

RESEARCH REPORT



CLINICAL LABORATORY MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE MARKETS.

Strategies and Trends. Forecasts by Application (Transplant, Respiratory, etc.)
by Country. With Market Analysis & 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 Guides18

 1.1 Situation Analysis 19

 1.2 Market Shares of Leading Companies – Table and Chart 21

2 Introduction and Market Definition23

 2.1 Market Definition 24

 2.1.1 Market Size 24

 2.1.2 Currency 24

 2.1.3 Years 25

 2.2 Methodology 26

 2.2.1 Methodology 26

 2.2.2 Sources 26

 2.2.3 Authors 26

 2.3 Perspective: Healthcare and the IVD Industry 28

 2.3.1 Global Healthcare Spending 28

 2.3.2 Spending on Diagnostics 29

 2.3.3 Important Role of Insurance for Diagnostics 31

3 The Infectious Diseases – Guide to the Pathogens.....32

 3.1 Infectious Disease Pathogens – The Big Picture 33

 3.1.1 Viruses 34

 3.1.2 Bacteria 35

 3.1.3 Fungi 37

 3.1.4 Parasites 37

 3.1.5 Prions 37

- 3.1.6 Virulence 38
- 3.1.7 Transmission..... 38
- 3.2 The Coronavirus..... 39
 - 3.2.1 Severe acute respiratory syndrome (SARS) 41
 - 3.2.2 Middle East respiratory syndrome (MERS) 43
 - 3.2.3 COVID-19. The SARS CoV 2 Virus..... 44
 - 3.2.3.1 Signs and symptoms 45
 - 3.2.3.2 Transmission 46
 - 3.2.3.3 Diagnosis 47
 - 3.2.3.4 Prevention 49
 - 3.2.3.5 Management..... 50
 - 3.2.3.6 Prognosis..... 51
- 3.4 HIV - Human Immunodeficiency Virus (AIDS) 52
 - 3.4.1 Virology 52
 - 3.4.1.1 Classification 52
 - 3.4.1.2 Structure and genome..... 53
 - 3.4.1.3 Tropism..... 55
 - 3.4.1.4 Replication cycle..... 57
 - 3.4.1.5 Genetic variability 63
 - 3.4.2 Diagnosis 65
 - 3.4.3 Testing..... 66
 - 3.4.3.1 Antibody tests 66
 - 3.4.3.2 Point of Care Tests (POCT) 69
 - 3.4.3.3 Antigen Tests 71
 - 3.4.3.4 Nucleic acid-based tests (NAT) 72
 - 3.4.3.5 Other tests used in HIV treatment..... 73

3.5	HBV – Hepatitis B.....	75
3.5.1	Virology	76
3.5.1.1	Genome	77
3.5.1.2	Pathogenesis.....	78
3.5.1.3	Hepatitis B virus replication	78
3.5.1.4	Serotypes and genotypes.....	79
3.5.2	Mechanisms.....	79
3.5.3	Diagnosis	80
3.5.4	Market Opportunity Analysis	81
3.6	HCV – Hepatitis C.....	83
3.6.1	Taxonomy.....	84
3.6.1.1	Structure	84
3.6.1.2	Genome	85
3.6.2	Molecular biology	86
3.6.3	Replication.....	87
3.6.4	Genotypes	89
3.6.4.1	Clinical importance.....	89
3.6.5	Market Opportunity Analysis	90
3.7	HPV - Human papillomavirus.....	91
3.7.1	Virology	93
3.7.1.1	E6/E7 proteins.....	93
3.7.1.2	Role in cancer.....	93
3.7.1.3	E2 research.....	94
3.7.1.4	Latency period	95
3.7.1.5	Clearance	95
3.7.2	Diagnosis	96

3.7.2.1	Cervical testing	96
3.7.2.2	Oral testing	98
3.7.2.3	Testing men	98
3.7.2.4	Other testing	99
3.7.3	Market Opportunity Analysis	100
3.8	Influenza.....	106
3.8.1	Virology	107
3.8.1.1	Types of virus	107
3.8.1.2	Influenzavirus A	107
3.8.1.3	Influenzavirus B.....	108
3.8.1.4	Influenzavirus C	108
3.8.1.5	Structure, properties, and subtype nomenclature	109
3.8.1.6	Replication	110
3.8.2	Testing.....	112
3.8.2.1	Advantages/Disadvantages of Molecular Assays.....	114
3.8.3	Market Opportunity Analysis	115
3.9	CTGC - Chlamydia/Gonorhea	124
3.9.1	Gonorrhea	124
3.9.1.1	Diagnosis	125
3.9.1.2	Screening	125
3.9.2	Chlamydia	125
3.9.2.1	Diagnosis	126
3.9.2.2	Screening	127
3.9.3	Testing.....	128
3.9.3.1	Nucleic acid amplification tests (NAATs).....	128
3.9.3.2	Performance of NAAT Tests.....	136

3.9.4	Market Opportunity Analysis	137
3.10	Tuberculosis.....	140
3.10.1	Mycobacteria.....	141
3.10.2	Diagnosis	142
3.10.2.1	Active tuberculosis	142
3.10.2.2	Latent tuberculosis.....	143
3.10.3	Epidemiology	143
3.10.4	Molecular Diagnostic Tests	145
3.10.5	Market Opportunity Analysis	146
3.11	MRSA - Methicillin-resistant Staphylococcus aureus	148
3.11.1	Diagnosis	148
3.11.2	FDA Approved Molecular Tests	149
3.11.3	Market Opportunity Analysis	150
3.12	VRE - Vancomycin-resistant Enterococcus	152
3.12.1	FDA Approved MDx Tests for VRE.....	153
3.12.2	Market Opportunity Analysis	154
3.13	VRE - Vancomycin-resistant Enterococcus.....	154
3.13.1	FDA Approved MDx Tests for VRE.....	155
3.13.2	Market Opportunity Analysis	156
4	Industry Overview.....	157
4.1	Players in a Dynamic Market.....	158
4.1.1	Academic Research Lab	159
4.1.2	Diagnostic Test Developer.....	159
4.1.3	Instrumentation Supplier	160
4.1.4	Chemical/Reagent Supplier.....	160
4.1.5	Pathology Supplier	160

- 4.1.6 Independent Clinical Laboratory 161
- 4.1.7 Public National/regional Laboratory 161
- 4.1.8 Hospital Laboratory 162
- 4.1.9 Physicians Office Lab (POLs) 162
- 4.1.10 Audit Body 163
- 4.1.11 Certification Body..... 163
- 4.2 The Clinical Laboratory Market Segments 165
 - 4.2.1 Traditional Market Segmentation..... 165
 - 4.2.2 Laboratory Focus and Segmentation..... 166
 - 4.2.3 Segmenting the Syndromic Testing Market..... 168
- 4.3 Industry Structure..... 169
 - 4.3.1 Hospital Testing Share 169
 - 4.3.2 Economies of Scale..... 169
 - 4.3.3 Hospital vs. Central Lab 170
 - 4.3.4 Physician Office Lab's..... 171
 - 4.3.5 Physician's and POCT 171
- 5 Market Trends 173
 - 5.1 Factors Driving Growth 174
 - 5.1.1 New Genotypes Creating New Markets 175
 - 5.1.2 Aging Population a Boon for All Diagnostics 175
 - 5.1.3 Developing World Driving ID Dx Growth..... 176
 - 5.1.4 Point of Care – Why Centralization is Losing Steam 176
 - 5.1.5 Self Testing..... 177
 - 5.1.6 The Need for Speed 177
 - 5.1.7 The COVID Pandemic..... 177
 - 5.2 Factors Limiting Growth 178

5.2.1	Lower Costs.....	178
5.2.2	Infectious Disease is Declining.....	180
5.2.3	Wellness Hurts.....	180
5.2.4	Economic Growth improves Living Standards	180
5.3	Instrumentation, Automation and Diagnostic Trends	181
5.3.1	Traditional Automation and Centralization.....	181
5.3.2	The New Automation, Decentralization and Point Of Care	181
5.3.3	Instruments Key to Market Share	183
5.3.4	Bioinformatics Plays a Role	183
5.3.5	PCR Takes Command.....	184
5.3.6	Next Generation Sequencing Fuels a Revolution.....	185
5.3.7	NGS Impact on Pricing.....	186
5.3.8	Whole Genome Sequencing, A Brave New World	186
5.3.9	Companion Diagnostics Blurs Diagnosis and Treatment	187
6	Clinical Laboratory MDx Infectious Disease Recent Developments.....	189
6.1	Recent Developments – Importance and How to Use This Section	190
6.1.1	Importance of These Developments	190
6.1.2	How to Use This Section.....	190
6.2	Takara Developing High-Throughput Multiplex Panels	190
6.3	BioGX Debuts New Point-of-Care Molecular Testing System	193
6.4	Nanopath MDx Platform Providing 15-Minute Results.....	198
6.5	ProtonDx Commercializing Rapid MDx Instrument.....	201
6.6	Siemens Healthineers to Develop Next-Gen, High-Throughput MDx Platform.....	203
6.7	Hologic Obtains CE Mark for MDx Epstein-Barr, BK Virus Assays.....	206
6.8	Pathogenomix Infectious Disease Platform Uses Cloud-Based Analytics, NGS	207
6.9	Accelerate Diagnostics Anticipates Growth.....	212

6.10	Growth of Decentralized Testing Expected to Continue.....	214
6.11	Lumos Diagnostics Expanding Test Portfolio	222
6.12	Study Validates Karius Cell-Free DNA to Detect Hundreds of Pathogens.....	226
6.13	CareDx, IDbyDNA Develop Infectious Disease Dx for Transplant Patients	230
6.14	Accelerated Development of CRISPR as a Diagnostic Platform	230
6.15	Lab-on-a-Chip Infection Test Threatens Clinical Laboratory Role.....	235
7	Key Companies and Competitive Analysis.....	238
7.1	Abbott Laboratories.....	239
7.2	Beckman Coulter Diagnostics.....	240
7.3	Becton, Dickinson and Company	241
7.4	bioMérieux Diagnostics.....	243
7.5	Bio-Rad Laboratories, Inc.	245
7.6	Cepheid (Danaher)	247
7.7	Hologic.....	249
7.8	Ortho Clinical Diagnostics	251
7.9	Perkin Elmer.....	252
7.10	Qiagen	254
7.11	Roche Molecular Diagnostics	256
7.12	Siemens Healthineers	258
7.13	Thermo Fisher Scientific Inc.....	259
8	The Global Market for Clinical Laboratory MDx Infectious Disease	261
8.1	Global Market Overview by Country	262
8.1.1	Table – Global Market by Country.....	262
8.1.2	Chart - Global Market by Country	263
8.2	Global Market by Application - Overview.....	264
8.2.1	Table – Global Market by Application	264

- 8.2.2 Chart – Global Market by Application – Base/Final Year Comparison 265
- 8.2.3 Chart – Global Market by Application – Base Year 266
- 8.2.4 Chart – Global Market by Application – End Year 267
- 8.2.5 Chart – Global Market by Application – Share by Year..... 268
- 8.2.6 Chart – Global Market by Application – Segments Growth..... 269
- 9 Global Clinical Laboratory MDx Infectious Disease Markets – By Application270
 - 9.1 Respiratory 271
 - 9.1.1 Table Respiratory – by Country 271
 - 9.1.2 Chart - Respiratory Growth..... 272
 - 9.2 Blood Borne Virus..... 273
 - 9.2.1 Table Blood Borne Virus – by Country 273
 - 9.2.2 Chart - Blood Borne Virus Growth 274
 - 9.3 Transplant 275
 - 9.3.1 Table Transplant – by Country 275
 - 9.3.2 Chart - Transplant Growth 276
 - 9.4 Hospital Acquired Infections 277
 - 9.4.1 Table Hospital Acquired Infections – by Country..... 277
 - 9.4.2 Chart - Hospital Acquired Infections Growth..... 278
 - 9.5 Reproductive Health 279
 - 9.5.1 Table Reproductive Health – by Country 279
 - 9.5.2 Chart – Reproductive Health Growth..... 280
 - 9.6 C19 Singleplex..... 281
 - 9.6.1 Table C19 Singleplex – by Country 281
 - 9.6.2 Chart – C19 Singleplex Growth 282
 - 9.7 Other 283
 - 9.7.1 Table Other – by Country 283

9.7.2 Chart - Other Growth..... 284

10 Appendices.....285

10.1 United States Medicare System: Clinical Laboratory Fees Schedule 285

10.2 The Most Used IVD Assays..... 380

10.3 The Highest Grossing Assays 385

Table of Tables

Table 1 Market Share of Leading Companies 21

Table 2 Viral Pathogens and Families 34

Table 3 Characteristics of Coronavirus Pandemic Infections 44

Table 4 COVID-19 Symptoms..... 46

Table 5 Classification of HIV Species..... 53

Table 6 HBV Tests - CMS Codes & Prices 83

Table 7 HCV Tests - CMS Codes & Prices 90

Table 8 HPV Clearance Rates 96

Table 9 HPV Tests - CMS Codes & Prices 101

Table 10 HPV Tests, Technology, Types 102

Table 11 Types of Influenza Tests 112

Table 12 Influenza Tests - CMS Codes & Prices..... 115

Table 13 FDA Cleared Molecular Assays for Influenza 117

Table 14 FDA Cleared NAAT CTGC Tests 129

Table 15 CTGC NAAT Target Sequences and Possible False Reactions 134

Table 16 Influenza Tests - CMS Codes & Prices..... 138

Table 17 FDA Approved MDx Tests for Tuberculosis 145

Table 18 Tuberculosis Tests - CMS Codes & Prices..... 146

Table 19 FDA Approved Tests for MRSA 149

Table 20 MRSA Tests - CMS Codes & Prices 151

Table 21 FDA Approved Tests for VRE 153

Table 22 VRE Tests - CMS Codes & Prices 154

Table 23 FDA Approved Tests for VRE 155

Table 24 VRE Tests - CMS Codes & Prices 156

Table 25 Market Players by Type 159

Table 26 Clinical Laboratory Departments and Segments 165

Table 27 Laboratory Management Focus – Different Approaches 166

Table 28 Key Segmentation Variables Going Forward..... 167

Table 29 Possible Market Segments of Syndromic Multiplex Market 168

Table 30 Five Factors Driving Growth 174

Table 31 Four Factors Limiting Growth 178

Table 32 Seven Key Diagnostic Laboratory Technology Trends 181

Table 33 - Global Market by Region 262

Table 34 Global Market by Application..... 264

Table 35 Respiratory by Country..... 271

Table 36 Blood Borne Virus by Country 273

Table 37 Transplant by Country 275

Table 38 Hospital Acquired Infections by Country..... 277

Table 39 Reproductive Health by Country 279

Table 40 C19 Singleplex by Country..... 281

Table 41 Other by Country..... 283

Table 42 Clinical Lab Fee Schedule 285

Table 43 The Most Common Assays..... 380

Table 44 Largest Revenue Assays..... 385

Table of Figures

Figure 1 Market Share of Leading Companies Chart..... 22

Figure 2 Global Health Care Spending..... 29

Figure 3 The Lab Test Pie 30

Figure 4 Structure of a Typical Virus..... 35

Figure 5 Mycobacterium Tuberculosis 36

FIGURE 6 STRUCTURE OF CORONAVIRUSES 40

Figure 7 HIV Virion 54

Figure 8 Diagram of the HIV Replication Cycle 58

Figure 9 The Structure of the HBV Virus..... 77

Figure 10 Hepatitis B Replication 78

Figure 11 Structure of the HCV Virus..... 85

Figure 12 HCV Replication Cycle 88

Figure 13 Structure of the Influenza Virion 109

Figure 14 Influenza Replication..... 110

Figure 15 Scanning Electronmicrograph of Tuberculosis..... 141

Figure 16 The Road to Diagnostics 158

Figure 17 Percentage of World Population Over 65..... 176

Figure 18 Chart Infectious Disease Decline 179

Figure 19 Centralized vs. Decentralized Laboratory Service 182

Figure 20 A Highly Multiplexed Syndromic Testing Unit..... 182

Figure 21 The Real Cost to Sequence the Human Genome..... 185

Figure 22 The Codevelopment Process 187

Figure 23 Global Market Share Chart 263

Figure 24 Global Market by Application - Base vs. Final 265

Figure 25 Global Market by Application Base Year..... 266

Figure 26 Global Market by Application End Year 267

Figure 27 Application Share by Year..... 268

Figure 28 Application Segments Growth..... 269

Figure 29 Respiratory Growth..... 272

Figure 30 Blood Borne Virus Diagnostics Growth..... 274

Figure 31 Transplant Growth 276

Figure 32 Hospital Acquired Infections Growth..... 278

Figure 33 Reproductive Health Growth 280

Figure 34 C19 Singleplex Growth..... 282

Figure 35 Other Growth..... 284