

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



RESPIRATORY INFECTION DIAGNOSTIC MARKETS

BY TECHNOLOGY, PLEX, PLACE AND BY REGION WITH
COVID-19 IMPACT & FORECASTING/ANALYSIS,
AND EXECUTIVE AND CONSULTANT GUIDES 2021-2025





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

i.	Respiratory Infections Dx Market, Situation Analysis & Impact of COVID-19	19
ii.	Guide for Executives, Marketing, Sales and Business Development Staff	21
iii.	Guide for Management Consultants and Investment Advisors	22
1.	Introduction and Market Definition	23
1.1	What are Respiratory Infections?	24
1.2	The Role of Diagnosis & Treatment.....	27
1.3	Market Definition	29
1.3.1	Revenue Market Size.....	29
1.4	Methodology	30
1.4.1	Authors	30
1.4.2	Sources	31
1.5	A Spending Perspective on Clinical Laboratory Testing	32
1.5.1	An Historical Look at Clinical Testing.....	32
2.	Market Overview	35
2.1	Players in a Dynamic Market	36
2.1.1	Academic Research Lab	37
2.1.2	Diagnostic Test Developer.....	37
2.1.3	Instrumentation Supplier	37
2.1.4	Distributor and Reagent Supplier	38
2.1.5	Independent Testing Lab.....	38
2.1.6	Public National/regional lab	39

2.1.7 Hospital lab	39
2.1.8 Physician Office Labs	40
2.1.9 Audit Body	40
2.1.10 Certification Body.....	41
2.2 Respiratory Infections	42
2.2.1 Upper vs. Lower - Marketing Implications.....	42
2.2.2 Understanding the Role of Pneumonia	44
2.2.3 Bacterial Infections.....	46
2.2.3.1 Streptococcal Infections	46
2.2.3.2 Acute Otitis Media	46
2.2.3.3 Bacterial Rhinosinusitis	47
2.2.3.4 Diphtheria	47
2.2.3.5 Pneumococcal Pneumonia	48
2.2.3.6 Haemophilus Pneumonia	49
2.2.3.7 Mycoplasma Pneumonia (Walking Pneumonia).....	49
2.2.3.8 Chlamydial Pneumonias and Psittacosis.....	50
2.2.3.9 Health Care-Associated Pneumonia.....	51
2.2.3.10 Pseudomonas Pneumonia	51
2.2.3.11 Pertussis (Whooping Cough)	52
2.2.3.12 Legionnaires Disease.....	54
2.2.4 Tuberculosis – A Special Case	56
2.2.5 Viral Infections	60
2.2.5.1 The Common Cold.....	60
2.2.5.2 Influenza.....	61

2.2.5.3 Viral Pneumonia	66
2.2.5.4 SARS and MERS	67
2.2.5.5 Measles (Rubeola)	68
2.2.5.6 Rubella (German Measles)	69
2.2.5.7 Chickenpox and Shingles	70
2.2.6 Fungal and Other Pathogens.....	73
2.2.6.1 Histoplasmosis	73
2.2.6.2 Coccidioidomycosis.....	74
2.2.6.3 Blastomycosis.....	75
2.2.6.4 Mucormycosis.....	75
2.2.6.5 Aspergillosis	77
2.2.6.6 Pneumocystis Pneumonia	77
2.2.6.7 Cryptococcosis	78
2.3 Diagnostics – A Changing Role	80
2.3.1 Historical Practice.....	80
2.3.2 Current Diagnostics	81
2.3.3 The Multiplex Vector.....	83
2.3.4 Future Diagnostics – The Question of When and Where	84
2.3.5 Respiratory Infection Diagnostics – The Destination	84
2.3.6 Diagnostics as Defensive Weapons.....	85
2.4 COVID-19	86
2.4.1 Signs and symptoms	87
2.4.2 Transmission.....	89
2.4.3 Diagnosis	90

2.4.4 Prevention	92
2.4.5 Management	93
2.4.6 Prognosis	94
2.5 Pandemic Diagnostics	95
2.5.1 Risk Management – Spark and Spread	95
2.5.2 Dx Technology – Nucleic Acid Based.....	97
2.5.3 Dx Technology - Immunoassay & Serology	98
2.5.4 Time to Market and Preparedness Issues.....	99
2.5.5 Unrecognized Role of Multiplex in Pandemic Mangement.....	99
3. Market Trends.....	101
3.1 Factors Driving Growth.....	102
3.1.1 Syndromic Multiplexing	102
3.1.2 T.A.T.....	103
3.1.3 Antimicrobial Resistance Movement.....	103
3.1.4 Pandemic Mitigation.....	103
3.1.5 An Aging at Risk Population	104
3.2 Factors Limiting Growth.....	106
3.2.1 The Cost Curve	106
3.2.2 Regulation and coverage.....	107
3.2.3 Laissez Faire	107
3.3 Instrumentation and Automation.....	108
3.3.1 The Shrinking Multiplexing Machine	108
3.3.2 Bioinformatics Networking and Anonymous Reporting	108
3.4 Diagnostic Technology Development.....	110

3.4.1 The Key Role of Time to Result	111
3.4.2 Single Cell Genomics Changes the Picture	111
3.4.3 Pharmacogenomics Blurs Diagnosis and Treatment.....	112
3.4.4 Pathogen Identification – A Projected Timetable of the Future.....	113
4. Respiratory Infection Diagnostics Recent Developments	114
4.1 Recent Developments – Importance and How to Use This Section.....	115
4.1.1 Importance of These Developments	115
4.1.2 How to Use This Section.....	115
Luminex Lands BARDA Grant to Develop Test for SARS-CoV-2, Flu, RSV.....	115
Becton Dickinson Charts Ramp-Up, Transition of COVID-19 Diagnostics	116
MiRxes Receives Approval for Multiplex SARS-CoV-2, Flu Test	120
New Approach Involves Silicon-Based Test for Infectious Disease Screening.....	120
GenMark to Meet Pent Up Demand for SARS-CoV-2, Respiratory Panel	125
Tempus Announces Large-Scale COVID-19 Testing, Data Initiative	129
Abacus Diagnostica Readying Multiplex Respiratory Test	132
Qiagen Acquires NeuMoDx Molecular	134
Dx Companies Shift Attention to Multiplex Tests for SARS-CoV-2, Influenza	135
Novacyt Gets CE Mark for Coronavirus, Flu, RSV Combo Panel	143
Cepheid Debuts 10-Color Technology With New Tuberculosis Test	143
BioMérieux's Pneumonia Panel Could Improve Care	147
Mammoth Biosciences Announces Rapid, CRISPR-Based COVID-19 Diagnostic.....	153
Genetic Signatures Gets CE Mark for Coronavirus Molecular Test	155
Qiagen Respiratory Panel with Coronavirus Receives CE Mark	156
Lumos Diagnostics Closes \$15M Series A Funding	157

Fusion Genomics Wins \$1M to Assess NGS-Based Respiratory Tract Infection Assay	158
Coronavirus Detection Test Development by Co-Diagnostics	159
Rapid Diagnostics Completes Asset Purchase of Enigma Diagnostics	161
Flu-Like Epidemic Could Kill 80 Mn Globally	162
Startup developing AI for TB detection	165
Nipah Virus a Global Threat	167
Novacyt S.A.: New Molecular Respiratory Panel Ready for US Market	169
New DRC Ebola cases confirmed as FDA OKs rapid test	169
CE Mark for Smartphone-based Diagnostic Test for Adult Respiratory Disease	171
Curetis Submits Lower Respiratory Tract Infection Test for FDA Clearance	172
New rapid test diagnoses pneumonia and other lower respiratory infections	173
Ontera Awarded Contract for Zika Genotyping Test	176
Two New Members Join Global Diagnostics Network	177
BARDA Funding Health Security Solutions	178
5. Profiles of Key Players	180
Abacus Diagnostica	181
Abbott Diagnostics	182
Accelerate Diagnostics	184
Ador Diagnostics	185
Akkoni Biosystems	186
Alveo Technologies	187
Applied BioCode	188
Atlas Genetics	190
Aus Diagnostics	191

BD Diagnostics	193
Biocartis	195
BioFire Diagnostics	196
bioMérieux	198
Bio-Rad Laboratories	199
Bosch Healthcare Solutions GmbH	201
Cepheid	202
Co-Diagnostics	204
Cue Health	205
Curetis	206
Diagenode Diagnostics	207
Diascopic	208
Diasorin	209
Expedeon	210
Fusion Genomics	211
GenePOC Diagnostics	213
Genetic Signatures	214
GenMark Dx	215
Hologic	216
Immunexpress	218
Inflamatix	219
Invetech	220
Janssen Diagnostics	221
Karius	222

Lexigene	223
Luminex	224
Lumos Diagnostics	226
Mammoth Biosciences	227
Mbio Diagnostics	228
Meridian Bioscience	229
Mesa Biotech	231
Mobidiag	232
Nanomix	233
Oxford Nanopore	234
Panagene	235
Primerdesign	236
Prominex	237
Qiagen (Statdx)	238
Quantumdx	240
Quidel	241
Roche Molecular Diagnostics	243
Saw Diagnostics	245
Seegene	246
Senovation	247
Siemens Healthineers (Fast Track Diagnostics)	248
SkylineDx	255
Sona Nanotech	256
T2 Biosystems	257

Thermo Fisher	258
Veradus Labs	260
Veramarx	261
6. The Global Market for Respiratory Infection Diagnostics	262
6.1 Global Market Overview by Country.....	263
6.1.1 Table – Global Market by Country.....	263
6.1.2 Chart - Global Market by Country	264
6.2 Global Market by Technology - Overview	265
6.2.1 Table – Global Market by Technology	265
6.2.2 Chart – Global Market by Technology – Base/End Year Comparison.....	266
6.2.3 Chart – Global Market by Technology – Base Year	267
6.2.4 Chart – Global Market by Technology – End Year	268
6.2.5 Chart – Global Market by Technology – Share by Year.....	269
6.3 Global Market by Plex - Overview	270
6.3.1 Table – Global Market by Plex.....	270
6.3.2 Chart – Global Market by Plex – Base/End Year Comparison.....	271
6.3.3 Chart – Global Market by Plex – Base Year.....	272
6.3.4 Chart – Global Market by Plex – End Year	273
6.3.5 Chart – Global Market by Plex – Share by Year.....	274
6.4 Global Market by Place - Overview	275
6.4.1 Table – Global Market by Place.....	275
6.4.2 Chart – Global Market by Place – Base/End Year Comparison.....	276
6.4.3 Chart – Global Market by Place – Base Year.....	277
6.4.4 Chart – Global Market by Place – End Year	278

6.4.5 Chart – Global Market by Place – Share by Year.....	279
7. Global Respiratory Infection Diagnostic Markets – By Technology	280
7.1 Microbiology	281
7.1.1 Table Microbiology – by Country	281
7.1.2 Chart - Microbiology Growth	282
7.2 PCR	283
7.2.1 Table PCR – by Country	283
7.2.2 Chart - PCR Growth.....	284
7.3 NGS	285
7.3.1 Table NGS – by Country	285
7.3.2 Chart - NGS Growth	286
7.4 Immunoassay/Other.....	287
7.4.1 Table Immunoassay – by Country	287
7.4.2 Chart – Immunoassay/Other Growth	288
7.5 C19 Singleplex	289
7.5.1 Table C19splex – by Country	289
7.5.2 Chart – C19splex Growth.....	290
8. Global Respiratory Infection Diagnostic Markets – by Plex.....	291
8.1 C19 Single Plex.....	292
8.1.1 Table C19 Single Plex – by Country	292
8.1.2 Chart – C19 Single Plex Growth.....	293
8.2 Singleplex	294
8.2.1 Table Singleplex – by Country	294
8.2.2 Chart - Singleplex Growth.....	295

8.3 Duplex/Triplex.....	296
8.3.1 Table Duplex/Triplex – by Country.....	296
8.3.2 Chart - Duplex/Triplex Growth.....	297
8.4 Multiplex Technology	298
8.4.1 Table Multiplex – by Country	298
8.4.2 Chart - Multiplex Growth.....	299
9. Global Respiratory Infection Diagnostic Markets – by Place	300
9.1 Hospital Lab	301
9.1.1 Table Hospital Lab – by Country	301
9.1.2 Chart - Hospital Lab Growth.....	302
9.2 Outpatient Lab	303
9.2.1 Table Outpatient Lab – by Country	303
9.2.2 Chart - Outpatient Lab Growth	304
9.3 POC	305
9.3.1 Table POC – by Country	305
9.3.2 Chart - POC Growth.....	306
9.4 Other Technology.....	307
9.4.1 Table Other – by Country	307
9.4.2 Chart - Other Growth.....	308
Appendices	309
I.United States Medicare System: January 2021 Clinical Laboratory Fees Schedule	309

Table of Tables

Table 1 Medicare Clinical Lab Expenditures Actual & Forecast 2014 to 2020 (\$million)	34
Table 2 Market Players by Type	36
Table 3 Bacterial Causes of Pneumonia.....	45
Table 4 List of Influenza Pandemics.....	64
Table 5 Viral Infections of the Respiratory Tract	72
Table 6 Fungal Infections of the Respiratory Tract	79
TABLE 7 CHARACTERISTICS OF CORONAVIRUS PANDEMIC INFECTIONS.....	86
TABLE 8 COVID-19 SYMPTOMS	88
Table 9 Five Factors Driving Growth.....	102
Table 10 Three Factors Limiting Growth	106
Table 11 Key Diagnostic Laboratory Technology Trends	110
Table 12 Long Term Pathogen Identification Timetable	113
Table 13 - Global Market by Region	263
Table 14 Global Market by Technology	265
Table 15 Global Market by Plex.....	270
Table 16 Global Market by Place.....	275
Table 17 Microbiology by Country	281
Table 18 PCR by Country	283
Table 19 NGS by Country	285
Table 20 Immunoassay/Other by Country.....	287
Table 21 C19splex by Country	289

Table 22 C19 Single Plex by Country.....	292
Table 23 Singleplex by Country	294
Table 24 Duplex/Triplex by Country.....	296
Table 25 Multiplex by Country	298
Table 26 Hospital Lab by Country	301
Table 27 Outpatient Lab by Country	303
Table 28 POC by Country	305
Table 29 Other by Country.....	307
Table 30 2021 Laboratory Fee Schedule	309

Table of Figures

Figure 1 Upper vs. Lower Respiratory Tract	24
Figure 2 The LRI Mortality Rate Globally	26
Figure 3 Global Pandemic Pathogen Status	27
Figure 4 Medicare Clinical Lab Expenditures 2004 to 2020 (\$Million)	33
Figure 5 The BioFire Respiratory Panel	43
Figure 6 Pneumonia.....	44
Figure 7 Bacterial Infections of the Respiratory Tract.....	56
Figure 8 The Development Cycle of Tuberculosis	58
Figure 9 A Flu Epidemic in Europe – Historical Pattern.....	66
Figure 10 The Multiplex Paradigm Shift.....	83
Figure 11 Percentage of World Population Over 65.....	104
Figure 12 Global Market Share Chart	264
Figure 13 Global Market by Technology – Base vs. End Year.....	266
Figure 14 Global Market by Technology Base Year.....	267
Figure 15 Global Market by Technology End Year	268
Figure 16 Technology Share by Year.....	269
Figure 17 Plex - Base vs. End Year Segment Shift	271
Figure 18 Plex Market Base Year.....	272
Figure 19 Plex Market End Year	273
Figure 20 Plex Share by Year.....	274
Figure 21 Place - Base vs. End Year.....	276

Figure 22 Place Market Base Year.....	277
Figure 23 Place Market End Year	278
Figure 24 Place Share by Year.....	279
Figure 25 Microbiology Growth	282
Figure 26 PCR Diagnostics Growth	284
Figure 27 NGS Growth	286
Figure 28 Immunoassay/Other Growth.....	288
Figure 29 C19splex Growth	290
Figure 30 C19 Single Plex Growth	293
Figure 31 Singleplex Growth	295
Figure 32 Duplex/Triplex Growth.....	297
Figure 33 Multiplex Growth	299
Figure 34 Hospital Lab Growth.....	302
Figure 35 Outpatient Lab Growth	304
Figure 36 POC Growth.....	306
Figure 37 Other Growth.....	308