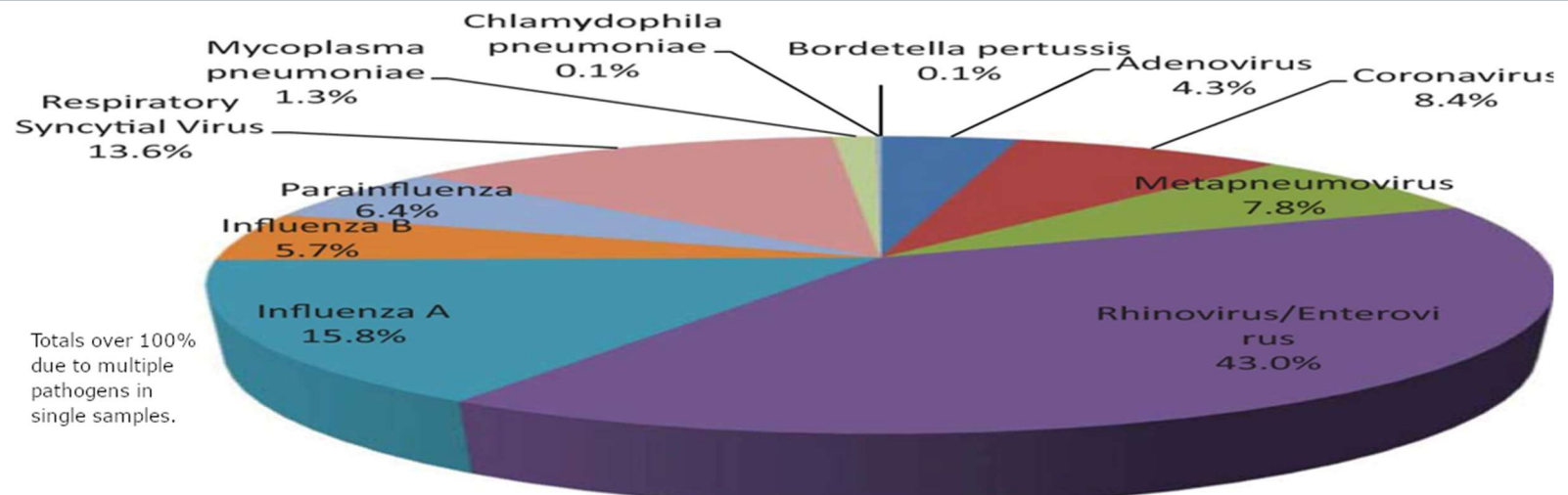


RESEARCH REPORT



SYNDROMIC MULTIPLEX PANELS MARKETS.

Strategies and Trends. Forecasts by Syndrome (Respiratory, Sepsis, GI etc.) by Place and by Product. With Market Analysis and Executive Guides.

2024 to 2028





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 Guides19

1.1 Situation Analysis 20

1.2 Guide for Executives and Marketing Staff 23

1.3 Guide for Investment Analysts and Management Consultants..... 25

2 Introduction and Market Definition27

2.1 What are Syndromic Multiplex Tests? 28

2.2 Syndromic Testing – the quiet revolution in diagnostics 29

2.2.1 Syndromic Testing – more than Panels. 30

2.3 Market Definition 31

2.3.1 Multiplex Market Size..... 31

2.3.2 Currency. 31

2.3.3 Years..... 32

2.4 Methodology..... 33

2.4.1 Methodology..... 33

2.4.2 Sources..... 33

2.4.3 Authors 33

2.5 Perspective: Healthcare and the IVD Industry 35

2.5.1 Global Healthcare Spending 35

2.5.2 Spending on Diagnostics 36

2.5.3 Important Role of Insurance for Diagnostics..... 38

3 Infectious Disease.....39

3.1 Infections – The Big Picture 40

3.2 The Pathogens..... 40

- 3.2.1 Bacteria..... 41
- 3.2.2 Fungi and Protozoa 43
- 3.2.3 Viruses..... 44
- 3.2.4 Prions 46
- 3.3 Symptoms and Syndromes..... 46
 - 3.3.1 Bacterial or viral..... 46
 - 3.3.2 Typical Viral Symptoms 46
 - 3.3.3 Typical Bacterial Symptoms..... 47
- 3.4 Disease..... 47
- 3.5 Transmission 47
- 3.6 Infectious Disease Diagnostics..... 48
 - 3.6.1 Microbial culture..... 49
 - 3.6.2 Microscopy 50
 - 3.6.3 Biochemical tests..... 51
 - 3.6.4 PCR-based diagnostics..... 52
 - 3.6.5 Metagenomic sequencing 52
- 3.7 Defining Infections 53
- 3.8 Syndromic Infection 54
- 4 Industry Overview.....55
 - 4.1 Players in a Dynamic Market..... 56
 - 4.1.1 Academic Research Lab 57
 - 4.1.2 Diagnostic Test Developer..... 57
 - 4.1.3 Instrumentation Supplier 58
 - 4.1.4 Chemical/Reagent Supplier..... 58
 - 4.1.5 Pathology Supplier 58
 - 4.1.6 Independent Clinical Laboratory 58

- 4.1.7 Public National/regional Laboratory 59
- 4.1.8 Hospital Laboratory 60
- 4.1.9 Physicians Office Lab (POLs) 60
- 4.1.10 Audit Body 61
- 4.1.11 Certification Body..... 61
- 4.2 The Clinical Laboratory Market Segments 63
 - 4.2.1 Traditional Market Segmentation..... 63
 - 4.2.2 Laboratory Focus and Segmentation..... 64
 - 4.2.3 Segmenting the Syndromic Testing Market..... 65
- 4.3 Industry Structure..... 67
 - 4.3.1 Hospital Testing Share 67
 - 4.3.2 Economies of Scale..... 67
 - 4.3.2.1 Hospital vs. Central Lab..... 68
 - 4.3.3 Physician Office Lab's..... 69
 - 4.3.4 Physician's and POCT 69
- 5 Market Trends71
 - 5.1 Factors Driving Growth 72
 - 5.1.1 Speed of Diagnosis..... 72
 - 5.1.2 Effect of Syndromic Testing on Costs..... 73
 - 5.1.3 Point of Care Advantage..... 73
 - 5.1.4 Accuracy and Diagnostic Risk..... 73
 - 5.1.5 Single Visits..... 73
 - 5.1.6 Improvement in Outcomes..... 74
 - 5.1.7 Impact of the Pandemic..... 74
 - 5.2 Factors Limiting Growth 75
 - 5.2.1 Lower Prices..... 75

- 5.2.2 Administration/reimbursement..... 76
- 5.2.3 Infectious Disease is Declining But..... 78
- 5.2.4 Wellness Hurts..... 78
- 5.2.5 Economic Growth improves Living Standards. 78
- 5.2.6 Impact of the Pandemic 79
- 5.3 Instrumentation, Automation and Diagnostic Trends 80
 - 5.3.1 Traditional Automation and Centralization..... 80
 - 5.3.2 The New Automation, Decentralization and Point of Care..... 80
 - 5.3.3 Instruments Key to Market Share 82
 - 5.3.4 Bioinformatics Plays a Role 82
 - 5.3.5 PCR Takes Command..... 83
 - 5.3.6 Next Generation Sequencing Fuels a Revolution..... 84
 - 5.3.7 NGS Impact on Pricing..... 85
 - 5.3.8 Whole Genome Sequencing, A Brave New World 85
 - 5.3.9 Companion Diagnostics Blurs Diagnosis and Treatment 86
 - 5.3.10 Comparing Syndrome and Targeted Testing 87
 - 5.3.11 The Multiplex Paradigm Shift..... 89
 - 5.3.12 The Sepsis Testing Market – Bellwether for Syndromics..... 90
 - 5.3.13 The Single Visit and AntiMicrobial Resistance 90
 - 5.3.14 Syndromics drives POCT adoption..... 91
- 6 Syndromic Testing Recent Developments92
 - 6.1 Recent Developments – Importance and How to Use This Section 93
 - 6.1.1 Importance of These Developments 93
 - 6.1.2 How to Use This Section..... 93
 - 6.2 BioMérieux Submits Application for Respiratory, Sore Throat Panel..... 93
 - 6.3 Sensible Diagnostics Nabs Award for Respiratory Panel..... 94

6.4	Aptitude Medical Systems to Develop At-Home STI Test	95
6.5	Multiplex Meningitis/Encephalitis Panel Market Expanding	95
6.6	Burst Dx to Deliver Lab-Accurate ELISA-in-a-Cartridge	104
6.7	OpGen Seeking Approval for UTI Panel	108
6.8	Altratech to Enter MDx, POC Space by Supplanting PCR.....	109
6.9	BIOFIRE Announces New SPOTFIRE® System.....	114
6.10	Cambridge Nucleomics to Develop 'Nanobait' Tech	115
6.11	Takara Bio Developing Multiplex Panels.....	118
6.12	Rover Diagnostics Developing Optical Multiplex PCR	119
6.13	Nanopath Secures Funding to Develop POC Dx	120
6.14	Genetic Signatures Wins Public Health Wales Contract	122
6.15	Qiagen Looks to Long-Term Growth.....	122
6.16	LexaGene Gets Investment.....	127
6.17	Seegene Multiplex COVID-19/Flu/RSV Test Receives Approval	127
6.18	BforCure to Adapt Rapid PCR Platform for Cancer	128
6.19	Accelerated Growth for Decentralized Testing.....	129
6.20	QuantuMDx Developing Syndromic Panels for European Launch.....	137
6.21	Quidel Gains CE Mark for Savanna Analyzer, Respiratory Panel	141
6.22	QuantumDx Gets CE Mark for Rapid PoC PCR System.....	142
6.23	Bio-Rad Laboratories, Seegene Partner for MDx Development.....	143
6.24	Baebies to Expand Finder Platform.....	144
6.25	With Luminex Acquisition, DiaSorin to Broaden MDx Portfolio	147
6.26	Binx Health Targeting Clinics, DTC & OTC With STI Tests	151
6.27	Luminex Lands BARDA Grant to Develop Test for SARS-CoV-2, Flu, RSV	155
6.28	Molzylm, Fraunhofer Developing Rapid Sepsis Diagnostic	156
6.29	MiRxes Receives Approval for Multiplex SARS-CoV-2, Flu Test.....	160

6.30 New Approach Involves Silicon-Based Test for Infectious Disease Screening..... 161

6.31 Scanogen's Portable Battery Operated Instrument for 90 Minute Multiplex Test 165

6.32 Qiagen sees NeuMoDx as Growth Vehicle 168

6.33 Torus Biosystems Developing Syndromic Test with 30-Minute Turnaround..... 173

6.34 Roche, Speedx Partner to Expand Access to Antibiotic Resistance Tests 176

6.35 BioMérieux's BioFire SARS-CoV-2 Respiratory Panel Wins FDA EAU..... 177

6.36 Infectious Disease Testing Firm Curative Acquires KorvaLabs 178

6.37 ChromaCode Raises Additional \$10M 178

6.38 COVID-19 Patients Need Syndromic Testing..... 179

6.39 GenMark Diagnostics – New Respiratory Panel due in June..... 181

6.40 Qiagen Respiratory Panel with Coronavirus Targets Receives CE Mark..... 182

6.41 Exact Diagnostics launches respiratory panel control..... 183

6.42 bioMérieux submits enhanced BIOFIRE® BCID2 Panel to FDA 183

7 Profiles of Key Syndromic Testing Companies186

7.1 Abacus Diagnostica 187

7.2 Abbott Laboratories..... 188

7.3 Accelerate Diagnostics 189

7.4 Ador Diagnostics 190

7.5 ADT Biotech 191

7.6 Akonni Biosystems 192

7.7 Alveo Technologies..... 193

7.8 Antelope Dx..... 194

7.9 Applied BioCode 195

7.10 Aureum Diagnostics 197

7.11 Aus Diagnostics 198

7.12 Baebies 199

7.13	Beckman Coulter Diagnostics.....	201
7.14	Becton, Dickinson and Company	202
7.15	Binx Health	204
7.16	Biocartis.....	205
7.17	BioFire Diagnostics (bioMérieux)	206
7.18	bioMérieux Diagnostics.....	208
7.19	Bio-Rad Laboratories, Inc.....	210
7.20	Bosch Healthcare Solutions GmbH.....	212
7.21	Cepheid (Danaher)	213
7.22	Credo Diagnostics Biomedical	215
7.23	Cue Health.....	216
7.24	Curetis N.V. / Curetis GmbH.....	218
7.25	Detect	219
7.26	Diagenode Diagnostics	220
7.27	Diasorin S.p.A.....	221
7.28	Domus Diagnostics.....	223
7.29	Enzo Biochem	224
7.30	Eurofins Scientific	225
7.31	Fluxergy	227
7.32	Fusion Genomics.	228
7.33	Genetic Signatures.....	230
7.34	GenMark Dx (Roche)	231
7.35	Grip Molecular Technologies	233
7.36	Hibergene Diagnostics.....	234
7.37	Hologic	235
7.38	Immunexpress.....	237

7.39	Inflammatix	238
7.40	Invetech.....	239
7.41	Janssen Diagnostics	240
7.42	Karius	241
7.43	Lexogene	242
7.44	LightDeck Diagnostics	243
7.45	Lucira Health.....	244
7.46	Luminex Corp (DiaSorin)	245
7.47	Maxim Biomedical	247
7.48	Meridian Bioscience.....	248
7.49	Mesa Biotech (Thermo Fisher)	250
7.50	MicroGem.....	251
7.51	Millipore Sigma	252
7.52	Minute Molecular	253
7.53	Mobidiag (Hologic).....	254
7.54	Molbio Diagnostics.....	255
7.55	Nanomix.....	256
7.56	Novel Microdevices	257
7.57	OnsiteGene	258
7.58	Operon.....	259
7.59	Oxford Nanopore Technologies	260
7.60	Panagene.....	261
7.61	Perkin Elmer.....	262
7.62	Primerdesign (Novacyt)	263
7.63	Prominex	264
7.64	Proof Diagnostics.....	265

7.65 Qiagen 266

7.66 QuantuMDx 268

7.67 QuidelOrtho 269

7.68 Roche Molecular Diagnostics 270

7.69 Saw Diagnostics 272

7.70 Scope Fluidics 273

7.71 Seegene..... 274

7.72 Siemens Healthineers 276

7.73 Sona Nanotech 277

7.74 Speedx..... 278

7.75 T2 Biosystems..... 279

7.76 Talis Biomedical 280

7.77 Thermo Fisher Scientific Inc..... 281

7.78 Vela Diagnostics..... 283

7.79 Veramarx 284

7.80 Visby Medical 285

7.81 XCR Diagnostics 287

8 The Global Market for Syndromic Multiplex Diagnostics.....288

8.1 Global Market Overview by Country 289

8.1.1 Table – Global Market by Country..... 289

8.1.2 Chart - Global Market by Country 290

8.2 Global Market by Syndrome - Overview 291

8.2.1 Table – Global Market by Syndrome 291

8.2.2 Chart – Global Market by Syndrome – Base/Final Year Comparison 292

8.2.3 Chart – Global Market by Syndrome – Base Year 293

8.2.4 Chart – Global Market by Syndrome – End Year..... 294

- 8.2.5 Chart – Global Market by Syndrome – Share by Year 295
- 8.2.6 Chart – Global Market by Syndrome – Segments Growth..... 296
- 8.3 Global Market by Place - Overview 297
 - 8.3.1 Table – Global Market by Place..... 297
 - 8.3.2 Chart – Global Market by Place – Base/Final Year Comparison 298
 - 8.3.3 Chart – Global Market by Place – Base Year..... 299
 - 8.3.4 Chart – Global Market by Place – End Year 300
 - 8.3.5 Chart – Global Market by Place – Share by Year..... 301
 - 8.3.6 Chart – Global Market by Place – Segments Growth 302
- 8.4 Global Market by Product - Overview 303
 - 8.4.1 Table – Global Market by Product..... 303
 - 8.4.2 Chart – Global Market by Product – Base/Final Year Comparison..... 304
 - 8.4.3 Chart – Global Market by Product – Base Year..... 305
 - 8.4.4 Chart – Global Market by Product – End Year 306
 - 8.4.5 Chart – Global Market by Product – Share by Year 307
 - 8.4.6 Chart – Global Market by Product – Segments Growth 308
- 9 Global Syndromic Multiplex Markets – By Syndrome309
 - 9.1 Respiratory 310
 - 9.1.1 Table Respiratory – by Country 310
 - 9.1.2 Chart - Respiratory Growth..... 311
 - 9.2 Gastrointestinal..... 312
 - 9.2.1 Table Gastrointestinal – by Country 312
 - 9.2.2 Chart - Gastrointestinal Growth 313
 - 9.3 Blood 314
 - 9.3.1 Table Blood – by Country 314
 - 9.3.2 Chart - Blood Growth..... 315

- 9.4 Meningitis/Encephalitis 316
 - 9.4.1 Table Meningitis/Encephalitis – by Country..... 316
 - 9.4.2 Chart - Meningitis/Encephalitis Growth 317
- 9.5 Sexually Transmitted Disease..... 318
 - 9.5.1 Table Sexually Transmitted Disease – by Country 318
 - 9.5.2 Chart – Sexually Transmitted Disease Growth..... 319
- 9.6 Other Syndrome 320
 - 9.6.1 Table Other – by Country 320
 - 9.6.2 Chart - Other Growth..... 321
- 10 Global MDx Infectious Disease Markets – by Place322
 - 10.1 Hospital Lab 323
 - 10.1.1 Table Hospital Lab – by Country 323
 - 10.1.2 Chart - Hospital Lab Growth..... 324
 - 10.2 Outpatient Lab..... 325
 - 10.2.1 Table Outpatient Lab – by Country 325
 - 10.2.2 Chart - Outpatient Lab Growth 326
 - 10.3 Point of Care..... 327
 - 10.3.1 Table Point of Care – by Country..... 327
 - 10.3.2 Chart – Point of Care Growth..... 328
 - 10.4 Other Place 329
 - 10.4.1 Table Other – by Country 329
 - 10.4.2 Chart - Other Place Growth 330
- 11 Global MDx Infectious Disease Markets – by Product331
 - 11.1 Instruments..... 332
 - 11.1.1 Table Instruments – by Country 332
 - 11.1.2 Chart - Instruments Growth..... 333

- 11.2 Cartridges 334
 - 11.2.1 Table Cartridges – by Country 334
 - 11.2.2 Chart - Cartridges Growth..... 335
- 11.3 Reagents..... 336
 - 11.3.1 Table Reagents – by Country 336
 - 11.3.2 Chart - Reagents Growth 337
- 11.4 Other Product..... 338
 - 11.4.1 Table Other Product – by Country 338
 - 11.4.2 Chart – Other Product Growth..... 339
- 12 Appendices340
 - 12.1 United States Medicare System: Clinical Laboratory Fees Schedule 341
 - 12.2 The Most Used IVD Assays..... 443
 - 12.3 The Highest Grossing Assays 448

Table of Tables

Table 1 Market Players by Type 57

Table 2 Clinical Laboratory Departments and Segments 63

Table 3 Laboratory Management Focus – Different Approaches 64

Table 4 Key Segmentation Variables Going Forward..... 65

Table 5 Possible Market Segments of Syndromic Multiplex Market 65

Table 6 Five Factors Driving Growth..... 72

Table 7 How SMT Improves Outcomes..... 74

Table 8 Four Factors Limiting Growth 75

Table 9 Seven Key Diagnostic Laboratory Technology Trends 80

Table 10 - Global Market by Region 289

Table 11 Global Market by Syndrome 291

Table 12 Global Market by Place..... 297

Table 13 Global Market by Product..... 303

Table 14 Respiratory by Country..... 310

Table 15 Gastrointestinal by Country 312

Table 16 Blood by Country..... 314

Table 17 Meningitis/Encephalitis by Country..... 316

Table 18 Sexually Transmitted Disease by Country 318

Table 19 Other by Country..... 320

Table 20 Hospital Lab by Country 323

Table 21 Outpatient Lab by Country 325

Table 22 Point of Care by Country 327

Table 23 Other by Country..... 329

Table 24 Instruments by Country 332

Table 25 Cartridges by Country..... 334

Table 26 Reagents by Country 336

Table 27 Other Product by Country 338

Table 28 Clinical Lab Fee Schedule 341

Table 29 The Most Common Assays..... 443

Table 30 Largest Revenue Assays..... 448

Table of Figures

Figure 1 Global Healthcare Spending 36

Figure 2 The Lab Test Pie 37

Figure 3 The Road to Diagnostics 56

Figure 4 Chart Death Rates and Infectious Disease Decline 77

Figure 5 Centralized vs. Decentralized Laboratory Service 81

Figure 6 A Highly Multiplexed Syndromic Testing Unit..... 81

Figure 7 The Real Cost to Sequence the Human Genome..... 84

Figure 8 The Codevelopment Process 86

Figure 9 Comparing Syndromic and Targeted Testing..... 88

Figure 17 The Multiplex Paradigm Shift..... 89

Figure 11 Global Market Share Chart 290

Figure 12 Global Market by Syndrome - Base vs. Final 292

Figure 13 Global Market by Syndrome Base Year 293

Figure 14 Global Market by Syndrome End Year 294

Figure 15 Syndrome Share by Year 295

Figure 16 Syndrome Segments Growth..... 296

Figure 17 Global Market by Place - Base vs. Final..... 298

Figure 18 Global Market by Place Base Year..... 299

Figure 19 Global Market by Place End Year 300

Figure 20 Place Share by Year..... 301

Figure 21 Place Segments Growth 302

Figure 22 Global Market by Product - Base vs. Final..... 304

Figure 23 Global Market by Product Base Year 305

Figure 24 Global Market by Product End Year..... 306

Figure 25 Product Share by Year 307

Figure 26 Product Segments Growth 308

Figure 27 Respiratory Growth..... 311

Figure 28 Gastrointestinal Diagnostics Growth..... 313

Figure 29 Blood Growth..... 315

Figure 30 Meningitis/Encephalitis Growth..... 317

Figure 31 Sexually Transmitted Disease Growth 319

Figure 32 Other Growth..... 321

Figure 33 Hospital Lab Growth..... 324

Figure 34 Outpatient Lab Growth 326

Figure 35 Point of Care Growth 328

Figure 36 Other Growth..... 330

Figure 37 Instruments Growth 333

Figure 38 Cartridges Growth..... 335

Figure 39 Reagents Growth 337

Figure 40 Other Product Growth 339