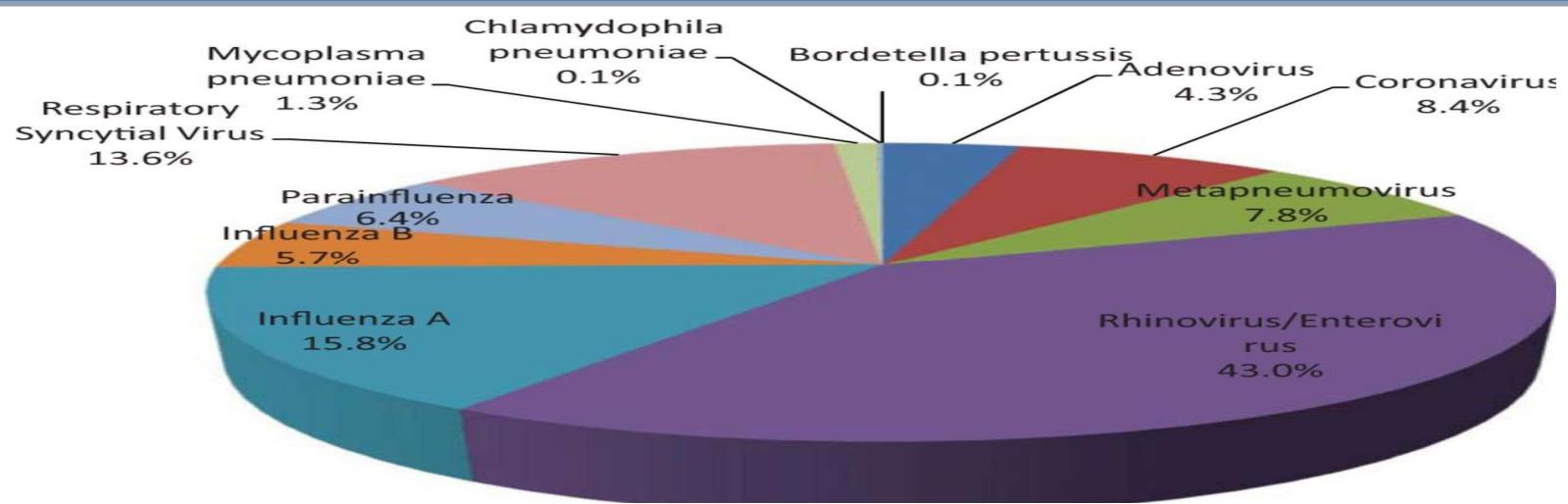


RESEARCH REPORT



SYNDROMIC MULTIPLEX PANELS MARKETS.

Strategies and Trends. Forecasts by Syndrome (Respiratory, Sepsis, GI etc.) by Place and by Product. With Market Analysis, Executive Guides and Customization. 2022 to 2026





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	23
1.2	Guide for Executives and Marketing Staff	26
1.3	Guide for Investment Analysts and Management Consultants.....	28
2	Introduction and Market Definition	30
2.1	What are Syndromic Multiplex Tests?	31
2.2	Syndromic Testing – the quiet revolution in diagnostics	32
2.2.1	Syndromic Testing – more than Panels.	33
2.3	Market Definition	34
2.3.1	Multiplex Market Size.....	34
2.3.2	Currency.	34
2.3.3	Years.....	35
2.4	Methodology.....	36
2.4.1	Authors	36
2.4.2	Sources.....	36
2.5	Perspective: Healthcare, the IVD Industry, and the COVID-19 Pandemic	37
2.5.1	Global Healthcare Spending	37
2.5.2	Spending on Diagnostics.....	39
2.5.3	Important Role of Insurance for Diagnostics	40
3	The Infectious Diseases – Guide to the Pathogens.....	41
3.1	The Coronavirus.....	42
3.1.1	Severe acute respiratory syndrome (SARS)	44
3.1.2	Middle East respiratory syndrome (MERS)	46

3.1.3 COVID-19. The SARS CoV 2 Virus.....	47
3.1.3.1 Signs and symptoms.....	48
3.1.3.2 Transmission	49
3.1.3.3 Diagnosis	50
3.1.3.4 Prevention	52
3.1.3.5 Management.....	53
3.1.3.6 Prognosis.....	54
3.1.3.7 New Strains and Subsequent Mutations	55
3.3 HIV - Human Immunodeficiency Virus (AIDS)	56
3.3.1 Virology	56
3.3.1.1 Classification	56
3.3.1.2 Structure and genome.....	57
3.3.1.3 Tropism.....	59
3.3.1.4 Replication cycle.....	62
3.3.1.5 Genetic variability	67
3.3.2 Diagnosis	69
3.3.3 Testing.....	70
3.3.3.1 Antibody tests	70
3.3.3.2 Point of Care Tests (POCT)	73
3.3.3.3 Antigen Tests	76
3.3.3.4 Nucleic acid-based tests (NAT)	76
3.3.3.5 Other tests used in HIV treatment.....	77
3.4 HBV – Hepatitis B.....	79
3.4.1 Virology	80
3.4.1.1 Genome	81
3.4.1.2 Pathogenesis.....	82

3.4.1.3 Hepatitis B virus replication	82
3.4.1.4 Serotypes and genotypes.....	83
3.4.2 Mechanisms.....	83
3.4.3 Diagnosis	84
3.4.4 Market Opportunity Analysis	85
3.5 HCV – Hepatitis C.....	87
3.5.1 Taxonomy.....	88
3.5.1.1 Structure	88
3.5.1.2 Genome	89
3.5.2 Molecular biology	90
3.5.3 Replication.....	91
3.5.4 Genotypes	93
3.5.4.1 Clinical importance.....	93
3.5.5 Market Opportunity Analysis	94
3.6 2.4 HPV - Human papillomavirus.....	95
3.6.1 Virology	97
3.6.1.1 E6/E7 proteins.....	97
3.6.1.2 Role in cancer.....	97
3.6.1.3 E2 research.....	98
3.6.1.4 Latency period	99
3.6.1.5 Clearance	99
3.6.2 Diagnosis	100
3.6.2.1 Cervical testing	100
3.6.2.2 Oral testing	102
3.6.2.3 Testing men	102
3.6.2.4 Other testing	103

3.6.3 Market Opportunity Analysis	104
3.7 Influenza.....	110
3.7.1 Virology	111
3.7.1.1 Types of virus	111
3.7.1.2 Influenzavirus A	111
3.7.1.3 Influenzavirus B	112
3.7.1.4 Influenzavirus C	113
3.7.1.5 Structure, properties, and subtype nomenclature	113
3.7.1.6 Replication	114
3.7.2 Testing.....	117
3.7.2.1 Advantages/Disadvantages of Molecular Assays.....	119
3.7.3 Market Opportunity Analysis	120
3.8 CTGC - Chlamydia/Gonorhea	128
3.8.1 Gonorrhea	128
3.8.1.1 Diagnosis	129
3.8.1.2 Screening	129
3.8.2 Chlamydia	129
3.8.2.1 Diagnosis	130
3.8.2.2 Screening	131
3.8.3 Testing.....	132
3.8.3.1 Nucleic acid amplification tests (NAATs).....	132
3.8.3.2 Performance of NAAT Tests.....	140
3.8.4 Market Opportunity Analysis	141
3.9 Tuberculosis.....	143
3.9.1 Mycobacteria.....	144
3.9.2 Diagnosis	145

3.9.2.1	Active tuberculosis	145
3.9.2.2	Latent tuberculosis.....	146
3.9.3	Epidemiology.....	146
3.9.4	Molecular Diagnostic Tests	148
3.9.5	Market Opportunity Analysis	149
3.10	MRSA - Methicillin-resistant Staphylococcus aureus	151
3.10.1	Diagnosis	151
3.10.2	FDA Approved Molecular Tests.....	152
3.10.3	Market Opportunity Analysis	153
3.11	VRE - Vancomycin-resistant Enterococcus.....	154
3.11.1	FDA Approved MDx Tests for VRE.....	155
3.11.2	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?	180

5.4 Diagnostic Technology Development	182
5.4.1 Syndromictrends.com.....	182
5.4.2 Comparing Syndrome and Targeted Testing	183
5.4.3 The Multiplex Paradigm Shift.....	184
5.4.4 The Sepsis Testing Market – Bellwether for Syndromics.....	185
5.4.5 The Single Visit and AntiMicrobial Resistance	185
5.4.6 Syndromics drives POCT adoption.....	186
5.4.7 A Big Future for PCR?	186
6 Syndromic Testing Recent Developments	188
6.1 Recent Developments – Importance and How to Use This Section	189
6.1.1 Importance of These Developments	189
6.1.2 How to Use This Section.....	189
6.2 Genetic Signatures Wins Public Health Wales Contract.....	189
6.3 Qiagen Looks to Long-Term Growth.....	190
6.4 LexaGene Gets Investment	194
6.5 Seegene Multiplex COVID-19/Flu/RSV Test Receives Approval.....	195
6.6 BforCure to Adapt Rapid PCR Platform for Cancer.....	196
6.7 Accelerated Growth for Decentralized Testing	196
6.8 QuantuMDx Developing Syndromic Panels for European Launch.....	204
6.9 Quidel Gains CE Mark for Savanna Analyzer, Respiratory Panel.....	209
6.10 QuantumDx Gets CE Mark for Rapid PoC PCR System.....	209
6.11 Bio-Rad Laboratories, Seegene Partner for MDx Development.....	211
6.12 Baebies to Expand Finder Platform.....	211
6.13 With Luminex Acquisition, DiaSorin to Broaden MDx Portfolio	215
6.14 Binx Health Targeting Clinics, DTC & OTC With STI Tests	219
6.15 Luminex Lands BARDA Grant to Develop Test for SARS-CoV-2, Flu, RSV	223

6.16	Molzym, Fraunhofer Developing Rapid Sepsis Diagnostic	224
6.17	MiRxes Receives Approval for Multiplex SARS-CoV-2, Flu Test	227
6.18	New Approach Involves Silicon-Based Test for Infectious Disease Screening.....	228
6.19	Scanogen's Portable Battery Operated Instrument for 90 Minute Multiplex Test	233
6.20	Qiagen sees NeuMoDx as Growth Vehicle	236
6.21	Torus Biosystems Developing Syndromic Test with 30-Minute Turnaround.....	240
6.22	Roche, SpeeDx Partner to Expand Access to Antibiotic Resistance Tests	244
6.23	BioMérieux's BioFire SARS-CoV-2 Respiratory Panel Wins FDA EAU.....	244
6.24	Infectious Disease Testing Firm Curative Acquires KorvaLabs	245
6.25	ChromaCode Raises Additional \$10M	246
6.26	COVID-19 Patients Need Syndromic Testing.....	246
6.27	GenMark Diagnostics – New Respiratory Panel due in June.....	248
6.28	Qiagen Respiratory Panel with Coronavirus Targets Receives CE Mark.....	249
6.29	Exact Diagnostics launches respiratory panel control.....	250
6.30	bioMérieux submits enhanced BIOFIRE® BCID2 Panel to FDA	251
6.31	Nanomix Receives CE Mark for Diagnostic.....	252
6.32	Applied BioCode Applies to FDA for Syndromic Respiratory Panel.....	253
6.33	Expedeon AG and Sona Nanotech to Collaborate on Multiplex POC	255
6.34	QIAGEN's New GI Panel Performance Assessed.....	255
6.35	McKesson to Distribute QIAstat-Dx Syndromic Testing Solution in USA	257
6.36	Applied BioCode Obtains FDA Clearance	258
6.37	Meridian Bioscience to Acquire GenePOC Inc.....	258
6.38	Curetis Introduces Rapid DNA Testing for Antibiotic Resistance	259
6.39	Qiagen gets FDA clearance for syndromic testing system	261
6.40	Entasis Therapeutics Signs Rapid Diagnostic Agreement with bioMérieux	262
6.41	Akronni Biosystems Submits Multiplex Diagnostics System to FDA	262

6.42	Ador Diagnostic to receive \$30M in Funding for 100-Plex PoC	264
6.43	SAW Diagnostics Receives Funding for Commercialisation of PoC Platform.....	265
6.44	QuantuMDx and Molbio announce MoU	267
6.45	Immunexpress Wins \$745K Contract for Rapid Sepsis Assay.....	268
6.46	Mobidiag Inks European, Middle Eastern Distribution Deals.....	269
6.47	BIOFIRE® FILMARRAY® System chosen for Phase 3 clinical trial	269
7	Profiles of Key Syndromic Testing Companies	271
7.1	Abacus Diagnostica	272
7.2	Abbott Diagnostics	273
7.3	Accelerate Diagnostics.....	275
7.4	Ador Diagnostics	276
7.5	Akronni Biosystems	277
7.6	Alveo Technologies.....	278
7.7	Antelope Dx.....	279
7.8	Applied BioCode	280
7.9	Aus Diagnostics	281
7.10	Baebies	282
7.11	Beckman Coulter Diagnostics.....	284
7.12	Becton, Dickinson and Company	285
7.13	Binx Health	287
7.14	Biocartis.....	289
7.15	BioFire Diagnostics (bioMérieux)	290
7.16	bioMérieux Diagnostics.....	292
7.17	Bio-Rad Laboratories, Inc.....	294
7.18	Bosch Healthcare Solutions GmbH.....	296
7.19	Cepheid (Danaher)	297

7.20	Credo Diagnostics Biomedical	299
7.21	Cue Health.....	300
7.22	Curetis N.V. / Curetis GmbH	302
7.23	Diagenode Diagnostics	303
7.24	Diasorin S.p.A.....	304
7.25	Enzo Life Sciences, Inc.	306
7.26	Eurofins Scientific	308
7.27	Fluxergy	310
7.28	Fusion Genomics.	311
7.29	Genetic Signatures.....	313
7.30	GenMark Dx (Roche)	314
7.31	Hibergene Diagnostics.....	316
7.32	Hologic	317
7.33	Immunexpress.....	319
7.34	Inflamatix	320
7.35	Invetech.....	321
7.36	Janssen Diagnostics	322
7.37	Karius	323
7.38	Lexogene	325
7.39	LightDeck Diagnostics	326
7.40	Lucira Health.....	327
7.41	Luminex Corp	328
7.42	Maxim Biomedical	330
7.43	Meridian Bioscience.....	331
7.44	Mesa Biotech (Thermo Fisher)	333
7.45	Millipore Sigma	334

7.46	Mobidiag (Hologic)	335
7.47	Molbio Diagnostics.....	336
7.48	Nanomix.....	337
7.49	Novel Microdevices	338
7.50	Operon.....	339
7.51	Oxford Nanopore Technologies	340
7.52	Panagene	341
7.53	Perkin Elmer.....	342
7.54	Primerdesign (Novacyt)	344
7.55	Prominex	345
7.56	Qiagen Gmbh	346
7.57	Quantumdx	348
7.58	Quidel.....	349
7.59	Roche Molecular Diagnostics	351
7.60	Saw Diagnostics	353
7.61	Seegene.....	354
7.62	Siemens Healthineers	356
7.63	Sona Nanotech	358
7.64	SpeeDx.....	359
7.65	T2 Biosystems.....	360
7.66	Talis Biomedical	361
7.67	Thermo Fisher Scientific Inc.....	362
7.68	Veramarx	364
7.69	Visby Medical	365
7.70	XCR Diagnostics	367
8	The Global Market for Syndromic Multiplex Diagnostics.....	368

8.1	Global Market Overview by Country	369
8.1.1	Table – Global Market by Country.....	369
8.1.2	Chart - Global Market by Country.....	370
8.2	Global Market by Syndrome - Overview	371
8.2.1	Table – Global Market by Syndrome	371
8.2.2	Chart – Global Market by Syndrome – Base/Final Year Comparison	372
8.2.3	Chart – Global Market by Syndrome – Base Year	373
8.2.4	Chart – Global Market by Syndrome – End Year.....	374
8.2.5	Chart – Global Market by Syndrome – Share by Year	375
8.2.6	Chart – Global Market by Syndrome – Segments Growth.....	376
8.3	Global Market by Place - Overview	377
8.3.1	Table – Global Market by Place.....	377
8.3.2	Chart – Global Market by Place – Base/Final Year Comparison	378
8.3.3	Chart – Global Market by Place – Base Year.....	379
8.3.4	Chart – Global Market by Place – End Year	380
8.3.5	Chart – Global Market by Place – Share by Year.....	381
8.3.6	Chart – Global Market by Place – Segments Growth	382
8.4	Global Market by Product - Overview	383
8.4.1	Table – Global Market by Product.....	383
8.4.2	Chart – Global Market by Product – Base/Final Year Comparison.....	384
8.4.3	Chart – Global Market by Product – Base Year.....	385
8.4.4	Chart – Global Market by Product – End Year	386
8.4.5	Chart – Global Market by Product – Share by Year	387
8.4.6	Chart – Global Market by Product – Segments Growth	388
9	Global Syndromic Multiplex Markets – By Syndrome	389
9.1	Respiratory	390

9.1.1	Table Respiratory – by Country	390
9.1.2	Chart - Respiratory Growth.....	391
9.2	Gastrointestinal.....	392
9.2.1	Table Gastrointestinal – by Country	392
9.2.2	Chart - Gastrointestinal Growth	393
9.3	Blood	394
9.3.1	Table Blood – by Country	394
9.3.2	Chart - Blood Growth.....	395
9.4	Meningitis/Encephalitis	396
9.4.1	Table Meningitis/Encephalitis – by Country.....	396
9.4.2	Chart - Meningitis/Encephalitis Growth	397
9.5	Sexually Transmitted Disease.....	398
9.5.1	Table Sexually Transmitted Disease – by Country	398
9.5.2	Chart – Sexually Transmitted Disease Growth.....	399
9.6	Other Syndrome	400
9.6.1	Table Other – by Country	400
9.6.2	Chart - Other Growth.....	401
10	Global MDx Infectious Disease Markets – by Place	402
10.1	Hospital Lab	403
10.1.1	Table Hospital Lab – by Country	403
10.1.2	Chart - Hospital Lab Growth.....	404
10.2	Outpatient Lab.....	405
10.2.1	Table Outpatient Lab – by Country	405
10.2.2	Chart - Outpatient Lab Growth	406
10.3	Point of Care.....	407
10.3.1	Table Point of Care – by Country.....	407

10.3.2 Chart – Point of Care Growth.....	408
10.4 Other Place	409
10.4.1 Table Other – by Country	409
10.4.2 Chart - Other Place Growth.....	410
11 Global MDx Infectious Disease Markets – by Product	411
11.1 Instruments.....	412
11.1.1 Table Instruments – by Country	412
11.1.2 Chart - Instruments Growth.....	413
11.2 Cartridges	414
11.2.1 Table Cartridges – by Country	414
11.2.2 Chart - Cartridges Growth.....	415
11.3 Reagents.....	416
11.3.1 Table Reagents – by Country	416
11.3.2 Chart - Reagents Growth	417
11.4 Other Product.....	418
11.4.1 Table Other Product – by Country	418
11.4.2 Chart – Other Product Growth.....	419
12 Appendices.....	420
12.1 United States Medicare System: 2022 Clinical Laboratory Fees Schedule.....	421

Table of Tables

Table 1 Characteristics of Coronavirus Pandemic Infections	47
Table 2 COVID-19 Symptoms.....	49
Table 3 Classification of HIV Species.....	57
Table 4 HBV Tests - CMS Codes & Prices.....	87
Table 5 HCV Tests - CMS Codes & Prices	94
Table 6 HPV Clearance Rates	100
Table 7 HPV Tests - CMS Codes & Prices	105
Table 8 HPV Tests, Technology, Types	106
Table 9 Types of Influenza Tests	117
Table 10 Influenza Tests - CMS Codes & Prices.....	120
Table 11 FDA Cleared Molecular Assays for Influenza	121
Table 12 FDA Cleared NAAT CTGC Tests	133
Table 13 CTGC NAAT Target Sequences and Possible False Reactions	138
Table 14 Influenza Tests - CMS Codes & Prices.....	142
Table 15 FDA Approved MDx Tests for Tuberculosis	148
Table 16 Tuberculosis Tests - CMS Codes & Prices.....	149
Table 17 FDA Approved Tests for MRSA	152
Table 18 MRSA Tests - CMS Codes & Prices	154
Table 19 FDA Approved Tests for VRE	155
Table 20 VRE Tests - CMS Codes & Prices	156
Table 21 Market Players by Type	158
Table 22 Clinical Laboratory Departments and Segments	163
Table 23 Laboratory Management Focus – Different Approaches	164

Table 24 Key Segmentation Variables Going Forward.....	165
Table 25 Possible Market Segments of Syndromic Multiplex Market	165
Table 26 Five Factors Driving Growth.....	172
Table 27 How SMT Improves Outcomes.....	174
Table 28 Four Factors Limiting Growth	175
Table 29 - Global Market by Region	369
Table 30 Global Market by Syndrome	371
Table 31 Global Market by Place.....	377
Table 32 Global Market by Product.....	383
Table 33 Respiratory by Country.....	390
Table 34 Gastrointestinal by Country	392
Table 35 Blood by Country.....	394
Table 36 Meningitis/Encephalitis by Country.....	396
Table 37 Sexually Transmitted Disease by Country	398
Table 38 Other by Country.....	400
Table 39 Hospital Lab by Country	403
Table 40 Outpatient Lab by Country	405
Table 41 Point of Care by Country	407
Table 42 Other by Country.....	409
Table 43 Instruments by Country	412
Table 44 Cartridges by Country.....	414
Table 45 Reagents by Country	416
Table 46 Other Product by Country	418
Table 47 2022 Clinical Lab Fee Schedule	421

Table of Figures

Figure 1 The Global Healthcare Spending Picture.....	38
Figure 3 The Lab Test Pie	39
FIGURE 3 STRUCTURE OF CORONAVIRUSES	43
Figure 4 HIV Virion	58
Figure 5 Diagram of the HIV Replication Cycle	62
Figure 6 The Structure of the HBV Virus.....	81
Figure 7 Hepatitis B Replication	82
Figure 8 Structure of the HCV Virus.....	89
Figure 9 HCV Replication Cycle	92
Figure 10 Structure of the Influenza Virion	114
Figure 11 Influenza Replication.....	115
Figure 12 Scanning Electronmicrograph of Tuberculosis.....	144
Figure 13 Chart Death Rates and Infectious Disease Decline	177
Figure 14 Comparing Syndromic and Targeted Testing.....	183
Figure 16 The Multiplex Paradigm Shift.....	184
Figure 16 Global Market Share Chart	370
Figure 17 Global Market by Syndrome - Base vs. Final	372
Figure 18 Global Market by Syndrome Base Year	373
Figure 19 Global Market by Syndrome End Year	374
Figure 20 Syndrome Share by Year	375
Figure 21 Syndrome Segments Growth.....	376
Figure 22 Global Market by Place - Base vs. Final.....	378
Figure 23 Global Market by Place Base Year.....	379
Figure 24 Global Market by Place End Year	380

Figure 25 Place Share by Year.....	381
Figure 26 Place Segments Growth	382
Figure 27 Global Market by Product - Base vs. Final.....	384
Figure 28 Global Market by Product Base Year	385
Figure 29 Global Market by Product End Year.....	386
Figure 30 Product Share by Year	387
Figure 31 Product Segments Growth	388
Figure 32 Respiratory Growth.....	391
Figure 33 Gastrointestinal Diagnostics Growth.....	393
Figure 34 Blood Growth.....	395
Figure 35 Meningitis/Encephalitis Growth.....	397
Figure 36 Sexually Transmitted Disease Growth	399
Figure 37 Other Growth.....	401
Figure 38 Hospital Lab Growth.....	404
Figure 39 Outpatient Lab Growth	406
Figure 40 Point of Care Growth	408
Figure 41 Other Growth.....	410
Figure 42 Instruments Growth	413
Figure 43 Cartridges Growth.....	415
Figure 44 Reagents Growth	417
Figure 45 Other Product Growth	419