



RESEARCH REPORT NOVEMBER 2018



SYNDROMIC MULTIPLEX DIAGNOSTIC MARKETS.

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

2019 to 2023 - Global Version



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 18
 - iA. Situation Analysis..... 19
 - iB. Guide for Executives and Marketing Staff 21
 - iC. Guide for Investment Analysts and Management Consultants 22
- 1. Introduction and Market Definition 23
 - 1.1 What are Syndromic Multiplex Tests? 24
 - 1.2 Syndromic Testing – the quiet revolution in diagnostics..... 25
 - 1.2.1 Syndromic Testing – more than Panels..... 26
 - 1.3 Market Definition..... 27
 - 1.3.1 Multiplex Market Size 27
 - 1.3.2 Panel Market Size 27
 - 1.3.2 Currency 27
 - 1.3.3 Years 28
 - 1.4 Methodology..... 28
 - 1.4.1 Authors 28
 - 1.4.2 Sources 29
 - 1.5 U.S. Medical Market and Clinical Laboratory Testing - Perspective 29
 - 1.5.1 U.S. Medicare Expenditures for Clinical Testing 30
- 2. The Infectious Diseases – Guide to the Pathogens 32
 - 2.1 HIV - Human Immunodeficiency Virus (AIDS) 33
 - 2.1.1 Virology 33
 - 2.1.1.1 Classification..... 33
 - 2.1.1.2 Structure and genome..... 34

- 2.1.1.3 Tropism 36
- 2.1.1.4 Replication cycle 38
- 2.1.1.5 Genetic variability 43
- 2.1.2 Diagnosis 44
- 2.1.3 Testing 45
 - 2.1.3.1 Antibody tests 45
 - 2.1.3.2 Point of Care Tests (POCT) 48
 - 2.1.3.4 Antigen Tests 50
 - 2.1.3.5 Nucleic acid-based tests (NAT) 50
 - 2.1.3.6 Other tests used in HIV treatment 51
- 2.2 HBV – Hepatitis B 53
 - 2.2.1 Virology 54
 - 2.2.1.1 Genome 54
 - 2.2.1.2 Pathogenesis 55
 - 2.2.1.3 Hepatitis B virus replication 56
 - 2.2.1.4 Serotypes and genotypes 56
 - 2.2.2 Mechanisms 56
 - 2.2.3 Diagnosis 57
 - 2.2.4 Market Opportunity Analysis 58
- 2.3 HCV – Hepatitis C 60
 - 2.3.1 Taxonomy 61
 - 2.3.2.1 Structure 61
 - 2.3.2.2 Genome 62
 - 2.3.3 Molecular biology 62
 - 2.3.4 Replication 64
 - 2.3.5 Genotypes 66

- 2.3.5.1 Clinical importance 66
- 2.3.6 Market Opportunity Analysis 66
- 2.4 HPV - Human papillomavirus 68
 - 2.4.1 Virology 69
 - 2.4.1.1 E6/E7 proteins 69
 - 2.4.1.2 Role in cancer 70
 - 2.4.1.3 E2 research 70
 - 2.4.1.4 Latency period 72
 - 2.4.1.5 Clearance 72
 - 2.4.2 Diagnosis 72
 - 2.4.2.1 Cervical testing 72
 - 2.4.2.2 Oral testing 74
 - 2.4.2.3 Testing men 74
 - 2.4.2.4 Other testing 75
 - 2.4.3 Market Opportunity Analysis 75
- 2.5 Influenza..... 82
 - 2.5.1 Virology 83
 - 2.5.1.1 Types of virus..... 83
 - 2.5.1.2 Influenzavirus A 83
 - 2.5.1.3 Influenzavirus B 84
 - 2.5.1.4 Influenzavirus C 84
 - 2.5.1.5 Structure, properties, and subtype nomenclature..... 84
 - 2.5.1.6 Replication 85
 - 2.5.2 Testing 87
 - 2.5.2.1 Advantages/Disadvantages of Molecular Assays 89
 - 2.5.3 Market Opportunity Analysis 90

2.6 CTGC - Chlamydia/Gonorrhea 99

 2.6.1 Gonorrhea 99

 2.6.1.1 Diagnosis..... 99

 2.6.1.2 Screening 100

 2.6.2 Chlamydia 100

 2.6.2.1 Diagnosis..... 101

 2.6.2.2 Screening 102

 2.6.3 Testing 102

 2.6.3.1 Nucleic acid amplification tests (NAATs)..... 102

 2.6.3.2 Performance of NAAT Tests 110

 2.6.4 Market Opportunity Analysis 111

2.7 Tuberculosis 114

 2.7.1 Mycobacteria..... 115

 2.7.2 Diagnosis 116

 2.7.2.1 Active tuberculosis 116

 2.7.2.2 Latent tuberculosis 117

 2.7.3 Epidemiology..... 117

 2.7.4 Molecular Diagnostic Tests 118

 2.7.5 Market Opportunity Analysis 119

2.8 MRSA - Methicillin-resistant Staphylococcus aureus..... 121

 2.8.1 Diagnosis 121

 2.8.2 FDA Approved Molecular Tests..... 122

 2.8.3 Market Opportunity Analysis 123

2.9 VRE - Vancomycin-resistant Enterococcus 124

 2.9.1 FDA Approved MDx Tests for VRE..... 125

 2.9.2 Market Opportunity Analysis 126

- 3. Industry Overview 127
 - 3.1 Industry Participants 128
 - 3.1.1 IVD Supplier 128
 - 3.1.2 Independent lab specialized/esoteric 129
 - 3.1.3 Independent lab national/regional 129
 - 3.1.4 Independent lab analytical 130
 - 3.1.5 Public National/regional lab 130
 - 3.1.6 Hospital lab 130
 - 3.1.7 Physician lab 131
 - 3.1.8 Audit body 131
 - 3.2 The Clinical Laboratory Market Segments 133
 - 3.2.1 Traditional Market Segmentation 133
 - 3.2.2 Laboratory Focus and Segmentation 134
 - 3.2.3 Segmenting the Syndromic Testing Market 135
 - 3.3 Industry Structure 137
 - 3.3.1 Hospital Testing Share 137
 - 3.3.2 Economies of Scale 137
 - 3.3.2.1 Hospital vs. Central Lab 138
 - 3.3.3 Physician Office Lab’s 139
 - 3.3.4 Physician’s and POCT 139
- 4. Market Trends 140
 - 4.1 Factors Driving Growth 141
 - 4.1.1 Speed of Diagnosis 141
 - 4.1.2 Effect of Syndromic Testing on Costs 142
 - 4.1.3 Point of Care Advantage 142
 - 4.1.4 Syndrome Testing, Accuracy and Diagnostic Risk 142

- 4.1.5 Single Visits..... 142
- 4.1.6 Improvement in Outcomes. 143
- 4.2 Factors Limiting Growth..... 144
 - 4.2.1 Lower Prices 144
 - 4.2.2 Infectious Disease is Declining But..... 146
 - 4.2.3 Wellness Hurts. 146
 - 4.2.4 Economic Growth improves Living Standards..... 146
- 4.3 Instrumentation and Automation..... 148
 - 4.3.1 Instruments Key to Market Share 148
 - 4.3.2 The Shrinking Machine..... 148
 - 4.3.3 Syndrome Testing Moving to Big Instruments? 148
- 4.4 Diagnostic Technology Development 149
 - 4.4.1 Comparing Syndrome and Targeted Testing..... 150
 - 4.4.2 The Multiplex Paradigm Shift..... 151
 - 4.4.2 The Sepsis Testing Market – Bellwether for Syndromics..... 152
 - 4.4.3 The Single Visit and AntiMicrobial Resistance 152
 - 4.4.4 Syndromics drives POCT adoption 153
 - 4.4.5 A Big Future for PCR? 153
- 5. Syndromic Testing Recent Developments..... 154
 - Recent Developments – Importance and How to Use This Section 155
 - Importance of These Developments..... 155
 - How to Use This Section..... 155
 - XCR Diagnostics and Luminex Enter into License Agreement 155
 - Palmetto Final LCD Denies Coverage to Large Respiratory Panels..... 156
 - Karius Test to Be Available in Brazil 157
 - Panagene’s STD kit gains Approval 158

GenePOC's Investment Validated by Medicare Decision 159

Startup Prominex Raises \$4M in Series A1 160

Alveo Closes Financing to Create Accessible Diagnostics Devices..... 161

GenePOC® launches its GenePOC® CDiff test in Canada 161

Siemens Healthineers completes takeover of Fast Track Diagnostics..... 162

Chembio and FIND to Develop Point-of-Care Multiplex Test 162

Applied BioCode Receives CE Mark for 18-plex Gastrointestinal Pathogen Panel..... 164

Rapid Molecular Flu Tests Gain Ground 165

Cepheid Receives FDA Clearance and CLIA Waiver for Xpert® Xpress Flu Test..... 167

bioMérieux seeks FDA Clearance of Pneumonia Panel..... 168

Mobidiag Announces Release of a Multiplex qPCR Test for Detection of Antibiotic Resistant Bacteria 169

Fast Track Diagnostics Gets CE Mark for Real-Time PCR Detection of High-Risk HPV..... 170

SEEGENE develops Multiplex PCR tests in 4 days 171

Seegene enters the U.S. diagnostic market in collaboration with Thermo Fisher Scientific..... 172

Fusion Genomics Developing All Pathogens Diagnostic. 173

Anapa Biotech Announces MeltPlex® Technology 174

First multiplex test for tick-borne diseases..... 174

ArcherDx, MGH Suing Qiagen Over Anchored Multiplex PCR Technology..... 176

Akonni Biosystems Forms Chinese Commercialization Partnership with Righton 176

Vela Buys Great Basin Scientific..... 177

BARDA Awards up to \$30M to Cue Health for Influenza, Respiratory Pathogen Test 178

QIAGEN enters into agreement to acquire STAT-Dx..... 179

GA-EMS receives diagnostic device contract..... 181

Biocartis & Immunexpress Sign Partnership for Sepsis 181

6. Profiles of Key Syndromic Testing Companies..... 183

Abbott Diagnostics (Alere) 184

Accelerate Diagnostics 185

Alveo Technologies 186

Applied BioCode..... 187

Atlas Genetics 188

Aus Diagnostics 189

BD Diagnostics 191

Biocartis 193

BioFire Diagnostics..... 194

bioMérieux..... 196

Bio-Rad Laboratories..... 197

Bosch Healthcare Solutions GmbH 199

Cepheid 200

Curetis 201

Diagenode Diagnostics..... 202

Diasorin 203

Fusion Genomics..... 204

GenePOC Diagnostics..... 205

GenMark Dx 206

Hologic 207

Invetech 208

Janssen Diagnostics..... 209

Karius 210

Lexigene 211

Luminex..... 212

Mesa Biotech 213

Mobidiag 214

Nanomix 215

Panagene 216

Primerdesign 217

Prominex 218

Qiagen (Statdx) 219

Quantumdx 221

Roche Molecular Diagnostics..... 222

Seegene..... 224

Siemens Healthineers (Fast Track Diagnostics) 225

SkylineDx..... 231

T2 Biosystems 232

Thermo Fisher 233

Veramarx..... 235

XCR Diagnostics..... 236

7. Global Market Size 237

 7.1 Syndromic Global Market Size by Country with Charts 238

 7.2 Syndromic Global Market Size by Syndrome with Charts 240

8. Global Market by Syndrome..... 242

 8.1 Respiratory Syndrome Market..... 243

 8.1.1 Respiratory Syndrome Market by Country 243

 8.2 GI-Enteric Syndrome Market 245

 8.2.1 GI-Enteric Market by Country with Chart 245

 8.3 Blood-Sepsis Syndrome Market..... 247

 8.3.1 Blood-Sepsis Market by Country with Chart..... 247

 8.4 Meningitis Syndrome Market 249

 8.4.1 Meningitis Market by Country with Chart 249

- 8.5 Sexually Transmitted Disease Syndrome Market 251
 - 8.5.1 Sexually Transmitted Disease Market by Country with Chart 251
- 8.6 Other Syndrome Market 253
 - 8.6.1 Other Market by Country with Chart 253
- 9. Panel Testing Market – Volumes and Price Forecast with MDx Share..... 255
 - 9.1 Respiratory Panel Market 256
 - 9.2 GI-Enteric Panel Market..... 258
 - 9.3 Blood-Sepsis Panel Market 260
 - 9.4 Meningitis Panel Market..... 262
 - 9.5 Sexually Transmitted Disease Panel Market..... 264
 - 9.6 Other Panel Market 266
- Appendices 268
 - I. United States Medicare System: 2018 Clinical Laboratory Fees Schedule – National Limit and Midpoint.. 268
 - II. FDA Approved Microbial Tests..... 320

Table of Tables

- Table 1 Medicare Clinical Lab Expenditures Actual & Forecast 2004 to 2020 (\$Billion)..... 31
- Table 2 Classification of HIV Species 34
- Table 3 HBV Tests - CMS Codes & Prices..... 60
- Table 4 HCV Tests - CMS Codes & Prices..... 67
- Table 5 HPV Clearance Rates..... 72
- Table 6 HPV Tests - CMS Codes & Prices 76
- Table 7 HPV Tests, Technology, Types 78
- Table 8 Types of Influenza Tests..... 88
- Table 9 Influenza Tests - CMS Codes & Prices..... 90

Table 10 FDA Cleared Molecular Assays for Influenza 92

Table 11 FDA Cleared NAAT CTGC Tests..... 104

Table 12 CTGC NAAT Target Sequences and Possible False Reactions 108

Table 13 Influenza Tests - CMS Codes & Prices..... 112

Table 14 FDA Approved MDx Tests for Tuberculosis 118

Table 15 Tuberculosis Tests - CMS Codes & Prices 120

Table 16 FDA Approved Tests for MRSA 122

Table 17 MRSA Tests - CMS Codes & Prices 124

Table 18 FDA Approved Tests for VRE..... 125

Table 19 VRE Tests - CMS Codes & Prices 126

Table 20 Market Players by Type..... 128

Table 21 Clinical Laboratory Departments and Segments 133

Table 22 Laboratory Management Focus – Different Approaches 134

Table 23 Key Segmentation Variables Going Forward 135

Table 24 Possible Market Segments of Syndromic Multiplex Market 135

Table 25 Five Factors Driving Growth..... 141

Table 26 How SMT Improves Outcomes 143

Table 27 Four Factors Limiting Growth 144

Table 28 Syndromic Global Market by Country/Region..... 238

Table 29 Syndromic Global Market by Syndrome 240

Table 30 Gi-enteric Syndromic Testing market by country 245

Table 31 Blood-sepsis Syndromic Testing market by country..... 247

Table 32 Meningitis Syndromic Testing market by country 249

Table 33 Sexually Transmitted Disease Syndromic Testing market by country 251

Table 34 Other Syndromic Testing market by country..... 253

Table 35 Respiratory Panel Testing market – North America 256

Table 36 Respiratory Panel Testing market – Europe 256

Table 37 Respiratory Panel Testing market – Asia Pacific 257

Table 38 GI-Enteric Panel Testing market – North America 258

Table 39 GI-Enteric Panel Testing market – Europe 258

Table 40 GI-Enteric Panel Testing market – Asia Pacific 259

Table 41 Blood-Sepsis Panel Testing market – North America 260

Table 42 Blood-Sepsis Panel Testing market – Europe 260

Table 43 Blood-Sepsis Panel Testing market – Asia Pacific 261

Table 44 Meningitis Panel Testing market – North America 262

Table 45 Meningitis Panel Testing market – Europe 262

Table 46 Meningitis Panel Testing market – Asia Pacific 263

Table 47 Sexually Transmitted Disease Panel Testing market – North America 264

Table 48 Sexually Transmitted Disease Panel Testing market – Europe 264

Table 49 Sexually Transmitted Disease Panel Testing market – Asia Pacific 265

Table 50 Other Panel Testing market – North America 266

Table 51 Other Panel Testing market – Europe 266

Table 52 Other Panel Testing market – Asia Pacific 267

Table 53 2018 Clinical Lab Fee Schedule 268

Table of Figures

Figure 1 Medicare Clinical Lab Expenditures 2004 to 2020 (\$Million)..... 30

Figure 2 HIV Virion..... 35

Figure 3 Diagram of the HIV Replication Cycle..... 38

Figure 4 The Structure of the HBV Virus..... 54

Figure 5 Hepatitis B Replication 55

Figure 6 Structure of the HCV Virus..... 62

Figure 7 HCV Replication Cycle..... 65

Figure 8 Structure of the Influenza Virion 85

Figure 9 Influenza Replication 86

Figure 10 Scanning Electronmicrograph of Tuberculosis 115

Figure 11 Chart Death Rates and Infectious Disease Decline..... 146

Figure 12 Comparing Syndromic and Targeted Testing 150

Figure 13 The Multiplex Paradigm Shift 151

Figure 14 Market Size by Country - Key Countries 239

Figure 15 Global Market by Country 239

Figure 16 Chart of Global Market by Syndrome..... 240

Figure 17 Growth Rates of Syndrome Segments..... 241

Figure 18 Chart - Respiratory market by country..... 244

Figure 19 Chart – Gi-enteric market by country..... 246

Figure 20 Chart – Blood-sepsis market by country 248

Figure 21 Chart - Meningitis market by country 250

Figure 22 Chart – Sexually Transmitted Disease market by country..... 252

Figure 23 Chart – Other Syndromic Testing market by country..... 254