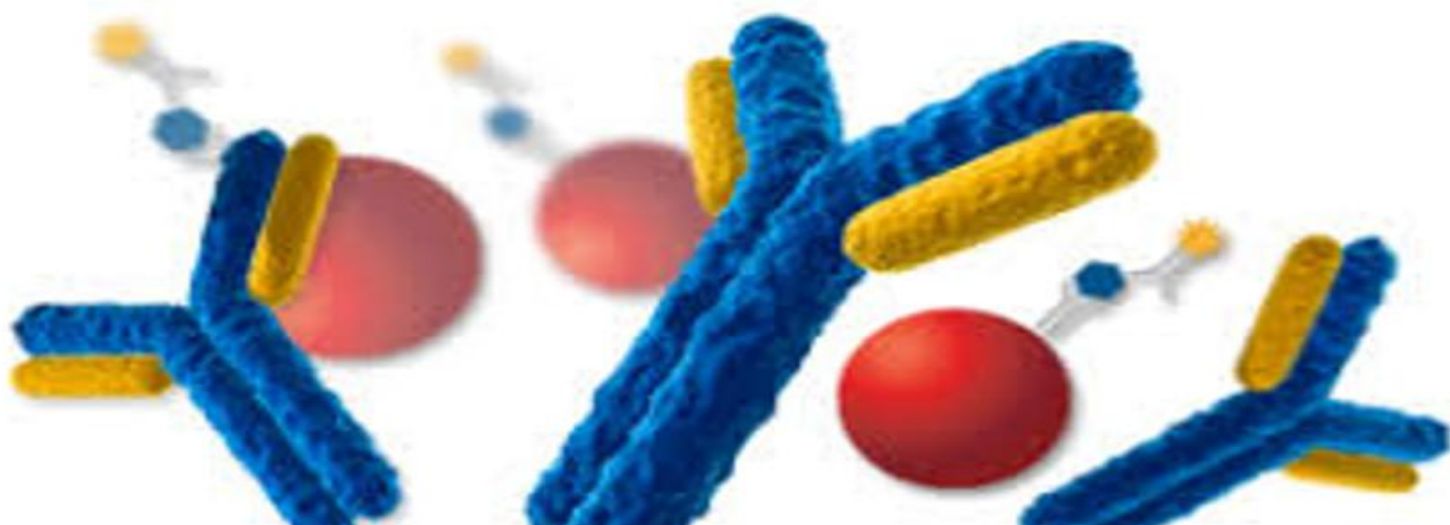


COVID-19 IMPACT

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



IMMUNOASSAY MARKETS

Strategies and Trends. Forecasts by Instrument Type and by Application and by Country. With Multiplex and Point of Care Market Analysis, Executive Guides and including Customized Forecasting and Analysis.

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 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. Immunoassay Market - Strategic Situation Analysis & COVID Impact	14
ii. Guide for Executives, Marketing, Sales and Business Development Staff	16
iii. Guide for Management Consultants and Investment Advisors	17
1. Introduction and Market Definition	18
1.1 Immunoassay Markets Definition In This Report.....	19
1.1.1 Enzyme Based.....	19
1.1.2 Immunofluorescence	20
1.1.3 Chemiluminescence	20
1.1.4 DNA/NAT	20
1.1.5 RIA & Other	20
1.1.6 Reagents/Kits, Analyzers, Software & Services.....	21
1.1.7 Infectious Disease	21
1.1.8 Auto Immune	21
1.1.9 Endocrinology.....	21
1.1.10 Oncology	21
1.1.11 Cardiology	21
1.1.12 Other Specialty.....	22
1.2 Market Definition	23
1.2.1 Market Sizes.....	23
1.2.2 Currency	23
1.2.3 Years	23
1.3 Methodology	24
1.3.1 Authors	24
1.3.2 Sources	24

1.4 U.S. Medical Market and Clinical Laboratory Testing - Perspective.....	26
2. Industry Overview	29
2.1 Industry Participants	30
2.1.1 IVD Supplier.....	30
2.1.2 Independent lab specialized/esoteric	31
2.1.3 Independent lab national/regional.....	31
2.1.4 Independent lab analytical	32
2.1.5 Public National/regional lab	32
2.1.6 Hospital lab	32
2.1.7 Physician lab	33
2.1.8 Audit body	33
2.2 The Clinical Laboratory Market Segments.....	35
2.2.1 Traditional Market Segmentation.....	35
2.2.2 Laboratory Focus and Segmentation.....	37
2.2.3 Hospital Testing Share	39
2.2.4 Economies of Scale	39
2.2.4.1 Hospital vs. Central Lab	40
2.2.5 Physician Office Lab's	41
2.2.6 Physician's and POCT	41
2.3 Immunoassay –Markets and Discussion	43
2.3.1 Instruments – Genetics changes the picture	43
2.3.1.1 RIA – A Technology Shows its Age	44
2.3.1.2 Immunoassay vs. PCR vs. Sequencing – A See Saw Battle	44
2.3.1.3 The Smart Shrinking Instrument – Serious Implications	45
2.3.1.4 Research Funding and Capital Expense – Instrument Pooling.....	45
2.3.1.4 Multiplex vs. POC – A Tradeoff Analysis	47
2.3.2 Reagents and Kits – Genetics changes the picture	47

- 2.3.1.1 Bigger Test Menus a Boon for Kit Market 48
- 2.3.3 Physician Office Labs – A New Frontier 48
- 2.3.4 Rapid and POCT to Threaten Instrument Markets 49
- 2.3.5 OTC and DTC – Huge Market Potential 49
- 2.3.6 Economies of Scale. Going Away? 49
- 2.3.7 Lower Barriers to Entry for Instruments/Analyzers 50
- 2.3.8 Miniturization and Technology Drive Acquisition 50
- 3. Market Trends 52
- 3.1 Factors Driving Growth 53
 - 3.1.1 Diagnostic Factors 53
 - 3.1.2 Changing Technologies Spur Early Instrument Retirement. 54
 - 3.1.3 Consumer Channels Open Wider. 54
 - 3.1.4 Immunity Technology Comes of Age 54
- 3.2 Factors Limiting Growth 55
 - 3.2.1 Increased Competition Lowers Price 55
 - 3.2.2 Threat from PCR Based Instruments. 56
 - 3.2.3 Lower Barriers to Entry. 56
 - 3.2.4 Wellness has a downside 56
- 3.3 Immunoassay Instrumentation 57
 - 3.3.1 Instrumentation Tenacity. 57
 - 3.3.2 Declining Cost of Instruments Changes Industry Structure. 57
 - 3.3.3 LISTING of CURRENT INSTRUMENT SPECIFICATIONS. 58
 - 3.3.4 Immunoassay – CRISPR Diagnostics. 69
- 4. Immunoassay Recent Developments 70
- 4.1 Recent Developments – Importance and How to Use This Section 71
 - 4.1.1 Importance of These Developments 71
 - 4.1.2 How to Use This Section 71

COVID-19 Portfolio to Accelerate At-Home Infectious Disease Testing	71
Roche Diagnostics Expanding Testing Portfolio in 2021	76
PerkinElmer Long-Term Outlook.....	79
Quidel Updates Outlook for C19 Testing	81
Dx Companies Look at Multiplex Tests for SARS-CoV-2, Influenza	86
Becton Dickinson and NAT Diagnostics Acquisition	93
New test diagnoses Lyme disease within 15 minutes	96
Multiplexed Immunoassay System Differentiates Malaria Species.....	98
ERBA Mannheim Unveils Next-Generation Nexus unit	99
Uman Diagnostics And Bio-Techne Announce Agreement For Neurofilament Light Assay ..	99
Software reduces variability in ELISA biomarker tests	100
Arrayit Corporation Allergy Testing Network Doubles	101
Expedeon Signs License Deal With Cell Guidance Systems for Biotin Tech	102
Efficacy Investigated for Electrochemiluminescence Immunoassay	102
5. Profiles of Key Companies	105
Abbott Diagnostics.....	106
Abcam	108
Arlington Scientific	109
Arrayit Corporation	111
Awareness Technology	112
Beckman Coulter Diagnostics	113
Becton, Dickinson and Company.....	114
Biocartis	116
bioMérieux Diagnostics	117
Bioneer Corporation.....	120
Bio-Rad Laboratories, Inc.....	122
BioTek Instruments.....	124

Boditech Med, Inc 125

Boster Biological Technology 126

Diamedix (Erba Diagnostics) 127

Diasorin S.p.A. 129

Dynex Technologies 130

Enzo Life Sciences, Inc. 131

Eurofins Scientific 132

FUJIFILM Wako Diagnostics 134

Fujirebio 135

Gold Standard Diagnostics 136

Grifols..... 137

Hycor Biomedical 138

Immunodiagnostic Systems (IDS) 139

Immunodiagnostik AG 140

Inova Diagnostics 141

JR Biomedical 142

Luminex Corp..... 143

Maxim Biomedical..... 144

Meso Scale Discovery 145

Millipore Sigma..... 146

Mindray 147

Molecular Devices..... 148

MP Biomedical..... 149

MyCartis 150

Operon 151

Ortho Clinical Diagnostics 152

Perkin Elmer 153

Qiagen Gmbh	154
Quidel.....	156
R&D Systems.....	157
Randox Toxicology	158
Roche Molecular Diagnostics	159
Serametrix	161
Siemens Healthineers	162
Sysmex.....	165
Tecan.....	167
Thermo Fisher Scientific Inc.	168
TOSOH Bioscience	171
6. The Global Market	172
6.1 Global Market by Country	173
6.1.1 Global Market by Country Table	173
6.1.2 Global Market by Country Chart	174
6.2 Global Market by Application.....	175
6.2.1 Global Market by Application Table	175
6.2.2 Global Market by Application Segment Growth Chart	176
6.2.3 Global Market by Application Segment Annual Chart	177
6.2.4 Global Market by Application Segment Base vs. Final	178
6.2.5 Global Market by Application Base Year.....	179
6.2.6 Global Market by Application Final Year	180
6.3 Global Market by Technology.....	181
6.3.1 Global Market by Technology Table	181
6.3.2 Global Market by Technology Segment Growth Chart.....	182
6.3.3 Global Market by Technology Segment Annual Chart	183
6.3.4 Global Market by Technology Segment Base vs. Final	184

6.3.5 Global Market by Technology Base Year	185
6.3.6 Global Market by Application Final Year	186
7. Global Market by Application.....	187
7.1 Endocrinology Applications.....	188
7.1.1 Endocrinology Applications by Country Table	188
7.1.2 Endocrinology Applications Growth Chart	189
7.2 Immune Applications	190
7.2.1 Immune Applications by Country Table.....	190
7.2.2 Immune Applications Growth Chart.....	191
7.3 Oncology Applications	192
7.3.1 Oncology Applications by Country Table.....	192
7.3.2 Oncology Applications Growth Chart	193
7.4 Infectious Disease Applications.....	194
7.4.1 Infectious Disease Applications by Country Table	194
7.4.2 Infectious Disease Applications Growth Chart	195
7.4 Cardiology Applications	196
7.4.1 Cardiology Applications by Country Table.....	196
7.4.2 Cardiology Applications Growth Chart.....	197
7.5 Other Applications	198
7.5.1 Other Applications by Country Table	198
7.5.2 Other Applications Growth Chart.....	199
8. Immunoassay by Technology.....	200
8.1 Enzyme	201
8.1.1 Enzyme by Country Table	201
8.1.2 Enzyme Growth Chart.....	202
8.2 Fluorescence	203
8.2.1 Fluorescence by Country Table	203

8.2.2 Fluorescence Growth Chart 204

8.3 Chemiluminescence 205

8.3.1 Chemiluminescence by Country Table 205

8.3.2 Chemiluminescence Growth Chart..... 206

8.4 Nucleic Acid 207

8.4.1 Nucleic Acid by Country Table 207

8.4.2 Nucleic Acid Growth Chart 208

8.4 Rapid/POC..... 209

8.4.1 Rapid/POC by Country Table 209

8.4.2 Rapid/POC Growth Chart 210

8.5 Other Technology..... 211

8.5.1 Other Technology by Country Table 211

8.5.2 Other Technology Growth Chart 212

9. Vision of the Future of Immunoassay213

Appendices214

I. United States Medicare System: 2021 laboratory Fees Schedule..... 214

Table of Tables

TABLE 1 MEDICARE CLINICAL LAB EXPENDITURES ACTUAL & FORECAST 2014 TO 2024 (\$BILLION) 28

Table 2 Market Players by Type 30

Table 3 Clinical Laboratory Departments and Segments 35

Table 4 Laboratory Management Focus – Different Approaches 37

Table 5 Key Segmentation Variables Going Forward..... 38

Table 6 The Different Markets for Immunoassay..... 43

Table 7 The Factors Driving Growth..... 53

Table 8 Factors Limiting Growth 55

Table 9 - Listing of Current Instrument Specifications 58

Table 10 The Global Immunoassay Market by Country 173

Table 11 Global Market by Application..... 175

Table 12 Global Market by Technology 181

Table 13 Endocrinology Immunoassay by Country 188

Table 14 Immune Immunoassay by Country 190

Table 15 Oncology Immunoassay by Country 192

Table 16 Infectious Disease Immunoassay by Country..... 194

Table 17 Cardiology Immunoassay by Country 196

Table 18 Other Immunoassay by Country 198

Table 19 Enzyme Immunoassay by Country 201

Table 20 Fluorescence Immunoassay by Country 203

Table 21 Chemiluminescence Immunoassay by Country..... 205

Table 22 Nucleic Acid Immunoassay by Country 207

Table 23 Rapid/POC Immunoassay by Country 209

Table 24 Other Technology Immunoassay by Country 211

Table 25 2021 Clinical Lab Fee Schedule 214

Table of Figures

Figure 1 Medicare Clinical Lab Expenditures 2014 to 2024 (\$Million)	27
Figure 2 Immunoassay – Country Sharea	174
Figure 3 Chart of Growth by Application	176
Figure 4 Chart of Segment by Year.....	177
Figure 5 Chart of Base vs. Final	178
Figure 6 Chart of Base Year by Application	179
Figure 7 Chart of Final Year by Application.....	180
Figure 8 Chart of Growth by Technology	182
Figure 9 Chart of Technology Segment by Year.....	183
Figure 10 Chart of Technology Base vs. Final	184
Figure 11 Chart of Base Year by Technology	185
Figure 12 Chart of Final Year by Technology	186
Figure 13 Chart – Endocrine Segment vs Total Market Growth	189
Figure 14 Chart - Immune Growth vs. Total	191
Figure 15 Chart - Oncology vs Total.....	193
Figure 16 Chart - Infectious Disease Immunoassay vs Total	195
Figure 17 Chart - Cardiology Immunoassay vs total.....	197
Figure 18 Chart - Other Immunoassay vs Total.....	199
Figure 19 Chart – Enzyme Segment vs Total Market Growth	202
Figure 20 Chart Fluorescence Growth vs. Total.....	204
Figure 21 Chart - Chemiluminescence vs Total.....	206
Figure 22 Chart - Nucleic Acid Immunoassay vs Total.....	208
Figure 23 Chart - Rapid/POC Immunoassay vs total	210
Figure 24 Chart - Other Technology Immunoassay vs Total.....	212