

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



Global Clinical In Vitro Diagnostic Medical Laboratory Services Market.

Strategy & Trends with Volume & Price Forecasts by Chemistry, Hematology, Microbiology, Pathology, Covid-19, and Molecular Dx by Country. Updated with Impact of COVID-19 Pandemic. Situation Analysis and Executive & Consultant Guides. 2021 to 2025.



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 and Impact Analysis of COVID Recession 14
- ii. Guide for Executives, Marketing, Sales and Business Development Staff 17
- iii. Guide for Management Consultants and Investment Advisors 18
- 1. Introduction and Market Definition 19
 - 1.1 The Growing Demand for Clinical Testing 20
 - 1.2 Defining the Opportunity 22
 - 1.2.1 Volumes..... 22
 - 1.2.2 Prices 23
 - 1.2.3 Revenue Market Size..... 23
 - 1.3 Methods and Sources 24
 - 1.3.1 Authors 24
 - 1.3.2 Sources..... 24
 - 1.4 U.S. Medical Market and laboratory Testing - Perspective 25
 - 1.4.1 U.S. Medicare Expenditures for Laboratory Testing 25
- 2. Overview of a Dynamic Market 27
 - 2.1 Market Players – Roles & Impacts..... 28
 - 2.1.1 Supplier/pharmaceutical 28
 - 2.1.2 Independent lab specialized/esoteric 29
 - 2.1.3 Independent lab national/regional..... 29
 - 2.1.4 Independent lab analytical 30
 - 2.1.5 Public National/regional lab 30
 - 2.1.6 Hospital lab 30
 - 2.1.7 Physician lab 31
 - 2.1.8 Audit body 31

2.2 Segmentation – Different Approaches.....	33
2.2.1 Traditional Market Segmentation.....	33
2.2.2 Laboratory Focus and Segmentation.....	34
2.3 Structure of Clinical Testing Industry.....	36
2.3.1 The Hospital Lab – Share of the Pie.....	36
2.3.2 Key Role for Economies of Scale.....	36
2.3.3 Physician Office Lab's are Still Here.....	38
2.3.4 Physician's and POCT – Reviving Patient Service in China.....	39
2.4 National and Regional Diversity.....	40
3. Trends Driving a Changing Market.....	42
3.1 Growth Is Pushed from Many Sides.....	43
3.1.1 Understanding the Impact of Aging Population.....	44
3.1.2 COVID Related Testing Growth.....	44
3.1.3 Point of Care Testing can increase demand.....	44
3.1.4 Alternative Medicine Creates Testing Opportunity.....	45
3.1.5 Esoteric Testing Moving Mainstream.....	46
3.1.6 Genetic Based Testing Creates New Department and New Discipline.....	46
3.2 Factors at Work to Shrink The Market.....	47
3.2.1 COVID 19 Recession.....	47
3.2.2 Economic or population contraction.....	48
3.2.3 Testing usage analysis curtailing growth.....	48
3.2.4 Wellness has a downside.....	48
3.2.5 Test Displacement Impacts Important.....	48
3.2.6 Point of Care Testing.....	49
3.3 Automation.....	50
3.3.1 Stranded LIMS Investment.....	50
3.3.2 Software as a Service.....	50

3.3.3 Physician Office and Access Systems..... 51

3.4 Environment and Evolution 52

3.5 Diagnostic Technology Development 53

 3.5.1 Next Generation Sequencing Fuels a Revolution..... 54

 3.5.2 Impact of NGS on pricing 55

 3.5.3 POCT/Self Testing Disruptive Force 55

 3.5.4 Pharmacogenomics Blurs Diagnosis and Treatment 56

 3.5.5 CGES Testing, A Brave New World 57

 3.5.6 Molecular Diagnostics Technologies at The Forefront of Growth 58

 3.5.7 Biochips/Giant magneto resistance based assay 59

4. Laboratory, Molecular Diagnostics and Genomic Testing Recent Developments60

 4.1 Recent Developments – Importance and How to Use This Section 61

 4.1.1 Importance of These Developments 61

 4.1.2 How to Use This Section..... 61

 Thermo Fisher Gets CE Mark for High-Throughput COVID-19 Assay 61

 FDA Issues Alert - False Negatives due to SARS-CoV-2 Mutations 62

 Will Labs Use Expanded Molecular Testing Capacities Post-COVID-19? 63

 Cooperative Aims to Expand Clinical, Commercial NGS Access..... 68

 Emerging COVID-19 Sequencing Assays - An Alternative to Existing Diagnostics? 71

 CDC Ranks Two More Microbes as 'Urgent Threat' 76

 ACLA Requests \$5 billion to keep private labs going..... 77

 Applied Biology to Launch New Laboratory for Hair and Skin Disorders 79

 Quest Diagnostics Acquires Outreach Operations 80

 Quest Diagnostics Buys Assets of Boston Clinical Laboratory Services 80

 CLA Urges FDA to Halt Crackdown on PGx Testing..... 81

 Quest Diagnostics Subsidiary Buys True Health Dx Assets 83

 BioReference Laboratories selected by IPA Association 83

Predictive Laboratories Announces Research Collaboration	84
NEOMED-LABS / Pacific Biomarkers Acquires PAIRimmune Français	85
LabCorp and Envigo Complete Transactions.....	86
PathGroup Acquires Pathologists Bio-Medical Laboratories	87
Predictive Technology Acquires Taueret Laboratories	88
Quest Diagnostics Acquires Laboratory Services Business of Boyce & Bynum Pathology Laboratories	89
Gestalt Diagnostics Expands Market Reach with Peak Medical Acquisition	90
Amazon exploring consumer health diagnostics	91
Quest Diagnostics Acquires Laboratory Services Operation in Central Michigan	92
NeoGenomics to acquire Genoptix, Inc.....	93
Quest Diagnostics to Acquire U.S. Laboratory Services Business of Oxford Immunotec	94
Charles River Labs to acquire contract research firm for \$800M	95
GROUPE BIO7 to be Sold to CERBA HEALTHCARE.....	95
GE Healthcare and Roche Partner to Develop Digital Diagnostics Platform	96
5. Profiles of Key Companies	98
Acibadem Labmed Laboratory	99
ACM Medical Laboratory.....	101
Adicon Clinical Laboratories.....	102
American Bio-Clinical Laboratories, Int'l.....	103
American Pathology Partners	104
ARUP Laboratories.....	105
Ascend Clinical	107
Aurora Diagnostics.....	108
Bio-Reference Laboratories.....	109
Bioscientia Institut für Medizinische Diagnostik GmbH	110
BP Healthcare Group.....	111

Clinical Reference Laboratory	112
Clongen Laboratories	113
CompuNet Clinical Laboratories	114
Diagnósticos da América	115
DIAN Diagnostics Co., Ltd.....	116
Enzo Life Sciences, Inc.	118
Eurofins Scientific	119
Exagen Diagnostics.....	122
Genomic Health.....	123
Genzyme Corporation.....	124
Gribbles Pathology.....	126
Guangzhou Kingmed Diagnostics Group Co., Ltd.....	127
Integrated Regional Laboratories.....	128
KDL Group.....	129
Laboratory Corporation of America	130
Lifelabs	132
Mayo Clinic Laboratories.....	133
Mid America Clinical Laboratories	134
Myriad Genetics/Myriad RBM	135
NeoGenomics	136
Pathology, Inc.	137
Psychemedics Corporation.....	138
Quest Diagnostics	139
RDL Reference Laboratory	140
Sonic Healthcare.....	141
Spectra Laboratories	142
Synlab Group.....	143

Unilabs	144
6. The Global Market for Clinical Laboratory Testing	145
6.1 Global Market Overview by Country	146
6.1.1 Table – Global Market by Country	146
6.1.2 Chart - Global Market by Country	147
6.2 Global Market by Assay Type - Overview	148
6.2.1 Table – Global Market by Assay Type	148
6.2.2 Chart – Global Market by Assay Type – Base/Final Year Comparison	149
6.2.3 Chart – Global Market by Assay Type – Base Year	150
6.2.4 Chart – Global Market by Assay Type – End Year	151
6.2.5 Chart – Global Market by Assay Type – Share by Year	152
6.2.6 Chart – Global Market by Assay Type – Segments Growth	153
7. Global Clinical Laboratory Diagnostic Markets – By Assay Type	154
7.1 Chemistry	155
7.1.1 Table Chemistry – by Country	155
7.1.2 Chart - Chemistry Growth	156
7.2 Microbiology	157
7.2.1 Table Microbiology – by Country	157
7.2.2 Chart - Microbiology Growth	158
7.3 Hematology	159
7.3.1 Table Hematology – by Country	159
7.3.2 Chart - Hematology Growth	160
7.4 Anatomic Pathology	161
7.4.1 Table Anatomic Pathology – by Country	161
7.4.2 Chart - Anatomic Pathology Growth	162
7.5 Covid-19	163
7.5.1 Table Covid-19 – by Country	163

7.5.2 Chart – Covid-19Growth..... 164

7.6 Molecular Diagnostics..... 165

7.6.1 Table Molecular Diagnostics – by Country..... 165

7.6.2 Chart - Molecular Diagnostics Growth 166

8. Global Clinical Laboratory Diagnostic Markets – Price and Volume Charts167

8.1 Chemistry Price and Volume 168

8.1.1 Table Chemistry Price – by Country 168

8.1.2 Table Chemistry Volume – by Country 169

8.2 Microbiology Price and Volume 170

8.2.1 Table Microbiology Price – by Country..... 170

8.2.2 Table Microbiology Volume – by Country..... 171

8.3 Hematology Price and Volume..... 172

8.3.1 Table Hematology Price – by Country..... 172

8.3.2 Table Hematology Volume – by Country..... 173

8.4 Anatomic Pathology Price and Volume 174

8.4.1 Table Anatomic Pathology Price – by Country 174

8.4.2 Table Anatomic Pathology Volume – by Country..... 175

8.5 Covid-19 Price and Volume 176

8.5.1 Table Covid-19 Price – by Country..... 176

8.5.2 Table Covid-19 Volume – by Country..... 177

8.6 Molecular Diagnostics Price and Volume 178

8.6.1 Table Molecular Diagnostics Price – by Country 178

8.6.2 Table Molecular Diagnostics Volume – by Country 179

9. The Future of the Clinical Laboratory181

Appendices 182

I. United States Medicare System: 2021 Clinical Laboratory Fees Schedule 182

Table of Tables

Table 1 Lab Spending 2014 to 2024	26
Table 2 Market Players by Type	28
Table 3 Clinical Laboratory Departments and Segments	33
Table 4 Laboratory Management Focus – Different Approaches	34
Table 5 Key Segmentation Variables Going Forward.....	35
Table 6 Factors Affecting Local Clinical Testing Demand	40
Table 7 Seven Factors Driving Growth	43
Table 8 Alternative Medicine Creates New Clinical Testing Markets.....	45
Table 9 Six Factors Limiting Growth	47
Table 10 Key Diagnostic Laboratory Technology Trends	53
Table 11 Next Generation Sequencing Technologies – Speed and Cost	54
Table 12 Key Point of Care Testing Uses.....	56
Table 13 Clinical Application Areas for Molecular Diagnostics	58
Table 14 - Global Market by Region	146
Table 15 Global Market by Assay Type.....	148
Table 16 Chemistry by Country	155
Table 17 Microbiology by Country	157
Table 18 Hematology by Country	159
Table 19 Anatomic Pathology by Country	161
Table 20 Covid-19 by Country	163
Table 21 Molecular Diagnostics by Country.....	165
Table 22 Chemistry Price by Country	168
Table 23 Chemistry Volume by Country	169

Table 24 Microbiology Price by Country 170

Table 25 Microbiology Volume by Country 171

Table 26 Hematology Price by Country 172

Table 27 Hematology Volume by Country 173

Table 28 Anatomic Pathology Price by Country 174

Table 29 Anatomic Pathology Volume by Country 175

Table 30 Covid-19 Price by Country 176

Table 31 Covid-19 Volume by Country 177

Table 32 Molecular Diagnostics Price by Country 178

Table 33 Molecular Diagnostics Volume by Country 179

Table 34 2021 Clinical Lab Fee Schedule 182

Table of Figures

Figure 1 Clinical Lab Spending 2014 to 2024 25

Figure 2 Global Market Density Chart..... 147

Figure 3 Global Market by Assay Type - Base vs. Final..... 149

Figure 4 Global Market by Assay Type Base Year 150

Figure 5 Global Market by Assay Type End Year 151

Figure 6 Assay Type Share by Year..... 152

Figure 7 Assay Type Segments Growth 153

Figure 8 Chemistry Growth..... 156

Figure 9 Microbiology Growth 158

Figure 10 Hematology Growth 160

Figure 11 Anatomic Pathology Growth 162

Figure 12 Covid-19 Growth 164

Figure 13 Molecular Diagnostics Growth 166