

RESEARCH REPORT



Genetic Testing Markets.

Global Market Analysis with Forecasts by Applications,
Technologies, Product and User. With Executive and Consultant
Guides.

2024 to 2028





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 X-Ray 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	25
1.1	Genetic Testing - Strategic Situation Analysis	26
1.2	Guide for Executives, Marketing, Sales and Business Development Staff	28
1.3	Guide for Management Consultants and Investment Advisors	30
2	Introduction and Market Definition	32
2.1	Genetic Testing Definition in This Report.....	33
2.2	The Genomics Revolution.....	34
2.3	Market Definition	36
2.3.1	Revenue Market Size.....	36
2.3.2	Newborn Screening	37
2.3.3	Non Invasise Pregnancy Testing.....	37
2.3.4	Predictive	37
2.3.5	Oncology	37
2.3.6	Direct to Consumer	37
2.3.7	Other Application.....	38
2.3.8	PCR	38
2.3.9	NGS.....	38
2.3.10	Cytogenetic.....	38
2.3.11	Other Technology.....	38
2.4	Methodology.....	39
2.4.1	Methodology.....	39

2.4.2	Sources	39
2.4.3	Authors	39
2.5	Perspective: Healthcare and the IVD Industry	41
2.5.1	Global Healthcare Spending	41
2.5.2	Spending on Diagnostics	42
2.5.3	Important Role of Insurance for Diagnostics	44
2.6	Chromosomes, Genes and Epigenetics.....	45
2.6.1	Chromosomes	45
2.6.2	Genes	47
2.6.3	Epigenetics	50
3	Market Overview.....	52
3.1	Players in a Dynamic Market.....	53
3.1.1	Academic Research Lab	54
3.1.2	Diagnostic Test Developer.....	54
3.1.3	Instrumentation Supplier	55
3.1.4	Chemical/Reagent Supplier.....	55
3.1.5	Pathology Supplier	55
3.1.6	Independent Clinical Laboratory	56
3.1.7	Public National/regional Laboratory	56
3.1.8	Hospital Laboratory	57
3.1.9	Physicians Office Lab (POLs)	57
3.1.10	Audit Body.....	58
3.1.11	Certification Body.....	58
3.2	Genetic Tests –Types, Examples and Discussion	60

- 3.2.1 Preimplantation Genetic Diagnosis- An Emerging Market 60
- 3.2.2 Prenatal Diagnosis – New Technologies Create Opportunity 61
- 3.2.3 Newborn Screening 61
- 3.2.4 Diagnostic Testing 62
- 3.2.5 Carrier Testing 62
- 3.2.6 Predictive and Presymptomatic Testing..... 63
- 3.2.7 Pharmacogenomics 63
- 3.2.8 Forensic Testing..... 64
- 3.2.9 Parental Testing 64
- 3.2.10 Ancestral Testing..... 64
- 3.3 Industry Structure 66
 - 3.3.1 Hospital's Testing Share 66
 - 3.3.2 Economies of Scale 66
 - 3.3.3 Hospital vs. Central Lab 67
 - 3.3.4 Physician Office Lab's 68
 - 3.3.5 Physician's and POCT 68
- 4 Market Trends 69
 - 4.1 Factors Driving Growth 70
 - 4.1.1 Genetic Discoveries Impact..... 70
 - 4.1.2 The Aging Effect 71
 - 4.1.3 Pharmacogenomics 73
 - 4.1.4 Oncology and Liquid Biopsy Factors 74
 - 4.1.5 Fertility Practice 74
 - 4.1.6 Direct to Consumer 74

4.2	Factors Limiting Growth	75
4.2.1	The Competition Effect	75
4.2.2	The Cost Situation	76
4.2.3	Testing usage analysis	76
4.2.4	Wellness Effects.....	76
4.3	Instrumentation, Automation and Diagnostic Trends	78
4.3.1	Traditional Automation and Centralization.....	78
4.3.2	The New Automation, Decentralization and Point of Care.....	78
4.3.3	Instruments Key to Market Share.....	80
4.3.4	Bioinformatics Plays a Role	80
4.3.5	PCR Takes Command.....	81
4.3.6	Next Generation Sequencing Fuels a Revolution.....	82
4.3.7	NGS Impact on Pricing.....	83
4.3.8	Whole Genome Sequencing, A Brave New World	83
4.3.9	Companion Diagnostics Blurs Diagnosis and Treatment	84
4.3.10	Shifting Role of Diagnostics.....	85
5	Genetic Testing Recent Developments	87
5.1	Recent Developments.....	88
5.1.1	Importance of This Section	88
5.1.2	How to Use This Section.....	88
5.2	Revvity Launches NGS Panel for Newborn Screening	88
5.3	LetsGetChecked: MyGeneticScreen	92
5.4	Systemex, Hitachi to Develop Low-Cost Sequencers	93
5.5	Fore Genomics Offering WGS Newborn Screening to Parents	93

5.6	Clinical Validation of Long-Read WGS Assay	97
5.7	Resolution Bio Acquisition - Exact Sciences Aims at Liquid Biopsy Market	101
5.8	Novitas Rescinds Coverage for Multiple Genetic Tests.....	106
5.9	PerkinElmer (now Revvity) Becomes Dx Life Science Firm	108
5.10	New POC Genotyping Tests Based on Electromagnetic Detection.....	112
5.11	GenoMe Dx Launching dPCR Cancer Test.....	116
5.12	mDetect To Trial Breast Cancer Liquid Biopsy.....	119
5.13	Genomics England, Aims to Sequence 100K Newborns	127
5.14	Juno Diagnostics NIPT With At-Home Sample Collection	130
5.15	Cardio Diagnostics Launches Genetic Cardio Risk Test.....	134
5.16	Universal Genetic Testing in Breast Cancer Further Supported.....	137
5.17	Aniling Gets CE-IVD Marks for Cancer Sequencing Tests	139
5.18	MyOme Lands Investment for WGS	139
5.19	Type 2 Diabetes GWAS Enables Risk Prediction.....	140
5.20	LetsGetChecked to Acquire Veritas Genetics	142
5.21	Guardant Health Plans New Comprehensive Assay.....	143
5.22	Tesis Labs Raises \$20M.....	146
5.23	Sema4: Sema4 Elements	147
5.24	Clarified Precision Medicine Acquires Interpares Biomedicine.....	147
5.25	Genetic Technologies to Acquire DTC Genetic Test Provider EasyDNA	148
5.26	Illumina, Belgium Genetic Centers Partner on WGS-Based Dx.....	148
5.27	NIH, Genomics England Launch Sequencing Studies Using Nanopore Technology	149
5.28	Progenity Revenues Fall on COVID-19 Effect.....	150
5.29	Natera Launches Tumor Genomic Profiling Assay	152

5.30	23andMe To Go Public	155
5.31	Guardant Health to Offer Tumor Tissue Sequencing.....	156
5.32	Ancestry Quits Health Offering.....	160
5.33	DTC Firm MyDNA Merges With Gene by Gene	164
6	Profiles of Key Companies.....	165
6.1	10x Genomics, Inc.....	166
6.2	23andME Inc.....	168
6.3	Abbott Laboratories.....	169
6.4	Adaptive Biotechnologies.....	171
6.5	Admera Health, LLC.....	173
6.6	Agilent	174
6.7	Akonni Biosystems	176
6.8	Amoy Diagnostics Co., Ltd.	177
6.9	Ancestry.com LLC	178
6.10	Anchor Dx.....	180
6.11	Arrayit Corporation	182
6.12	ARUP Laboratories.....	184
6.13	Aus Diagnostics	186
6.14	BaseClear.....	187
6.15	Baylor Miraca Genetics Laboratories	188
6.16	Beckman Coulter Diagnostics (Danaher)	189
6.17	Becton, Dickinson and Company	190
6.18	BGI Genomics Co. Ltd	192
6.19	Bioarray Genetics.....	194

6.20	BioBam	195
6.21	Biocept, Inc.....	196
6.22	Biodesix Inc.	197
6.23	BioFluidica.....	198
6.24	BioGenex	199
6.25	BioGX.....	201
6.26	Biolidics Ltd.....	202
6.27	bioMérieux Diagnostics.....	203
6.28	Bioneer Corporation	206
6.29	Bio-Rad Laboratories, Inc.....	208
6.30	Bio-Techne	209
6.31	Burning Rock.....	211
6.32	C2i Genomics.....	213
6.33	Cantata Bio	214
6.34	CareDx	215
6.35	Caris Molecular Diagnostics	216
6.36	Celemics	217
6.37	CellMax Life	218
6.38	Centogene	219
6.39	Cepheid (Danaher)	220
6.40	Circulogene.....	222
6.41	Clearbridge Biomedics	223
6.42	Clinical Genomics	224
6.43	Color Genomics	225

6.44	Complete Genomics (MGI Tech)	226
6.45	CosmosID	227
6.46	Dante Labs.....	228
6.47	Datar Cancer Genetics Limited.....	230
6.48	Diasorin S.p.A.	231
6.49	DNAe	232
6.50	Easy DNA.....	233
6.51	Element Biosciences	234
6.52	Epic Sciences.....	236
6.53	Epigenomics AG.....	237
6.54	Eurofins Scientific	238
6.55	Excellerate Bioscience.....	239
6.56	Fabric Genomics	240
6.57	Freenome.....	241
6.58	FUJIFILM Wako Diagnostics.....	242
6.59	Fujirebio	243
6.60	Fulgent Genetics	244
6.61	Gene by Gene, Ltd.....	246
6.62	Genedrive.....	248
6.63	GeneDx Holdings	249
6.64	GeneFirst Ltd.....	250
6.65	Genetic Technologies Ltd.	251
6.66	Genetron Holdings	252
6.67	Genomics England	253

6.68	Genomics Personalized Health (GPH)	255
6.69	GenomOncology.....	256
6.70	Genzyme Corporation.....	257
6.71	Grifols.....	259
6.72	Guardant Health	261
6.73	Guardiome	262
6.74	Helix	264
6.75	Hologic	265
6.76	HTG Molecular Diagnostics	267
6.77	Human Longevity, Inc.	268
6.78	iCellate	270
6.79	Illumina	271
6.80	Incell Dx.....	272
6.81	Inivata	273
6.82	Invitae Corporation.....	274
6.83	Invivoscribe	275
6.84	Karius	276
6.85	Letsgetchecked	278
6.86	Lunglife AI Inc	279
6.87	Macrogen.....	280
6.88	MDNA Life SCIENCES, Inc.....	281
6.89	MDx Health	282
6.90	Medgenome	283
6.91	Menarini Silicon Biosystems.....	284

6.92	Meridian Bioscience.....	285
6.93	Mesa Laboratories, Inc.	287
6.94	Metabionics Corp	289
6.95	miR Scientific.....	290
6.96	NantHealth, Inc.	292
6.97	Natera	294
6.98	Nebula Genomics	296
6.99	NeoGenomics	297
6.100	New England Biolabs, Inc.	298
6.101	NGeneBio.....	299
6.102	Norgen Biotek Corp.	300
6.103	Novogene.....	301
6.104	Omega Bioservices	302
6.105	Oncocyte.....	304
6.106	OncoDNA	305
6.107	OpGen	306
6.108	Origene Technologies.....	308
6.109	Oxford Nanopore Technologies.....	309
6.110	Pacific Biosciences.....	311
6.111	Panagene.....	312
6.112	PathoQuest S.A.....	313
6.113	Personalis.....	314
6.114	PGDx (Labcorp).....	315
6.115	Precipio	316

6.116	PrecisionMed	317
6.117	Predictive Oncology	318
6.118	Promega	320
6.119	Qiagen	322
6.120	QuantuMDx	324
6.121	Revvity	325
6.122	Roche Diagnostics	327
6.123	Roswell Biotechnologies.....	329
6.124	Seegene.....	330
6.125	Sequencing.com.....	331
6.126	Siemens Healthineers	333
6.127	simfo GmbH	334
6.128	Singlera Genomics Inc.....	335
6.129	Singular Genomics	336
6.130	SkylineDx.....	338
6.131	Standard BioTools	339
6.132	Sysmex.....	341
6.133	Sysmex Inostics.....	343
6.134	Tempus Labs, Inc.	344
6.135	Thermo Fisher Scientific	345
6.136	Ultima Genomics	347
6.137	Ultima Genomics	348
6.138	Variantyx	349
6.139	Vela Diagnostics.....	350

6.140	VolitionRX	351
6.141	Zymo Research Corp	352
7	Global Market Size	353
7.1	Global Market by Country.....	354
7.1.1	Table – Global Market by Country.....	354
7.1.2	Chart – Country Market Shares	355
7.2	Global Market by Application	356
7.2.1	Table – Global Market by Application	356
7.2.2	Chart – Application Share by Year	357
7.2.3	Chart – Application Segment Growth Rates	358
7.2.4	Chart – Application Segment Share Shifts.....	359
7.2.5	Chart – Application Segment Share Base Year	360
7.2.6	Chart – Application Segment Share Final Year	361
7.3	Global Market by Technology	362
7.3.1	Table – Global Market by Technology	362
7.3.2	Chart – Technology Share by Year	363
7.3.3	Chart – Technology Segment Growth Rates	364
7.3.4	Chart – Technology Segment Share Shifts.....	365
7.3.5	Chart – Technology Segment Share Base Year	366
7.3.6	Chart – Technology Segment Share Final Year	367
7.4	Global Market by Product.....	368
7.4.1	Table – Global Market by Product.....	368
7.4.2	Chart – Product Share by Year.....	369
7.4.3	Chart – Product Segment Growth Rates.....	370

7.4.4	Chart – Product Segment Share Shifts	371
7.4.5	Chart – Product Segment Share Base Year	372
7.4.6	Chart – Product Segment Share Final Year.....	373
7.5	Global Market by User	374
7.5.1	Table – Global Market by User	374
7.5.2	Chart – User Share by Year	375
7.5.3	Chart – User Segment Growth Rates	376
7.5.4	Chart – User Segment Share Shifts	377
7.5.5	Chart – User Segment Share Base Year.....	378
7.5.6	Chart – User Segment Share Final Year	379
8	Market Sizes by Application	380
8.1	Newborn Testing Market.....	381
8.1.1	Table Newborn – by Country.....	381
8.1.2	Chart – Newborn Growth	382
8.2	NIPT Market	383
8.2.1	Table NIPT – by Country	383
8.2.2	Chart – NIPT Growth	384
8.3	Predictive Testing Market	385
8.3.1	Table Predictive – by Country	385
8.3.2	Chart – Predictive Growth	386
8.4	Oncology Testing Market	387
8.4.1	Table Oncology – by Country	387
8.4.2	Chart – Oncology Growth	388
8.5	DTC Testing Market	389

8.5.1	Table DTC – by Country	389
8.5.2	Chart – DTC Growth	390
8.6	Other Testing Market.....	391
8.6.1	Table Other – by Country	391
8.6.2	Chart – Other Growth	392
9	Global Genetic Testing Market by Technology.....	393
9.1	PCR Testing Market	394
9.1.1	Table PCR – by Country	394
9.1.2	Chart – PCR Growth.....	395
9.2	NGS Market.....	396
9.2.1	Table NGS – by Country.....	396
9.2.2	Chart – NGS Growth.....	397
9.3	Cytogenetic Testing Market.....	398
9.3.1	Table Cytogenetic – by Country.....	398
9.3.2	Cytogenetic – Predictive Growth	399
9.4	Other Testing Market.....	400
9.4.1	Table Other – by Country	400
9.4.2	Chart – Other Growth	401
10	Global Genetic Testing Market by Product.....	402
10.1	Instruments Market	403
10.1.1	Table Instruments – by Country	403
10.1.2	Chart – Instrument Growth.....	404
10.2	Reagents and Kits Market.....	405
10.2.1	Table Reagents and Kits – by Country	405

10.2.2	Chart – Reagents and Kits Growth.....	406
10.3	Software Market.....	407
10.3.1	Table Software – by Country	407
10.3.2	Software Growth.....	408
10.4	Services Market	409
10.4.1	Table Services – by Country.....	409
10.4.2	Chart – Services Growth	410
11	Global Genetic Testing Market by User	411
11.1	Academic Market.....	412
11.1.1	Table Academic – by Country	412
11.1.2	Chart – Academic Growth.....	413
11.2	Clinical Market.....	414
11.2.1	Table Clinical – by Country.....	414
11.2.2	Chart – Clinical Growth.....	415
11.3	Pharmaceutical Market.....	416
11.3.1	Table Pharmaceutical – by Country	416
11.3.2	Pharmaceutical – Predictive Growth	417
11.4	Industrial and Other Market	418
11.4.1	Table Industrial and Other – by Country.....	418
11.4.2	Chart – Industrial and Other Growth.....	419
12	The Future of Genetic Testing	420
13	Appendices.....	421
13.1	Growth of Approved IVD Test Menu	422
13.2	Growth of Approved Average IVD Test Fee	423

13.3	The Most Used IVD Assays.....	424
13.4	The Highest Grossing Assays	429
13.5	Laboratory Fees Schedule.....	436

Table of Tables

Table 1 Most Common Traditional Genetic Disorders	34
Table 2 The Base Pairs.....	48
Table 3 Market Players by Type	54
Table 4 The Different Types of Genetic Tests	60
Table 5 Five Factors Driving Growth	70
Table 6 Four Factors Limiting Growth	75
Table 7 Seven Key Diagnostic Laboratory Technology Trends	78
Table 8 Global Market by Country.....	354
Table 9 Global Market by Application	356
Table 10 Global Market by Technology	362
Table 11 Global Market by Product.....	368
Table 12 Global Market by User	374
Table 13 Newborn Segment by Country	381
Table 14 NIPT Segment by Country	383
Table 15 Predictive Segment by Country	385
Table 16 Oncology Segment by Country.....	387
Table 17 DTC Segment by Country	389
Table 18 Other Segment by Country	391
Table 19 PCR Segment by Country.....	394
Table 20 NGS Segment by Country.....	396
Table 21 Cytogenetic Segment by Country	398

Table 22 Other Segment by Country	400
Table 23 Instruments Segment by Country	403
Table 24 Reagents and Kits Segment by Country	405
Table 25 Software Segment by Country	407
Table 26 Services Segment by Country	409
Table 27 Academic Segment by Country.....	412
Table 28 Clinical Segment by Country	414
Table 29 Pharmaceutical Segment by Country.....	416
Table 30 Industrial and Other Segment by Country	418
Table 31 The Most Common Assays.....	424
Table 32 Largest Revenue Assays.....	429
Table 33 Clinical Lab Fee Schedule	436

Table of Figures

Figure 1 Global Health Care Spending.....	42
Figure 2 The Lab Test Pie	43
Figure 3 DNA Strands and Chromosomes	45
Figure 4 Karyogram of Human Chromosomes.....	46
Figure 5 Size of Various Genomes	49
Figure 6 The Road to Diagnostics	53
Figure 7 The Changing Age of the World Population.....	72
Figure 8 Health Care Consumption by Age	72
Figure 9 Cancer Incidence - Age at Diagnosis.....	73
Figure 10 Centralized vs. Decentralized Laboratory Service	79
Figure 11 A Highly Multiplexed Syndromic Testing Unit.....	79
Figure 12 The Real Cost to Sequence the Human Genome.....	82
Figure 13 The Codevelopment Process	84
Figure 14 Comparing MDx Diagnostic and Traditional Testing.....	86
Figure 15 Country Market Shares.....	355
Figure 16 Application Share by Year.....	357
Figure 17 Application Segment Growth Rates.....	358
Figure 18 Segment Share Shifts	359
Figure 19 Application Segment Share Base Year	360
Figure 20 Application Segment Share Final Year.....	361
Figure 21 Technology Share by Year.....	363

Figure 22 Technology Segment Growth Rates.....	364
Figure 23 Technology Segment Share Shifts	365
Figure 24 Technology Segment Share Base Year	366
Figure 25 Technology Segment Share Final Year.....	367
Figure 26 Product Share by Year	369
Figure 27 Product Segment Growth Rates	370
Figure 28 Product Segment Share Shifts.....	371
Figure 29 Product Segment Share Base Year	372
Figure 30 Product Segment Share Final Year	373
Figure 31 User Share by Year	375
Figure 32 User Segment Growth Rates.....	376
Figure 33 User Segment Share Shifts.....	377
Figure 34 User Segment Share Base Year	378
Figure 35 User Segment Share Final Year.....	379
Figure 36 Newborn vs. Total Market Growth	382
Figure 37 NIPT vs. Total Market Growth	384
Figure 38 Predictive vs. Total Market Growth	386
Figure 39 Oncology vs. Total Market Growth	388
Figure 40 DTC vs. Total Market Growth	390
Figure 41 Other vs. Total Market Growth	392
Figure 42 PCR vs. Total Market Growth	395
Figure 43 NGS vs. Total Market Growth.....	397
Figure 44 Cytogenetic vs. Total Market Growth.....	399
Figure 45 Other vs. Total Market Growth	401

Figure 46 Instrument vs. Total Market Growth..... 404

Figure 47 Reagents and Kits vs. Total Market Growth..... 406

Figure 48 Software vs. Total Market Growth 408

Figure 49 Services vs. Total Market Growth 410

Figure 50 Academic vs. Total Market Growth 413

Figure 51 Clinical vs. Total Market Growth..... 415

Figure 52 Pharmaceutical vs. Total Market Growth..... 417

Figure 53 Industrial and Other vs. Total Market Growth..... 419

Figure 54 IVD Test Menu Growth 422

Figure 55 IVD Test Average Fees – A Ten Year View..... 423