

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



SYNDROMIC MULTIPLEX DIAGNOSTIC MARKETS with COVID-19 IMPACTS.

Strategies and Trends. Forecasts by Syndrome (Respiratory, Sepsis, GI etc.) by Place and by Product. With Market Analysis, Executive Guides and Customization. 2021 to 2025





Call: 604 377 8604 Email: service@howesoundresearch.com

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	22
1.1	Situation Analysis & COVID Impact Overview	23
1.2	Guide for Executives and Marketing Staff	26
1.3	Guide for Investment Analysts and Management Consultants.....	28
1.4	Market Shares of Leading Companies – Table and Chart	29
2	Introduction and Market Definition	31
2.1	What are Syndromic Multiplex Tests?	32
2.2	Syndromic Testing – the quiet revolution in diagnostics	33
2.2.1	Syndromic Testing – more than Panels.	34
2.3	Market Definition	35
2.3.1	Multiplex Market Size.	35
2.3.2	Currency.	35
2.3.3	Years.	36
2.4	Methodology.....	37
2.4.1	Authors	37
2.4.2	Sources.....	37
2.5	Perspective: Healthcare, the IVD Industry, and the COVID-19 Pandemic	38
2.5.1	Global Healthcare Spending	38
2.5.2	Spending on Diagnostics.....	40
2.5.3	Important Role of Insurance for Diagnostics	41
3	The Infectious Diseases – Guide to the Pathogens.....	42
3.1	The Coronavirus.....	43
3.1.1	Severe acute respiratory syndrome (SARS)	45

3.1.2	Middle East respiratory syndrome (MERS)	47
3.1.3	COVID-19. The SARS CoV 2 Virus.....	48
3.1.3.1	Signs and symptoms	49
3.1.3.2	Transmission	50
3.1.3.3	Diagnosis	51
3.1.3.4	Prevention	53
3.1.3.5	Management.....	54
3.1.3.6	Prognosis.....	55
3.1.3.7	New Strains and Subsequent Mutations	56
3.2	HIV - Human Immunodeficiency Virus (AIDS)	57
3.2.1	Virology	57
3.2.1.1	Classification	57
3.2.1.2	Structure and genome.....	58
3.2.1.3	Tropism.....	60
3.2.1.4	Replication cycle.....	63
3.2.1.5	Genetic variability	68
3.2.2	Diagnosis	70
3.2.3	Testing.....	71
3.2.3.1	Antibody tests	71
3.2.3.2	Point of Care Tests (POCT)	74
3.2.3.3	Antigen Tests	77
3.2.3.4	Nucleic acid-based tests (NAT)	77
3.2.3.5	Other tests used in HIV treatment.....	78
3.3	HBV – Hepatitis B.....	80
3.3.1	Virology	81
3.3.1.1	Genome	82

3.3.1.2	Pathogenesis.....	83
3.3.1.3	Hepatitis B virus replication	83
3.3.1.4	Serotypes and genotypes.....	84
3.3.2	Mechanisms	84
3.3.3	Diagnosis	85
3.3.4	Market Opportunity Analysis	86
3.4	HCV – Hepatitis C.....	88
3.4.1	Taxonomy.....	89
3.4.1.1	Structure	89
3.4.1.2	Genome	90
3.4.2	Molecular biology	91
3.4.3	Replication.....	92
3.4.4	Genotypes	94
3.4.4.1	Clinical importance.....	94
3.4.5	Market Opportunity Analysis	95
3.5	2.4 HPV - Human papillomavirus.....	96
3.5.1	Virology	98
3.5.1.1	E6/E7 proteins.....	98
3.5.1.2	Role in cancer.....	98
3.5.1.3	E2 research.....	99
3.5.1.4	Latency period	100
3.5.1.5	Clearance	100
3.5.2	Diagnosis	101
3.5.2.1	Cervical testing	101
3.5.2.2	Oral testing	103
3.5.2.3	Testing men	103

3.5.2.4	Other testing	104
3.5.3	Market Opportunity Analysis	105
3.6	Influenza.....	111
3.6.1	Virology	112
3.6.1.1	Types of virus	112
3.6.1.2	Influenzavirus A	112
3.6.1.3	Influenzavirus B	113
3.6.1.4	Influenzavirus C	113
3.6.1.5	Structure, properties, and subtype nomenclature	114
3.6.1.6	Replication	115
3.6.2	Testing.....	117
3.6.2.1	Advantages/Disadvantages of Molecular Assays.....	119
3.6.3	Market Opportunity Analysis	120
3.7	CTGC - Chlamydia/Gonorhea	128
3.7.1	Gonorrhea	128
3.7.1.1	Diagnosis	129
3.7.1.2	Screening	129
3.7.2	Chlamydia	129
3.7.2.1	Diagnosis	130
3.7.2.2	Screening	131
3.7.3	Testing.....	132
3.7.3.1	Nucleic acid amplification tests (NAATs).....	132
3.7.3.2	Performance of NAAT Tests.....	140
3.7.4	Market Opportunity Analysis	141
3.8	Tuberculosis.....	143
3.8.1	Mycobacteria.....	144

3.8.2 Diagnosis	145
3.8.2.1 Active tuberculosis	145
3.8.2.2 Latent tuberculosis.....	146
3.8.3 Epidemiology.....	146
3.8.4 Molecular Diagnostic Tests	148
3.8.5 Market Opportunity Analysis	149
3.9 MRSA - Methicillin-resistant Staphylococcus aureus	151
3.9.1 Diagnosis	151
3.9.2 FDA Approved Molecular Tests	152
3.9.3 Market Opportunity Analysis	153
3.10 VRE - Vancomycin-resistant Enterococcus.....	154
3.10.1 FDA Approved MDx Tests for VRE.....	155
3.10.2 Market Opportunity Analysis	156
4 Industry Overview.....	157
4.1 Industry Participants.....	158
4.1.1 IVD Supplier.....	158
4.1.2 Independent lab specialized/esoteric	159
4.1.3 Independent lab national/regional.....	159
4.1.4 Independent lab analytical	160
4.1.5 Public National/regional lab	160
4.1.6 Hospital lab	160
4.1.7 Physician lab	161
4.1.8 Audit body	161
4.2 The Clinical Laboratory Market Segments	163
4.2.1 Traditional Market Segmentation.....	163
4.2.2 Laboratory Focus and Segmentation.....	164

4.2.3	Segmenting the Syndromic Testing Market.....	165
4.3	Industry Structure.....	167
4.3.1	Hospital Testing Share	167
4.3.2	Economies of Scale.....	167
4.3.2.1	Hospital vs. Central Lab.....	168
4.3.3	Physician Office Lab's.....	169
4.3.4	Physician's and POCT	169
5	Market Trends	171
5.1	Factors Driving Growth	172
5.1.1	Speed of Diagnosis.....	172
5.1.2	Effect of Syndromic Testing on Costs.....	173
5.1.3	Point of Care Advantage.....	173
5.1.4	Syndrome Testing, Accuracy and Diagnostic Risk.....	173
5.1.5	Single Visits.....	173
5.1.6	Improvement in Outcomes.....	174
5.1.7	Impact of the COVID-19 Pandemic.	174
5.2	Factors Limiting Growth	175
5.2.1	Lower Prices.....	175
5.2.2	Administration/reimbursement.....	176
5.2.3	Infectious Disease is Declining But.....	178
5.2.4	Wellness Hurts.....	178
5.2.5	Economic Growth improves Living Standards.	178
5.2.6	Impact of the Pandemic Recession	179
5.3	Instrumentation and Automation	180
5.3.1	Instruments Key to Market Share	180
5.3.2	The Shrinking Machine.	180

5.3.3	Syndrome Testing Moving to Big Instruments?	181
5.4	Diagnostic Technology Development	181
5.4.1	Comparing Syndrome and Targeted Testing	182
5.4.2	The Multiplex Paradigm Shift.....	183
5.4.3	The Sepsis Testing Market – Bellwether for Syndromics.....	184
5.4.4	The Single Visit and AntiMicrobial Resistance	184
5.4.5	Syndromics drives POCT adoption.....	185
5.4.6	A Big Future for PCR?	185
6	Syndromic Testing Recent Developments	187
6.1	Recent Developments – Importance and How to Use This Section	188
6.1.1	Importance of These Developments	188
6.1.2	How to Use This Section.....	188
6.2	Quidel Gains CE Mark for Savanna Analyzer, Respiratory Panel	188
6.3	QuantumDx Gets CE Mark for Rapid PoC PCR System	189
6.4	Bio-Rad Laboratories, Seegene Partner for MDx Development	190
6.5	Baebies to Expand Finder Platform	191
6.6	With Luminex Acquisition, DiaSorin to Broaden MDx Portfolio	194
6.7	Binx Health Targeting Clinics, DTC & OTC With STI Tests	198
6.8	Luminex Lands BARDA Grant to Develop Test for SARS-CoV-2, Flu, RSV	202
6.9	Molzym, Fraunhofer Developing Rapid Sepsis Diagnostic	203
6.10	MiRxes Receives Approval for Multiplex SARS-CoV-2, Flu Test	207
6.11	New Approach Involves Silicon-Based Test for Infectious Disease Screening.....	208
6.12	Scanogen's Portable Battery Operated Instrument for 90 Minute Multiplex Test	212
6.13	Qiagen sees NeuMoDx as Growth Vehicle	215
6.14	Torus Biosystems Developing Syndromic Test with 30-Minute Turnaround.....	219
6.15	Roche, SpeeDx Partner to Expand Access to Antibiotic Resistance Tests	223

6.16	BioMérieux's BioFire SARS-CoV-2 Respiratory Panel Wins FDA EAU.....	224
6.17	Infectious Disease Testing Firm Curative Acquires KorvaLabs	225
6.18	ChromaCode Raises Additional \$10M	225
6.19	COVID-19 Patients Need Syndromic Testing.....	226
6.20	GenMark Diagnostics – New Respiratory Panel due in June.....	227
6.21	Qiagen Respiratory Panel with Coronavirus Targets Receives CE Mark.....	229
6.22	Exact Diagnostics launches respiratory panel control	230
6.23	bioMérieux submits enhanced BIOFIRE® BCID2 Panel to FDA	230
6.24	Nanomix Receives CE Mark for Diagnostic.....	232
6.25	Applied BioCode Applies to FDA for Syndromic Respiratory Panel	233
6.26	Expedeon AG and Sona Nanotech to Collaborate on Multiplex POC	234
6.27	QIAGEN's New GI Panel Performance Assessed.....	235
6.28	McKesson to Distribute QIAstat-Dx Syndromic Testing Solution in USA	236
6.29	Applied BioCode Obtains FDA Clearance	237
6.30	Meridian Bioscience to Acquire GenePOC Inc.....	238
6.31	Curetis Introduces Rapid DNA Testing for Antibiotic Resistance	239
6.32	Qiagen gets FDA clearance for syndromic testing system	240
6.33	Entasis Therapeutics Signs Rapid Diagnostic Agreement with bioMérieux	241
6.34	Akronni Biosystems Submits Multiplex Diagnostics System to FDA	242
6.35	Ador Diagnostic to receive \$30M in Funding for 100-Plex PoC	243
6.36	SAW Diagnostics Receives Funding for Commercialisation of PoC Platform.....	244
6.37	QuantuMDx and Molbio announce MoU	246
6.38	Immunexpress Wins \$745K Contract for Rapid Sepsis Assay	248
6.39	Mobidiag Inks European, Middle Eastern Distribution Deals.....	248
6.40	BIOFIRE® FILMARRAY® System chosen for Phase 3 clinical trial	249
7	Profiles of Key Syndromic Testing Companies	251

7.1	Abacus Diagnostica	252
7.2	Abbott Diagnostics	253
7.3	Accelerate Diagnostics	255
7.4	Ador Diagnostics	256
7.5	Akronni Biosystems	257
7.6	Alveo Technologies.....	258
7.7	Antelope Dx.....	259
7.8	Applied BioCode	260
7.9	Aus Diagnostics	261
7.10	Baebies	262
7.11	Beckman Coulter Diagnostics.....	264
7.12	Becton, Dickinson and Company	265
7.13	Binx Health	267
7.14	Biocartis	269
7.15	BioFire Diagnostics (bioMérieux)	270
7.16	bioMérieux Diagnostics.....	272
7.17	Bio-Rad Laboratories, Inc.....	274
7.18	Bosch Healthcare Solutions GmbH.....	276
7.19	Cepheid (Danaher)	277
7.20	Credo Diagnostics Biomedical	279
7.21	Cue Health.....	280
7.22	Curetis N.V. / Curetis GmbH	282
7.23	Diagenode Diagnostics	283
7.24	Diasorin S.p.A.	284
7.25	Enzo Life Sciences, Inc.	286
7.26	Eurofins Scientific	288

7.27	Fluxergy	290
7.28	Fusion Genomics.....	291
7.29	Genetic Signatures.....	293
7.30	GenMark Dx (Roche)	294
7.31	Hibergene Diagnostics.....	296
7.32	Hologic	297
7.33	Immunexpress.....	299
7.34	Inflamatix	300
7.35	Invetech.....	301
7.36	Janssen Diagnostics	302
7.37	Karius	303
7.38	Lexagene.....	305
7.39	LightDeck Diagnostics	306
7.40	Lucira Health.....	307
7.41	Luminex Corp	308
7.42	Maxim Biomedical	310
7.43	Meridian Bioscience.....	311
7.44	Mesa Biotech (Thermo Fisher)	313
7.45	Millipore Sigma	314
7.46	Mobidiag (Hologic)	315
7.47	Molbio Diagnostics.....	316
7.48	Nanomix.....	317
7.49	Novel Microdevices	318
7.50	Operon.....	319
7.51	Oxford Nanopore Technologies	320
7.52	Panagene.....	321

7.53	Perkin Elmer.....	322
7.54	Primerdesign (Novacyt)	324
7.55	Prominex	325
7.56	Qiagen Gmbh	326
7.57	Quantumdx	328
7.58	Quidel.....	329
7.59	Roche Molecular Diagnostics	331
7.60	Saw Diagnostics	333
7.61	Seegene.....	334
7.62	Siemens Healthineers	336
7.63	Sona Nanotech	338
7.64	SpeeDx.....	339
7.65	T2 Biosystems.....	340
7.66	Talis Biomedical	341
7.67	Thermo Fisher Scientific Inc.....	342
7.68	Veramarx	344
7.69	Visby Medical	345
7.70	XCR Diagnostics	347
8	The Global Market for Syndromic Multiplex Diagnostics.....	348
8.1	Global Market Overview by Country	349
8.1.1	Table – Global Market by Country	349
8.1.2	Chart - Global Market by Country	350
8.2	Global Market by Syndrome - Overview	351
8.2.1	Table – Global Market by Syndrome	351
8.2.2	Chart – Global Market by Syndrome – Base/Final Year Comparison	352
8.2.3	Chart – Global Market by Syndrome – Base Year	353

8.2.4	Chart – Global Market by Syndrome – End Year.....	354
8.2.5	Chart – Global Market by Syndrome – Share by Year	355
8.2.6	Chart – Global Market by Syndrome – Segments Growth.....	356
8.3	Global Market by Place - Overview.....	357
8.3.1	Table – Global Market by Place.....	357
8.3.2	Chart – Global Market by Place – Base/Final Year Comparison	358
8.3.3	Chart – Global Market by Place – Base Year.....	359
8.3.4	Chart – Global Market by Place – End Year	360
8.3.5	Chart – Global Market by Place – Share by Year.....	361
8.3.6	Chart – Global Market by Place – Segments Growth	362
8.4	Global Market by Product - Overview	364
8.4.1	Table – Global Market by Product.....	364
8.4.2	Chart – Global Market by Product – Base/Final Year Comparison.....	365
8.4.3	Chart – Global Market by Product – Base Year.....	366
8.4.4	Chart – Global Market by Product – End Year	367
8.4.5	Chart – Global Market by Product – Share by Year	368
8.4.6	Chart – Global Market by Product – Segments Growth	369
9	Global Syndromic Multiplex Markets – By Syndrome	370
9.1	Respiratory	371
9.1.1	Table Respiratory – by Country	371
9.1.2	Chart - Respiratory Growth.....	372
9.2	Gastrointestinal.....	373
9.2.1	Table Gastrointestinal – by Country	373
9.2.2	Chart - Gastrointestinal Growth	374
9.3	Blood	375
9.3.1	Table Blood – by Country	375

9.3.2	Chart - Blood Growth.....	376
9.4	Meningitis/Encephalitis	377
9.4.1	Table Meningitis/Encephalitis – by Country.....	377
9.4.2	Chart - Meningitis/Encephalitis Growth	378
9.5	Sexually Transmitted Disease.....	379
9.5.1	Table Sexually Transmitted Disease – by Country	379
9.5.2	Chart – Sexually Transmitted Disease Growth	380
9.6	Other Syndrome	381
9.6.1	Table Other – by Country	381
9.6.2	Chart - Other Growth.....	382
10	Global MDx Infectious Disease Markets – by Place	383
10.1	Hospital Lab	384
10.1.1	Table Hospital Lab – by Country	384
10.1.2	Chart - Hospital Lab Growth.....	385
10.2	Outpatient Lab.....	386
10.2.1	Table Outpatient Lab – by Country	386
10.2.2	Chart - Outpatient Lab Growth	387
10.3	Point of Care.....	388
10.3.1	Table Point of Care – by Country.....	388
10.3.2	Chart – Point of Care Growth.....	389
10.4	Other Place	390
10.4.1	Table Other – by Country	390
10.4.2	Chart - Other Place Growth	391
11	Global MDx Infectious Disease Markets – by Product	392
11.1	Instruments.....	393
11.1.1	Table Instruments – by Country	393

11.1.2 Chart - Instruments Growth.....	394
11.2 Cartridges	395
11.2.1 Table Cartridges – by Country	395
11.2.2 Chart - Cartridges Growth.....	396
11.3 Reagents.....	397
11.3.1 Table Reagents – by Country	397
11.3.2 Chart - Reagents Growth	398
11.4 Other Product.....	399
11.4.1 Table Other Product – by Country	399
11.4.2 Chart – Other Product Growth.....	400
12 Appendices.....	401
12.1 United States Medicare System: 2021 Clinical Laboratory Fees Schedule.....	402

Table of Tables

Table 1 Market Share of Leading Companies	29
Table 2 Characteristics of Coronavirus Pandemic Infections	48
Table 3 COVID-19 Symptoms.....	50
Table 4 Classification of HIV Species.....	58
Table 5 HBV Tests - CMS Codes & Prices.....	88
Table 6 HCV Tests - CMS Codes & Prices	95
Table 7 HPV Clearance Rates	101
Table 8 HPV Tests - CMS Codes & Prices.....	106
Table 9 HPV Tests, Technology, Types	107
Table 10 Types of Influenza Tests	117
Table 11 Influenza Tests - CMS Codes & Prices.....	120
Table 12 FDA Cleared Molecular Assays for Influenza	121
Table 13 FDA Cleared NAAT CTGC Tests	133
Table 14 CTGC NAAT Target Sequences and Possible False Reactions	138
Table 15 Influenza Tests - CMS Codes & Prices.....	142
Table 16 FDA Approved MDx Tests for Tuberculosis	148
Table 17 Tuberculosis Tests - CMS Codes & Prices.....	149
Table 18 FDA Approved Tests for MRSA	152
Table 19 MRSA Tests - CMS Codes & Prices	154
Table 20 FDA Approved Tests for VRE	155
Table 21 VRE Tests - CMS Codes & Prices	156
Table 22 Market Players by Type	158
Table 23 Clinical Laboratory Departments and Segments	163

Table 24 Laboratory Management Focus – Different Approaches	164
Table 25 Key Segmentation Variables Going Forward.....	165
Table 26 Possible Market Segments of Syndromic Multiplex Market	165
Table 27 Five Factors Driving Growth.....	172
Table 28 How SMT Improves Outcomes.....	174
Table 29 Four Factors Limiting Growth	175
Table 30 - Global Market by Region	349
Table 31 Global Market by Syndrome	351
Table 32 Global Market by Place.....	357
Table 33 Global Market by Product.....	364
Table 34 Respiratory by Country.....	371
Table 35 Gastrointestinal by Country	373
Table 36 Blood by Country.....	375
Table 37 Meningitis/Encephalitis by Country	377
Table 38 Sexually Transmitted Disease by Country	379
Table 39 Other by Country.....	381
Table 40 Hospital Lab by Country	384
Table 41 Outpatient Lab by Country	386
Table 42 Point of Care by Country	388
Table 43 Other by Country.....	390
Table 44 Instruments by Country	393
Table 45 Cartridges by Country.....	395
Table 46 Reagents by Country	397
Table 47 Other Product by Country	399
Table 48 2021 Clinical Lab Fee Schedule	402

Table of Figures

Figure 1 Market Share of Leading Companies Chart	30
Figure 2 The Global Healthcare Spending Picture.....	39
Figure 3 The Lab Test Pie	40
FIGURE 4 STRUCTURE OF CORONAVIRUSES	44
Figure 5 HIV Virion	59
Figure 6 Diagram of the HIV Replication Cycle	63
Figure 7 The Structure of the HBV Virus.....	82
Figure 8 Hepatitis B Replication	83
Figure 9 Structure of the HCV Virus.....	90
Figure 10 HCV Replication Cycle	93
Figure 11 Structure of the Influenza Virion	114
Figure 12 Influenza Replication.....	115
Figure 13 Scanning Electronmicrograph of Tuberculosis.....	144
Figure 14 Chart Death Rates and Infectious Disease Decline	177
Figure 15 Comparing Syndromic and Targeted Testing	182
Figure 16 The Multiplex Paradigm Shift.....	183
Figure 17 Global Market Share Chart	350
Figure 18 Global Market by Syndrome - Base vs. Final	352
Figure 19 Global Market by Syndrome Base Year	353
Figure 20 Global Market by Syndrome End Year	354
Figure 21 Syndrome Share by Year	355
Figure 22 Syndrome Segments Growth.....	356
Figure 23 Global Market by Place - Base vs. Final.....	358

Figure 24 Global Market by Place Base Year.....	359
Figure 25 Global Market by Place End Year	360
Figure 26 Place Share by Year.....	361
Figure 27 Place Segments Growth	362
Figure 28 Global Market by Product - Base vs. Final.....	365
Figure 29 Global Market by Product Base Year	366
Figure 30 Global Market by Product End Year.....	367
Figure 31 Product Share by Year.....	368
Figure 32 Product Segments Growth	369
Figure 33 Respiratory Growth.....	372
Figure 34 Gastrointestinal Diagnostics Growth.....	374
Figure 35 Blood Growth.....	376
Figure 36 Meningitis/Encephalitis Growth.....	378
Figure 37 Sexually Transmitted Disease Growth	380
Figure 38 Other Growth.....	382
Figure 39 Hospital Lab Growth.....	385
Figure 40 Outpatient Lab Growth	387
Figure 41 Point of Care Growth	389
Figure 42 Other Growth.....	391
Figure 43 Instruments Growth	394
Figure 44 Cartridges Growth.....	396
Figure 45 Reagents Growth	398
Figure 46 Other Product Growth	400