

RESEARCH REPORT



Molecular Diagnostics at the Point of Care

By Application, Technology, Place, Product and by
Country. With Executive Guides and Analysis

2025 - 2029





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 and Business Development Staff.....	25
1.3	Guide for Management Consultants and Investment Advisors	26
2	Introduction and Market Definition	27
2.1	What are Molecular Diagnostics at the Point of Care?	28
2.2	The Diagnostics Revolution.....	30
2.3	Market Definition	32
2.3.1	Revenues.....	32
2.4	Methodology.....	34
2.4.1	Methodology	34
2.4.2	Sources	34
2.4.3	Authors	34
2.5	Perspective: Healthcare Spending.....	36
2.5.1	Global Healthcare Spending	36
2.5.2	Spending on Healthcare and Pharmaceuticals.....	38
2.5.3	Spending on Diagnostics	38
2.5.4	Important Role of Insurance for Medical Services.....	39
3	Instrumentation, Automation and Diagnostic Trends	40
3.1	Instrumentation and Automation	41

3.1.1	Traditional Automation and Centralization.....	41
3.1.2	The New Automation, Decentralization and Point Of Care	41
3.1.3	Instruments Key to Market Share	43
3.1.4	Bioinformatics Plays a Role	43
3.1.5	PCR Takes Command	44
3.1.6	Next Generation Sequencing Fuels a Revolution.....	45
3.1.7	NGS Impact on Pricing.....	46
3.1.8	Whole Genome Sequencing, A Brave New World	46
3.1.9	Companion Diagnostics Blurs Diagnosis and Treatment	47
4	Industry Overview.....	49
4.1	Players in a Dynamic Market.....	50
4.1.1	Academic Research Lab	51
4.1.2	Diagnostic Test Developer.....	51
4.1.3	Instrumentation Supplier	52
4.1.4	Chemical/Reagent Supplier.....	52
4.1.5	Pathology Supplier	52
4.1.6	Independent Clinical Laboratory	53
4.1.7	Public National/regional Laboratory	53
4.1.8	Hospital Laboratory	54
4.1.9	Physicians Office Lab (POLs)	54
4.1.10	Audit Body.....	55
4.1.11	Certification Body.....	55
4.2	The Clinical Laboratory Market Segments	57
4.2.1	Traditional Market Segmentation.....	57

4.2.2	Laboratory Focus and Segmentation.....	59
4.3	Industry Structure.....	61
4.3.1	Hospital Testing Share	61
4.3.2	Economies of Scale.....	61
4.3.2.1	Hospital vs. Central Lab.....	62
4.3.3	Physician Office Lab's.....	63
4.3.4	Physician's and POCT	63
5	Profiles of Key MDx Companies	65
5.1	Abbott Laboratories.....	66
5.2	Abionic.....	68
5.3	Accelerate Diagnostics	69
5.4	Access Bio.....	70
5.5	Ador Diagnostics	71
5.6	ADT Biotech	72
5.7	Akonni Biosystems	73
5.8	Alveo Technologies.....	74
5.9	Anitda.....	75
5.10	Applied BioCode.....	76
5.11	Aureum Diagnostics	78
5.12	Aus Diagnostics	79
5.13	Autonomous Medical Devices.....	80
5.14	Baebies	81
5.15	Beckman Coulter Diagnostics (Danaher)	83
5.16	Becton, Dickinson and Company	84

5.17	Binx Health	86
5.18	Biocartis.....	88
5.19	BioFire Diagnostics (bioMérieux)	89
5.20	bioMérieux Diagnostics.....	91
5.21	Bio-Rad Laboratories, Inc.....	94
5.22	Bosch Healthcare Solutions GmbH.....	95
5.23	Cepheid (Danaher)	96
5.24	Credo Diagnostics Biomedical	98
5.25	Cue Health.....	99
5.26	Curetis (OpGen).....	101
5.27	Detect	102
5.28	Diagenode Diagnostics (Hologic)	103
5.29	Diasorin S.p.A.	104
5.30	DNAe.....	105
5.31	Domus Diagnostics.....	106
5.32	Enzo Biochem	107
5.33	Eurofins Scientific	108
5.34	Fluxergy	109
5.35	Fusion Genomics.	110
5.36	Genedrive.....	111
5.37	Genetic Signatures.....	112
5.38	GenMark Dx (Roche)	113
5.39	Genomadix.....	115
5.40	Getlabs.....	116

5.41	Global Access Diagnostics.....	117
5.42	Grip Molecular Technologies	118
5.43	Hologic	119
5.44	Immunexpress.....	121
5.45	Inflammatix	122
5.46	Invetech.....	123
5.47	Iollo	124
5.48	J&J Innovative Medicine	125
5.49	Karius	126
5.50	Lucira Health (Pfizer)	128
5.51	LumiraDx	129
5.52	Maxim Biomedical	130
5.53	Meep.....	131
5.54	Meridian Bioscience.....	132
5.55	Millipore Sigma	134
5.56	Molbio Diagnostics.....	135
5.57	NanoDx	136
5.58	Nanomix.....	137
5.59	Novacyt	138
5.60	Novel Microdevices	139
5.61	Novus Diagnostics	140
5.62	Nuclein	141
5.63	OnsiteGene	142
5.64	Operon.....	143

5.65	OraSure Technologies.....	144
5.66	Oxford Nanopore Technologies	146
5.67	Panagene.....	148
5.68	Prenetics.....	149
5.69	Primerdesign (Novacyt)	150
5.70	Prominex	151
5.71	Proof Diagnostics.....	153
5.72	Qiagen	154
5.73	QuantuMDx	156
5.74	QuidelOrtho.....	157
5.75	R-Biopharm AG.....	159
5.76	Response Biomedical.....	160
5.77	Revvity	161
5.78	Roche Diagnostics	163
5.79	Salignostics.....	165
5.80	SD Biosensor	166
5.81	Seegene.....	168
5.82	Sekisui Diagnostics.....	169
5.83	Siemens Healthineers	170
5.84	Sona Nanotech	171
5.85	SpeedX.....	172
5.86	T2 Biosystems.....	173
5.87	Talis Biomedical	174
5.88	Thermo Fisher Scientific	175

5.89	Uniogen.....	177
5.90	Veramarx	179
5.91	Veredus Laboratories.....	180
5.92	XCR Diagnostics	181
5.93	Zhejiang Orient Gene Biotech	183
6	Market Trends	184
6.1	Factors Driving Growth	185
6.1.1	New Genotypes Creating New Markets	186
6.1.2	Aging Population a Boon for All Diagnostics	186
6.1.3	Developing World Driving ID Dx Growth.....	187
6.1.4	Point of Care – Why Centralization is Losing Steam	187
6.1.5	Self Testing.....	188
6.1.6	The Need for Speed	188
6.2	Factors Limiting Growth	189
6.2.1	Lower Costs.....	189
6.2.2	Infectious Disease is Declining.....	191
6.2.3	Wellness Hurts.....	191
6.2.4	Economic Growth improves Living Standards	191
7	Molecular Dx – Infectious Disease Recent Developments	192
7.1	Recent Developments – Importance and How to Use This Section	193
7.1.1	Importance of These Developments	193
7.1.2	How to Use This Section.....	193
7.2	Cubit Dx Secures Funding for High-Sensitivity, Low-Cost Platform.....	193
7.3	Roche receives FDA clearance for STI at POC.....	195

7.4	Smartphone-Enabled Platform Transforms POC Testing	196
7.5	Credo Preps MDx System, Multiplex Respiratory Test for US Launch	197
7.6	A low-cost CRISPR-based paper strip test for flu.....	199
7.7	AMDI Receives Award to Develop 10 Minute POC Respiratory Panel.....	201
7.8	Roche to Acquire LumiraDx Point-of-Care Testing Tech.....	202
7.9	DiaSorin to Deliver Updated Instruments, New Assays in 2024/25	203
7.10	ReadyGo Diagnostics, Gemina Labs Expand MDx Pact.....	205
7.11	DiagMetrics Developing Breath Assays.....	209
7.12	Fortis Life Sciences Acquires IPOC	212
7.13	Domus Diagnostics Wins NIH RADx Tech Contract.....	213
7.14	Llusern Scientific to Launch POC MDx UTI Panel.....	214
7.15	Altratech Enters POC MDx Testing Space with Unique Tech.....	215
7.16	BioMérieux SpotFire MDx POC System Leverages Novel Approach.....	220
7.17	Katalyst Labs to Distribute ProtonDx Dragonfly Rapid IVD System	225
7.18	LEX Diagnostics Developing Ultra-Fast Low-Cost PCR.....	226
7.19	Sherlock Biosciences Adds to Infectious Disease Dx Toolkit.....	228
7.20	NanoDx Prepares for Point-of-Care Commercialization.....	232
7.21	Paragraf to Study New POC Test to Guide Antibiotic Selection	235
7.22	MicroGEM to Expand 30-Minute RT-PCR System	238
7.23	Startup Detect to Roll Out Next-Gen Molecular Instrument	242
7.24	Diagnostics for the Real World Third-Generation POC Platform	245
7.25	Salignostics Closes Funding Round	249
7.26	Cue Health Targets DTC Market in 2022.....	250
7.27	Grip Molecular Developing Home Respiratory Panel	253

7.28	Mainz Biomed Developing Home ColoAlert Assay	258
7.29	MFB Fertility Closes Series A Financing Round	261
7.30	Home Test Company Prenetics to go Public	262
7.31	Roche to Acquire TIB Molbiol to Expand Infectious Disease Portfolio.....	263
7.32	BforCure Preparing Multiple Panels for Point-of-Care qPCR Platform	264
7.33	Talis Biomedical Discusses Point-of-Care.....	268
7.34	Roche to Acquire GenMark Diagnostics for \$1.8B	272
7.35	Pandemic Pushes Handheld qPCR Devices Closer to Commercialization.....	273
7.36	Hologic to Acquire Mobidiag	281
7.37	Lucira Health Focuses on User Friendly Approach to Home Testing	282
7.38	Infectious Disease Dx Firm Talis Biomedical Raises \$254M in IPO.....	288
7.39	Fluidigm Plans 'Durable' Diagnostics, Clinical Business.....	288
7.40	Thermo Fisher Scientific to Acquire Mesa Biotech for Up to \$550M	292
7.41	Mammoth Biosciences Developing Pathogen Detection Tech	293
7.42	Illumina, IDbyDNA Developing Sequencing-Based Respiratory Tests	296
7.43	Scanogen Developing 90 Minute Infection Test.....	301
7.44	Malaria Assays Use CRISPR for Point-of-Care Multispecies Detection	304
7.45	FDA Provides Self Testing SARS-CoV-2 EAU Guidance	307
7.46	Mammoth Biosciences Announces Rapid, CRISPR-Based COVID-19 Diagnostic	309
7.47	Genetic Signatures Gets CE Mark for Coronavirus Molecular Test	310
7.48	Qiagen Respiratory Panel with Coronavirus Receives CE Mark.....	311
7.49	Lumos Diagnostics Closes \$15M Series A Funding	312
8	The Global Market for Molecular Diagnostics at the Point of Care.....	314
8.1	Global Market Overview by Country	315

8.1.1	Table – Global Market by Country.....	315
8.1.2	Chart - Global Market by Country.....	316
8.2	Global Market by Application - Overview	317
8.2.1	Table – Global Market by Application	317
8.2.2	Chart – Global Market by Application – Base/Final Year Comparison	318
8.2.3	Chart – Global Market by Application – Base Year	319
8.2.4	Chart – Global Market by Application – End Year	320
8.2.5	Chart – Global Market by Application – Share by Year.....	321
8.2.6	Chart – Global Market by Application – Segments Growth.....	322
8.3	Global Market by Technology - Overview.....	323
8.3.1	Table – Global Market by Technology	323
8.3.2	Chart – Global Market by Technology – Base/Final Year Comparison	324
8.3.3	Chart – Global Market by Technology – Base Year	325
8.3.4	Chart – Global Market by Technology – End Year	326
8.3.5	Chart – Global Market by Technology – Share by Year.....	327
8.3.6	Chart – Global Market by Technology – Segments Growth.....	328
8.4	Global Market by Place - Overview	329
8.4.1	Table – Global Market by Place.....	329
8.4.2	Chart – Global Market by Place – Base/Final Year Comparison	330
8.4.3	Chart – Global Market by Place – Base Year.....	331
8.4.4	Chart – Global Market by Place – End Year	332
8.4.5	Chart – Global Market by Place – Share by Year.....	333
8.4.6	Chart – Global Market by Place – Segments Growth	334
8.5	Global Market by Product - Overview	335

8.5.1	Table – Global Market by Product.....	335
8.5.2	Chart – Global Market by Product – Base/Final Year Comparison.....	336
8.5.3	Chart – Global Market by Product – Base Year.....	337
8.5.4	Chart – Global Market by Product – End Year	338
8.5.5	Chart – Global Market by Product – Share by Year	339
8.5.6	Chart – Global Market by Product – Segments Growth	340
9	Global MDx at the Point of Care Markets – By Application	341
9.1	Respiratory Infectious Disease.....	342
9.1.1	Table Respiratory Infectious Disease – by Country	342
9.1.2	Chart - Respiratory Infectious Disease Growth	343
9.2	Gastrointestinal Infectious Disease	344
9.2.1	Table Gastrointestinal Infectious Disease – by Country.....	344
9.2.2	Chart - Gastrointestinal Infectious Disease Growth	345
9.3	Sexually Transmitted Disease.....	346
9.3.1	Table Sexually Transmitted Disease – by Country	346
9.3.2	Chart - Sexually Transmitted Disease Growth	347
9.4	Other Application	348
9.4.1	Table Other Application – by Country.....	348
9.4.2	Chart - Other Application Growth	349
10	Global MDx Markets at the Point of Care – by Technology.....	350
10.1	PCR.....	351
10.1.1	Table PCR – by Country	351
10.1.2	Chart - PCR Growth.....	352
10.2	NGS/Probe.....	353

10.2.1	Table NGS/Probe – by Country	353
10.2.2	Chart - NGS/Probe Growth.....	354
10.3	Other Technology	355
10.3.1	Table Other Technology – by Country.....	355
10.3.2	Chart - Other Technology Growth	356
11	Global MDx at the Point of Care Markets – by Place	357
11.1	Hospital Point of Care	358
11.1.1	Table Hospital Point of Care – by Country	358
11.1.2	Chart - Hospital Point of Care Growth.....	359
11.2	Clinic or Physician Office Lab.....	360
11.2.1	Table Clinic or Physician Office Lab – by Country	360
11.2.2	Chart - Clinic or Physician Office Lab Growth	361
11.3	Seniors Facility	362
11.3.1	Table Seniors Facility – by Country	362
11.3.2	Chart – Seniors Facility Growth	363
11.4	Other Place	364
11.4.1	Table Other Place– by Country	364
11.4.2	Chart – Other Place Growth.....	365
12	Global MDx at the Point of Care Markets – by Product	366
12.1	Instrument	367
12.1.1	Table Instrument – by Country	367
12.1.2	Chart - Instrument Growth	368
12.2	Cartridge.....	369
12.2.1	Table Cartridge – by Country	369

12.2.2	Chart - Cartridge Growth	370
12.3	Other Product.....	371
12.3.1	Table Other Product – by Country	371
12.3.2	Chart – Other Product Growth	372
13	Appendices.....	373
13.1	Growth of Approved IVD Test Menu	374
13.2	Growth of Approved Average IVD Test Fee	375
13.3	The Most Used IVD Assays.....	376
13.4	The Highest Grossing Assays	381
13.5	Laboratory Fees Schedule.....	388

Table of Tables

Table 1 Seven Key Diagnostic Laboratory Technology Trends	41
Table 2 Market Players by Type	51
Table 3 Clinical Laboratory Departments and Segments	58
Table 4 Laboratory Management Focus – Different Approaches	59
Table 5 Key Segmentation Variables Going Forward.....	60
Table 6 Five Factors Driving Growth.....	185
Table 7 Four Factors Limiting Growth	189
Table 8 - Global Market by Region	315
Table 9 Global Market by Application	317
Table 10 Global Market by Technology	323
Table 11 Global Market by Place.....	329
Table 12 Global Market by Product.....	335
Table 13 Respiratory Infectious Disease by Country	342
Table 14 Gastrointestinal Infectious Disease by Country.....	344
Table 15 Sexually Transmitted Disease by Country	346
Table 16 Other Application by Country.....	348
Table 17 PCR by Country	351
Table 18 NGS/Probe by Country	353
Table 19 Other Technology by Country.....	355
Table 20 Hospital Point of Care by Country	358

Table 21 Clinic or Physician Office Lab by Country 360

Table 22 Seniors Facility by Country 362

Table 23 Other Place by Country 364

Table 24 Instrument by Country 367

Table 25 Cartridge by Country 369

Table 26 Other Product by Country 371

Table 27 The Most Common Assays 376

Table 28 Largest Revenue Assays..... 381

Table 29 Clinical Lab Fee Schedule 388

Table of Figures

Figure 1 Global Healthcare Spending	37
Figure 2 Centralized vs. Decentralized Laboratory Service	42
Figure 3 A Highly Multiplexed Syndromic Testing Unit	42
Figure 4 The Real Cost to Sequence the Human Genome.....	45
Figure 5 The Codevelopment Process	47
Figure 6 The Road to Diagnostics	50
Figure 7 Percentage of World Population Over 65.....	187
Figure 8 Chart Infectious Disease Decline	190
Figure 9 Global Market Shares Chart	316
Figure 10 Global Market by Application - Base vs. Final	318
Figure 11 Global Market by Application Base Year.....	319
Figure 12 Global Market by Application End Year	320
Figure 13 Application Share by Year.....	321
Figure 14 Application Segments Growth.....	322
Figure 15 Global Market by Technology - Base vs. Final	324
Figure 16 Global Market by Technology Base Year.....	325
Figure 17 Global Market by Technology End Year	326
Figure 18 Technology Share by Year.....	327
Figure 19 Technology Segments Growth.....	328
Figure 20 Global Market by Place - Base vs. Final.....	330
Figure 21 Global Market by Place Base Year.....	331

Figure 22 Global Market by Place End Year	332
Figure 23 Place Share by Year.....	333
Figure 24 Place Segments Growth	334
Figure 25 Global Market by Product - Base vs. Final.....	336
Figure 26 Global Market by Product Base Year	337
Figure 27 Global Market by Product End Year.....	338
Figure 28 Product Share by Year	339
Figure 29 Product Segments Growth	340
Figure 30 Respiratory Infectious Disease Diagnostics Growth.....	343
Figure 31 Gastrointestinal Infectious Disease Growth.....	345
Figure 32 Sexually Transmitted Disease Growth	347
Figure 33 Other Application Growth.....	349
Figure 34 PCR Growth	352
Figure 35 NGS/Probe Growth	354
Figure 36 Other Technology Growth.....	356
Figure 37 Hospital Point of Care Growth.....	359
Figure 38 Clinic or Physician Office Lab Growth	361
Figure 39 Seniors Facility Growth	363
Figure 40 Other Place Growth	365
Figure 41 Instrument Growth.....	368
Figure 42 Cartridge Growth	370
Figure 43 Other Product Growth	372
Figure 44 IVD Test Menu Growth	374
Figure 45 IVD Test Average Fees – A Ten Year View	375

