



# RESEARCH REPORT



## HOME DIAGNOSTICS MARKETS

Strategies and Trends. Forecasts by Application by Channel by Technology and by Country. With Market Analysis and Executive Guides,

2023 to 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 .....19

1.1 Situation Analysis ..... 20

1.2 Guide for Executives and Marketing Staff ..... 22

1.3 Guide for Investment Analysts and Management Consultants..... 23

2 Introduction and Market Definition .....24

2.1 What are Home Diagnostics? ..... 25

2.2 Home Testing – the quiet revolution in diagnostics ..... 26

2.3 Self vs. Send vs. In House – Who knew?..... 27

2.3.1 Self ..... 27

2.3.2 Send..... 28

2.3.3 In-House ..... 28

2.4 Market Definition ..... 28

2.4.1 Retail vs. Wholesale ..... 29

2.5 Application Segments ..... 30

2.5.1 Channel Segments..... 30

2.5.2 Technology Segments ..... 31

2.5.3 Currency ..... 31

2.5.4 Years ..... 31

2.6 Methodology..... 32

2.6.1 Methodology ..... 32

2.6.2 Sources ..... 32

2.6.3 Authors ..... 32

2.7 Perspective: Healthcare and the IVD Industry ..... 34

- 2.7.1 Global Healthcare Spending ..... 34
- 2.7.2 Spending on Diagnostics ..... 35
- 2.7.3 Important Role of Insurance for Diagnostics ..... 37
- 3 Industry Overview .....38
- 3.1 Players in a Dynamic Market..... 39
  - 3.1.1 Academic Research Lab ..... 40
  - 3.1.2 Diagnostic Test Developer..... 41
  - 3.1.3 Instrumentation Supplier ..... 41
  - 3.1.4 Chemical/Reagent Supplier..... 41
  - 3.1.5 Pathology Supplier ..... 41
  - 3.1.6 Independent Clinical Laboratory ..... 42
  - 3.1.7 Public National/regional Laboratory ..... 42
  - 3.1.8 Hospital Laboratory ..... 43
  - 3.1.9 Physicians Office Lab (POLs) ..... 43
  - 3.1.10 Audit Body ..... 44
  - 3.1.11 Certification Body..... 44
- 3.2 Diagnostic Market Segments ..... 46
  - 3.2.1 Traditional Market Segmentation..... 46
  - 3.2.2 Laboratory Focus and Segmentation..... 47
  - 3.2.3 Segmenting the Home Diagnostics Market ..... 48
- 3.3 Industry Structure..... 50
  - 3.3.1 Hospital Testing Share ..... 50
  - 3.3.2 Economies of Scale..... 50
  - 3.3.3 Hospital vs. Central Lab ..... 51
  - 3.3.4 Physician Office Lab's..... 52
    - 3.3.4.1 The Problem with POLs..... 52

- 3.3.5 Physician's and Home Diagnostics ..... 53
- 3.3.6 Pharmacies and Home Diagnostics ..... 53
  - 3.3.6.1 The Diagnostic Plight of Pharmacies – Trying to do good..... 53
  - 3.3.6.2 The Theranos Legacy ..... 54
- 4 Market Trends .....55
  - 4.1 Factors Driving Growth ..... 56
    - 4.1.1 Privacy and Anonymity..... 56
    - 4.1.2 The Internet Effect ..... 56
    - 4.1.3 Rapid Result ..... 57
    - 4.1.4 The Wellness Movement ..... 57
    - 4.1.5 The COVID-19 Impact..... 57
  - 4.2 Factors Limiting Growth ..... 59
    - 4.2.1 Trust Factor ..... 59
    - 4.2.2 Infectious Disease is Declining But..... 61
    - 4.2.3 Wellness Hurts..... 61
    - 4.2.4 Economic Growth improves Living Standards ..... 61
  - 4.3 Diagnostic Technology Development ..... 62
    - 4.3.1 The Multiplex Paradigm Shift..... 62
    - 4.3.2 NAT vs. Lateral Flow ..... 64
    - 4.3.3 The Unusual Role of GPS ..... 64
    - 4.3.4 Self and Send Competition ..... 64
    - 4.3.5 The Relationship to DTC Genetic ..... 65
    - 4.3.6 The Relationship to TeleHealth ..... 66
    - 4.3.7 Sample Collection – Who Knew?..... 66
- 5 Home Diagnostics Recent Developments .....67
  - 5.1 Recent Developments – Importance and How to Use This Section ..... 68

5.1.1	Importance of These Developments .....	68
5.1.2	How to Use This Section.....	68
5.2	DiagMetrics Developing Breath Assays.....	68
5.3	Co-Diagnostics Awarded \$2.3M for TB, HPV Tests .....	72
5.4	POC Developers Nuclein and Minute Molecular Dx Merge .....	72
5.5	ReadyGo Dx to Make MDx Testing a 'Snap' .....	73
5.6	Altratech Enters POC Testing Space by Supplanting PCR.....	78
5.7	Sherlock Biosciences to Acquire Sense Biodetection .....	82
5.8	Scripps Research, Cue Health to Offer Home Based Test-to-Treat Program .....	83
5.9	KSL Pulse Scientific to Distribute Home Molecular Test in Canada .....	85
5.10	Juno Diagnostics Offers NIPT With At-Home Sample Collection .....	86
5.11	Sherlock Biosciences Adds to Diagnostic Toolkit .....	89
5.12	Morgan Health Invests in LetsGetChecked .....	93
5.13	Prenetics ColoClear by Circle .....	93
5.14	Detect to Roll Out Next-Gen Molecular Instrument .....	94
5.15	Diagnostics for the Real World Third-Generation POC Platform .....	97
5.16	Labcorp Partnering With Getlabs for Home Collection .....	100
5.17	Salignostics Closes Funding Round .....	100
5.18	Cue Health Targets DTC Market in 2022.....	101
5.19	Grip Molecular Developing Home Respiratory Panel .....	105
5.20	Mainz Biomed Developing Home ColoAlert Assay .....	109
5.21	MFB Fertility Closes Series A Financing Round.....	112
5.22	Continued Demand for SARS-CoV-2 Rapid Tests .....	113
5.23	Rapid Covid-19 Test Results Risk Going Uncounted .....	114
5.24	FDA Grants EUAs for Direct-to-Consumer Coronavirus Kit .....	117
5.25	Researchers Develop 15-Minute PCR System .....	117

5.26	Stanford Developing Low-Cost, At-Home, COVID-19 Saliva Test.....	119
5.27	Lucira Health Files for \$115M IPO .....	124
5.28	Spectrum Solutions Gets CE Mark for Saliva Collection Devices .....	125
5.29	Sherlock Biosciences Receives Gates Foundation Grant for COVID-19 Self-Test .....	125
5.30	LabCorp Receives EUA for OTC COVID-19 Test Home Collection Kit .....	127
6	Profiles of Key Home Diagnostics Companies .....	129
6.1	1DropDiagnostics .....	130
6.2	23andME Inc.....	131
6.3	Abbott Laboratories.....	132
6.4	ADT Biotech .....	133
6.5	Akonni Biosystems .....	134
6.6	Alveo Technologies.....	135
6.7	Anitoo .....	136
6.8	Antelope Dx.....	137
6.9	Applied BioCode .....	138
6.10	Atomo Diagnostics.....	140
6.11	Aureum Diagnostics .....	141
6.12	Aus Diagnostics .....	142
6.13	Becton, Dickinson and Company .....	143
6.14	Binx Health .....	145
6.15	Biocartis.....	146
6.16	BioFire Diagnostics (bioMérieux) .....	147
6.17	bioMérieux Diagnostics.....	149
6.18	Bio-Rad Laboratories, Inc.....	151
6.19	Bosch Healthcare Solutions GmbH.....	153
6.20	Cepheid (Danaher) .....	154



6.21	Cue Health.....	156
6.22	Curetis N.V. / Curetis GmbH.....	158
6.23	DBS Systems .....	159
6.24	Detect .....	160
6.25	Diagenode Diagnostics.....	161
6.26	Diasorin S.p.A.....	162
6.27	Domus Diagnostics.....	164
6.28	Ellume .....	165
6.29	Everywell .....	166
6.30	Genomadix.....	167
6.31	Getlabs.....	168
6.32	Grip Molecular Technologies .....	169
6.33	Healthy.io .....	170
6.34	Hologic .....	171
6.35	Inflammatix .....	172
6.36	Invetech.....	173
6.37	Janssen Diagnostics .....	174
6.38	Karius .....	175
6.39	Laboratory Corporation of America.....	176
6.40	Letsgetchecked .....	177
6.41	Lexogene .....	178
6.42	Lucira Health.....	179
6.43	Luminex Corp (DiaSorin) .....	180
6.44	LumiraDx .....	182
6.45	Mbio Diagnostics.....	183
6.46	Mesa Biotech (Thermo Fisher) .....	184

6.47	MFB Fertility.....	185
6.48	Mobidiag (Hologic).....	186
6.49	myLabBox .....	187
6.50	Mylan.....	188
6.51	NanoDx .....	189
6.52	Nanomix.....	190
6.53	OraSure Technologies.....	191
6.54	Oxford Nanopore Technologies .....	192
6.55	Panagene.....	193
6.56	Prenetics.....	194
6.57	Primerdesign (Novacyt) .....	195
6.58	Prominex .....	196
6.59	Qiagen .....	197
6.60	QuantuMDx .....	199
6.61	Quest Diagnostics .....	200
6.62	QuidelOrtho.....	201
6.63	Randox Toxicology.....	202
6.64	Roche Molecular Diagnostics .....	203
6.65	Salignostics.....	205
6.66	Scanwell Health.....	206
6.67	SD Biosensor .....	207
6.68	Seegene.....	208
6.69	Seventh Sense Biosystems.....	209
6.70	Siemens Healthineers .....	210
6.71	T2 Biosystems.....	211
6.72	TestCard.....	212

- 6.73 Thermo Fisher Scientific Inc..... 213
- 6.74 Thriva ..... 215
- 6.75 Visby Medical ..... 216
- 6.76 XCR Diagnostics ..... 218
- 7 Global Market Size .....219
  - 7.1 Home Diagnostics Global Market Size by Country ..... 220
    - 7.1.1 Home Diagnostics Global Market Size by Country Table ..... 220
    - 7.1.2 Home Diagnostics Global Market Size by Country Chart ..... 221
  - 7.2 Home Diagnostics Global Market Size by Application ..... 222
    - 7.2.1 Home Diagnostics Global Market Size by Application Table ..... 222
    - 7.2.2 Home Diagnostics Global Market Size by Application Share by Year..... 223
    - 7.2.3 Home Diagnostics Global Market Size by Application Base vs Final ..... 224
    - 7.2.4 Home Diagnostics Global Market Size by Application Base Year..... 225
    - 7.2.5 Home Diagnostics Global Market Size by Application Final Year ..... 226
    - 7.2.6 Home Diagnostics Global Market Size by Application Segment Growth ..... 227
  - 7.3 Home Diagnostics Global Market Size by Channel ..... 228
    - 7.3.1 Home Diagnostics Global Market Size by Channel Table ..... 228
    - 7.3.2 Home Diagnostics Global Market Size by Channel Share by Year ..... 229
    - 7.3.3 Home Diagnostics Global Market Size by Channel Base vs Final..... 230
    - 7.3.4 Home Diagnostics Global Market Size by Channel Base Year..... 231
    - 7.3.5 Home Diagnostics Global Market Size by Channel Final Year ..... 232
    - 7.3.6 Home Diagnostics Global Market Size by Channel Segment Growth..... 233
  - 7.4 Home Diagnostics Global Market Size by Technology ..... 234
    - 7.4.1 Home Diagnostics Global Market Size by Technology Table ..... 234
    - 7.4.2 Home Diagnostics Global Market Size by Technology Share by Year..... 235
    - 7.4.3 Home Diagnostics Global Market Size by Technology Base vs Final ..... 236

- 7.4.4 Home Diagnostics Global Market Size by Technology Base Year..... 237
- 7.4.5 Home Diagnostics Global Market Size by Technology Final Year..... 238
- 7.4.6 Home Diagnostics Global Market Size by Technology Segment Growth ..... 239
- 8 Global Market by Application .....240
  - 8.1 Respiratory Market ..... 241
    - 8.1.1 Respiratory Market by Country Table ..... 241
    - 8.1.2 Respiratory Market Chart..... 242
  - 8.2 STD Market ..... 243
    - 8.2.1 STD Market by Country Table ..... 243
    - 8.2.2 STD Market Chart..... 244
  - 8.3 UTI Market ..... 245
    - 8.3.1 UTI Market by Country Table ..... 245
    - 8.3.2 UTI Market Chart ..... 246
  - 8.4 Pregnancy Market ..... 247
    - 8.4.1 Pregnancy Market by Country Table ..... 247
    - 8.4.2 Pregnancy Market by Chart..... 248
  - 8.5 Ovulation Market ..... 249
    - 8.5.1 Ovulation Market by Country Table ..... 249
    - 8.5.2 Ovulation Market by Chart..... 250
  - 8.6 DNA Market ..... 251
    - 8.6.1 DNA Market by Country Table ..... 251
    - 8.6.2 DNA Market Chart..... 252
  - 8.7 Other Market ..... 253
    - 8.7.1 Other Market by Country Table ..... 253
    - 8.7.2 Other Market Chart..... 254
- 9 Global Market by Channel .....255

- 9.1 Store Market ..... 256
  - 9.1.1 Store Market by Country Table ..... 256
  - 9.1.2 Store Market Chart ..... 257
- 9.2 Online Market..... 258
  - 9.2.1 Online Market by Country Table ..... 258
  - 9.2.2 Online Market Chart ..... 259
- 9.3 Other Channel Market ..... 260
  - 9.3.1 Other Channel by Country Table..... 260
  - 9.3.2 Other Channel Market Chart ..... 261
- 10 Global Market by Technology .....262
  - 10.1 Immunoassay Market..... 263
    - 10.1.1 Immunoassay Market by Country Table..... 263
    - 10.1.2 Immunoassay Market Chart ..... 264
  - 10.2 Chemistry Market ..... 265
    - 10.2.1 Chemistry Market by Country Table ..... 265
    - 10.2.2 Chemistry Market Chart..... 266
  - 10.3 Nucleic Acid Market ..... 267
    - 10.3.1 Nucleic Acid Market by Country Table ..... 267
    - 10.3.2 Nucleic Acid Market Chart..... 268
  - 10.4 Other Technology Market ..... 269
    - 10.4.1 Other Technology Market by Country Table ..... 269
    - 10.4.2 Other Technology Market Chart..... 270
- 11 Appendices .....271
  - 11.1 United States Medicare System: Clinical Laboratory Fees Schedule ..... 271
  - 11.2 The Most Used IVD Assays..... 366
  - 11.3 The Highest Grossing Assays ..... 371



Table of Tables

Table 1 Application Segment Definitions..... 30

Table 2 Channel Segment Definitions..... 30

Table 3 Technology Segment Definitions..... 31

Table 4 Market Players by Type ..... 40

Table 5 Clinical Laboratory Departments and Segments ..... 46

Table 6 Laboratory Management Focus – Different Approaches ..... 47

Table 7 Key Segmentation Variables Going Forward..... 48

Table 8 Possible Market Segments of HOME Market ..... 48

Table 9 Five Factors Driving Growth ..... 56

Table 10 Four Factors Limiting Growth ..... 59

Table 11 Self vs. Send TAT..... 65

Table 12 Home Diagnostics Global Market by Country/Region..... 220

Table 13 Home Diagnostics Global Market by Application..... 222

Table 14 Home Diagnostics Global Market by Channel..... 228

Table 15 Home Diagnostics Global Market by Technology..... 234

Table 16 Respiratory by Country..... 241

Table 17 STD market by country ..... 243

Table 18 UTI Market by country ..... 245

Table 19 Pregnancy Market by country ..... 247

Table 20 Ovulation Market by country ..... 249

Table 21 DNA Market by country ..... 251

Table 22 Other Market by country ..... 253

Table 23 Store Market by Country..... 256

Table 24 Online market by country ..... 258

Table 25 Other Channel Market by country ..... 260

Table 26 Immunoassay by Country ..... 263

Table 27 Chemistry Market by country ..... 265

Table 28 Nucleic Acid Market by country ..... 267

Table 29 Other Technology Market by country ..... 269

Table 30 Clinical Lab Fee Schedule ..... 271

Table 31 The Most Common Assays ..... 366

Table 32 Largest Revenue Assays..... 371



Table of Figures

Figure 1 Standard Test Paradigm ..... 26

Figure 2 The New Test Paradigm ..... 27

Figure 3 Global Healthcare Spending ..... 35

Figure 4 The Lab Test Pie ..... 36

Figure 5 The Road to Diagnostics ..... 39

Figure 6 Chart Death Rates and Infectious Disease Decline ..... 60

Figure 6 The Multiplex Paradigm Shift..... 63

Figure 8 Market Size by Country - Key Countries..... 221

Figure 9 Chart of Global Market by Application by Year ..... 223

Figure 10 Application Segment Shares Base vs Final ..... 224

Figure 11 Application Share Base Year..... 225

Figure 12 Application Share Final Year ..... 226

Figure 13 Application Segment Growth Rates ..... 227

Figure 14 Chart of Global Market by Channel by Year..... 229

Figure 15 Channel Segment Shares Base vs Final ..... 230

Figure 16 Channel Share Base Year ..... 231

Figure 17 Channel Share Final Year ..... 232

Figure 18 Channel Segment Growth Rates ..... 233

Figure 19 Chart of Global Market by Technology by Year ..... 235

Figure 20 Technology Segment Shares Base vs Final..... 236

Figure 21 Technology Share Base Year..... 237

Figure 22 Technology Share Final Year ..... 238

Figure 23 Technology Segment Growth Rates..... 239

Figure 24 Chart - Respiratory Market Growth ..... 242

Figure 25 Chart – STD Market Growth ..... 244

Figure 26 Chart – UTI Market Growth..... 246

Figure 27 Chart - Pregnancy Market Growth ..... 248

Figure 28 Chart - Ovulation Market Growth ..... 250

Figure 29 Chart – DNA Market Growth ..... 252

Figure 30 Chart – Other Market Growth ..... 254

Figure 31 Chart - Store Market Growth ..... 257

Figure 32 Chart – Online Market Growth ..... 259

Figure 33 Chart – Other Channel Market Growth..... 261

Figure 34 Chart - Immunoassay Market Growth ..... 264

Figure 35 Chart – Chemistry Market Growth ..... 266

Figure 36 Chart – Nucleic Acid Market Growth ..... 268

Figure 37 Chart - Other Technology Market Growth ..... 270