

# RESEARCH REPORT



## COMPANION DIAGNOSTIC MARKETS

THE FUTURE OF DIAGNOSTICS

BY APPLICATION, TECHNOLOGY AND FUNDING.

WITH EXECUTIVE AND CONSULTANT GUIDES

2023-2027



Howe Sound Research is a market research and consulting company based in Vancouver, British Columbia, Canada. In our spare time we like to sail in a large body of water nearby called Howe Sound. We publish market research reports that address scientific industries with an emphasis on Biotechnology and Clinical Diagnostic markets. We consider ourselves experts in these areas.

We approach market research differently than other companies. At any one time we have a limited number of reports and we update them frequently, sometimes several times a year. Our reports are prepared by people who understand the industry and have worked and studied in the area. This contrasts with the many research mills who produce canned reports on the Handbag market one day and the XRay market the next.

Our intellectual property is encryption protected. If you have issues with this or would like to upgrade to a corporate license that is not encrypted, please contact us at the email above.

Please feel free to contact us if you have any questions. We believe in customer service and are more than willing to provide after sales assistance and custom data.

All Rights Reserved. This document contains copyrighted intellectual property. No part of it may be circulated, copied, quoted, or otherwise reproduced without the approval of Howe Sound Research.

Please respect our intellectual property and do not distribute this document beyond the terms of your license.

## Table of Contents

1	Market Guides .....	22
1.1	Strategic Situation Analysis.....	23
1.2	Guide for Executives, Marketing, Sales and Business Development Staff .....	25
1.3	Guide for Management Consultants and Investment Advisors.....	27
2	Introduction and Market Definition .....	28
2.1	What are Companion Diagnostics? .....	29
2.2	The Personalized Medicine Revolution.....	49
2.3	Market Definition.....	51
2.3.1	Revenue Market Size.....	51
2.4	Methodology.....	53
2.4.1	Methodology.....	53
2.4.2	Sources.....	53
2.4.3	Authors .....	53
2.5	Perspective: Healthcare and the IVD Industry .....	55
2.5.1	Global Healthcare Spending .....	55
2.5.2	Spending on Diagnostics .....	56
2.5.3	Important Role of Insurance for Diagnostics.....	58
3	Market Overview.....	59
3.1	Players in a Dynamic Market.....	60
3.1.1	Academic Research Lab .....	61

3.1.2	Diagnostic Test Developer.....	61
3.1.3	Instrumentation Supplier .....	62
3.1.4	Chemical/Reagent Supplier.....	62
3.1.5	Pathology Supplier .....	62
3.1.6	Independent Clinical Laboratory .....	63
3.1.7	Public National/regional Laboratory .....	63
3.1.8	Hospital Laboratory .....	64
3.1.9	Physicians Office Lab (POLs) .....	64
3.1.10	Audit Body .....	65
3.1.11	Certification Body.....	65
3.2	Personalized Medicine and Companion Diagnostics .....	67
3.2.1	Basics .....	67
3.2.2	Method.....	68
3.2.3	Disease risk assessment .....	68
3.2.4	Applications.....	68
3.2.5	Diagnosis and intervention .....	69
3.2.5.1	Companion Diagnostics .....	70
3.2.6	Drug development and usage .....	70
3.2.7	Respiratory proteomics .....	71
3.2.8	Cancer genomics .....	72
3.2.9	Population screening .....	73
3.2.10	Challenges.....	73
3.2.11	Regulatory oversight .....	73
3.2.12	Intellectual property rights.....	74

3.2.13	Reimbursement policies.....	74
3.2.14	Patient privacy and confidentiality .....	74
3.3	Chromosomes, Genes and Epigenetics .....	76
3.3.1	Chromosomes .....	76
3.3.2	Genes.....	78
3.3.3	Epigenetics .....	81
3.4	Cancer Genes.....	82
3.4.1	Germline vs Somatic .....	84
3.4.2	Changing Clinical Role .....	86
3.5	Structure of Industry Plays a Part.....	87
3.5.1	New Pharmaceutical Funding Market .....	87
3.5.2	Economies of Scale.....	87
3.5.2.1	Hospital vs. Central Lab.....	88
3.5.3	Physician Office Labs .....	89
3.5.4	Physicians and POCT.....	89
4	Market Trends .....	91
4.1	Factors Driving Growth .....	92
4.1.1	Level of Care. ....	92
4.1.2	Immuno-oncology.....	93
4.1.3	Liability.....	93
4.1.4	The Aging World .....	93
4.2	Factors Limiting Growth .....	97
4.2.1	State of knowledge.....	97
4.2.2	Genetic Blizzard.....	98

4.2.3	Protocol Resistance.....	98
4.2.4	Regulation and coverage.....	98
4.3	Instrumentation, Automation and Diagnostic Trends .....	99
4.3.1	Traditional Automation and Centralization.....	99
4.3.2	The New Automation, Decentralization and Point Of Care .....	99
4.3.3	Instruments Key to Market Share .....	101
4.3.4	Bioinformatics Plays a Role .....	101
4.3.5	PCR Takes Command.....	102
4.3.6	Next Generation Sequencing Fuels a Revolution.....	103
4.3.7	NGS Impact on Pricing.....	104
4.3.8	Whole Genome Sequencing, A Brave New World .....	104
4.3.9	Companion Diagnostics Blurs Diagnosis and Treatment .....	104
4.3.10	Shifting Role of Diagnostics.....	106
5	Companion Diagnostics Recent Developments.....	108
5.1	Recent Developments – Importance and How to Use This Section .....	109
5.1.1	Importance of These Developments .....	109
5.1.2	How to Use This Section.....	109
5.2	JaxBio to Create Array-Based Cancer Tests .....	109
5.3	Agilent, Qiagen Win FDA Approvals Companion Diagnostics .....	113
5.4	Navignostics Using Single-Cell Spatial Proteomics .....	114
5.5	HMNC Brain Health to Develop Companion Diagnostics .....	117
5.6	Propath UK, Nucleai Partner on Spatial Proteomics.....	118
5.7	Becton Dickinson, Labcorp Collaborate for Flow Cytometry-Based Companion Diagnostics.....	118

5.8	Almac, AstraZeneca Strike CDx Development Pact .....	119
5.9	Avalon GloboCare, Lu Daopei Hematology Institute to Develop Cell Therapy CDx ..	120
5.10	Burning Rock Secures Lung Cancer NGS Test Approval in China.....	121
5.11	TenSixteen Bio Developing Drugs, Companion NGS Tests.....	121
5.12	Guardant Health Plans New Comprehensive Assay.....	124
5.13	Thermo Fisher, Oncocyte Ink Comarketing Deal for Cancer IVDs.....	127
5.14	Qiagen, Denovo Biopharma to Develop Liquid Biopsy CDx Test .....	128
5.15	Japanese Approves Thermo Fisher Scientific Oncomine Assay as CDx.....	129
5.16	Promega, Henlius to Develop Microsatellite Instability CDx for Cancer Drug.....	130
5.17	Natera Aims to Lead Market in Solid Tumor Adjuvant CDx .....	131
5.18	Oncocyte Details Expansions Plans .....	135
5.19	Agilent Acquires Resolution Biosciences .....	138
5.20	Qiagen, Inovio Expand CDx Partnership .....	141
5.21	AmoyDx, AstraZeneca Strike Ovarian Cancer CDx Alliance .....	142
5.22	NeoGenomics to Grow Through CDx Agreements, Acquisitions.....	142
5.23	Personalis Neoantigen Platform Driving Improved Immunotherapy Prediction .....	148
5.24	Biocartis Collaborating with Endpoint Health on CDx Tests for Idylla Platform .....	151
5.25	FDA Approves Foundation Medicine Test as CDx for Three Targeted Therapies .....	153
5.26	Promega to Develop MSI Assay as CDx.....	158
5.27	Guardant Health to Develop CDx for Janssen.....	159
5.28	Burning Rock Bio, CStone Pharmaceuticals to Codevelop CDx .....	159
5.29	FDA Approval for FoundationOne®CDx.....	160
5.30	FDA finalizes CDx Guidance.....	161
5.31	QIAGEN Launches CDx Therascreen BRAF Test.....	163



6	Profiles of Key Players.....	164
6.1	10x Genomics, Inc.....	165
6.2	Abbott Laboratories.....	167
6.3	AccuraGen Inc. ....	169
6.4	Adaptive Biotechnologies.....	170
6.5	Aethlon Medical .....	172
6.6	Agilent/Dako .....	173
6.7	Anchor Dx.....	176
6.8	ANGLE plc.....	178
6.9	ARUP Laboratories.....	179
6.10	AVIVA Systems Biology.....	181
6.11	Baylor Miraca Genetics Laboratories .....	182
6.12	Beckman Coulter Diagnostics.....	183
6.13	Becton, Dickinson and Company .....	184
6.14	BGI Genomics Co. Ltd .....	186
6.15	Bioarray Genetics.....	188
6.16	Biocartis.....	189
6.17	Biocept, Inc.....	190
6.18	Biodesix Inc. ....	192
6.19	BioFluidica.....	193
6.20	BioGenex .....	194
6.21	BioIVT .....	196
6.22	Biolidics Ltd.....	197
6.23	bioMérieux Diagnostics.....	198

6.24	Bioneer Corporation .....	201
6.25	Bio-Rad Laboratories, Inc.....	203
6.26	Bio-Reference Laboratories.....	206
6.27	Bio-Techne .....	208
6.28	Bioview .....	210
6.29	Bolidics .....	212
6.30	Boreal Genomics.....	213
6.31	Bristol-Myers Squibb.....	214
6.32	Burning Rock.....	216
6.33	Cardiff Oncology .....	218
6.34	Caris Molecular Diagnostics.....	219
6.35	Castle Biosciences, Inc. ....	220
6.36	CellCarta .....	221
6.37	CellMax Life .....	222
6.38	Cepheid (Danaher) .....	223
6.39	Charles River Laboratories.....	225
6.40	Circulogene.....	227
6.41	Cizzle Biotech .....	228
6.42	Clinical Genomics .....	229
6.43	Cytolumina Technologies Corp. ....	230
6.44	Datar Cancer Genetics Limited.....	231
6.45	Diagnologix LLC.....	232
6.46	Diasorin S.p.A.....	233
6.47	Dxcover.....	236

6.48	Element Biosciences .....	237
6.49	Enzo Biochem .....	238
6.50	Epic Sciences.....	240
6.51	Epigenomics AG.....	241
6.52	Eurofins Scientific .....	242
6.53	Fabric Genomics .....	245
6.54	Fluxion Biosciences.....	246
6.55	Freenome.....	247
6.56	FUJIFILM Wako Diagnostics.....	248
6.57	Fyr Diagnostics.....	249
6.58	GeneFirst Ltd. ....	251
6.59	Genetron Holdings .....	252
6.60	GenomOncology .....	254
6.61	GILUPI Nanomedizin.....	255
6.62	Guardant Health .....	256
6.63	HansaBiomed .....	257
6.64	HeiScreen.....	258
6.65	Helomics.....	260
6.66	HTG Molecular Diagnostics .....	262
6.67	iCellate.....	264
6.68	Illumina .....	266
6.69	Incell Dx.....	267
6.70	Inivata .....	268
6.71	INOVIQ .....	269

6.72	Integrated Diagnostics .....	270
6.73	Invitae Corporation.....	271
6.74	Invivogen .....	272
6.75	Invivoscribe .....	274
6.76	Janssen Diagnostics .....	275
6.77	Lunglife AI Inc .....	276
6.78	MDNA Life SCIENCES, Inc.....	277
6.79	MDx Health .....	278
6.80	Menarini Silicon Biosystems.....	280
6.81	Mesa Laboratories, Inc. ....	281
6.82	Millipore Sigma .....	283
6.83	Miltenyi Biotec .....	284
6.84	miR Scientific.....	285
6.85	Myriad Genetics/Myriad RBM .....	286
6.86	NantHealth, Inc. ....	288
6.87	Natera .....	290
6.88	NeoGenomics .....	292
6.89	NGeneBio.....	294
6.90	Novogene Bioinformatics Technology Co., Ltd.....	297
6.91	Oncocyte.....	299
6.92	OncoDNA .....	300
6.93	Ortho Clinical Diagnostics .....	301
6.94	Oxford Nanopore Technologies .....	303
6.95	PamGene .....	305

6.96	Panagene.....	306
6.97	Perkin Elmer.....	307
6.98	Personal Genome Diagnostics.....	309
6.99	Personalis.....	310
6.100	Precipio.....	311
6.101	Precision Medicine Group.....	312
6.102	PrecisionMed.....	313
6.103	Predicine.....	314
6.104	Promega.....	315
6.105	Qiagen.....	317
6.106	Rarecells SAS.....	320
6.107	RareCyte.....	321
6.108	Roche Molecular Diagnostics.....	322
6.109	ScreenCell.....	324
6.110	Sema4 Holdings.....	325
6.111	Sense Biodetection.....	327
6.112	Siemens Healthineers.....	329
6.113	simfo GmbH.....	331
6.114	Singlera Genomics Inc.....	332
6.115	Singular Genomics.....	333
6.116	Singulomics.....	335
6.117	SkylineDx.....	337
6.118	Standard BioTools.....	338
6.119	Stilla Technologies.....	340

6.120	Sysmex Inostics.....	341
6.121	Tempus Labs, Inc.....	342
6.122	Thermo Fisher Scientific Inc.....	343
6.123	Todos Medical.....	346
6.124	Ultima Genomics.....	347
6.125	Veracyte.....	349
6.126	Volition.....	350
6.127	Vortex Biosciences.....	351
6.128	Vyant Bio.....	352
7	The Global Market for Companion Diagnostics.....	353
7.1	Global Market Overview by Country.....	354
7.1.1	Table – Global Market by Country.....	354
7.1.2	Chart - Global Market by Country.....	355
7.2	Global Market by Application - Overview.....	356
7.2.1	Table – Global Market by Application.....	356
7.2.2	Chart – Global Market by Application – Base/Final Year Comparison.....	357
7.2.3	Chart – Global Market by Application – Base Year.....	358
7.2.4	Chart – Global Market by Application – Final Year.....	359
7.2.5	Chart – Global Market by Application – Share by Year.....	360
7.3	Global Market Funding Source - Overview.....	361
7.3.1	Table – Global Market by Funding Source.....	361
7.3.2	Chart – Global Market Funding Source – Base/Final Year Comparison.....	362
7.3.3	Chart – Global Market Funding Source – Base Year.....	363
7.3.4	Chart – Global Market Funding Source – Final Year.....	364

7.3.5	Chart – Global Market Funding Source – Share by Year .....	365
7.4	Global Market Technology - Overview .....	366
7.4.1	Table – Global Market by Technology .....	366
7.4.2	Chart – Global Market Technology – Base/Final Year Comparison.....	367
7.4.3	Chart – Global Market Technology – Base Year.....	368
7.4.4	Chart – Global Market Technology – Final Year .....	369
7.4.5	Chart – Global Market Technology – Share by Year.....	370
8	Global Companion Diagnostic Markets – By Application.....	371
8.1	Oncology.....	372
8.1.1	Table Oncology – by Country .....	372
8.1.2	Chart - Oncology Growth.....	373
8.2	Neurology .....	374
8.2.1	Table Neurology – by Country.....	374
8.2.2	Chart - Neurology Growth.....	375
8.3	Cardiology.....	376
8.3.1	Table Cardiology – by Country .....	376
8.3.2	Chart - Cardiology Growth.....	377
8.4	Other Application .....	378
8.4.1	Table Other Application – by Country.....	378
8.4.2	Chart - Other Application Growth .....	379
9	Global Companion Diagnostic Markets – Funding Source .....	380
9.1	Global Market Pharmaceutical.....	381
9.1.1	Table Pharmaceutical – by Country.....	381
9.1.2	Chart - Pharmaceutical Growth .....	382

9.2	Global Market Venture.....	383
9.2.1	Table Venture – by Country.....	383
9.2.2	Chart - Venture Growth.....	384
9.3	Global Market Clinical.....	385
9.3.1	Table Clinical – by Country.....	385
9.3.2	Chart - Clinical Growth.....	386
9.4	Global Market Other Funding.....	387
9.4.1	Table Other Funding – by Country.....	387
9.4.2	Chart - Other Funding Growth.....	388
10	Global Companion Diagnostic Markets – Technology.....	389
10.1	Global Market Next Generation Sequencing.....	390
10.1.1	Table Next Generation Sequencing – by Country.....	390
10.1.2	Chart - Next Generation Sequencing Growth.....	391
10.2	Global Market PCR.....	392
10.2.1	Table PCR – by Country.....	392
10.2.2	Chart - PCR Growth.....	393
10.3	Global Market IHC/ISH.....	394
10.3.1	Table IHC/ISH – by Country.....	394
10.3.2	Chart - IHC/ISH Growth.....	395
10.4	Global Market Other Technology.....	396
10.4.1	Table Other Technology – by Country.....	396
10.4.2	Chart - Other Technology Growth.....	397
11	Appendices.....	398
11.1	United States Medicare System: Clinical Laboratory Fees Schedule.....	399



11.2	The Most Used IVD Assays.....	502
11.3	The Highest Grossing Assays .....	507
11.4	Pharmacogenomic Biomarkers in Drug Labeling.....	514

## Table of Tables

Table 1 FDA Approved Companion Dx.....	30
Table 2 Market Players by Type .....	61
Table 3 The Base Pairs.....	79
Table 4 Five Factors Driving Growth .....	92
Table 5 Four Factors Limiting Growth .....	97
Table 6 Seven Key Diagnostic Laboratory Technology Trends .....	99
Table 7 Global Companion Diagnostic Market by Region.....	354
Table 8 Global Market by Application .....	356
Table 9 Global Market by Funding Source .....	361
Table 10 Global Market by Technology .....	366
Table 11 Oncology by Country .....	372
Table 12 Neurology by Country.....	374
Table 13 Cardiology by Country .....	376
Table 14 Other Application by Country.....	378
Table 15 Pharmaceutical by Country .....	381
Table 16 Venture by Country.....	383
Table 17 Clinical by Country.....	385
Table 18 Other Funding by Country .....	387
Table 19 Next Generation Sequencing by Country .....	390
Table 20 PCR by Country .....	392
Table 21 IHC/ISH by Country.....	394
Table 22 Other Technology by Country.....	396

Table 23 Clinical Laboratory Fee Schedule.....	399
Table 24 The Most Common Assays.....	502
Table 25 Largest Revenue Assays.....	507
Table 26 Pharmacogenomic Biomarkers .....	514

## Table of Figures

Figure 1 Global Healthcare Spending .....	56
Figure 2 The Lab Test Pie - Wholesale & Retail.....	57
Figure 3 The Road to Diagnostics .....	60
Figure 4 DNA Strands and Chromosomes .....	76
Figure 5 Karyogram of Human Chromosomes.....	77
Figure 6 Size of Various Genomes .....	80
Figure 7 Germline vs Somatic Mutations.....	84
Figure 8 Comparing Genomic Diagnostic and Traditional Testing .....	86
Figure 9 The Changing Age of The World's Population.....	94
Figure 10 Health Care Consumption by Age .....	95
Figure 11 Cancer Incidence by Age .....	95
Figure 12 Centralized vs. Decentralized Laboratory Service .....	100
Figure 13 A Highly Multiplexed Syndromic Testing Unit.....	101
Figure 14 The Real Cost to Sequence the Human Genome.....	103
Figure 15 The Codevelopment Process .....	105
Figure 16 Comparing MDx Diagnostic and Traditional Testing .....	107
Figure 17 Base Year Country Market Share Chart .....	355
Figure 18 CDx Market by Application - Base vs. Final Year .....	357
Figure 19 CDx Market by Application Base Year .....	358
Figure 20 CDx Market by Application Final Year.....	359
Figure 21 Application Type Share by Year.....	360

Figure 22 Funding Source – Base vs. Final Year .....	362
Figure 23 Funding Source Market Base Year .....	363
Figure 24 Funding Source Market Final Year .....	364
Figure 25 Funding Source Share by Year .....	365
Figure 26 Technology – Base vs. Final Year .....	367
Figure 27 Technology Market Base Year .....	368
Figure 28 Technology Market Final Year .....	369
Figure 29 Technology Share by Year .....	370
Figure 30 Oncology Growth .....	373
Figure 31 Neurology Growth .....	375
Figure 32 Cardiology Growth .....	377
Figure 33 Other Application Growth .....	379
Figure 34 Pharmaceutical Growth .....	382
Figure 35 Venture Growth .....	384
Figure 36 Clinical Growth .....	386
Figure 37 Other Funding Growth .....	388
Figure 38 Next Generation Sequencing Growth .....	391
Figure 39 PCR Growth .....	393
Figure 40 IHC/ISH Growth .....	395
Figure 41 Other Technology Growth .....	397