

OCTOBER 2019

# RESEARCH REPORT



## Global Clinical In Vitro Diagnostic Medical Laboratory Services Market.

Strategy & Trends with Volume & Price Forecasts by Chemistry, Hematology, Microbiology, Pathology, Molecular Diagnostic and Esoteric by Country. 2020 to 2024. With Situation Analysis and Executive & Consultant Guides



HOWE SOUND RESEARCH



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 X-Ray 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. Clinical Laboratory Services - Strategic Situation Analysis.....	22
ii. Guide for Executives, Marketing, Sales and Business Development Staff .....	25
iii. Guide for Management Consultants and Investment Advisors .....	26
1. Introduction and Market Definition .....	27
1.1 The Growing Demand for Clinical Testing .....	28
1.2 Defining the Opportunity .....	30
1.2.1 Volumes.....	30
1.2.2 Prices .....	31
1.2.3 Revenue Market Size .....	31
1.3 Methods and Sources .....	32
1.3.1 Authors .....	32
1.3.2 Sources .....	32
1.4 U.S. Medical Market and laboratory Testing - Perspective .....	33
1.4.1 U.S. Medicare Expenditures for Laboratory Testing .....	33
2. Overview of a Dynamic Market .....	35
2.1 Market Players – Roles & Impacts.....	36
2.1.1 Supplier/pharmaceutical .....	36
2.1.2 Independent lab specialized/esoteric .....	37
2.1.3 Independent lab national/regional.....	37
2.1.4 Independent lab analytical .....	38
2.1.5 Public National/regional lab .....	38
2.1.6 Hospital lab .....	38
2.1.7 Physician lab .....	39
2.1.8 Audit body .....	39
2.2 Segmentation – Different Approaches.....	41

2.2.1 Traditional Market Segmentation.....	41
2.2.2 Laboratory Focus and Segmentation.....	42
2.3 Structure of Clinical Testing Industry.....	44
2.3.1 The Hospital Lab – Share of the Pie.....	44
2.3.2 Key Role for Economies of Scale.....	44
2.3.3 Physician Office Lab's are Still Here.....	46
2.3.4 Physician's and POCT – Reviving Patient Service in China.....	47
2.4 Profiles of Key Companies.....	48
Acibadem Labmed Laboratory.....	48
ACM Medical Laboratory.....	50
Adicon Clinical Laboratories.....	51
American Bio-Clinical Laboratories, Int'l.....	52
American Pathology Partners.....	53
ARUP Laboratories.....	54
Ascend Clinical.....	56
Aurora Diagnostics.....	57
Bio-Reference Laboratories.....	58
Bioscientia Institut für Medizinische Diagnostik GmbH.....	59
BP Healthcare Group.....	60
Clinical Reference Laboratory.....	61
Clongen Laboratories.....	62
CompuNet Clinical Laboratories.....	63
Diagnósticos da América.....	64
DIAN Diagnostics Co., Ltd.....	65
Enzo Life Sciences, Inc.....	67
Eurofins Scientific.....	68
Exagen Diagnostics.....	71

Genomic Health..... 72

Genzyme Corporation..... 73

Gribbles Pathology..... 75

Guangzhou Kingmed Diagnostics Group Co., Ltd..... 76

Integrated Regional Laboratories..... 77

KDL Group..... 78

Laboratory Corporation of America ..... 79

Lifelabs ..... 81

Mayo Clinic Laboratories..... 82

Mid America Clinical Laboratories ..... 83

Myriad Genetics/Myriad RBM ..... 84

NeoGenomics ..... 85

Pathology, Inc. .... 86

Psychemedics Corporation..... 87

Quest Diagnostics ..... 88

RDL Reference Laboratory ..... 89

Sonic Healthcare..... 90

Spectra Laboratories ..... 91

Unilabs..... 92

2.5 National and Regional Diversity ..... 93

3. Trends Driving a Changing Market.....95

3.1 Growth Is Pushed from Many Sides ..... 96

3.1.1 Understanding the Impact of Aging Population. .... 97

3.1.2 Economic growth a Key Driver..... 97

3.1.3 Point of Care Testing can increase demand..... 97

3.1.4 Alternative Medicine Creates Testing Opportunity ..... 97

3.1.5 Esoteric Testing Moving Mainstream..... 98

- 3.1.6 Genetic Based Testing Creates New Department and New Discipline ..... 99
- 3.2 Factors at Work To Shrink The Market..... 100
  - 3.2.1 Lower costs trend to continue..... 100
  - 3.2.2 Economic or population contraction..... 101
  - 3.2.3 Testing usage analysis curtailing growth. .... 101
  - 3.2.4 Wellness has a downside ..... 101
  - 3.2.5 Test Displacement Impacts Important..... 101
  - 3.2.6 Point of Care Testing ..... 101
- 3.3 Automation ..... 103
  - 3.3.1 Stranded LIMS Investment ..... 103
  - 3.3.2 Software as a Service..... 103
  - 3.3.3 Physician Office and Access Systems..... 104
- 3.4 Environment and Evolution ..... 105
- 3.5 Diagnostic Technology Development ..... 106
  - 3.5.1 Next Generation Sequencing Fuels a Revolution. .... 107
  - 3.5.2 Impact of NGS on pricing..... 108
  - 3.5.3 POCT/Self Testing Disruptive Force..... 108
  - 3.5.4 Pharmacogenomics Blurs Diagnosis and Treatment..... 109
  - 3.5.5 CGES Testing, A Brave New World ..... 110
  - 3.5.6 Molecular Diagnostics Technologies at The Forefront of Growth ..... 111
  - 3.5.7 Biochips/Giant magneto resistance based assay ..... 112
- 4. Laboratory, Molecular Diagnostics and Genomic Testing Recent Developments ....113
  - 4.1 Recent Developments – Importance and How to Use This Section..... 114
    - 4.1.1 Importance of These Developments ..... 114
    - 4.1.2 How to Use This Section..... 114
- CLA Urges FDA to Halt Crackdown on PGx Testing..... 114
- Quest Diagnostics Subsidiary Buys True Health Dx Assets ..... 116

BioReference Laboratories selected by IPA Association .....	116
Predictive Laboratories Announces Research Collaboration .....	117
NEOMED-LABS / Pacific Biomarkers Acquires PAIRimmune Français .....	118
LabCorp and Envigo Complete Transactions.....	119
PathGroup Acquires Pathologists Bio-Medical Laboratories .....	120
Predictive Technology Acquires Taueret Laboratories .....	121
Quest Diagnostics Acquires Laboratory Services Business of Boyce & Bynum Pathology Laboratories .....	122
Gestalt Diagnostics Expands Market Reach with Peak Medical Acquisition .....	123
Amazon exploring consumer health diagnostics .....	124
Quest Diagnostics Acquires Laboratory Services Operation in Central Michigan .....	125
NeoGenomics to acquire Genoptix, Inc.....	126
Quest Diagnostics to Acquire U.S. Laboratory Services Business of Oxford Immunotec .....	127
Charles River Labs to acquire contract research firm for \$800M .....	128
GROUPE BIO7 to be Sold to CERBA HEALTHCARE.....	128
GE Healthcare and Roche Partner to Develop Digital Diagnostics Platform .....	129
Digipath Enters into Letter of Intent to Acquire Clinical Lab Companies .....	130
PSP to acquire European medical lab services company .....	131
Mars, Incorporated to Acquire VCA Inc. ....	132
Grifols acquires Hologic's blood screening unit for \$1.85bn.....	135
LabCorp to acquire clinical laboratories from Mount Sinai.....	135
PerkinElmer to buy Germany's Euroimmun for about \$1.3 billion .....	137
LabCorp to Acquire Chiltern for Approximately \$1.2 Billion in Cash.....	137
Precipio Diagnostics and Transgenomic Complete Merger .....	138
\$550 Dock Turns a Smartphone into a Medical Lab.....	140
LabCorp & Interpace Extend Deal, Boost Cancer Portfolio .....	141
Quest Diagnostics to Acquire Shiel Medical Laboratory from Fresenius Medical Care .....	141



Quest Diagnostics to Acquire MedXM .....	142
Overview of Clinical Diagnostic Acquisition Activity .....	144
New Sysmex Device Provides Blood Test Results at Point of Care in Minutes.....	146
FDA, Congress Return Attention to Direct-to-Consumer Genetic Testing .....	147
QIAGEN Enters into Agreement to Acquire STAT-Dx.....	148
5. Country Market Sizes – North America 2016 to 2024.....	150
5.1 United States of America 2016 to 2024 .....	151
5.1.1 Clinical Chemistry – Volumes, Prices, Revenues .....	151
5.1.2 Microbiology – Volumes, Prices, Revenues .....	151
5.1.3 Hematology – Volumes, Prices, Revenues .....	152
5.1.4 Anatomic Pathology – Volumes, Prices, Revenues .....	152
5.1.5 Molecular Diagnostics – Volumes, Prices, Revenues.....	153
5.1.6 All Clinical Testing – Volumes, Prices, Revenues .....	153
5.1.7 Esoteric – Volumes, Prices, Revenues .....	154
5.2 Canada 2016 to 2024.....	155
5.2.1 Clinical Chemistry – Volumes, Prices, Revenues .....	155
5.2.2 Microbiology – Volumes, Prices, Revenues .....	155
5.2.3 Hematology – Volumes, Prices, Revenues .....	156
5.2.4 Anatomic Pathology – Volumes, Prices, Revenues .....	156
5.2.5 Molecular Diagnostics – Volumes, Prices, Revenues.....	157
5.2.6 All Clinical Testing – Volumes, Prices, Revenues .....	157
5.2.7 Esoteric – Volumes, Prices, Revenues .....	158
6. Country Markets – Europe 2016 to 2024.....	159
6.1 France 2016 to 2024 .....	160
6.1.1 Clinical Chemistry – Volumes, Prices, Revenues .....	160
6.1.2 Microbiology – Volumes, Prices, Revenues .....	160
6.1.3 Hematology – Volumes, Prices, Revenues .....	161

6.1.4 Anatomic Pathology – Volumes, Prices, Revenues .....	161
6.1.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	162
6.1.6 All Clinical Testing – Volumes, Prices, Revenues .....	162
6.1.7 Esoteric – Volumes, Prices, Revenues .....	163
6.2 Germany 2016 to 2024 .....	164
6.2.1 Clinical Chemistry – Volumes, Prices, Revenues .....	164
6.2.2 Microbiology – Volumes, Prices, Revenues .....	164
6.2.3 Hematology – Volumes, Prices, Revenues .....	165
6.2.4 Anatomic Pathology – Volumes, Prices, Revenues .....	165
6.2.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	166
6.2.6 All Clinical Testing – Volumes, Prices, Revenues .....	166
6.2.7 Esoteric – Volumes, Prices, Revenues .....	167
6.3 United Kingdom 2016 to 2024 .....	168
6.3.1 Clinical Chemistry – Volumes, Prices, Revenues .....	168
6.3.2 Microbiology – Volumes, Prices, Revenues .....	168
6.3.3 Hematology – Volumes, Prices, Revenues .....	169
6.3.4 Anatomic Pathology – Volumes, Prices, Revenues .....	169
6.3.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	170
6.3.6 All Clinical Testing – Volumes, Prices, Revenues .....	170
6.3.7 Esoteric – Volumes, Prices, Revenues .....	171
6.4 Spain 2016 to 2024 .....	172
6.4.1 Clinical Chemistry – Volumes, Prices, Revenues .....	172
6.4.2 Microbiology – Volumes, Prices, Revenues .....	172
6.4.3 Hematology – Volumes, Prices, Revenues .....	173
6.4.4 Anatomic Pathology – Volumes, Prices, Revenues .....	173
6.4.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	174
6.4.6 All Clinical Testing – Volumes, Prices, Revenues .....	174

6.4.7 Esoteric – Volumes, Prices, Revenues .....	175
6.5 Italy 2016 to 2024 .....	176
6.5.1 Clinical Chemistry – Volumes, Prices, Revenues .....	176
6.5.2 Microbiology – Volumes, Prices, Revenues .....	176
6.5.3 Hematology – Volumes, Prices, Revenues .....	177
6.5.4 Anatomic Pathology – Volumes, Prices, Revenues .....	177
6.5.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	178
6.5.6 All Clinical Testing – Volumes, Prices, Revenues .....	178
6.5.7 Esoteric – Volumes, Prices, Revenues .....	179
6.6 Russia 2016 to 2024 .....	180
6.6.1 Clinical Chemistry – Volumes, Prices, Revenues .....	180
6.6.2 Microbiology – Volumes, Prices, Revenues .....	180
6.6.3 Hematology – Volumes, Prices, Revenues .....	181
6.6.4 Anatomic Pathology – Volumes, Prices, Revenues .....	181
6.6.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	182
6.6.6 All Clinical Testing – Volumes, Prices, Revenues .....	182
6.6.7 Esoteric – Volumes, Prices, Revenues .....	183
6.7 Remainder of Europe and Former Soviet Union 2016 to 2024.....	184
6.7.1 Clinical Chemistry – Volumes, Prices, Revenues .....	184
6.7.2 Microbiology – Volumes, Prices, Revenues .....	184
6.7.3 Hematology – Volumes, Prices, Revenues .....	185
6.7.4 Anatomic Pathology – Volumes, Prices, Revenues .....	185
6.7.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	186
6.7.6 All Clinical Testing – Volumes, Prices, Revenues .....	186
6.7.7 Esoteric – Volumes, Prices, Revenues .....	187
7. Country Markets – Asia Pacific 2016 to 2024 .....	188
7.1 China 2016 to 2024.....	188

7.1.1 Clinical Chemistry – Volumes, Prices, Revenues .....	189
7.1.2 Microbiology – Volumes, Prices, Revenues .....	189
7.1.3 Hematology – Volumes, Prices, Revenues .....	190
7.1.4 Anatomic Pathology – Volumes, Prices, Revenues .....	190
7.1.5 Molecular Diagnostics – Volumes, Prices, Revenues.....	191
7.1.6 All Clinical Testing – Volumes, Prices, Revenues .....	191
7.1.7 Esoteric – Volumes, Prices, Revenues .....	192
7.2 Japan 2016 to 2024 .....	193
7.2.1 Clinical Chemistry – Volumes, Prices, Revenues .....	193
7.2.2 Microbiology – Volumes, Prices, Revenues .....	193
7.2.3 Hematology – Volumes, Prices, Revenues .....	194
7.2.4 Anatomic Pathology – Volumes, Prices, Revenues .....	194
7.2.5 Molecular Diagnostics – Volumes, Prices, Revenues.....	195
7.2.6 All Clinical Testing – Volumes, Prices, Revenues .....	195
7.2.7 Esoteric – Volumes, Prices, Revenues .....	196
7.3 South Korea 2016 to 2024.....	197
7.3.1 Clinical Chemistry – Volumes, Prices, Revenues .....	197
7.3.2 Microbiology – Volumes, Prices, Revenues .....	197
7.3.3 Hematology – Volumes, Prices, Revenues .....	198
7.3.4 Anatomic Pathology – Volumes, Prices, Revenues .....	198
7.3.5 Molecular Diagnostics – Volumes, Prices, Revenues.....	199
7.3.6 All Clinical Testing – Volumes, Prices, Revenues .....	199
7.3.7 Esoteric – Volumes, Prices, Revenues .....	200
7.4 India 2016 to 2024.....	201
7.4.1 Clinical Chemistry – Volumes, Prices, Revenues .....	201
7.4.2 Microbiology – Volumes, Prices, Revenues .....	201
7.4.3 Hematology – Volumes, Prices, Revenues .....	202

7.4.4 Anatomic Pathology – Volumes, Prices, Revenues .....	202
7.4.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	203
7.14.6 All Clinical Testing – Volumes, Prices, Revenues .....	203
7.4.7 Esoteric – Volumes, Prices, Revenues .....	204
7.5 Australia 2016 to 2024.....	205
7.5.1 Clinical Chemistry – Volumes, Prices, Revenues .....	205
7.5.2 Microbiology – Volumes, Prices, Revenues .....	205
7.5.3 Hematology – Volumes, Prices, Revenues .....	206
7.5.4 Anatomic Pathology – Volumes, Prices, Revenues .....	206
7.5.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	207
7.5.6 All Clinical Testing – Volumes, Prices, Revenues .....	207
7.5.7 Esoteric – Volumes, Prices, Revenues .....	208
7.6 Rest of Asia Pacific 2016 to 2024 .....	209
7.6.1 Clinical Chemistry – Volumes, Prices, Revenues .....	209
7.6.2 Microbiology – Volumes, Prices, Revenues .....	209
7.6.3 Hematology – Volumes, Prices, Revenues .....	210
7.6.4 Anatomic Pathology – Volumes, Prices, Revenues .....	210
7.6.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	211
7.6.6 All Clinical Testing – Volumes, Prices, Revenues .....	211
7.6.7 Esoteric – Volumes, Prices, Revenues .....	212
8. Country Markets – Latin America, Africa & The Middle East 2016 to 2024.....	213
8.1 Brazil 2016 to 2024.....	214
8.1.1 Clinical Chemistry – Volumes, Prices, Revenues .....	214
8.1.2 Microbiology – Volumes, Prices, Revenues .....	214
8.1.3 Hematology – Volumes, Prices, Revenues .....	215
8.1.4 Anatomic Pathology – Volumes, Prices, Revenues .....	215
8.1.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	216

8.1.6 All Clinical Testing – Volumes, Prices, Revenues .....	216
8.1.7 Esoteric – Volumes, Prices, Revenues .....	217
8.2 Mexico 2016 to 2024.....	218
8.2.1 Clinical Chemistry – Volumes, Prices, Revenues .....	218
8.2.2 Microbiology – Volumes, Prices, Revenues .....	218
8.2.3 Hematology – Volumes, Prices, Revenues .....	219
8.2.4 Anatomic Pathology – Volumes, Prices, Revenues .....	219
8.2.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	220
8.2.6 All Clinical Testing – Volumes, Prices, Revenues .....	220
8.2.7 Esoteric – Volumes, Prices, Revenues .....	221
8.3 Remainder of Latin America 2016 to 2024 .....	222
8.3.1 Clinical Chemistry – Volumes, Prices, Revenues .....	222
8.3.2 Microbiology – Volumes, Prices, Revenues .....	222
8.3.3 Hematology – Volumes, Prices, Revenues .....	223
8.3.4 Anatomic Pathology – Volumes, Prices, Revenues .....	223
8.3.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	224
8.3.6 All Clinical Testing – Volumes, Prices, Revenues .....	224
8.3.7 Esoteric – Volumes, Prices, Revenues .....	225
8.4 Africa & The Middle East 2016 to 2024 .....	226
8.4.1 Clinical Chemistry – Volumes, Prices, Revenues .....	226
8.4.2 Microbiology – Volumes, Prices, Revenues .....	226
8.4.3 Hematology – Volumes, Prices, Revenues .....	227
8.4.4 Anatomic Pathology – Volumes, Prices, Revenues .....	227
8.4.5 Molecular Diagnostics – Volumes, Prices, Revenues .....	228
8.4.6 All Clinical Testing – Volumes, Prices, Revenues .....	228
8.4.7 Esoteric – Volumes, Prices, Revenues .....	229
9. Global Market Summary 2016 to 2024 .....	230

9.1 Global Market 2016 to 2024..... 231

    9.1.1 Clinical Chemistry – Volumes, Prices, Revenues ..... 231

    9.1.2 Microbiology – Volumes, Prices, Revenues ..... 231

    9.1.3 Hematology – Volumes, Prices, Revenues ..... 232

    9.1.4 Anatomic Pathology – Volumes, Prices, Revenues ..... 232

    9.1.5 Molecular Diagnostics – Volumes, Prices, Revenues ..... 233

    9.1.6 All Clinical Testing – Volumes, Prices, Revenues ..... 233

    9.1.7 Esoteric – Volumes, Prices, Revenues ..... 234

10. The Future of the Clinical Laboratory .....235

Appendices .....236

    I. United States Medicare System: January 2019 Clinical Laboratory Fees Schedule ..... 236

Table of Tables

Table 1 Lab Spending 2014 to 2024 ..... 34

Table 2 Market Players by Type ..... 36

Table 3 Clinical Laboratory Departments and Segments ..... 41

Table 4 Laboratory Management Focus – Different Approaches ..... 42

Table 5 Key Segmentation Variables Going Forward..... 43

Table 6 Factors Affecting Local Clinical Testing Demand ..... 93

Table 7 Seven Factors Driving Growth ..... 96

Table 8 Alternative Medicine Creates New Clinical Testing Markets..... 98

Table 9 Six Factors Limiting Growth ..... 100

Table 10 Key Diagnostic Laboratory Technology Trends ..... 106

Table 11 Next Generation Sequencing Technologies – Speed and Cost ..... 107



Table 12 Key Point of Care Testing Uses.....	109
Table 13 Clinical Application Areas for Molecular Diagnostics .....	111
Table 14 Clinical Chemistry - Volume Price and Revenue Forecast .....	151
Table 15 Microbiology - Volume Price and Revenue Forecast .....	151
Table 16 Hematology - Volume Price and Revenue Forecast .....	152
Table 17 Anatomic Pathology - Volume Price and Revenue Forecast .....	152
Table 18 Molecular Diagnostics - Volume Price and Revenue Forecast .....	153
Table 19 All Clinical Testing - Volume Price and Revenue Forecast.....	153
Table 20 Esoteric - Volume Price and Revenue Forecast.....	154
Table 21 Clinical Chemistry - Volume Price and Revenue Forecast .....	155
Table 22 Microbiology - Volume Price and Revenue Forecast .....	155
Table 23 Hematology - Volume Price and Revenue Forecast .....	156
Table 24 Anatomic Pathology - Volume Price and Revenue Forecast .....	156
Table 25 Molecular Diagnostics - Volume Price and Revenue Forecast .....	157
Table 26 All Clinical Testing - Volume Price and Revenue Forecast.....	157
Table 27 Esoteric - Volume Price and Revenue Forecast.....	158
Table 28 Clinical Chemistry - Volume Price and Revenue Forecast .....	160
Table 29 Microbiology - Volume Price and Revenue Forecast .....	160
Table 30 Hematology - Volume Price and Revenue Forecast .....	161
Table 31 Anatomic Pathology - Volume Price and Revenue Forecast .....	161
Table 32 Molecular Diagnostics - Volume Price and Revenue Forecast .....	162
Table 33 All Clinical Testing - Volume Price and Revenue Forecast.....	162
Table 34 Esoteric - Volume Price and Revenue Forecast.....	163
Table 35 Clinical Chemistry - Volume Price and Revenue Forecast .....	164
Table 36 Microbiology - Volume Price and Revenue Forecast .....	164
Table 37 Hematology - Volume Price and Revenue Forecast .....	165
Table 38 Anatomic Pathology - Volume Price and Revenue Forecast .....	165



Table 39 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 166

Table 40 All Clinical Testing - Volume Price and Revenue Forecast..... 166

Table 41 Esoteric - Volume Price and Revenue Forecast..... 167

Table 42 Clinical Chemistry - Volume Price and Revenue Forecast ..... 168

Table 43 Microbiology - Volume Price and Revenue Forecast ..... 168

Table 44 Hematology - Volume Price and Revenue Forecast ..... 169

Table 45 Anatomic Pathology - Volume Price and Revenue Forecast ..... 169

Table 46 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 170

Table 47 All Clinical Testing - Volume Price and Revenue Forecast..... 170

Table 48 Esoteric - Volume Price and Revenue Forecast..... 171

Table 49 Clinical Chemistry - Volume Price and Revenue Forecast ..... 172

Table 50 Microbiology - Volume Price and Revenue Forecast ..... 172

Table 51 Hematology - Volume Price and Revenue Forecast ..... 173

Table 52 Anatomic Pathology - Volume Price and Revenue Forecast ..... 173

Table 53 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 174

Table 54 All Clinical Testing - Volume Price and Revenue Forecast..... 174

Table 55 Esoteric - Volume Price and Revenue Forecast..... 175

Table 56 Clinical Chemistry - Volume Price and Revenue Forecast ..... 176

Table 57 Microbiology - Volume Price and Revenue Forecast ..... 176

Table 58 Hematology - Volume Price and Revenue Forecast ..... 177

Table 59 Anatomic Pathology - Volume Price and Revenue Forecast ..... 177

Table 60 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 178

Table 61 All Clinical Testing - Volume Price and Revenue Forecast..... 178

Table 62 Esoteric - Volume Price and Revenue Forecast..... 179

Table 63 Clinical Chemistry - Volume Price and Revenue Forecast ..... 180

Table 64 Microbiology - Volume Price and Revenue Forecast ..... 180

Table 65 Hematology - Volume Price and Revenue Forecast ..... 181

Table 66 Anatomic Pathology - Volume Price and Revenue Forecast ..... 181

Table 67 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 182

Table 68 All Clinical Testing - Volume Price and Revenue Forecast..... 182

Table 69 Esoteric - Volume Price and Revenue Forecast..... 183

Table 70 Clinical Chemistry - Volume Price and Revenue Forecast ..... 184

Table 71 Microbiology - Volume Price and Revenue Forecast ..... 184

Table 72 Hematology - Volume Price and Revenue Forecast ..... 185

Table 73 Anatomic Pathology - Volume Price and Revenue Forecast ..... 185

Table 74 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 186

Table 75 All Clinical Testing - Volume Price and Revenue Forecast..... 186

Table 76 Esoteric - Volume Price and Revenue Forecast..... 187

Table 77 Clinical Chemistry - Volume Price and Revenue Forecast ..... 189

Table 78 Microbiology - Volume Price and Revenue Forecast ..... 189

Table 79 Hematology - Volume Price and Revenue Forecast ..... 190

Table 80 Anatomic Pathology - Volume Price and Revenue Forecast ..... 190

Table 81 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 191

Table 82 All Clinical Testing - Volume Price and Revenue Forecast..... 191

Table 83 Esoteric - Volume Price and Revenue Forecast..... 192

Table 84 Clinical Chemistry - Volume Price and Revenue Forecast ..... 193

Table 85 Microbiology - Volume Price and Revenue Forecast ..... 193

Table 86 Hematology - Volume Price and Revenue Forecast ..... 194

Table 87 Anatomic Pathology - Volume Price and Revenue Forecast ..... 194

Table 88 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 195

Table 89 All Clinical Testing - Volume Price and Revenue Forecast..... 195

Table 90 Esoteric - Volume Price and Revenue Forecast..... 196

Table 91 Clinical Chemistry - Volume Price and Revenue Forecast ..... 197

Table 92 Microbiology - Volume Price and Revenue Forecast ..... 197

Table 93 Hematology - Volume Price and Revenue Forecast ..... 198

Table 94 Anatomic Pathology - Volume Price and Revenue Forecast ..... 198

Table 95 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 199

Table 96 All Clinical Testing - Volume Price and Revenue Forecast..... 199

Table 97 Esoteric - Volume Price and Revenue Forecast..... 200

Table 98 Clinical Chemistry - Volume Price and Revenue Forecast ..... 201

Table 99 Microbiology - Volume Price and Revenue Forecast ..... 201

Table 100 Hematology - Volume Price and Revenue Forecast ..... 202

Table 101 Anatomic Pathology - Volume Price and Revenue Forecast ..... 202

Table 102 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 203

Table 103 All Clinical Testing - Volume Price and Revenue Forecast..... 203

Table 104 Esoteric - Volume Price and Revenue Forecast..... 204

Table 105 Clinical Chemistry - Volume Price and Revenue Forecast ..... 205

Table 106 Microbiology - Volume Price and Revenue Forecast ..... 205

Table 107 Hematology - Volume Price and Revenue Forecast ..... 206

Table 108 Anatomic Pathology - Volume Price and Revenue Forecast ..... 206

Table 109 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 207

Table 110 All Clinical Testing - Volume Price and Revenue Forecast..... 207

Table 111 Esoteric - Volume Price and Revenue Forecast..... 208

Table 112 Clinical Chemistry - Volume Price and Revenue Forecast ..... 209

Table 113 Microbiology - Volume Price and Revenue Forecast ..... 209

Table 114 Hematology - Volume Price and Revenue Forecast ..... 210

Table 115 Anatomic Pathology - Volume Price and Revenue Forecast ..... 210

Table 116 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 211

Table 117 All Clinical Testing - Volume Price and Revenue Forecast..... 211

Table 118 Esoteric - Volume Price and Revenue Forecast..... 212

Table 119 Clinical Chemistry - Volume Price and Revenue Forecast ..... 214

Table 120 Microbiology - Volume Price and Revenue Forecast ..... 214

Table 121 Hematology - Volume Price and Revenue Forecast ..... 215

Table 122 Anatomic Pathology - Volume Price and Revenue Forecast ..... 215

Table 123 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 216

Table 124 All Clinical Testing - Volume Price and Revenue Forecast..... 216

Table 125 Esoteric - Volume Price and Revenue Forecast..... 217

Table 126 Clinical Chemistry - Volume Price and Revenue Forecast ..... 218

Table 127 Microbiology - Volume Price and Revenue Forecast ..... 218

Table 128 Hematology - Volume Price and Revenue Forecast ..... 219

Table 129 Anatomic Pathology - Volume Price and Revenue Forecast ..... 219

Table 130 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 220

Table 131 All Clinical Testing - Volume Price and Revenue Forecast..... 220

Table 132 Esoteric - Volume Price and Revenue Forecast..... 221

Table 133 Clinical Chemistry - Volume Price and Revenue Forecast ..... 222

Table 134 Microbiology - Volume Price and Revenue Forecast ..... 222

Table 135 Hematology - Volume Price and Revenue Forecast ..... 223

Table 136 Anatomic Pathology - Volume Price and Revenue Forecast ..... 223

Table 137 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 224

Table 138 All Clinical Testing - Volume Price and Revenue Forecast..... 224

Table 139 Esoteric - Volume Price and Revenue Forecast..... 225

Table 140 Clinical Chemistry - Volume Price and Revenue Forecast ..... 226

Table 141 Microbiology - Volume Price and Revenue Forecast ..... 226

Table 142 Hematology - Volume Price and Revenue Forecast ..... 227

Table 143 Anatomic Pathology - Volume Price and Revenue Forecast ..... 227

Table 144 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 228

Table 145 All Clinical Testing - Volume Price and Revenue Forecast..... 228

Table 146 Esoteric - Volume Price and Revenue Forecast..... 229

Table 147 Clinical Chemistry - Volume Price and Revenue Forecast ..... 231

Table 148 Microbiology - Volume Price and Revenue Forecast ..... 231

Table 149 Hematology - Volume Price and Revenue Forecast ..... 232

Table 150 Anatomic Pathology - Volume Price and Revenue Forecast ..... 232

Table 151 Molecular Diagnostics - Volume Price and Revenue Forecast ..... 233

Table 152 All Clinical Testing - Volume Price and Revenue Forecast..... 233

Table 153 Esoteric - Volume Price and Revenue Forecast..... 234

Table 154 2019 Clinical Lab Fee Schedule ..... 236

Table of Figures

Figure 1 Clinical Lab Spending 2014 to 2024 ..... 33

## 1.1 The Growing Demand for Clinical Testing

### **The demand for clinical testing services continues to expand**

The modern clinical laboratory sits at the centre of the changing world of global healthcare. Not only must the clinical laboratory cope with the constant pressure to guarantee quality but it must now contend with financial pressures, ever more complex and competing technologies, new more complex testing regimes, external audits, accreditation and an increasing level of scrutiny from government and the public. A constantly evolving information technology environment, and the pervasive presence of the internet, has left many Laboratory Information Management Systems stranded. New low-cost Point of Care tests are leaving instrumentation and training investments stranded and promise to erode traditional services. But the demand for reliable clinical testing continues to expand as growth in the global economy permits greater levels of healthcare expenditures throughout the world.

### **Clinical testing is becoming a global business**

The modern clinical laboratory will become a global enterprise. Increasing sophistication in cross-border transfer and containment of tissue samples permits testing to occur in places far distant from the point of collection. Economies of scale can dramatically affect the cost of testing, though this too is shifting. Clinical testing is fast becoming a global business. This report is concerned with a global view of the global market for clinical testing services (see Market Definition following). It is intended to provide facts on the consumption of clinical testing services worldwide. The global size of the market is now over 12 billion tests per year. By 2023, the market will, conservatively, be over 19 billion tests per year.

### **The possibilities for developing new markets are unlimited**

Despite a shrinking world, the state of healthcare in different parts of the globe varies enormously, as this report clearly shows. The possibilities to develop new markets for clinical testing services, instruments, reagents, supplies, and diagnostic technology are, without hyperbole, unlimited. Most clinical testing today (if it is performed at all) is still performed in hospitals or doctor's offices. Increasingly the national and regional patchworks of regulatory controls will permit wider choice in clinical testing services, and competition, in every jurisdiction. These developments will occur faster in the developing economies but even

## 1.2 Defining the Opportunity

This report forecasts the market spending on *in vitro clinical testing services*. It presents baseline data and forecasts for the next five years. This report includes estimates of test volumes, prices and resulting revenue streams to provide a more accurate view of market developments not found in any other market research.

Clinical testing is a reliable indicator of health services consumption, and so the information can be used to project overall and relative global consumption of a wide range of health care supplies, products and services.<sup>2</sup> It is possible to provide factors for many related medical services, diagnostic and otherwise. The data presented is useful for estimating potential global and national consumption of new clinical or diagnostic procedures.

**The forecasts can be used to project consumption of a wide variety of health care products and services**

The report does not include drug screening, paternity testing, insurance testing, forensic testing or any tests not ordered by a medical practitioner during patient care<sup>3</sup>. The report does not include any Point of Care self-testing (consumer tests e.g. pregnancy, glucose strips, etc.) but it does include such testing where carried out in a hospital or by the laboratory.

**1.2.1 Volumes.** Testing volumes are reported as individual assays, not collections. The volumes reported are the number of individual tests performed as they would be ordered on a request form. For instance, a series of fasting blood sugars would count as a single test. A cholesterol

---

<sup>2</sup> Please email Howe Sound Research – [service@howesoundresearch.com](mailto:service@howesoundresearch.com) with your inquiry. Forecasts for specific tests or market segments can be ordered with this report and are normally provided without additional cost.

<sup>3</sup> Tests carried out on a widespread basis by public health authorities (e.g. ebola testing) are most often ad hoc and are not included.

## 2.3 Structure of Clinical Testing Industry

**2.3.1 The Hospital Lab – Share of the Pie** The first clinical laboratory serving a specific region is almost always associated with a hospital. The developed economies, the United States being the most developed, have moved the farthest away from this genesis point. Developed economies generally display large stand alone regional/national laboratories, not necessarily associated with a hospital, providing services to a network of physicians, a region or a nation. These facilities may be privately or publicly owned (see Market Participants above) depending on the national health program. Despite this development the majority of testing still remains in the hospital laboratory. By volume, in the United States in 2014 hospitals do about 55% of all clinical testing (excluding Anatomical Pathology). Hospitals in the U.S.A do about 46% (by volume) of all Anatomic Pathology testing.

**2.3.2 Key Role for Economies of Scale** Clinical testing (all test services for that matter) lend themselves dramatically to economies of scale. The more identical tests performed at a single time the lower the unit cost of testing, often by orders of magnitude. Theoretically all clinical testing procedures can be performed most efficiently out of a single lab<sup>8</sup>. Operating against these cost savings are the logistics and costs of sample collection and transport. The timeliness of testing results and sample integrity are important logistical factors. This alone ensures that most hospitals will continue to maintain on-premise laboratory testing capability. Note that Point of Care Testing (POCT) has the potential to disrupt, or make irrelevant, economies of scale as the

---

<sup>8</sup> This is not practically true of course. In fact some research shows that blood banking, beyond a certain size laboratory, shows a declining economy of scale. See "Economies of Scale in Blood Banking. A study based on data envelopment analysis." Periera, A., Vox Sanguinis, volume 90, issue 4, page 308-315, May 2006.



## ARUP Laboratories

[www.aruplab.com](http://www.aruplab.com)

500 Chipeta Way  
Salt Lake City, UT 84108

USA  
1 800-522-2787

### Description:

ARUP Laboratories is an American national reference laboratory and a nonprofit enterprise of the University of Utah, and its Department of Pathology. ARUP offers more than 3,000 tests and test combinations, ranging from routine screening tests to molecular and genetic assays. The diagnostic-testing and disease-management menu encompasses all areas of clinical medicine, including allergy and immunology, clinical chemistry, cytogenetics and molecular genetics, endocrinology, obstetrics, neonatology and pediatrics, hematology, infectious diseases, neurology, oncology, preventive medicine, and anatomic pathology.

ARUP Laboratories has nearly 3,000 employees and occupies facilities in Salt Lake City. The laboratories are housed in a single 300,000-square-foot (28,000 m<sup>2</sup>) facility, where more than 30,000–35,000 specimens of blood, fluid, and tissue samples are processed each day.

ARUP Laboratories' oncology test menu offers a wide variety of testing designed to answer important clinical questions in the areas of screening, risk prediction, diagnosis, prognosis, monitoring, pharmacogenomics, and therapeutic triage of malignancies. Categorized by disease indication, the menu includes tests that utilize a large selection of methodologies, including molecular techniques, FISH, flow cytometry, and immunohistochemistry, as well as a wide variety of specimen types, including tissue, cells, and peripheral fluids. In addition, a large menu of established tumor markers, including traditional markers such as CEA, CA-125, and CA 27.29, is also available for disease monitoring.

## 4.1 Recent Developments – Importance and How to Use This Section

### 4.1.1 Importance of These Developments

Many users, especially those in the financial community, have noted that this section of the report can be extremely valuable in helping to understand industry current events and the evolution of key market players. These items are not chosen at random. They have been selected by the author(s) as significant and worth reading about, i.e. important. Please keep this in mind in reviewing them.

### 4.1.2 How to Use This Section

These items are not necessarily in date order. This report is updated regularly and new items are incorporated and others removed. Please refer to the date of an item to understand its currency. Reading this entire section is recommended for those not familiar with the industry. Many of the trends and issues noted elsewhere are illustrated in these actual events.

## CLA Urges FDA to Halt Crackdown on PGx Testing

September 19, 2019

The American Clinical Laboratory Association (ACLA) is urging the FDA to halt its recent crackdown on laboratory developed tests (LDTs) and other pharmacogenomics (PGx) tests that reference specific drugs or drug classes unless approved by the agency.

In a letter to FDA Acting Commissioned Ned Sharpless, M.D., signed by ACLA President Julie Khani, the Association urged the agency to instead FDA encourage “responsible” LDT development by adopting recommendations such as those offered by professional groups, and formally recognizing existing peer-reviewed, evidence-based guidelines as a basis for establishing clinical validity of a PGx test

ACLA cited the Association for Molecular Pathology (AMP)'s position statement for pharmacogenomic testing, published September 4, that spells out “best practices” criteria for laboratories to follow. The three-page statement included criteria that are designed to ensure

## 6.1 France 2016 to 2024

### 6.1.1 Clinical Chemistry – Volumes, Prices, Revenues

V = Volumes in millions of tests. P = Price is 2019 US\$. R = Revenues in millions of dollars.

**TABLE 28 CLINICAL CHEMISTRY - VOLUME PRICE AND REVENUE FORECAST**

	2016	2017	2018	2019	2020	2021	2022	2023	2024	CAGR
V	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
P	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
R	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

### 6.1.2 Microbiology – Volumes, Prices, Revenues

V = Volumes in millions of tests. P = Price is 2019 US\$. R = Revenues in millions of dollars.

**TABLE 29 MICROBIOLOGY - VOLUME PRICE AND REVENUE FORECAST**

	2016	2017	2018	2019	2020	2021	2022	2023	2024	CAGR
V	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
P	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
R	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx