



COVID-19 Diagnostics

Global Market Forecast by Technology, Product, Channel and Country. With Executive and Consultant 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 Guides22

1.1 Strategic Situation Analysis..... 23

1.2 Guidance for Executives 25

1.3 Guidance for Management Consultants and Investment Advisors 26

2 Introduction and Market Definition27

2.1 What are Pandemics? 28

2.2 The Role of Zoonosis..... 31

2.3 Market Definition 33

2.3.1 PCR 33

2.3.2 PCR Multiplex..... 33

2.3.3 SEQ 33

2.3.4 Antigen..... 34

2.3.5 Antibodies..... 34

2.3.6 Instruments 34

2.3.7 Reagents and Kits..... 34

2.3.8 Extract 35

2.3.9 Collect..... 35

2.3.10 Public..... 35

2.3.11 Hospital..... 35

2.3.12 Clinic..... 35

- 2.3.13 Workplace..... 35
- 2.3.14 DTC/OTC 35
- 2.3.15 Wastewater..... 36
- 2.4 Methodology..... 37
 - 2.4.1 Sources 37
 - 2.4.2 Authors 37
- 2.5 Historical Perspective on Pandemics 39
 - 2.5.1 HIV/AIDS PANDEMIC 2005-2012..... 39
 - 2.5.2 FLU PANDEMIC 1968 40
 - 2.5.3 ASIAN FLU 1956-1958 40
 - 2.5.4 SPANISH FLU 1918..... 41
 - 2.5.5 SIXTH CHOLERA PANDEMIC 1910-1911 41
 - 2.5.6 FLU PANDEMIC 1889-1890..... 42
 - 2.5.7 THE BLACK DEATH 1346-1353 42
- 3 The Pandemic Overview44
 - 3.1 What is a Virus? 45
 - 3.1.1 Is a Virus Alive?..... 46
 - 3.1.2 Viral Structure..... 47
 - 3.1.3 The Viral Genome 48
 - 3.1.4 Viral Mutation 49
 - 3.2 The Coronavirus..... 51
 - 3.2.1 Severe acute respiratory syndrome (SARS) 53
 - 3.2.2 Middle East respiratory syndrome (MERS) 55
 - 3.2.3 COVID-19. The SARS CoV 2 Virus..... 56

- 3.2.3.1 Signs and symptoms 58
- 3.2.3.2 Transmission 59
- 3.2.3.3 Diagnosis 60
- 3.2.3.4 Prevention 62
- 3.2.3.5 Management..... 63
- 3.2.3.6 Prognosis..... 64
- 3.2.3.7 A Note on Global Statistics Reporting..... 65
- 3.3 Pandemic Diagnostics..... 66
 - 3.3.1 Risk Management – Spark and Spread 66
 - 3.3.2 Dx Technology – Nucleic Acid Based..... 68
 - 3.3.3 Dx Technology - Immunoassay 69
 - 3.3.4 Time to Market and Preparedness Issues 69
- 4 Industry Structure.....71
 - 4.1 Players in a Dynamic Market..... 72
 - 4.1.1 Academic Research Lab 73
 - 4.1.2 Diagnostic Test Developer..... 74
 - 4.1.3 Instrumentation Supplier 74
 - 4.1.4 Chemical/Reagent Supplier..... 74
 - 4.1.5 Pathology Supplier 75
 - 4.1.6 Independent Clinical Laboratory 75
 - 4.1.7 Public National/regional Laboratory 75
 - 4.1.8 Hospital Laboratory 76
 - 4.1.9 Physicians Office Lab (POLs) 76
 - 4.1.10 Audit Body 77

4.1.11 Certification Body..... 77

5 Diagnostic Company Profiles.....79

5.1 Abacus Diagnostica 80

5.2 Abbott Laboratories..... 81

5.3 Accel Diagnostics 82

5.4 Accelerate Diagnostics 84

5.5 Access Bio..... 85

5.6 ADT Biotech 86

5.7 Advanced Biological Laboratories..... 87

5.8 Agilent/Dako 88

5.9 Altona Diagnostics 90

5.10 Alveo Technologies..... 91

5.11 Anatolia Genetworks 92

5.12 Anitoo..... 93

5.13 Antelope Dx..... 94

5.14 Applied BioCode..... 95

5.15 Applied DNA Sciences..... 97

5.16 Assurance Scientific Laboratories 98

5.17 Aureum Diagnostics 99

5.18 Aurora Biomed 100

5.19 Aus Diagnostics 101

5.20 Autobio Diagnostics..... 102

5.21 Baebies 103

5.22 Beckman Coulter Diagnostics..... 105

5.23	Becton, Dickinson and Company	106
5.24	BGI Genomics Co. Ltd	108
5.25	BillionToOne	110
5.26	Binx Health	111
5.27	Biocartis.....	113
5.28	Biodesix Inc.	114
5.29	BioFire Diagnostics (bioMérieux)	115
5.30	Biolidics Ltd.....	117
5.31	bioMérieux Diagnostics.....	118
5.32	Bioneer Corporation	120
5.33	Bio-Rad Laboratories, Inc.....	122
5.34	Bio-Reference Laboratories.....	124
5.35	Bosch Healthcare Solutions GmbH.....	125
5.36	Celemics	126
5.37	Cepheid (Danaher)	127
5.38	Chembio	129
5.39	Co Diagnostics	130
5.40	Color Genomics	131
5.41	CTK Biotech.....	132
5.42	Cue Health.....	133
5.43	Curetis N.V. / Curetis GmbH.....	135
5.44	Detect	136
5.45	Diagenode Diagnostics	137
5.46	Diasorin S.p.A.....	138

5.47	Domus Diagnostics.....	140
5.48	Element Biosciences	141
5.49	Ellume	142
5.50	Enzo Biochem	143
5.51	Everywell	144
5.52	Fluxergy	145
5.53	Fujirebio	146
5.54	Fulgent Genetics	147
5.55	Fusion Genomics.	148
5.56	Fyr Diagnostics.....	150
5.57	Genedrive.....	151
5.58	Genetic Signatures.....	152
5.59	GenMark Dx (Roche)	153
5.60	Genomadix.....	155
5.61	Gold Standard Diagnostics	156
5.62	Hibergene Diagnostics.....	157
5.63	Hologic	158
5.64	Illumina	160
5.65	Immunexpress.....	161
5.66	Inflammatix	162
5.67	Janssen Diagnostics	163
5.68	Karius	164
5.69	Laboratory Corporation of America.....	165
5.70	Letsgetchecked	166

5.71 Lexagene 167

5.72 LightDeck Diagnostics 168

5.73 Luminex (DiaSorin) 169

5.74 LumiraDx 171

5.75 Mammoth Biosciences 172

5.76 Mayo Clinic Laboratories..... 173

5.77 Mbio Diagnostics 174

5.78 Meridian Bioscience..... 175

5.79 Mesa Biotech (Thermo Fisher) 177

5.80 Mesa Laboratories, Inc. 178

5.81 MicroGem..... 179

5.82 Minute Molecular 180

5.83 Mobidiag (Hologic) 181

5.84 Molbio Diagnostics..... 182

5.85 NanoDx 183

5.86 Nanomix..... 184

5.87 Novacyt 185

5.88 OnsiteGene 186

5.89 OraSure Technologies..... 187

5.90 Oxford Nanopore Technologies 188

5.91 Perkin Elmer..... 189

5.92 Prenetics..... 191

5.93 Primerdesign (Novacyt) 192

5.94 Prominex 193

5.95 Qiagen 194

5.96 QuantuMDx 196

5.97 Quest Diagnostics 197

5.98 QuidelOrtho 198

5.99 Randox Toxicology 199

5.100 Salignostics 201

5.101 Scope Fluidics 202

5.102 SD Biosensor 203

5.103 Seegene 204

5.104 Sense Biodetection 206

5.105 Sherlock Biosciences 207

5.106 Siemens Healthineers 208

5.107 Singular Genomics 209

5.108 SomaLogic 211

5.109 Sona Nanotech 212

5.110 SpeedX 213

5.111 Talis Biomedical 214

5.112 Thermo Fisher Scientific Inc. 215

5.113 Ultima Genomics 217

5.114 Vela Diagnostics 218

5.115 Veredus Laboratories 219

5.116 Vircell 220

5.117 Visby Medical 221

5.118 YD Diagnostics 223

5.119 Zhejiang Orient Gene Biotech 224

6 Covid-19 Diagnostics Recent Developments226

6.1 Recent Developments – Importance and How to Use This Section 227

6.1.1 Importance of These Developments 227

6.1.2 How to Use This Section..... 227

6.2 Labcorp Gets Approval for Sequencing-Based COVID Test..... 227

6.3 Post-Pandemic, Patients Savvy About ID Diagnostics 228

6.4 Discover Labs Obtains EUA for RT-PCR COVID Test 242

6.5 Sensible Dx to Launch 10-Minute POC PCR System 242

6.6 Aptitude Medical Systems Aiming for At-Home Market 245

6.7 Qorvo To Emerge as More Than a COVID Company 249

6.8 End of COVID-19 Emergency Lowers Diagnostics Revenue 254

6.9 FDA Issues EUA for GenBody At-Home COVID Test..... 257

6.10 CTK Biotech Gets EAU for At-Home COVID Antigen Test..... 258

6.11 FDA Grants EAU for Premier Medical At-Home COVID Assay 258

6.12 QuidelOrtho Seeks Home Testing Contract 259

6.13 Aptitude Medical Gets EUA for Over-the-Counter COVID Saliva MDx 261

6.14 Siemens Healthineers Gains CE Marks for Seasonal Viral Assays..... 262

6.15 NanoDx Prepares for POC Platform Commercialization With TBI, COVID Tests 263

6.16 North American Dx Recalls Covid Rapid Antigen Tests 265

6.17 Domus Dx to Launch OC Diagnostics Test System 266

6.18 Becton Dickinson, ReturnSafe Collaborate on COVID-19 Testing..... 269

6.19 Mammoth Biosciences High-Throughput CRISPR-Based COVID Test Gets FDA EUA 270

6.20 At-Home COVID Test Coverage 271

6.21	LuminUltra Wins 500-Site CDC Wastewater Testing Contract	271
6.22	Sense Biodetection to Debut Instrument-Free Point-of-Care MDx.....	273
6.23	Tests Called Back	277
6.24	Cepheid Obtains CE Mark for Expanded Combo COVID Test	277
6.25	CRISPR Tests for SARS-CoV-2 Using Saliva Samples.....	278
6.26	CVS Limits Purchases of Rapid Covid-19 Tests	282
6.27	Illumina, COVID-19 Surveillance Continue to Boost Business.....	282
6.28	LetsGetChecked Closes \$150M Funding Round	286
6.29	Novacyt Gets CE Mark for Multigene SARS-CoV-2 Test, Launches RUO Variant Assay 286	
6.30	Abbott Sees Sharp Decline in COVID-19 Test Revenue	287
6.31	Phosphorus Diagnostics Gets EUA for DTC C19 Test, Sample Collection Kit.....	288
6.32	NY Times Explores Multiplex Testing	289
6.33	Hologic Banking on MDx Acquisitions	290
6.34	Demand for Cepheid SARS-CoV-2 Point-of-Care Tests to Continue Through 2022..	295
6.35	DiaSorin Acquires Luminex to Broaden MDx Portfolio, Expand US Presence	297
6.36	LumiraDx to Go Public Through SPAC	302
6.37	Eurofins Test Helps to ID Mutations	303
6.38	Roche Sees Growing Opportunities for Diagnostics.....	309
6.39	Roche to Acquire GenMark Diagnostics for \$1.8B	313
6.40	Fulgent Genetics s to Use COVID-19 Testing Gains to Grow Clinical Sequencing ...	315
6.41	LexaGene Syndromic Panel Platform Lets Labs Customize Targets	318
6.42	FDA Grants EUAs for DTC Sample Collection Kit, Two Molecular Tests	323
6.43	At-Home Infectious Disease Test Developer Lucira Health Goes Public	324

7 The Global Market for COVID-19 Diagnostics.....326

7.1 Global Market Overview by Country 327

7.1.1 Table – Global Market by Country..... 327

7.1.2 Chart - Global Market by Country 328

7.2 Global Market by Technology - Overview..... 329

7.2.1 Table – Global Market by Technology 329

7.2.2 Chart – Global Market by Technology – Base/Final Year Comparison 330

7.2.3 Chart – Global Market by Technology – Base Year 331

7.2.4 Chart – Global Market by Technology – End Year 332

7.2.5 Chart – Global Market by Technology – Share by Year..... 333

7.2.6 Chart – Global Market by Technology – Segments Growth..... 334

7.3 Global Market by Product - Overview 335

7.3.1 Table – Global Market by Product..... 335

7.3.2 Chart – Global Market by Product – Base/Final Year Comparison..... 336

7.3.3 Chart – Global Market by Product – Base Year..... 337

7.3.4 Chart – Global Market by Product – End Year 338

7.3.5 Chart – Global Market by Product – Share by Year 339

7.3.6 Chart – Global Market by Product – Segments Growth 340

7.4 Global Market by Channel - Overview 341

7.4.1 Table – Global Market by Channel..... 341

7.4.2 Chart – Global Market by Channel – Base/Final Year Comparison 342

7.4.3 Chart – Global Market by Channel – Base Year..... 343

7.4.4 Chart – Global Market by Channel – End Year 344

7.4.5 Chart – Global Market by Channel – Share by Year..... 345

7.4.6 Chart – Global Market by Channel – Segments Growth 346

8 Global COVID-19 Diagnostic Markets – By Technology347

8.1 PCR..... 348

8.1.1 Table PCR – by Country 348

8.1.2 Chart - PCR Growth..... 349

8.2 PCR Multiplex..... 350

8.2.1 Table PCR Multiplex – by Country 350

8.2.2 Chart - PCR Multiplex Growth 351

8.3 Sequencing 352

8.3.1 Table Sequencing – by Country..... 352

8.3.2 Chart - Sequencing Growth 353

8.4 Antibody 354

8.4.1 Table Antibody – by Country..... 354

8.4.2 Chart - Antibody Growth 355

8.5 Antigen 356

8.5.1 Table Antigen – by Country..... 356

8.5.2 Chart – Antigen Growth..... 357

9 Global COVID-19 Diagnostic Markets – By Product358

9.1 Instruments..... 359

9.1.1 Table Instruments – by Country 359

9.1.2 Chart - Instruments Growth..... 360

9.2 Reagents & Kits..... 361

9.2.1 Table Reagents & Kits – by Country 361

9.2.2 Chart – Reagents & Kits Growth..... 362

9.3 Extraction..... 363

 9.3.1 Table Extraction – by Country 363

 9.3.2 Chart - Extraction Growth..... 364

9.4 Collection 365

 9.4.1 Table Collection – by Country..... 365

 9.4.2 Chart - Collection Growth 366

10 Global COVID-19 Diagnostic Markets – By Channel.....367

 10.1 Public..... 368

 10.1.1 Table Public – by Country 368

 10.1.2 Chart - Public Growth 369

 10.2 Hospital 370

 10.2.1 Table Hospital – by Country..... 370

 10.2.2 Chart - Hospital Growth 371

 10.3 Clinic..... 372

 10.3.1 Table Clinic – by Country..... 372

 10.3.2 Chart - Clinic Growth 373

 10.4 Workplace 374

 10.4.1 Table Workplace – by Country..... 374

 10.4.2 Chart - Workplace Growth..... 375

 10.5 DTC/OTC 376

 10.5.1 Table DTC/OTC – by Country 376

 10.5.2 Chart – DTC/OTC Growth 377

 10.6 Wastewater 378

 10.6.1 Table Wastewater – by Country..... 378

10.6.2 Chart – Wastewater Growth..... 379

11 Appendix380

11.1 U.S., Europe, Asia Approved COVID-19 Assays..... 381

Table of Tables

Table 1 Who List of Potential Pandemic Pathogens 46

Table 2 Characteristics of Coronavirus Pandemic Infections 57

Table 3 COVID-19 Symptoms..... 59

Table 4 Market Players by Type 73

Table 5 Global Market by Region 327

Table 6 Global Market by Technology 329

Table 7 Global Market by Product..... 335

Table 8 Global Market by Channel..... 341

Table 9 PCR by Country 348

Table 10 PCR Multiplex by Country 350

Table 11 Sequencing by Country 352

Table 12 Antibody by Country..... 354

Table 13 Antigen by Country 356

Table 14 Instruments by Country 359

Table 15 Reagents & Kits by Country 361

Table 16 Extraction by Country 363

Table 17 Collection by Country..... 365

Table 18 Public by Country 368

Table 19 Hospital by Country 370

Table 20 Clinic by Country..... 372

Table 21 Workplace by Country..... 374

Table 22 DTC/OTC by Country 376

Table 23 Wastewater by Country 378

Table 24 Approved Covid-19 Assays 381

Table of Figures

Figure 1 Global Distribution Pandemic Preparedness 29

Figure 2 Global Pandemic Pathogen Status 30

Figure 3 Estimated Economic Impact of Viral Pandemic by Region 32

Figure 4 Historical Pandemics Infographic 43

Figure 5 Antigenic Drift Creates a new Strain of Virus 50

Figure 6 Structure of Coronaviruses..... 53

Figure 7 The Road to Diagnostics 72

Figure 8 Global Market Share Chart 328

Figure 9 Base/Final Year Comparison Chart..... 330

Figure 10 Global Markets by Technology Base Year 331

Figure 11 Global Markets by Technology End Year..... 332

Figure 12 Global Markets by Technology Share by Year 333

Figure 13 Global Markets by Technology Segment Growth 334

Figure 14 Global Market by Product Base vs. Final..... 336

Figure 15 Global Market by Product Base Year 337

Figure 16 Global Market by Product End Year..... 338

Figure 17 Global Market by Product Share by Year 339

Figure 18 Global Market by Product Segments Growth..... 340

Figure 19 global Market by Channel – Base vs. Final..... 342

Figure 20 global Market by Channel – Base Year..... 343

Figure 21 global Market by Channel – End Year 344

Figure 22 global Market by Channel – Share by Year..... 345

Figure 23 global Market by Channel – Segments Growth 346

Figure 24 PCR Growth 349

Figure 25 PCR Multiplex Growth 351

Figure 26 Sequencing Growth 353

Figure 27 Antibody Growth 355

Figure 28 Antigen Growth 357

Figure 29 Instruments Growth 360

Figure 30 Reagents & Kits Growth 362

Figure 31 Extraction Growth..... 364

Figure 32 Collection Growth 366

Figure 33 Public Growth 369

Figure 34 Hospital Growth 371

Figure 35 Clinic Growth 373

Figure 36 Workplace Growth..... 375

Figure 37 DTC/OTC Growth..... 377

Figure 38 Wastewater Growth 379