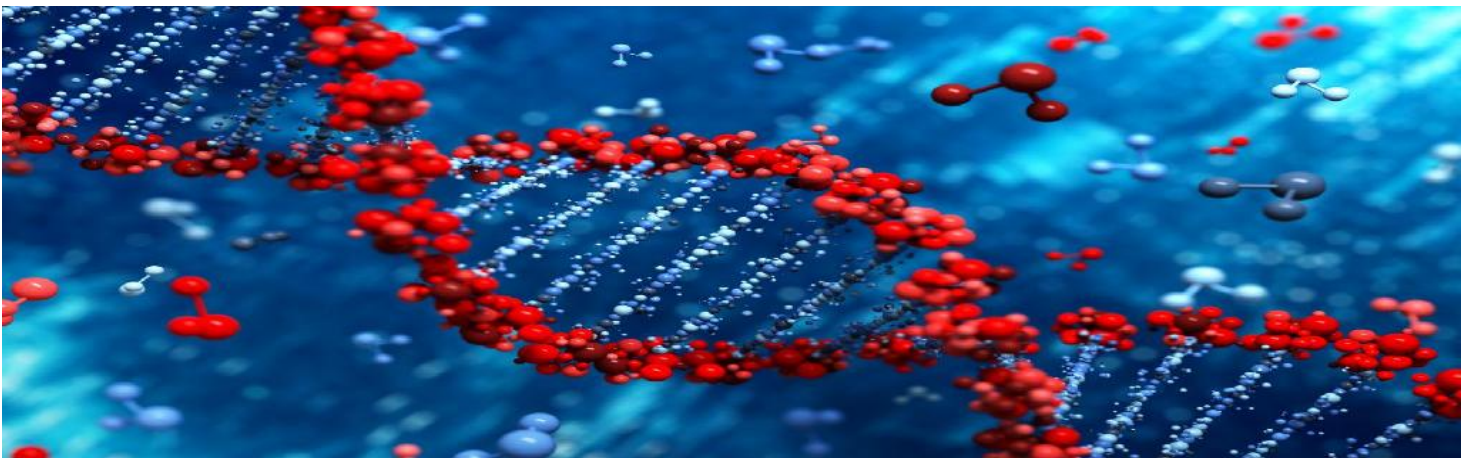


COVID-19 IMPACT

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



PCR Markets

Forecasts for qPCR, dPCR, Singleplex & Multiplex Markets with Executive and Consultant Guides, Including Customized Forecasting and Analysis. Updated to include impact of Covid-19 Diagnostics.

2021 to 2025





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

- i. Market Guides 17
 - iA. Situation Analysis 18
 - iB. Guide for Executives and Marketing Staff..... 20
 - iC. Guide for Investment Analysts and Management Consultants 21
- 1. Introduction and Market Definition 22
 - 1.1 What are PCR Technologies? 23
 - 1.2 PCR and Syndromic Testing 25
 - 1.3 Market Definition 26
 - 1.3.1 Market Size 26
 - 1.3.2 Currency..... 26
 - 1.3.3 Years 26
 - 1.4 Methodology 27
 - 1.4.1 Authors..... 27
 - 1.4.2 Sources 27
 - 1.5 U.S. Medical Market and laboratory Testing - Perspective 28
 - 1.4.1 U.S. Medicare Expenditures for Laboratory Testing 28
- 2. PCR – Guide to PCR Technologies 30
 - 2.1 Concepts 31
 - 2.1.1 Method..... 32
 - 2.2 Applications 36

- 2.2.1 Finding Specific DNA 36
- 2.2.2 Measuring DNA 37
- 2.2.3 Medical and diagnostic applications..... 38
 - 2.2.3.1 Carrier, prenatal and tissue typing..... 38
 - 2.2.3.2 Cancer Diagnosis and Management 38
 - 2.2.3.3 Infectious disease – New Levels of Accuracy and Sensitivity..... 38
 - 2.2.3.4 Forensic applications 40
 - 2.2.3.5 Science and Research 41
- 2.3 PCR – Advantages and Disadvantages 43
- 2.4 Different Types of PCR..... 44
 - 2.4.1 Simple Changes 44
 - 2.4.1.1 Multiplex-PCR 44
 - 2.4.1.2 VNTR PCR..... 44
 - 2.4.1.3 Asymmetric PCR 44
 - 2.4.1.4 Long PCR 45
 - 2.4.1.5 Nested PCR 45
 - 2.4.1.6 Quantitative PCR..... 45
 - 2.4.1.7 Hot-start PCR 45
 - 2.4.1.8 Touchdown PCR 46
 - 2.4.1.9 Assembly PCR 46
 - 2.4.1.10 Colony PCR 46
 - 2.4.1.11 Suicide PCR 46
 - 2.4.1.12 Cold PCR 47

- 2.4.2 Digital PCR 48
 - 2.4.2.1 Droplet Digital PCR..... 49
 - 2.4.2.2 Comparison between dPCR and Real-Time PCR (qPCR) 50
 - 2.4.2.3 Digital PCR in Use..... 51
 - 2.4.2.4 Digital PCR Commercial History..... 52
- 2.4.3 Isothermal PCR 53
- 3. Industry Overview..... 54
 - 3.1 Players in a Dynamic Market 55
 - 3.1.1 Academic Research Lab..... 55
 - 3.1.2 Diagnostic Test Developer 56
 - 3.1.3 Genomic Instrumentation Supplier..... 56
 - 3.1.3.1 Cell Separation and Viewing Instrumentation Supplier..... 57
 - 3.1.4 Pharmaceutical/Reagent Supplier..... 57
 - 3.1.5 Independent Testing Lab 57
 - 3.1.6 Public National/regional lab 58
 - 3.1.7 Hospital lab 58
 - 3.1.8 Physician Lab 58
 - 3.1.9 Audit Body 58
 - 3.1.10 Certification Body 59
- 4. Market Trends 60
 - 4.1 Factors Driving Growth 61
 - 4.1.1 A New Standard..... 62
 - 4.1.2 Down the Curve We Go 62

- 4.1.3 Multiplexing 62
- 4.1.4 Syndromic Diagnostics Looks Unstoppable 64
- 4.1.5 The Genetic Blizzard 65
- 4.2 Factors Limiting Growth 66
 - 4.2.1 The Cost Curve 66
 - 4.2.2 The Other Guys 67
 - 4.2.3 Systemic Roadblocks 67
- 4.3 Diagnostic Technology Development 68
 - 4.3.1 The Instrumentation Curve 68
 - 4.3.2 Shifting Role of Diagnostics 68
 - 4.3.3 Diagnostics Moves Out of the Hospital 69
 - 4.3.4 Disruption Looms 70
 - 4.3.5 The Next Five Years 71
- 5. PCR Recent Developments 72
 - 5.1 Recent Developments – Importance and How to Use This Section 73
 - 5.1.1 Importance of These Developments 73
 - 5.1.2 How to Use This Section 73
 - Scope Fluidics Secures €6.2M Supporting Rapid MDx 73
 - Quidel Expects SARS-CoV-2 Testing Demand to Continue 'Through 2022, and Beyond' 74
 - Malaria Assays Use CRISPR for Point-of-Care Multispecies Detection 78
 - Fluidigm Saliva Test for SARS-CoV-2 Uses Extraction-free RT-PCR 82
 - Visby Medical Gonorrhoea Test Wins \$19M AMR Diagnostic Competition 83
 - HelixBind Receives \$3M NIH Grant to Expand Bloodstream Infection Dx Platform 84

Israel's Nucleix Targeting US Market With Noninvasive Bladder, Lung Cancer Assays	84
Thermo Fisher Sees Many Complementary Offerings in Qiagen Combination	88
DxTerity Gets CE Mark for At-Home Blood Sample Collection Device.....	90
Fetal Cell-Based NIPT by Droplet Digital PCR Demonstrated in Japanese Pilot Study	90
ChromaCode Raises \$28M based on new High Definition PCR Technology.....	93
ddPCR Used for Fast and Low-Cost NIPT Screening	93
Study Validates ChromaCode HDPCR™ Testing for Tick-Borne Pathogens.....	94
Bio-Rad's ddPCR MSI RUO Assay is available	96
ctDNA Monitoring Is Important for BRAF-Mutant Melanoma	96
Sysmex Inostics Liquid Biopsy Demonstrates Two-fold Higher Detection	97
QIAGEN Plans for Next-Generation Digital PCR Systems.....	98
Bioneer HIV-1 Dx Kit Gets Korea FDA Approval	100
New PCR Technology: Transfer-PCR (tPCR) Applications	100
NimaGen Licenses PCR Tech from Salisbury NHS Foundation Trust	102
Natera Applies Massively Multiplexed PCR to Kidney Transplants	102
Paragon Genomics, MGI Tech Form Distribution Alliance	103
Synlab Pharma, Biotype Collaborate on Gastrointestinal, Endometrial Cancers	103
Qiagen, NeuMoDx Ink Partnership, Merger Agreement	104
Bruker to Acquire Majority in Hain Lifescience GmbH.....	105
Curetis to Cut 30 Percent of Workforce as Part of Strategic Restructuring.....	107
Cancer Early Detection Firm Ark Launches With \$40M Series A Investment	108
PredictImmune Wins £100K Grant for Study of IBD Prognostic	109
Biocartis, AstraZeneca Partner on European Lung Cancer Biomarker Study	109

Illumina Ventures Leads €16M Series A Investment in Digital PCR Firm Stilla Technologies 110

Bio-Rad Wins USDA Food Safety Testing Contract 111

Luminex, XCR Diagnostics Sign Nucleic Acid Amplification Tech Licensing Deal 111

6. Profiles of Key PCR Companies 112

 Abbott Diagnostics (Alere) 113

 Accelerate Diagnostics 115

 Agilent 116

 Alveo Technologies 117

 Applied BioCode 118

 Atlas Genetics 120

 Aus Diagnostics 121

 BD Diagnostics 123

 Biocartis 125

 BioFire Diagnostics 126

 bioMérieux 128

 Bioneer 129

 Bio-Rad Laboratories 130

 Bosch Healthcare Solutions GmbH 132

 Bruker 133

 Cepheid 134

 Curetis 136

 Diagenode Diagnostics 138

 Diasorin 139

Fluidigm 140

Fusion Genomics..... 141

GenePOC Diagnostics 142

GenMark Dx 144

Hologic 145

Invetech..... 146

Janssen Diagnostics 147

Karius 148

Lexigene 149

Luminex 150

Mesa Biotech 151

Mobidiag 153

Nanomix..... 154

Panagene..... 155

Precipio 156

Primerdesign 157

Prominex 158

Qiagen (Statdx) 159

Quantumdx 161

Roche Molecular Diagnostics 162

Seegene 164

Stilla Technologies 165

Siemens Healthineers (Fast Track Diagnostics) 166

SkylineDx	173
T2 Biosystems	174
Thermo Fisher.....	175
Veramarx.....	177
XCR Diagnostics.....	178
7. The PCR Markets.....	179
7.1 PCR – Global Market Overview by Country	180
7.1.1 Table – Global Market by Country	180
7.1.2 Chart - Global Market by Country.....	181
8. Global PCR Markets – By Application	182
8.1 Global Market by Application - Overview.....	183
8.1.1 Table – Global Market by Application.....	183
8.1.2 Chart – Global Market by Application – Base/Final Comparison	184
8.1.3 Chart – Global Market by Application – Base Year	185
8.1.4 Chart – Global Market by Application – Final Year.....	186
8.1.4 Chart – Global Market by Application – Share by Year	187
8.2 PCR Clinical Multiplex	188
8.2.1 Table PCR Clinical Multiplex Testing – by Country.....	188
8.2.2 Chart - PCR Clinical Multiplex Testing Growth	189
8.3 PCR Clinical Singleplex	190
8.3.1 Table PCR Clinical Singleplex Testing – by Country.....	190
8.3.2 Chart - PCR Clinical Singleplex Testing Growth	191
8.4 PCR Research	192

- 8.4.1 Table PCR Research – by Country 192
- 8.4.2 Chart - PCR Research Growth..... 193
- 8.5 PCR Single C19..... 194
 - 8.5.1 Table PCR Single C19 – by Country 194
 - 8.5.2 Chart - PCR Single C19 Growth..... 195
- 8.6 PCR Other 196
 - 8.6.1 Table PCR Other – by Country 196
 - 8.6.2 Chart - PCR Other Growth 197
- 9. Global PCR Markets – By Technology 198
 - 9.1 Global Market by Technology - Overview 199
 - 9.1.1 Table – Global Market by Technology 199
 - 9.1.2 Chart – Global Market by Technology – Base/Final Comparison 200
 - 9.1.3 Chart – Global Market by Technology – Base Year 201
 - 9.1.4 Chart – Global Market by Technology – Final Year..... 202
 - 9.1.4 Chart – Global Market by Technology – Share by Year 203
 - 9.2 qPCR..... 204
 - 9.2.1 Table qPCR – by Country 204
 - 9.2.2 Chart - qPCR Growth..... 205
 - 9.3 dPCR..... 206
 - 9.3.1 Table dPCR – by Country 206
 - 9.3.2 Chart - dPCR Growth..... 207
 - 9.4 Single C19 PCR..... 208
 - 9.4.1 Table Single C19 PCR – by Country 208

9.4.2 Chart - Single C19 PCR Growth.....	209
Appendices	210
I. United States Medicare System: 2020 Clinical Laboratory Fees Schedule	211

Table of Tables

Table 2 Lab Spending 2014 to 2024	29
Table 3 Market Players by Type	55
Table 4 Five Factors Driving Growth	61
Table 5 Three Factors Limiting Growth	66
Table 6 - Global PCR Market by Region	180
Table 7 Global Market by Application	183
Table 8 PCR Clinical Multiplex by Country	188
Table 9 PCR Clinical Singleplex by Country	190
Table 10 PCR Research by Country	192
Table 11 PCR Single C19 by Country	194
Table 12 PCR Other by Country	196
Table 13 Global Market by Technology	199
Table 14 qPCR by Country	204
Table 15 dPCR by Country	206
Table 16 Single C19 PCR by Country	208
Table 17 2020 Clinical Lab Fee Schedule	211

Table of Figures

Figure 2 Clinical Lab Spending 2014 to 2024..... 28

Figure 3 The PCR Process 35

Figure 4 Creation of Sample Droplets for Digital PCR 50

Figure 5 Comparing Syndromic and Targeted Testing 64

Figure 6 Comparing The New Diagnostics and Traditional Testing 69

Figure 7 Growth rates of PCR Diagnostic Segments 71

Figure 8 Base year Global Market Share Chart 181

Figure 9 PCR Market by Application – Base vs. final 184

Figure 10 PCR Market Base year 185

Figure 11 PCR Market Final Year 186

Figure 12 Application Share by Year 187

Figure 13 PCR Clinical Multiplex Testing Growth 189

Figure 14 PCR Clinical Singleplex Testing Growth 191

Figure 15 PCR Research Growth 193

Figure 16 PCR Single C19 Growth 195

Figure 17 PCR Other Growth..... 197

Figure 18 PCR Market by Technology - Base vs. Final 200

Figure 19 PCR Market Base Year 201

Figure 20 PCR Market Final Year 202

Figure 21 Technology Share by Year 203

Figure 22 qPCR Growth 205

Figure 23 dPCR Growth 207

Figure 24 Single C19 PCR Growth 209