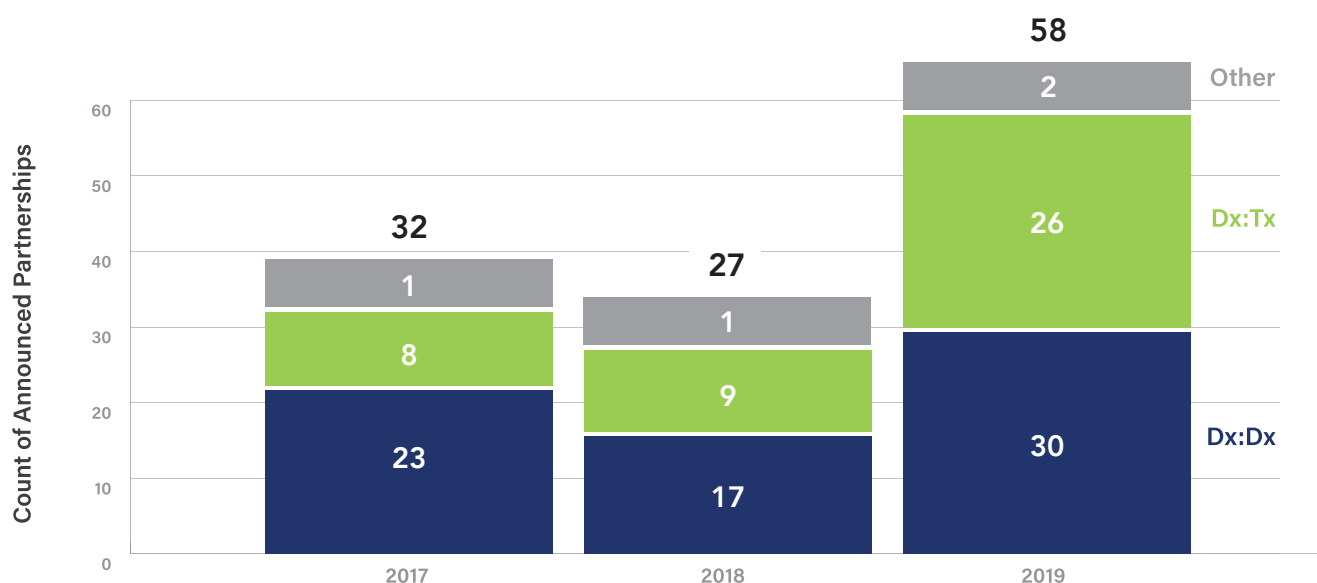
See Appendix for details.

Strategic buyers' appetite for tuck-under acquisitions of successful smaller Dx companies has been steady for each of the last ten years. Goals have been to:

- Gain access to new technology or IP
- Consolidate or expand geographic reach

Most buyers are other diagnostic companies, with a few major but not very successful exceptions.

## DIAGNOSTIC-RELATED PARTNERSHIP AGREEMENTS



Source: Evercore

See Appendix for details.

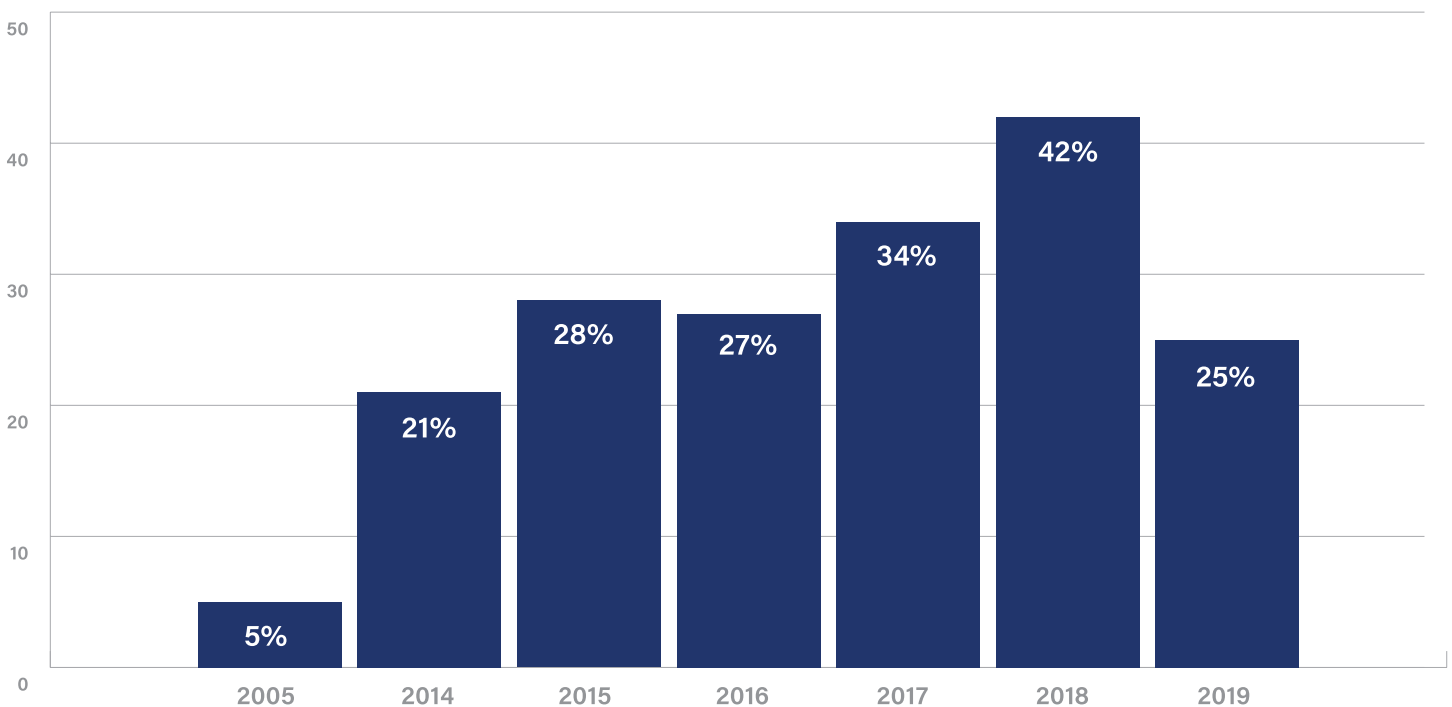
Partnership agreements are a clear way to limit capital investment and de-risk product development.

- Companion diagnostic agreements between Bio/Pharma and Diagnostics are steadily growing, demonstrating that this pathway is increasingly becoming standard. The FDA has also helped here by recognizing the importance of biomarkers in their drug approvals. (See next page)
- Intra-Dx industry partnerships are primarily of two types:
  1. Platform/Assay development agreements
  2. Geographic, market or segment expansion

There may be under-reporting for these deals as many are not announced publicly, but the upward trend is real.



## BIOMARKER-DEPENDENT DRUG APPROVALS AS A % OF TOTAL DRUG APPROVALS



**Source:** Personalized Medicine Coalition –  
The Scope and Significance of Progress in 2019

[See Appendix for details.](#)

**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.

The FDA continues to acknowledge the importance of biomarkers in drug approvals. Today, 70-80% of drugs start clinical development with biomarker guidance. In 2019, only 25% or 11 out of 44 drug approvals contained specific biomarker dependency in their label - i.e. approval was conditioned on the basis of a relevant diagnostic to select the right patients. We expect this metric to rise to over 50% in 2020 and 2021.

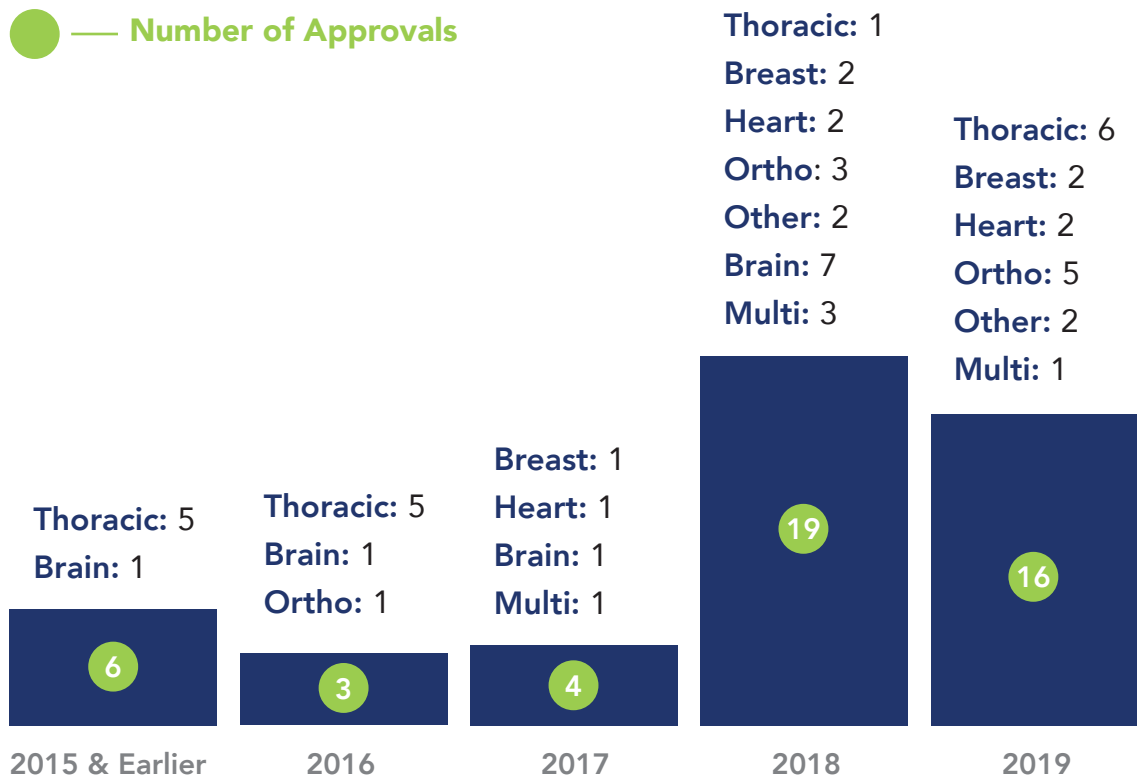
## FDA CLEARED / APPROVED COMPANION DIAGNOSTIC DEVICES

DIAGNOSTIC NAME	BIOMARKER	DECISION DATE FOR PREMARKET APPROVAL	DIAGNOSTIC MANUFACTURER	TRADE NAME (GENERIC) - NDA/BLA
therascreen FGFR RGQ RT-PCR Kit	FGFR	4/12/2019	Qiagen Manchester, Ltd.	Urothelial cancer • BALVERSA (erdafitinib) - NDA 212018
therascreen PIK3CA RGQ PCR Kit	PIK3CA	5/24/2019	Qiagen GmbH	Breast cancer (tissue and plasma) • PIQRAY (alpelisib) - NDA 212526
Myriad myChoice® CDx	BRCA 1 & 2 Variants + Instability	10/23/2019	Myriad Genetic Laboratories, Inc.	Ovarian Cancer • Zejula® (niraparib) - NDA 208447

Source: FDA Website

Drug approvals based on biomarkers are dependent on diagnostic approvals of individual marker or panel based tests. 2019 only saw a few approvals but this follows several years of approvals of other IVDs. Of course, this under-estimates the market which include several dozen LDT tests as well. Expect this group to expand broadly in coming years with additional diagnostic developers.

# FDA CLEARED ARTIFICIAL INTELLIGENCE (AI) ALGORITHMS



Source: FDA Website

See Appendix for details. Several algorithms are indicated for more than one body area.

**“Diagnostics is an Information Business with a Wet Lab on the Side.”** AI aided systems are here to stay. AI is being used for two purposes:

1. Pre-analysis to select aspects or regions of interest for human review
2. Full analysis just beginning to be approved (e.g. HER2 in breast cancer) but will grow to resolve the serious problem of human error in diagnostic analyses

# CONCERT GENETICS TESTING DATABASE EXPLAINED

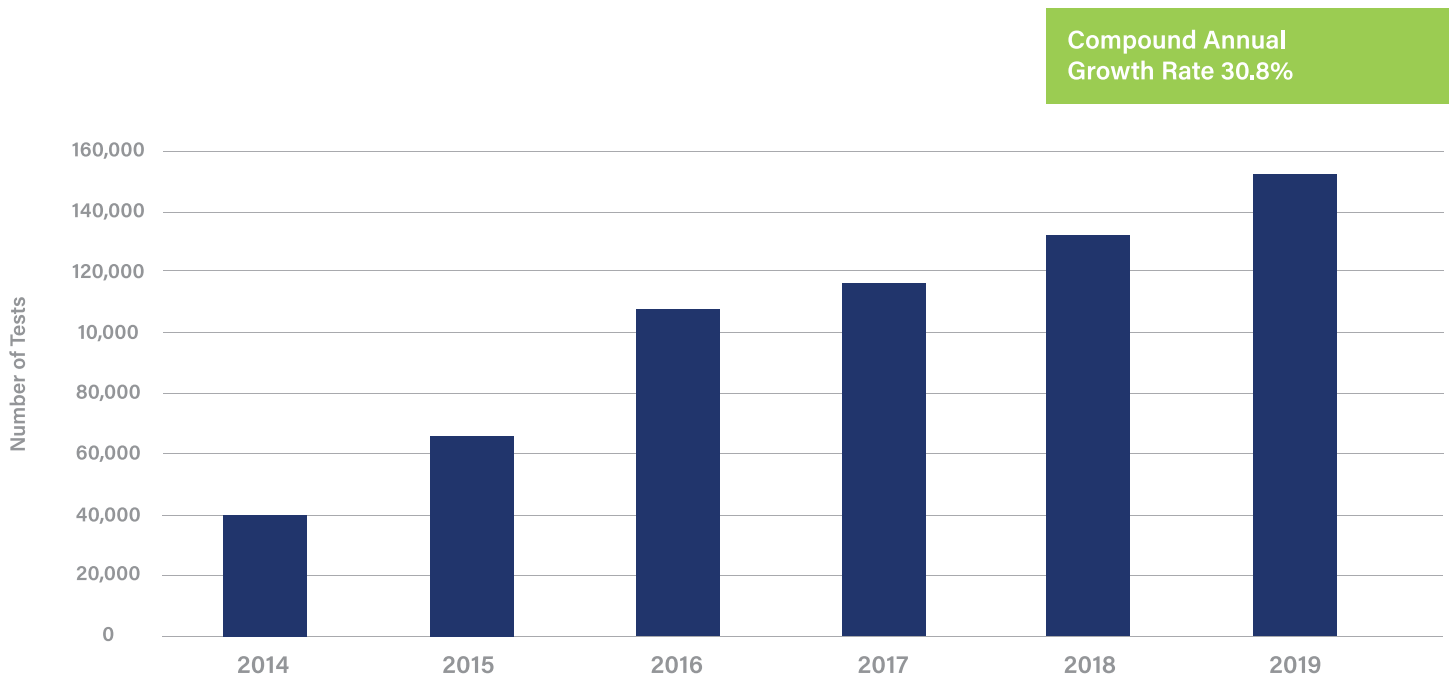
Concert Genetics maintains a database of all genomic tests available from CLIA-certified laboratories:

- The Concert Genetics Platform offers a database to serve clinical participants seeking to understand the genomic Dx landscape. Year to year growth has been extracted here to chart some of the basic trends in this increasingly essential genomic testing marketplace
- The basic element of this database is a single, distinct, orderable, genetic test performed by a specific laboratory: A genetic testing unit (GTU)
- A single GTU represents an orderable test. This varies broadly from a test investigating just one (or a very few) mutations in one specific gene offered by one laboratory, to a panel of genes, to a whole exome. Each offering is counted as 1 GTU independent of how comprehensive or expensive each order might be.
- A GTU is technology agnostic. A test may be performed on an NGS instrument (batched and barcoded or not) or by Amplicon identification, or a mix of the two by different laboratories.
- A test may be for any type of genomic alteration: heritable (germline) or not (e.g. autosomal variation in oncology), single variants, insertions, deletions, copy number variants, and epigenetic chemistry.



Source: Concert Genetics

## CLINICALLY AVAILABLE GENOMIC TESTS

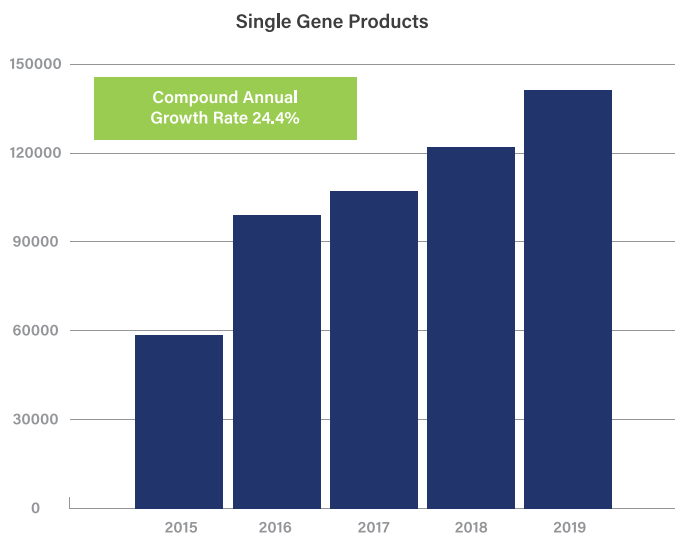
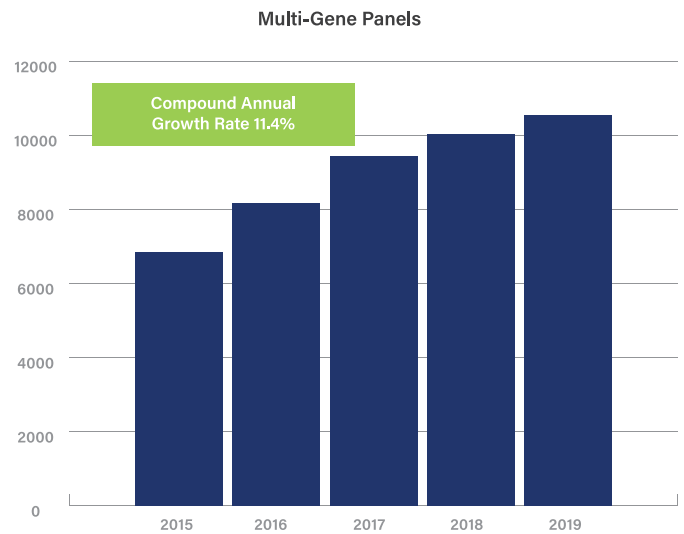
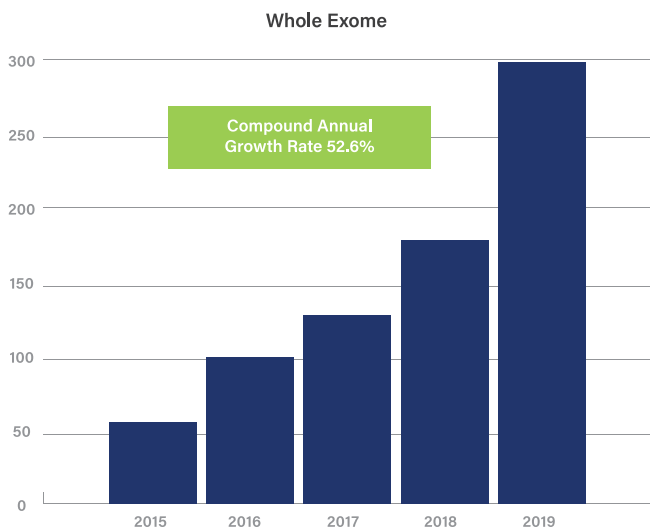


Source: Concert Genetics Test Database

**Genomic tests continue to be the fastest growing area of testing. This strong trend is driven by 5 forces:**

- Increasing research demonstrating the clinical relevance of genomics
- Multiple different ways to identify the status of any particular gene (amplicons, sequencing etc.)
- The exponential decrease in the cost of performing a test
- An increasing population of labs that can perform these tests
- Willingness of payers to reimburse at least some of these tests

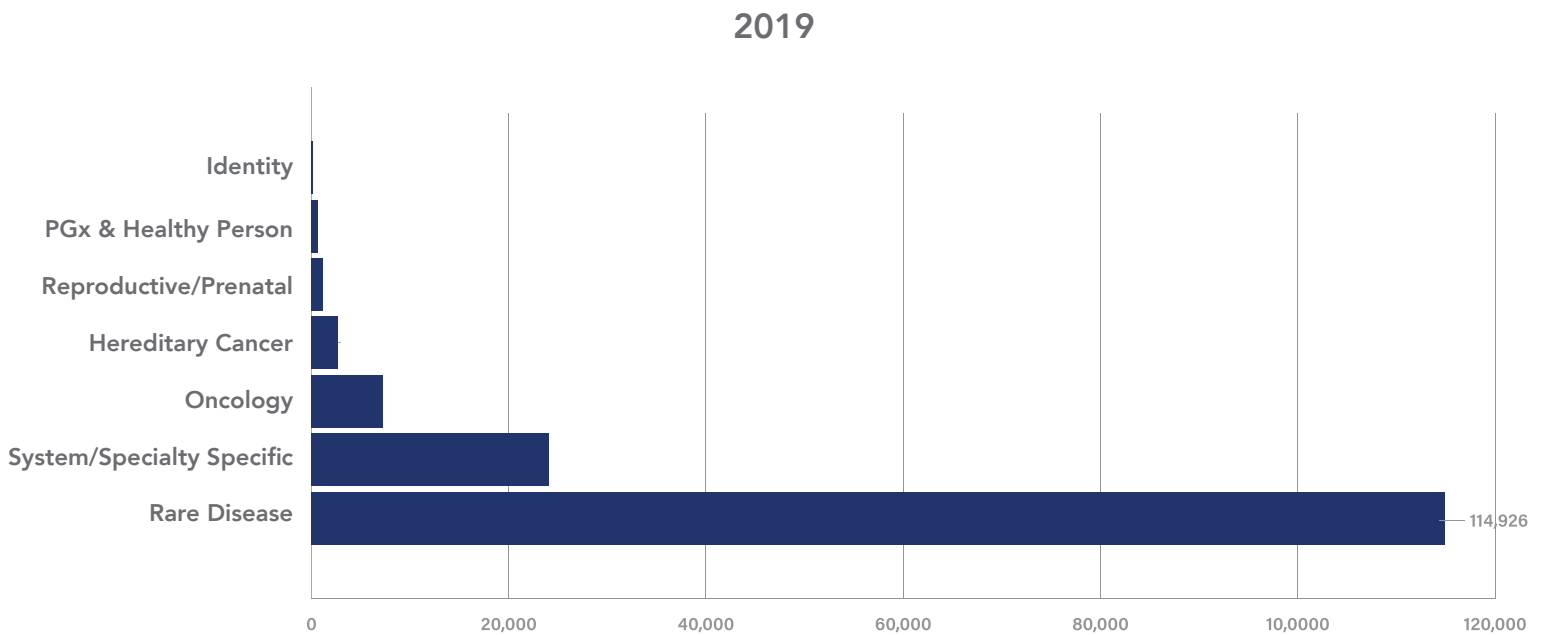
## MIX OF GENE TEST MENU ITEMS (AVAILABLE TESTS)



The number of unique orderable test menu items has risen across the board. Whole Exome and Multi-Gene Panels are addressed to distinguish between differential diagnoses within broader disease states (e.g. breast cancer; delayed neurodevelopment, etc.)

Source: Concert Genetics Test Database

## NET GTU BREAKDOWN BY TEST AREA & TECHNOLOGY



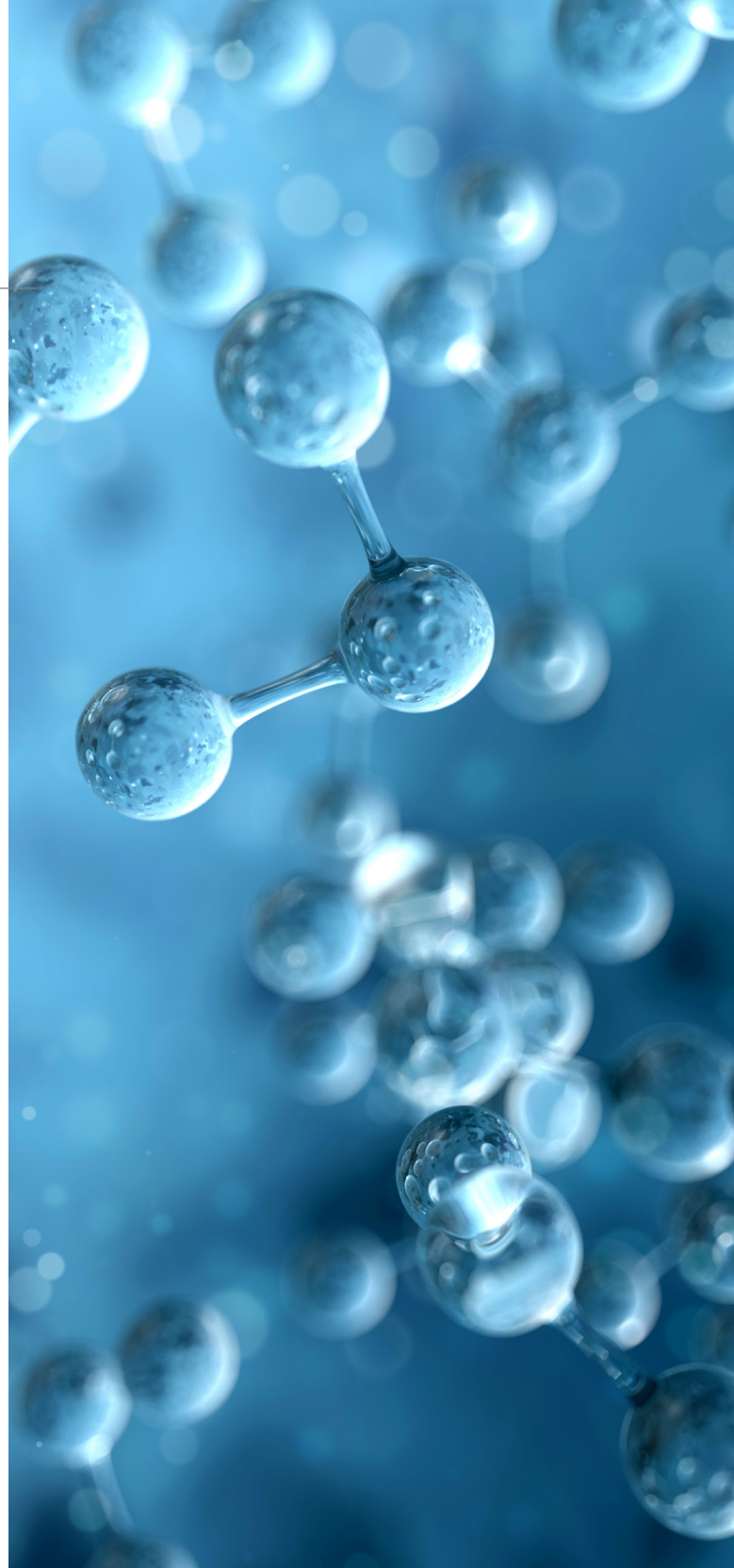
Source: Concert Genetics Test Database

Sequencing tests have become increasingly simple, faster and cheaper, empowering nearly all laboratories to be capable of offering single gene tests for rare heritable diseases. When looking at the total number of tests available (as opposed to tests ordered) – it is not surprising that tests for Rare Diseases dominate.

# APPENDIX

---

- MEGA Diagnostic Index
- Diagnostic Acquisitions
- Diagnostic Partnerships
- Biomarker-Dependent Drug Approvals
- FDA Cleared AI Algorithms





# MEGA DIAGNOSTIC INDEX 2019: TOTAL COMPANIES – 121

Abbott	ABT	USD	CoDiagnostics	CODX	USD
Abcam	ABC.L	GBP	Da An Gene	002030.SZ	CNY
Accelerate Dx	AXDX	USD	Danaher	DHR	USD
Agilent	A	USD	Dian diagnostics group	300244.SZ	CNY
Akers Biosciences	AKER	USD	DiaSorin SpA(Italy)	DIA.MI	EUR
amoy dx	300685.SZ	CNY	Dirui Industrial	300396.SZ	CNY
Anixa BioSciences (<10/1/18=ITUS)	ANIX	USD	Dong-A ST	170900.KS	KRW
Autobio Dx	603658.SS	CNY	EKF Diagnostics Holding PLC (UK)	EKF.L	GBP
Bard1 Life Sciences Ltd	BD1.AX	AUD	Enzo Biochem	ENZ	USD
Beckton Dickinson	BDX	USD	Epigenomcs (germany)	ECX.F	EUR
Beijing Strong Biotechnologies	300406.SZ	CNY	EuroBio Scientific (Diaxonhit)	ALERS.PA	EUR
BGI Genomics Co Ltd	300676.SZ	CNY	eurofins	ERF.PA	EUR
Bio-Rad	BIO	USD	Exact Sciences	EXAS	USD
Bio-Techne (was Techne)	TECH	USD	Fujifilm	FUJIIY	USD
Biocartis (Belgium)	BCART.BR	EUR	Fulgent Genetics	FLGT	USD
Biocept, Inc.	BIOC	USD	GeneNews Ltd (Canada)	GEN.TO	CAD
BioLight Life Sciences Ltd	BOLT.TA	ILS	Generex Biotechnology Corp (sub NuGene)	GNBT	USD
Biomerica inc	BMRA	USD	Genetic Signatures	GSS.AX	AUD
BioMerieux (Euro)	BIM.PA	EUR	Genetic Technologies Ltd (Australia)	GENE	USD
BioSino Biotechnology and Science	8247.HK	HKD	GenMark Dx	GNMK	USD
Biovica	BIOVIC-B.ST	SEK	Genomic Health	GHDX	USD
Bruker	BRKR	USD	Genomic Vision (France/Euro)	GV.PA	EUR
Cancer Genetics	CGIX	USD	Getein Biotech	603387.SS	CNY
CareDx Inc	CDNA	USD	Grifols	GRFS	USD
Celcuity	CELC	USD	Guardant	GH	USD
Cellmid	CDY.AX	AUD	Hologic	HOLX	USD
Cellnovo	CLNV.PA	EUR	HTG Molecular Dx	HTGM	USD
Check-Cap Ltd (Israel)	CHEK	USD	Hybri Biotech Co Ltd	300639.SZ	CNY
Chembio DX	CEMI	USD	illumina	ILMN	USD
illumina	ILMN	USD	Immunodiagnostic Systems	IDH.L	GBP
Immunodiagnostic Systems	IDH.L	GBP	Perkin Elmer	PKI	USD
Immunovia	IMMNOV.ST	SEK	Precipio (was TBIO)	PRPO	USD
IntegraGen	ALINT.PA	EUR	ProMIS Neurosciences	PMN.TO	CAD
Interpace Diagnostics	IDXG	USD	Proteomics International Laboratories Ltd	PIQ.AX	AUD
Invitae	NVTA	USD	Psychemedics Corp	PMD	USD
iRhythm Technologies	IRTC	USD	Qiagen	QGEN	USD
KonicaMinolta	4902.T	JPY	Quanterix	QTRX	USD
LabCorp	LH	USD	Quest	DGX	USD
Leadman Biochemistry Co Ltd	300289.SZ	CNY	Quidel	QDEL	USD
Luminex	LMNX	USD	Quotient Ltd UK	QTNT	USD
Maccura Biotechnology	300463.SZ	CNY	Roche	RHHBY	USD
MDX Health (Belgium)	MDXH.BR	EUR	Runda Medical Technology Co Ltd	603108.SS	CNY
MedicalSystem Biotechnology	300439.SZ	CNY	Senseonics	SENS	USD
Medmira (Canada)	MMIRF	USD	Shanghai Kehua Bioengineering	002022.SZ	CNY
Meridian Biosciences	VIVO	USD	Siemens Healthineers AG	SHL.DE	EUR
MetaStat Inc.	MTST	USD	Sienna Cancer Diagnostics (Australia)	SDX.AX	AUD
Miraca Holdings (Fujirebio Diagnostics)	4544.T	JPY	Sinocare (Shenzhen, China)	300298.SZ	CNY
Myriad Genetics	MYGN	USD	Spectral Medical	EDT.TO	CAD
Nanostring	NSTG	USD	SurModics Inc.	SRDX	USD
NantHealth	NH	USD	Sysmex	SSMXY	USD
Natera	NTRA	USD	T2 Biosystems	TTOO	USD
Navidea Biopharmaceuticals, Inc	NAVB	USD	TearLab Corp	TEAR	USD
NeoGenomics	NEO	USD	Telgen	300642.SZ	CNY
Oncocyte (2016 Spin out of Biotime)	OCX	USD	Thalys Medical Technology Inc.	603716.SS	CNY
OpGen, Inc	OPGN	USD	Theradiag	ALTER.PA	EUR
Opko Health (incl. BioRef Labs)	OPK	USD	Thermo Fisher	TMO	USD
OraSure Technologies	OSUR	USD	Trinity Biotech Plc (Ireland)	TRIB	USD
Oxford BioDynamics	OBD.L	GBP	Universal Biosensors	UBI.AX	AUD
Oxford Immunotech	OXFD	USD	Veracyte	VCYT	USD
			Vermillion Inc	VRML	USD
			VolitionRX Ltd (Belgium)	VNRX	USD
			Wondfo Biotech	300482.SZ	CNY
			Yougene Health	YGEN.L	GBP

## MEGA DX INDEX 2019: 16 COMPANIES WITH >\$1 BILLION DX REVENUE

			Total Company Revenue	Estimated Diagnostic Revenue
Roche	RHHBY	USD	\$43,563.00	\$9,859.00
LabCorp	LH	USD	\$11,340.00	\$7,523.00
Quest	DGX	USD	\$7,860.00	\$7,520.00
Danaher	DHR	USD	\$19,800.00	\$6,200.00
Abbott	ABT	USD	\$27,390.00	\$5,616.00
Thermo Fisher	TMO	USD	\$20,900.00	\$4,807.00
Siemens Healthineers AG	SHL.DE	EUR	\$15,371.00	\$4,535.00
eurofins	ERF.PA	EUR	\$3,800.00	\$3,800.00
Sysmex	SSMXY	USD	\$2,610.00	\$2,180.00
BioMerieux	BIM.PA	EUR	\$ 2,618.82	\$2,095.00
Miraca Holdings (Fujirebio Diagnostics)	4544.T	JPY	\$1,619.00	\$1,619.00
Becton Dickinson	BDX	USD	\$15,983.00	\$1,536.00
Bio-Rad	BIO	USD	\$2,160.15	\$1,447.20
Dian	300244.SZ	CNY	\$1,214.00	\$1,214.00
Hologic	HOLX	USD	\$3,217.90	\$1,158.00
Illumina	ILMN	USD	\$3,330.00	\$1,110.00

## MEGA DX INDEX 2019: 18 MAINLAND CHINA COMPANIES

Dian Diagnostics Group	300244.SZ	CNY	\$1,214.0
BGI Genomics Co Ltd	300676.SZ	CNY	\$498.5
Maccura Biotechnology	300463.SZ	CNY	\$480.8
MedicalSystem Biotechnology	300439.SZ	CNY	\$413.4
Autobio Dx	603658.SS	CNY	\$368.0
Shanghai Kehua Bioengineering	002022.SZ	CNY	\$339.4
Sinocare (Shenzhen, China)	300298.SZ	CNY	\$298.0
Runda Medical Technology Co Ltd	603108.SS	CNY	\$224.8
Dirui Industrial	300396.SZ	CNY	\$193.7
Da An Gene	002030.SZ	CNY	\$128.5
Beijing Strong Biotechnologies	300406.SZ	CNY	\$128.5
Leadman Biochemistry Co Ltd	300289.SZ	CNY	\$101.4
amoy dx	300685.SZ	CNY	\$88.7
Thalys Medical Technology Inc.	603716.SS	CNY	\$84.0
Wondfo Biotech	300482.SZ	CNY	\$74.1
Tellgen	300642.SZ	CNY	\$70.3
Hybri Biotech Co Ltd	300639.SZ	CNY	\$38.1
Getein Beach	603387.SS	CNY	\$6.5

Estimated US \$  
Diagnostic Revenue

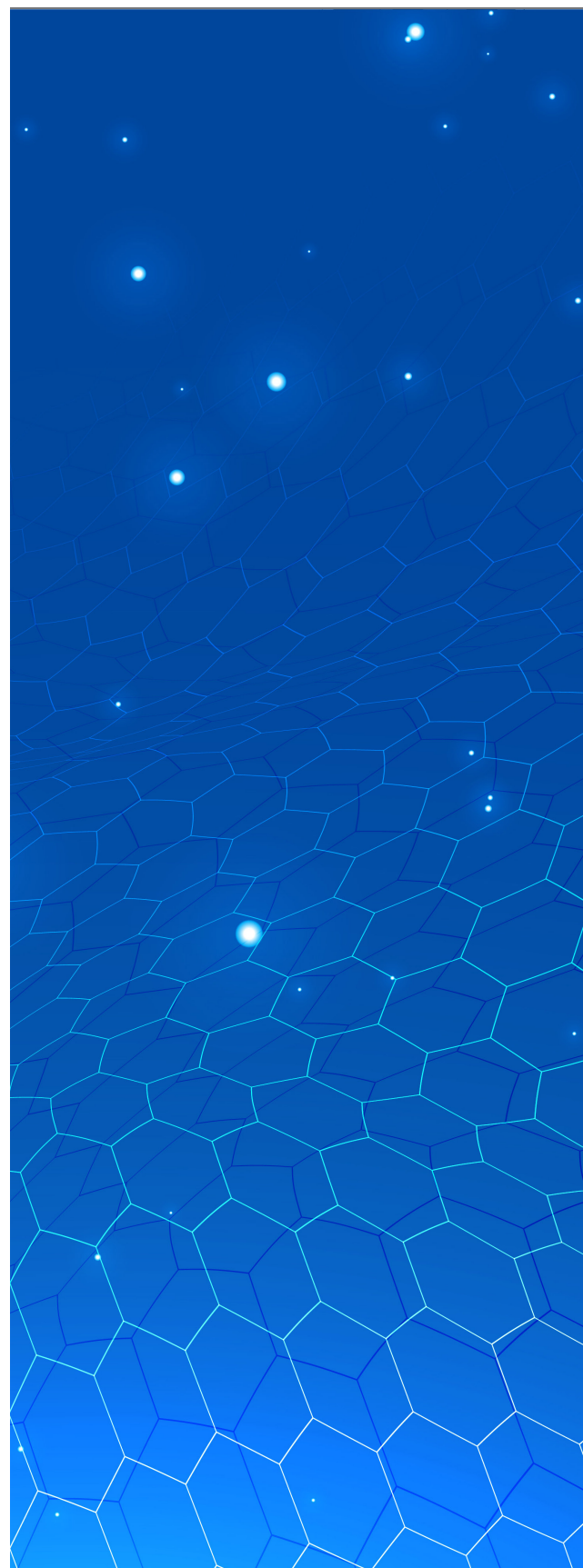
## DIAGNOSTIC ACQUISITIONS 2019: (< \$1 BILLION)

ANNOUNCED	CLOSING	ACQUIROR	TARGET	ESTIMATED VALUE (\$ MILLIONS)
4/2/19	4/2/19	Sienna Cancer Diagnostics	Sevident	\$3.0
3/19/19	3/19/19	Oncimmune	Protagen	\$5.0
6/25/19	6/25/19	Eurofins Scientific	Transplant Genomics	\$10.0
6/17	6/19/19	Invitae	Singular BIO	\$10.0
6/4	6/4/19	Bio-Techne	B-Mogen Biotechnologies	\$10.0
5/29/19	5/29/19	Lumos Diagnostics	RPS Diagnostics	\$10.0
4/23/19	4/23/19	Prescient Medicine	AutoGenomics	\$10.0
1/30/19	1/30/19	Danaher / Beckman Coulter	Labcyte	\$10.0
1/30/19	1/30/19	ArcherDX	Baby Genes	\$10.0
1/4/19	1/5/19	OraSure	Novosanis	\$10.0
1/2/19	1/2/19	Neogen Canada Inc.	Genotyping Services Assets of Delta Centre	\$10.0
9/4/19	Pending	OpGen	Curetis	\$19.0
6/26/19	6/26/19	Quanterix	UmanDiagnostics	\$23.0
9/16/19	10/1/19	CellaVision	RAL Diagnostics	\$28.0
3/27/19	4/30/19	Guardant Health	Bellweather Bio	\$30.0
11/11/19	11/12/19	Invitae	Clear Genetics	\$50.0
12/5/19	Pending	Sartorius	Biological Industries	\$100.0
4/29/19	6/3/19	Meridian BioScience	GenePOC	\$120.0
10/31/19	10/31/19	Mesa Labs	Gyros Protein Technologies	\$180.0
4/25/19	4/35/19	PerkinElmer	Cisbio Bioassays	\$215.0
10/21/19	Pending	Sartorius	Danaher Life Sciences	\$750.0

# DIAGNOSTIC PARTNERSHIP DEALS 2019

## COMPANION DIAGNOSTICS (DX/TX) DEALS

12/10/19	Invitae / BioMarin
11/22/19	Exagen / GSK
11/19/19	Personalis / Merck KGaA
11/19/19	Personalis / FLX Bio
11/18/19	Centogene / PTC Therapeutics
11/13/19	Centogene / Pfizer
9/24/19	Natera / Foundation Medicine
9/17/19	Adaptive Biotechnologies / Amgen
9/16/19	Curetis / AKO MED
9/9/19	Thermo Fisher / Lilly Oncology
9/3/19	Thermo Fisher / Cedars-Sinai
7/24/19	PerkinElmer / EverlyWell
7/18/19	Chembio / Takeda Pharmaceuticals
6/19/19	Qiagen / McKesson
6/5/19	Qiagen / DiaSorin
6/3/19	Thermo Fisher / Evosep
5/30/19	NanoString / Multiple CROs
5/29/19	Thermo Fisher / Scinogy
5/27/19	Sysmex / Osaka University
4/8/19	Thermo Fisher / Genovis
4/4/19	Myriad / AstraZeneca / Merck
4/3/19	Qiagen / LabCorp
3/28/19	ArcherDX / University College London
3/19/19	bioMérieux / Baxter
3/11/19	Natera / BGI Genomics
2/28/19	Centogene / Sarpeta Therapeutics



## DIAGNOSTIC PARTNERSHIP DEALS 2019 (CONT.)

INTRA DIAGNOSTICS (DX/DX) DEALS			
12/11/19	Twist BioScience / Pandion Therapeutics	4/30/19	HTG Molecular / Qiagen
12/3/19	NanoString / Veracyte	4/22/19	Bio-Techne / Elpiscience
12/3/19	ArcherDX / Illumina	4/16/19	Bruker / Translational Metabolic Laboratory
11/6/19	Avantor / National Institute of Bioprocessing Research and Training (NIBRT)	4/4/19	Twist BioScience / LakePharma
11/4/19	Quanterix (UmanDiagnostics) / Siemens Healthineers	4/2/19	NanoString / Leica
11/4/19	Quanterix (UmanDiagnostics) / Bio-Techne	4/2/19	Chembio / Perseus Science
10/7/19	Qiagen / Illumina	4/1/19	NanoString / Abcam
9/30/19	Illumina / Broad Institute of MIT and Harvard	3/28/19	NanoString / Bio-Techne
9/24/19	Adaptive Biotechnologies / Illumina	3/28/19	Sysmex / Bayer Yakuhin
9/9/19	Personalis / Invectys	3/26/19	Natera / AMAL Therapeutics
7/16/19	Fulgent / Parkinson's Foundation	2/12/19	ArcherDX / Genosity
7/15/19	NanoString / Model-AD Consortium	2/1/19	Natera / One Lamda (Thermo Fisher)
7/8/19	ArcherDX / Ayala Pharmaceuticals	1/4/19	Adaptive Biotechnologies / Genentech (Roche)
6/3/19	Thermo Fisher / Newomics	1/3/19	Fulgent / Columbia University Irving Medical
5/16/19	Qiagen / Inovio	2/26/19	Bio-Techne / Lisen Imprinting Diagnostics
		1/7/19	Biocartis / Nichirei Bioscience

# BIOMARKER-DEPENDENT DRUG APPROVALS – FDA 2019

11 of the 44 new therapeutic molecular entities + a new gene therapy are personalized - defined by biomarker status.

**1. Mayzent (siponimod):** Relapsing forms of multiple sclerosis. Use of this product is informed by CYP2C9 biomarker status.

**2. Balversa (erdafitinib):** Locally advanced or metastatic urothelial carcinoma. Use of this product is informed by the FGFR3 or FGFR2 biomarker statuses in tumors.

**3. Piqray (alpelisib):** for the treatment of advanced or metastatic breast cancer in combination with fulvestrant. Use of this product is informed by the HR, HER2, and PIK3CA-mutated biomarker statuses in tumors.

**4. Wakix (pitolisant):** for the treatment of excessive daytime sleepiness in adult patients with narcolepsy. Use of this product is informed by CYP2D6 biomarker status.

**5. Pretomanid (pretomanid):** Pulmonary drug resistant, treatment-intolerant or non-responsive multidrug-resistant tuberculosis. Use of this product is informed by XDR and/or MDR biomarker statuses.

**6. Rozlytrek (entrectinib):** Metastatic non-small cell lung cancer. Use of this product is informed by ROS1 biomarker status in tumors.

**7. Trikafta (elexacaftor/ivacaftor):**

Cystic fibrosis. Use of this product is informed by the CFTR F508del mutation status.

**8. Givlaari (givosiran):** Acute hepatic porphyria. This product selectively targets the aminolevulinic synthase-1 biomarker.

**9. Oxbryta (voxelotor):** Sickle cell disease. This product selectively targets the hemoglobin S (HbS) biomarker in patients.

**10. Vyondys53 (golodirsen):** Duchenne Muscular Dystrophy. Product selectively targets a mutated version of DMD gene that is amenable to exon 53 skipping.

**11. Enhertu (fam-trastuzumab deruxtecan-nxki):** Metastatic breast cancer. Use of this product is informed by HER2 biomarker status in tumors.

• **Gene Therapy:** Zolgensma: Spinal Muscular Atrophy. The treatment is a fully integrated gene therapy to correct bi-allelic mutations in the SMN1 gene.

**Source:** Personalized Medicine Coalition –The Scope and Significance of Progress in 2019

## 2019 FDA CLEARED AI ALGORITHMS

FDA CLEARED AI ALGORITHMS	COMPANY	BODY AREA	INDICATIONS FOR USE (EXCERPTS)
Syngo CT CaScoring	Siemens Medical Solutions USA, Inc.	Heart and Chest	Image analysis software for evaluating CT data sets for calcified coronary lesions.
HealthCXR	Zebra Medical Vision Ltd.	Chest	Workflow tool to aid clinical assessment of adult chest X-rays suggestive of pleural effusion.
RSI-MRI+	HealthLytix	Male Pelvis	Image processing software for diffusion-weighted and anatomical MRI data.
KOALA	IB Lab GmbH	Knee	Knee OsteoArthritis Labeling Assistant software provides metric measurements of joint space width and indicators for osteoarthritis (OA).
StoneChecker	Imaging Biometrics	Abdomen	Post-processing software for evaluating CT image studies of patients with kidney stones.

FDA CLEARED AI ALGORITHMS	COMPANY	BODY AREA	INDICATIONS FOR USE (EXCERPTS)
SubtleMR	Subtle Medical, Inc.	Head, Spine, Neck, Knee	Image processing software for enhancement of MRI images or to reduce image noise.
AI-Rad Companion-Cardiovascular	Siemens Medical Solutions USA, Inc.	Heart	Provides quantitative & qualitative analysis from CT images for evaluation and assessment of cardiovascular diseases.
Critical Care Suite	GE Medical Systems, LLC	Chest	Triage & notification device to analyze frontal chest x-ray images for prespecified critical findings (pneumothorax).
AI-Rad Companion-Pulmonary	Siemens Medical Solutions USA	Lungs	Provides quantitative & qualitative analysis from CT images for evaluation and assessment of lung diseases.
Koios DS for Breast	Koios Medical, Inc.	Breast	AI & ML algorithms to analyze user-identified regions of interest in ultrasound breast images.
HealthICH	Zebra Medical Vision Ltd.	Head	Software for assessment of non-contrast head CT cases with features suggestive of intracranial hemorrhage.

Source: FDA Website



## 2019 FDA CLEARED AI ALGORITHMS (CONT.)

FDA CLEARED AI ALGORITHMS	COMPANY	BODY AREA	INDICATIONS FOR USE (EXCERPTS)
Aidoc BriefCase- CSF	Aidoc Medical, Ltd.	Cervical Spine	Software for analysis of cervical spine CT images by flagging suspected linear lucencies compatible with fractures.
HealthPNX	Zebra Medical Vision Ltd.	Chest	Software for clinical assessment of adult Chest X-Rays with features suggestive of pneumothorax.
Aidoc Briefcase- ICH and PE triage	Aidoc Medical, Ltd.	Head & Chest	Software for analysis of non-enhanced CT & CTPA images by flagging suspected intracranial hemorrhage and pulmonary embolism.
cmTriage	CureMetrix, Inc.	Breast	Software to prioritize patients by flagging those suggestive of presence of at least one suspicious finding.
AI-Rad Companion -Engine	Siemens Medical Solutions USA	All	Provides basic visualization and external post-processing extension for medical images.

Source: FDA Website

## ACKNOWLEDGEMENTS – 2019 DIAGNOSTICS YEAR IN REVIEW

---

**To Haley Connolly**, thank you for your great work in designing this year’s Review and your patience with my edits of the many Year in Review “final” versions.

**To Grace Gegenheimer**, thank you for keeping me focused and organized as well as your careful reading of the Review.

**To Monica Lovato**, thank you for the logo and original Year in Review layout.

**To Rob Metcalf, Gillian Hooker and the rest of the team at Concert Genetics**, thank you for sharing your insights and your important Genomic Test database. Your work will herald the next generation of testing.

**To Bernhard Sakmann and Justin Reed of Evercore**, thank you for your continued partnership on the diagnostics’ industry public markets data. I enjoy our debates about where the market has been and will go.

---

### ABOUT HEALTH CATALYSTS GROUP

Health Catalysts Group is a consulting and informatics firm focused on the success of life sciences companies. Health Catalysts helps companies leverage their data and technology to accelerate growth and gain unique market position. Health Catalysts also helps build young companies through venture investment.

---

[mara.aspinall@healthcatalysts.com](mailto:mara.aspinall@healthcatalysts.com)