

COVID-19 IMPACT

This report has been affected by the COVID-19 pandemic. All forecasts and analysis have been revised to reflect the current view including the effect of the pandemic and associated recession.

RESEARCH REPORT



Genetic Testing.

Global Market Forecasts for Applications and Technologies.

Updated for COVID-19 Pandemic impact

With Executive and Consultant Guides

2021 to 2025





Call: 604 377 8604

Email: service@howesoundresearch.com

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

i. Genetic Testing - Strategic Situation Analysis & Impact of COVID-19 Pandemic	21
ii. Guide for Executives, Marketing, Sales and Business Development Staff	23
iii. Guide for Management Consultants and Investment Advisors	25
1. Introduction and Market Definition	27
1.1 Genetic Testing Definition in This Report	28
1.2 The Genomics Revolution	29
1.3 Market Definition	31
1.3.1 Revenue Market Size.....	31
1.3.1 Newborn Screening	32
1.3.2 Non Invasive Pregnancy Testing.....	32
1.3.3 Predictive	32
1.3.4 Oncology	32
1.3.5 Direct to Consumer	32
1.3.6 Other Application.....	32
1.3.7 PCR	33
1.3.4 NGS.....	33
1.3.5 Cytogenetic.....	33
1.3.6 Other Technology	33
1.4 U.S. Medical Market and laboratory Testing - Perspective	34
1.4.1 U.S. Medicare Expenditures for Laboratory Testing	35
2. Market Overview	37

2.1 Market Participants Play Different Roles	38
2.1.1 Supplier/pharmaceutical	39
2.1.2 Independent lab specialized/esoteric	39
2.1.3 Independent lab national/regional.....	39
2.1.4 Independent lab analytical	40
2.1.5 Public National/regional lab	40
2.1.6 Hospital lab	40
2.1.7 Physician lab	41
2.1.8 DTC Lab.....	41
2.1.9 Independent Genetic Testing Lab.....	41
2.1.10 Audit Body.....	42
2.2 Genetic Tests –Types, Examples and Discussion	43
2.2.1 Preimplantation Genetic Diagnosis- An Emerging Market	43
2.2.2 Prenatal Diagnosis – New Technologies Create Opportunity	44
2.2.3 Newborn Screening	44
2.2.2 Diagnostic Testing	45
2.2.3 Carrier Testing	45
2.2.6 Predictive and Presymptomatic Testing.....	46
2.2.7 Pharmacogenomics	46
2.2.8 Forensic Testing.....	47
2.2.9 Parental Testing	47
2.2.10 Ancestral Testing.....	47
2.3 Industry Structure	49
2.3.1 Hospital's Testing Share	49

2.3.2 Economies of Scale.....	49
2.3.2.1 Hospital vs. Central Lab	50
2.3.3 Physician Office Lab's.....	51
2.3.4 Physician's and POCT	51
2.4 Market Shares of Key Genetics Players - Analysis	52
3. Market Trends.....	53
3.1 Factors Driving Growth.....	54
3.1.1 Genetic Discoveries Creating New Diagnostic Markets	54
3.1.2 Aging Population a Boon for Diagnostics.....	55
3.1.3 Pharmacogenomics Drives Further Growth.....	56
3.1.4 Oncology and Liquid Biopsy Enter New Era.....	56
3.1.5 Fertility Practice Growth drives market	57
3.1.6 Direct to Consumer begins to break out.....	57
3.2 Factors Limiting Growth.....	58
3.2.1 Increased Competition Lowers Price.....	58
3.2.2 Lower Costs.....	59
3.2.3 Testing usage analysis curtailing growth.	59
3.2.4 Wellness has a downside	59
3.3 Instrumentation and Automation.....	61
3.3.1 Instruments Key to Market Share	61
3.3.2 Bioinformatics Plays a Role.	61
3.4 Diagnostic Technology Development.....	62
3.4.1 Next Generation Sequencing Fuels a Revolution.....	63
3.4.2 Impact of NGS on pricing	64

3.4.3 POCT/Self Testing Disruptive Force.....	64
3.4.4 Pharmacogenomics Blurs Diagnosis and Treatment.....	65
3.4.5 CGES Testing, A Brave New World	66
3.4.6 Biochips/Giant magneto resistance based assay.....	66
4. Genetic Testing Recent Developments.....	68
4.1.1 Importance of This Section	68
4.1.2 How to Use This Section.....	68
Progenity Revenues Fall on COVID-19 Effect.....	68
Natera Launches Tumor Genomic Profiling Assay.....	70
23andMe To Go Public	73
Guardant Health to Offer Tumor Tissue Sequencing	74
Ancestry Quits Health Offering	77
DTC Firm MyDNA Merges With Gene by Gene.....	82
Aetna Coverage for NIPT to Include All Pregnancies	82
Agios Pharmaceuticals, PerkinElmer Partner on Hereditary Anemia Genetic Testing	83
Tumor, Germline Testing of Cancer Patients Can Give Discordant Results	84
Invitae Completes Acquisition of ArcherDx	86
Prenetics Receives \$15M Investment.....	87
Sanford Health Invests \$800K in TruGenomix as Part of PTSD Test Alliance	88
Preconception Carrier Screening Trial Begins in Australia.....	88
Genetic Testing Clinical Use Just Beginning	89
Fulgent Genetics Q1 Revenues Jump 44 Percent.....	91
Blueprint Genetics, NICER Consortium Developing Genetic Test for Immunologic, Hematologic Disorders.....	92

Natera Terminates Qiagen Agreement for Developing NGS-Based Genetic Tests	93
Invitae Acquires Three Companies: YouScript, Genelex, Diploid.....	94
PerkinElmer SCID Test Chosen for Newborn Screening Evaluation in England	96
Germline Cancer Risk Mutations Sometimes Reported in Tumor Testing	97
Blueprint Genetics, Archimedlife to Launch Genetic Testing in North America	105
Invitae to Offer No-Charge Genetic Testing to Pancreatic Cancer Patients	105
Phosphorus Offers DNA Testing to Assess Disease Risk.....	107
Arivale Shuts Down Personalized Wellness Business	108
ArcherDX Acquires Baby Genes	109
MDxHealth, LifeLabs Ink Distribution Agreement for Prostate Cancer Assay	110
Thermo Fisher Purchases 9 Percent Stake in Yourgene Health	111
Invitae Partners to Expand Free Epilepsy Genetic Testing Program.....	112
Illumina, Chinese Firm Partner on NGS System for Genetic Disease Dx	113
NanoString Technologies Prices \$103.5M Common Stock Offering	114
Canine Consumer Genomics Firm Embark Veterinary Raises \$10M	115
Yourgene Health to Acquire Elucigene.....	115
Helix, AdventHealth Partner on Genetic Screening Study.....	116
5. Profiles of Key Companies	118
10x Genomics, Inc.....	119
23andME Inc.....	120
Abbott Diagnostics	122
AccuraGen Inc.	124
Adaptive Biotechnologies	125
Admerra Health, LLC.....	126

Agena Bioscience, Inc.....	127
Agilent	129
Akronni Biosystems	131
Ancestry.com LLC	132
Anchor Dx	134
ArcherDx, Inc.	135
ARUP Laboratories.....	136
Asuragen.....	138
Baylor Miraca Genetics Laboratories	140
Beckman Coulter, Inc.	141
Becton, Dickinson and Company	143
BGI Genomics Co. Ltd	145
Bioarray Genetics.....	147
Biocept, Inc.....	148
Biodesix Inc.	149
BioFluidica.....	150
BioGenex	151
Biolidics Ltd.....	153
bioMérieux Diagnostics.....	154
Bioneer Corporation	156
Bio-Rad Laboratories, Inc.	158
Bio-Techne	160
Cancer Genetics.....	162
Caris Molecular Diagnostics	164

CellMax Life	165
Centogene	166
Chronix Biomedical.....	170
Circulogene.....	171
Clinical Genomics.....	172
Color Genomics	173
Complete Genomics, Inc. – A BGI Company	174
Cynvenio.....	176
Dante Labs	177
Datar Cancer Genetics Limited.....	179
Diasorin S.p.A.....	180
Epic Sciences.....	181
Epigenomics AG	182
Eurofins Scientific	183
Excellerate Bioscience.....	186
Exosome Diagnostics	187
Fabric Genomics.....	189
Fluidigm Corp	190
Foundation Medicine	192
Freenome.....	193
FUJIFILM Wako Diagnostics.....	194
Fujirebio	195
GE Global Research	196
GE Healthcare Life Sciences	198

Gene by Gene, Ltd.....	200
Genedrive.....	202
GeneFirst Ltd.....	203
Genetron Health (Beijing) Co., Ltd.	204
Genewiz.....	205
Genomic Health.....	206
Genomics England	208
Genomics Personalized Health (GPH)	210
GenomOncology.....	212
Genzyme Corporation.....	213
Grail, Inc.....	215
Grifols.....	217
Guardant Health.....	218
Guardiome	219
HeiScreen.....	221
Helix	222
Helomics.....	224
Hologic	225
Horizon Discovery	227
HTG Molecular Diagnostics	229
Human Longevity, Inc.....	231
iCellate.....	233
Illumina	234
Incell Dx.....	235

Invata	236
Integrated Diagnostics	237
Invitae Corporation.....	238
Invivoscribe	240
Karius	241
Macrogen.....	242
MDNA Life SCIENCES, Inc.....	243
MDx Health	244
Medgenome	245
Meridian Bioscience.....	246
Mesa Biotech.....	248
MIODx.....	249
miR Scientific.....	250
MNG Labs	251
Molecular MD	252
NantHealth, Inc.	253
Natera	255
Nebula Genomics.....	257
NeoGenomics	258
New Oncology	260
Novogene Bioinformatics Technology Co., Ltd.....	261
Omega Bioservices	263
OncoDNA	265
ORIG3N, Inc.	266

Origene Technologies.....	268
Oxford Nanopore Technologies	269
Pacific Biosciences.....	272
Panagene.....	273
Perkin Elmer.....	274
Personal Genome Diagnostics.....	276
Personalis	277
Precipio	278
PrecisionMed	279
Promega	280
Protagen Diagnostics.....	282
Qiagen Gmbh.....	283
Quantumdx	286
Regeneron.....	287
Roche Molecular Diagnostics	289
Roswell Biotechnologies	291
Seegene	292
Sequencing.com.....	294
Siemens Healthineers	296
simfo GmbH	298
Singlera Genomics Inc.....	299
SkylineDx	300
Stratos Genomics	301
Sure Genomics, Inc.....	302

Sysmex.....	304
Sysmex Inostics	305
Tempus Labs, Inc.....	307
Thermo Fisher Scientific Inc.....	308
Veritas Genetics.....	310
Volition	312
6. Global Market Size.....	313
6.1 Global Market by Country	314
6.1.1 Table – Global Market by Country.....	314
6.1.2 Chart – Country Market Shares	315
6.2 Global Market by Application.....	316
6.2.1 Table – Global Market by Application	316
6.2.2 Chart – Application Share by Year	317
6.2.3 Chart – Application Segment Growth Rates	318
6.2.4 Chart – Application Segment Share Shifts.....	319
6.2.5 Chart – Application Segment Share Base Year.....	320
6.2.6 Chart – Application Segment Share Final Year	321
6.3 Global Market by Technology.....	322
6.3.1 Table – Global Market by Technology	322
6.3.2 Chart – Technology Share by Year	323
6.3.3 Chart – Technology Segment Growth Rates	324
6.3.4 Chart – Technology Segment Share Shifts.....	325
6.3.5 Chart – Technology Segment Share Base Year.....	326
6.3.6 Chart – Technology Segment Share Final Year	327

7. Market Sizes by Application.....	328
7.1 Newborn Testing Market	329
7.1.1 Table Newborn – by Country.....	329
7.1.2 Chart – Newborn Growth	330
7.2 NIPT Market	331
7.2.1 Table NIPT – by Country	331
7.2.2 Chart – NIPT Growth	332
7.3 Predictive Testing Market.....	333
7.3.1 Table Predictive – by Country	333
7.3.2 Chart – Predictive Growth	334
7.4 Oncology Testing Market.....	335
7.4.1 Table Oncology – by Country	335
7.4.2 Chart – Oncology Growth	336
7.5 DTC Testing Market.....	337
7.5.1 Table DTC – by Country	337
7.5.2 Chart – DTC Growth	338
7.6 Other Testing Market	339
7.6.1 Table Other – by Country	339
7.6.2 Chart – Other Growth	340
8. Global Genetic Testing Market by Technology	341
8.1 PCR Testing Market.....	342
8.1.1 Table PCR – by Country	342
8.1.2 Chart – PCR Growth	343
8.2 NGS Market	344

8.2.1 Table NGS – by Country	344
8.2.2 Chart – NGS Growth.....	345
8.3 Cytogenetic Testing Market	346
8.3.1 Table Cytogenetic – by Country.....	346
8.3.2 Cytogenetic – Predictive Growth	347
8.4 Other Testing Market	348
8.4.1 Table Other – by Country	348
8.4.2 Chart – Other Growth	349
9. The Future of Genetic Testing	350
Appendices	351
I. United States Medicare System: 2021 laboratory Fees Schedule.....	351
II Methodology	452
II.1 Authors.....	452
II.2 Sources	452

Table of Tables

Table 1 Most Common Traditional Genetic Disorders	29
Table 2 Lab Spending 2014 to 2024	36
Table 3 Market Players by Type	38
Table 4 The Different Types of Genetic Tests	43
Table 5 Five Factors Driving Growth.....	54
Table 6 Four Factors Limiting Growth	58
Table 7 Key Diagnostic Laboratory Technology Trends	62
Table 8 Next Generation Sequencing Technologies – Speed and Cost	63
Table 9 Global Market by Country.....	314
Table 10 Global Market by Application.....	316
Table 11 Global Market by Technology	322
Table 12 Newborn Segment by Country	329
Table 13 NIPT Segment by Country	331
Table 14 Predictive Segment by Country	333
Table 15 Oncology Segment by Country	335
Table 16 DTC Segment by Country	337
Table 17 Other Segment by Country	339
Table 18 PCR Segment by Country	342
Table 19 NGS Segment by Country.....	344
Table 20 Cytogenetic Segment by Country	346
Table 21 Other Segment by Country	348

Table 22 2021 CLINICAL LAB FEE SCHEDULE..... 351

Table of Figures

Figure 1 Clinical Lab Spending 2014 to 2024	35
Figure 2 Top Ten Sequencing Companies.....	52
Figure 3 Percentage of World Population Over 65	55
Figure 4 Country Market Shares.....	315
Figure 5 Application Share by Year.....	317
Figure 6 Application Segment Growth Rates.....	318
Figure 7 Segment Share Shifts	319
Figure 8 Application Segment Share Base Year	320
Figure 9 Application Segment Share Final Year	321
Figure 10 Technology Share by Year.....	323
Figure 11 Technology Segment Growth Rates	324
Figure 12 Technology Segment Share Shifts	325
Figure 13 Technology Segment Share Base Year	326
Figure 14 Technology Segment Share Final Year	327
Figure 15 Newborn vs. Total Market Growth	330
Figure 16 NIPT vs. Total Market Growth	332
Figure 17 Predictive vs. Total Market Growth	334
Figure 18 Oncology vs. Total Market Growth	336
Figure 19 DTC vs. Total Market Growth	338
Figure 20 Other vs. Total Market Growth	340
Figure 21 PCR vs. Total Market Growth	343

Figure 22 NGS vs. Total Market Growth.....	345
Figure 23 Cytogenetic vs. Total Market Growth.....	347
Figure 24 Other vs. Total Market Growth	349