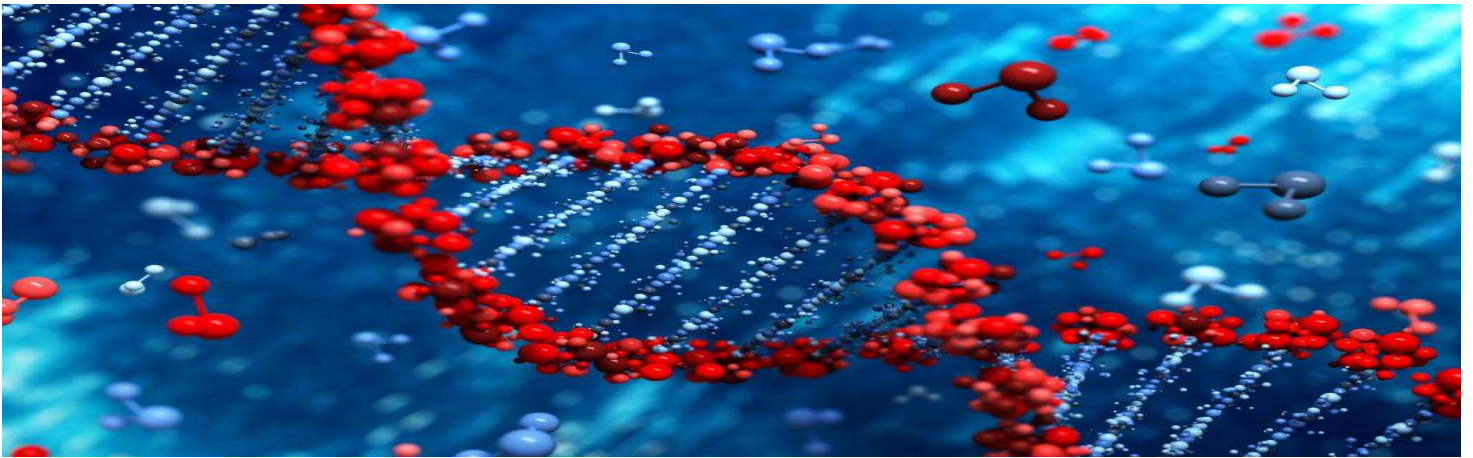


# RESEARCH REPORT



## PCR Markets

Forecasts for qPCR, dPCR, Singleplex & Multiplex Markets and by Application, Product and Place. With Executive and Consultant Guides, Including Customized Forecasting and Analysis.

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 .....20
  - 1.1 Situation Analysis ..... 21
  - 1.2 Guide for Executives and Marketing Staff ..... 23
  - 1.3 Guide for Investment Analysts and Management Consultants..... 24
- 2 Introduction and Market Definition .....25
  - 2.1 What are PCR Technologies? ..... 26
  - 2.2 PCR and Syndromic Testing ..... 28
  - 2.3 Market Definition ..... 29
    - 2.3.1 Market Size ..... 29
    - 2.3.2 Currency ..... 29
    - 2.3.3 Years ..... 29
  - 2.4 Methodology..... 30
    - 2.4.1 Methodology ..... 30
    - 2.4.2 Sources ..... 30
    - 2.4.3 Authors ..... 30
  - 2.5 Perspective: Healthcare and the IVD Industry ..... 32
    - 2.5.1 Global Healthcare Spending ..... 32
    - 2.5.2 Spending on Diagnostics ..... 33
    - 2.5.3 Important Role of Insurance for Diagnostics..... 35
- 3 PCR – Guide to PCR Technologies.....36
  - 3.1 Concepts..... 37
    - 3.1.1 Method..... 38
  - 3.2 Applications..... 41
    - 3.2.1 Finding Specific DNA..... 41

- 3.2.2 Measuring DNA..... 42
- 3.2.3 Medical and Diagnostic Applications..... 44
  - 3.2.3.1 Carrier, prenatal and tissue typing..... 44
  - 3.2.3.2 Cancer Diagnosis and Management..... 44
  - 3.2.3.3 Infectious Disease – New Levels of Accuracy and Sensitivity ..... 44
  - 3.2.3.4 Forensic Applications ..... 46
  - 3.2.3.5 Science and Research..... 47
- 3.3 PCR – Advantages and Disadvantages ..... 49
- 3.4 Different Types of PCR ..... 50
  - 3.4.1 Simple Changes ..... 50
    - 3.4.1.1 Multiplex-PCR ..... 50
    - 3.4.1.2 VNTR PCR..... 50
    - 3.4.1.3 Asymmetric PCR ..... 50
    - 3.4.1.4 Long PCR..... 51
    - 3.4.1.5 Nested PCR ..... 51
    - 3.4.1.6 Quantitative PCR..... 51
    - 3.4.1.7 Hot-start PCR ..... 51
    - 3.4.1.8 Touchdown PCR ..... 52
    - 3.4.1.9 Assembly PCR ..... 52
    - 3.4.1.10 Colony PCR ..... 52
    - 3.4.1.11 Suicide PCR ..... 52
    - 3.4.1.12 Cold PCR ..... 53
  - 3.4.2 Digital PCR ..... 54
    - 3.4.2.1 Droplet Digital PCR ..... 55
    - 3.4.2.2 Comparison between dPCR and Real-Time PCR (qPCR) ..... 56
    - 3.4.2.3 Digital PCR in Use..... 57
    - 3.4.2.4 Digital PCR Commercial History..... 57

- 3.4.3 Isothermal PCR ..... 58
- 4 Industry Overview.....60
  - 4.1 Players in a Dynamic Market..... 61
    - 4.1.1 Academic Research Lab ..... 62
    - 4.1.2 Diagnostic Test Developer..... 62
    - 4.1.3 Instrumentation Supplier ..... 63
    - 4.1.4 Chemical/Reagent Supplier..... 63
    - 4.1.5 Pathology Supplier ..... 63
    - 4.1.6 Independent Clinical Laboratory ..... 64
    - 4.1.7 Public National/regional Laboratory ..... 64
    - 4.1.8 Hospital Laboratory ..... 65
    - 4.1.9 Physicians Office Lab (POLs) ..... 65
    - 4.1.10 Audit Body ..... 66
    - 4.1.11 Certification Body..... 66
- 5 Market Trends .....68
  - 5.1 Factors Driving Growth ..... 69
    - 5.1.1 A New Standard ..... 69
    - 5.1.2 Down the Curve We Go ..... 70
    - 5.1.3 Multiplexing..... 71
    - 5.1.4 Syndromic Diagnostics Looks Unstoppable..... 72
    - 5.1.5 The Genetic Blizzard ..... 73
  - 5.2 Factors Limiting Growth ..... 74
    - 5.2.1 The Cost Curve ..... 74
    - 5.2.2 The Other Guys ..... 74
    - 5.2.3 Systemic Roadblocks ..... 75
  - 5.3 Diagnostic Technology Development ..... 76
    - 5.3.1 The Instrumentation Curve ..... 76

- 5.3.2 Shifting Role of Diagnostics..... 77
- 5.3.3 Diagnostics Moves Out of the Hospital..... 78
- 5.3.4 Disruption Looms..... 78
- 5.3.5 The Next Five Years..... 79
- 6 PCR Recent Developments.....80
  - 6.1 Recent Developments – Importance and How to Use This Section ..... 81
    - 6.1.1 Importance of These Developments ..... 81
    - 6.1.2 How to Use This Section..... 81
  - 6.2 Agilent, Qiagen Nab FDA Approvals for Lung Cancer Treatment CDx..... 81
  - 6.3 HealthTrackRx Investing in Rapid Turnaround Times ..... 82
  - 6.4 LEX Dx Developing Ultra-Fast Low-Cost PCR..... 85
  - 6.5 Next-Gen Dx Technologies Face Uncertain Future ..... 87
  - 6.6 Rover Dx Developing All-Optical Rapid POC qPCR Platform ..... 91
  - 6.7 ProtonDx Plans Rapid Molecular Dx Instrument..... 95
  - 6.8 Innova Medical Group Licenses MDx Tech ..... 97
  - 6.9 MicroGEM to Grow Market for 30-Minute RT-PCR System ..... 97
  - 6.10 Precipio Receives CE-IVD Mark for Cancer Panels ..... 101
  - 6.11 Siemens Healthineers to Develop Next-Gen MDx Platform..... 101
  - 6.12 New York State Approves Enzo Biochem HPV Molecular Test ..... 104
  - 6.13 Grip Molecular Developing Biosensor Panel to Detect Respiratory Infections ..... 105
  - 6.14 Co-Diagnostics Seeks EUA for At-Home PCR Diagnostic System ..... 109
  - 6.15 Chelex-Based Protocol to Reduce Cost, Time for PCR Testing ..... 113
  - 6.16 Finnish Firms to Form Point-of-Care Testing Firm..... 116
  - 6.17 Visby Medical Scales Up Handheld PCR Test for STIs ..... 117
  - 6.18 DnaNudge Raises \$60M..... 121
  - 6.19 Roche Reports Diagnostics Revenue Up 51 Percent ..... 122
  - 6.20 BforCure Preparing Multiple ID Panels for PoC qPCR Platform..... 125

6.21	Enzo Biochem, CLX Health Partner for C19 Testing for Travel.....	128
6.22	Bio Molecular Systems Gets Approval for Portable PCR Cyclers.....	129
6.23	Roche Acquires GenMark.....	129
6.24	Handheld qPCR Devices Close to Commercialization.....	130
6.25	Nuclein Closes \$14M in Funding.....	136
6.26	WuXi Diagnostics Closes \$150M Series B Financing Round.....	137
6.27	Visby Medical to develop rapid Flu-COVID PCR test.....	138
6.28	Thermo Fisher to acquire Mesa Biotech.....	139
6.29	Scope Fluidics Secures €6.2M Supporting Rapid MDx.....	140
6.30	SARS- Testing Demand to Continue 'Through 2022, and Beyond'.....	141
6.31	Malaria Assays Use CRISPR for Point-of-Care Multispecies Detection.....	145
6.32	Fluidigm Saliva Test for SARS-CoV-2 Uses Extraction-free RT-PCR.....	149
6.33	Visby Medical Gonorrhea Test Wins \$19M AMR Diagnostic Competition.....	150
7	Profiles of Key PCR Companies.....	151
7.1	Abacus Diagnostica.....	152
7.2	Abbott Laboratories.....	153
7.3	Accelerate Diagnostics.....	154
7.4	Ador Diagnostics.....	155
7.5	ADT Biotech.....	156
7.6	Agilent/Dako.....	157
7.7	Akonni Biosystems.....	159
7.8	Alveo Technologies.....	160
7.9	Amoy Diagnostics Co., Ltd.....	161
7.10	Anatolia Geneworks.....	162
7.11	Applied BioCode.....	163
7.12	Applied DNA Sciences.....	165
7.13	Aurora Biomed.....	166



7.14	Aus Diagnostics .....	167
7.15	AVIVA Systems Biology.....	168
7.16	Beckman Coulter Diagnostics.....	169
7.17	Becton, Dickinson and Company .....	170
7.18	Binx Health .....	172
7.19	Biocartis.....	173
7.20	bioMérieux Diagnostics.....	174
7.21	Bioneer Corporation .....	176
7.22	Bio-Rad Laboratories, Inc.....	178
7.23	Bosch Healthcare Solutions GmbH.....	180
7.24	Bruker.....	181
7.25	Caris Molecular Diagnostics .....	182
7.26	Cepheid (Danaher) .....	183
7.27	Credo Diagnostics Biomedical .....	185
7.28	Cue Health.....	186
7.29	Curetis N.V. / Curetis GmbH.....	188
7.30	Diagenode Diagnostics .....	189
7.31	Diasorin S.p.A.....	190
7.32	Enzo Biochem .....	192
7.33	Eurofins Scientific .....	193
7.34	Fluxergy .....	195
7.35	Genetic Signatures.....	196
7.36	GenMark Dx (Roche) .....	197
7.37	Hibergene Diagnostics.....	199
7.38	Hologic .....	200
7.39	Immunexpress.....	202
7.40	Inflammatix .....	203

7.41	Invetech.....	204
7.42	Janssen Diagnostics .....	205
7.43	Karius .....	206
7.44	Lexagene .....	207
7.45	LightDeck Diagnostics .....	208
7.46	Luminex Corp .....	209
7.47	Maxim Biomedical .....	211
7.48	Meridian Bioscience.....	212
7.49	Mesa Biotech (Thermo Fisher) .....	214
7.50	Millipore Sigma .....	215
7.51	Mobidiag (Hologic).....	216
7.52	Molbio Diagnostics.....	217
7.53	Nanomix.....	218
7.54	NGeneBio.....	219
7.55	Novacyt .....	221
7.56	Operon.....	222
7.57	Panagene.....	223
7.58	Perkin Elmer.....	224
7.59	Precipio .....	226
7.60	Primerdesign (Novacyt) .....	227
7.61	Promega .....	228
7.62	Prominex .....	230
7.63	Qiagen.....	231
7.64	QuantuMDx .....	233
7.65	Quidel.....	234
7.66	Randox Toxicology.....	236
7.67	Roche Molecular Diagnostics .....	237

7.68	SD Biosensor .....	239
7.69	Seegene.....	240
7.70	Siemens Healthineers .....	241
7.71	SkylineDx .....	242
7.72	Sona Nanotech .....	243
7.73	SpeedX.....	244
7.74	Standard BioTools .....	245
7.75	T2 Biosystems.....	246
7.76	Thermo Fisher Scientific Inc.....	247
7.77	Veramarx .....	249
7.78	Veredus Laboratories.....	250
7.79	Vircell.....	251
7.80	Visby Medical .....	252
7.81	XCR Diagnostics .....	254
7.82	YD Diagnostics.....	255
7.83	Zhejiang Orient Gene Biotech .....	256
8	The Global PCR Markets .....	257
8.1	PCR – Global Market Overview by Country .....	258
8.1.1	Table – Global Market by Country.....	258
8.1.2	Chart - Global Market by Country .....	259
8.2	Global Market by Application - Overview .....	260
8.2.1	Table – Global Market by Application .....	260
8.2.2	Chart – Global Market by Application – Segments Growth .....	261
8.2.3	Chart – Global Market by Application – Base/Final Comparison .....	262
8.2.4	Chart – Global Market by Application – Base Year .....	263
8.2.5	Chart – Global Market by Application – Final Year.....	264
8.2.6	Chart – Global Market by Application – Share by Year.....	265

8.3	Global Market by Technology - Overview.....	266
8.3.1	Table – Global Market by Technology .....	266
8.3.2	Chart – Global Market by Technology – Segments Growth.....	267
8.3.3	Chart – Global Market by Technology – Base/Final Comparison .....	268
8.3.4	Chart – Global Market by Technology – Base Year .....	269
8.3.5	Chart – Global Market by Technology – Final Year.....	270
8.3.6	Chart – Global Market by Technology – Share by Year.....	271
8.4	Global Market by Product - Overview .....	272
8.4.1	Table – Global Market by Product.....	272
8.4.2	Chart – Global Market by Product – Segments Growth .....	273
8.4.3	Chart – Global Market by Product – Base/Final Comparison.....	274
8.4.4	Chart – Global Market by Product – Base Year.....	275
8.4.5	Chart – Global Market by Product – Final Year .....	276
8.4.6	Chart – Global Market by Product – Share by Year .....	277
8.5	Global Market by Place - Overview .....	278
8.5.1	Table – Global Market by Place.....	278
8.5.2	Chart – Global Market by Place – Segments Growth .....	279
8.5.3	Chart – Global Market by Place – Base/Final Comparison .....	280
8.5.4	Chart – Global Market by Place – Base Year.....	281
8.5.5	Chart – Global Market by Place – Final Year.....	282
8.5.6	Chart – Global Market by Place – Share by Year.....	283
9	Global PCR Markets – By Application .....	284
9.1	PCR Clinical Multiplex .....	285
9.1.1	Table PCR Clinical Multiplex Testing – by Country .....	285
9.1.2	Chart - PCR Clinical Multiplex Testing Growth .....	286
9.2	PCR Clinical Singleplex .....	287
9.2.1	Table PCR Clinical Singleplex Testing – by Country .....	287

9.2.2	Chart - PCR Clinical Singleplex Testing Growth .....	288
9.3	PCR Research.....	289
9.3.1	Table PCR Research – by Country .....	289
9.3.2	Chart - PCR Research Growth.....	290
9.4	PCR Single C19 .....	291
9.4.1	Table PCR Single C19 – by Country .....	291
9.4.2	Chart - PCR Single C19 Growth.....	292
9.5	PCR Other .....	293
9.5.1	Table PCR Other – by Country .....	293
9.5.2	Chart - PCR Other Growth.....	294
10	Global PCR Markets – By Technology .....	295
10.1	qPCR .....	296
10.1.1	Table qPCR – by Country.....	296
10.1.2	Chart - qPCR Growth .....	297
10.2	dPCR .....	298
10.2.1	Table dPCR – by Country.....	298
10.2.2	Chart - dPCR Growth .....	299
10.3	Single C19 PCR .....	300
10.3.1	Table Single C19 PCR – by Country .....	300
10.3.2	Chart - Single C19 PCR Growth.....	301
10.4	Other PCR .....	302
10.4.1	Table Other PCR – by Country .....	302
10.4.2	Chart - Other PCR Growth.....	303
11	Global PCR Markets – By Product.....	304
11.1	PCR Instruments.....	305
11.1.1	Table PCR Instruments – by Country .....	305
11.1.2	Chart - PCR Instruments Growth.....	306

- 11.2 PCR Nucleic Acid Extraction ..... 307
  - 11.2.1 Table PCR Nucleic Acid Extraction – by Country ..... 307
  - 11.2.2 Chart - PCR Nucleic Acid Extraction Growth..... 308
- 11.3 PCR Consumables..... 309
  - 11.3.1 Table PCR Consumables – by Country ..... 309
  - 11.3.2 Chart - PCR Consumables Growth ..... 310
- 11.4 PCR Services ..... 311
  - 11.4.1 Table Services – by Country..... 311
  - 11.4.2 Chart - PCR Services Growth..... 312
- 12 Global PCR Markets – By Place .....313
  - 12.1 PCR Clinical Laboratory ..... 314
    - 12.1.1 Table PCR Clinical Clinical Laboratory – by Country..... 314
    - 12.1.2 Chart - PCR Clinical Clinical Laboratory Growth ..... 315
  - 12.2 PCR Point of Care ..... 316
    - 12.2.1 Table PCR Point of Care – by Country..... 316
    - 12.2.2 Chart - PCR Point of Care Growth ..... 317
  - 12.3 PCR Commercial..... 318
    - 12.3.1 Table PCR Commercial – by Country ..... 318
    - 12.3.2 Chart - PCR Commercial Growth ..... 319
  - 12.4 PCR Pharmaceutical ..... 320
    - 12.4.1 Table PCR Pharmaceutical – by Country..... 320
    - 12.4.2 Chart - PCR Pharmaceutical Growth ..... 321
  - 12.5 PCR Other Place ..... 322
    - 12.5.1 Table PCR Other Place – by Country..... 322
    - 12.5.2 Chart - PCR Other Place Growth ..... 323
- 13 Appendices .....324
  - 13.1 United States Medicare System: Laboratory Fees Schedule ..... 325

13.2	The Most Used IVD Assays.....	416
13.3	The Highest Grossing Assays .....	421

## Table of Tables

Table 1 Market Players by Type .....	62
Table 2 Five Factors Driving Growth.....	69
Table 3 Three Factors Limiting Growth .....	74
Table 4 Market Size by Country .....	258
Table 5 Global Market by Application .....	260
Table 6 Global Market by Technology .....	266
Table 7 Global Market by Product.....	272
Table 8 Global Market by Place.....	278
Table 9 PCR Clinical Multiplex by Country.....	285
Table 10 PCR Clinical Singleplex by Country.....	287
Table 11 PCR Research by Country .....	289
Table 12 PCR Single C19 by Country.....	291
Table 13 PCR Other by Country .....	293
Table 14 qPCR by Country.....	296
Table 15 Single C19 PCR by Country.....	300
Table 16 Other PCR by Country .....	302
Table 17 PCR Instruments by Country .....	305
Table 18 PCR Nucleic Acid Extraction by Country .....	307
Table 19 PCR Consumables by Country .....	309
Table 20 PCR Services by Country.....	311
Table 21 PCR Clinical Clinical Laboratory by Country.....	314
Table 22 PCR Point of Care by Country.....	316
Table 23 PCR Commercial by Country .....	318
Table 24 PCR Pharmaceutical by Country.....	320



Table 25 PCR Other Place by Country.....	322
Table 26 Clinical Lab Fee Schedule .....	325
Table 27 The Most Common Assays.....	416
Table 28 Largest Revenue Assays.....	421

Table of Figures

Figure 1 The Global Healthcare Market..... 33

Figure 2 the Lab Test Pie..... 34

Figure 3 The PCR Process ..... 41

Figure 4 Creation of Sample Droplets for Digital PCR..... 55

Figure 5 The Road to Diagnostics ..... 61

Figure 6 Comparing Syndromic and Targeted Testing..... 72

Figure 7 Comparing The New Diagnostics and Traditional Testing ..... 77

Figure 8 Growth rates of PCR Diagnostic Segments..... 79

Figure 9 Base year Global Market Share Chart..... 259

Figure 10 PCR Market by Application – Segments Growth..... 261

Figure 11 PCR Market by Application – Base vs. final..... 262

Figure 12 PCR Market Base year ..... 263

Figure 13 PCR Market Final Year..... 264

Figure 14 Application Share by Year..... 265

Figure 15 PCR Market by Technology – Segments Growth..... 267

Figure 16 PCR Market by Technology – Base vs. final..... 268

Figure 17 PCR Market by Technology Base year ..... 269

Figure 18 PCR Market by Technology Final Year..... 270

Figure 19 Technology Share by Year..... 271

Figure 20 PCR Market by Product – Segments Growth ..... 273

Figure 21 PCR Market by Product – Base vs. final ..... 274

Figure 22 PCR Market by Product Base year..... 275

Figure 23 PCR Market by Product Final Year ..... 276

Figure 24 Product Share by Year ..... 277

Figure 25 PCR Market by Place – Segments Growth ..... 279

Figure 26 PCR Market by Place – Base vs. final ..... 280

Figure 27 PCR Market by Place Base year ..... 281

Figure 28 PCR Market by Place Final Year..... 282

Figure 29 Place Share by Year..... 283

Figure 30 PCR Clinical Multiplex Testing Growth ..... 286

Figure 31 PCR Clinical Singleplex Testing Growth ..... 288

Figure 32 PCR Research Growth ..... 290

Figure 33 PCR Single C19 Growth..... 292

Figure 34 PCR Other Growth..... 294

Figure 35 qPCR Growth ..... 297

Figure 36 dPCR Growth ..... 299

Figure 37 Single C19 PCR Growth..... 301

Figure 38 Other PCR Growth..... 303

Figure 39 PCR Instruments Growth ..... 306

Figure 40 PCR Nucleic Acid Extraction Growth..... 308

Figure 41 PCR Consumables Growth ..... 310

Figure 42 PCR Services Growth..... 312

Figure 43 PCR Clinical Clinical Laboratory Growth..... 315

Figure 44 PCR Point of Care Growth..... 317

Figure 45 PCR Commercial Growth ..... 319

Figure 46 PCR Pharmaceutical Growth ..... 321

Figure 47 PCR Other Place Growth..... 323