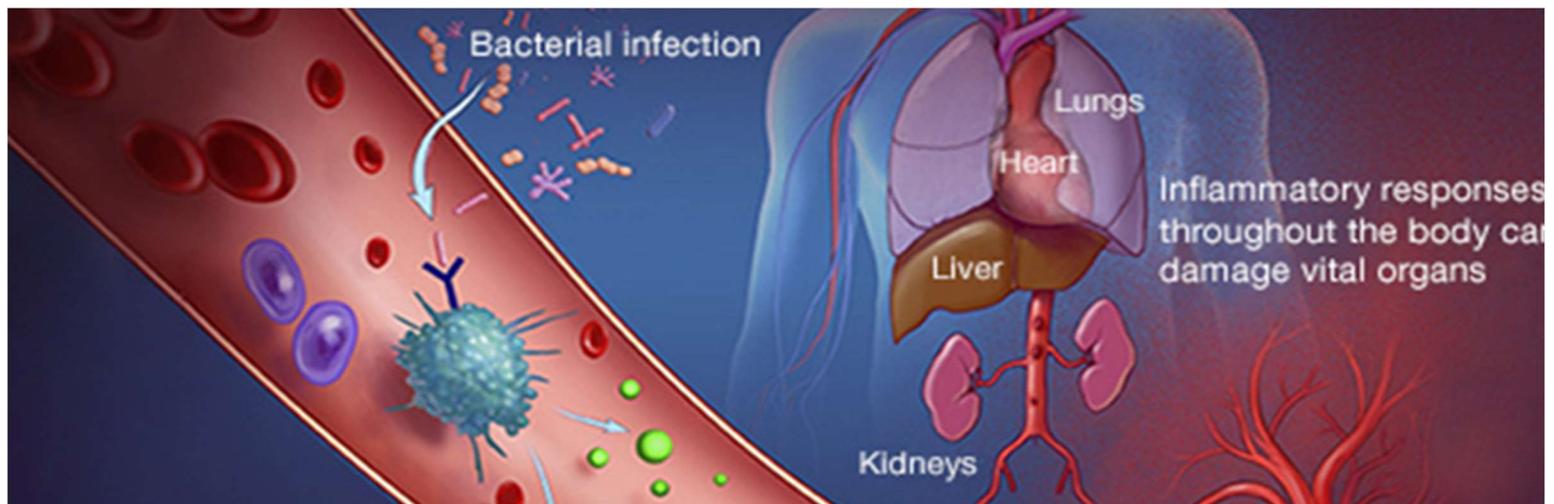


# RESEARCH REPORT



## SEPSIS DIAGNOSTIC MARKETS

Global Market Forecasts by Assay, by Cause, by Product, by Lab, and by Place. With Executive and Consultant Guides.

2023 - 2027



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 .....	20
1.1	Situation Analysis .....	21
1.2	Guide for Executives and Marketing Staff .....	23
1.3	Guide for Investment Analysts and Management Consultants .....	24
2	Introduction and Market Definition .....	25
2.1	An Overview of Sepsis Diagnostics .....	26
2.1.1	Sepsis the medical emergency .....	27
2.1.2	Sepsis Diagnosis and Comorbidity .....	28
2.2	Market Definition .....	29
2.2.1	Market Size .....	29
2.2.2	Currency .....	29
2.2.3	Years .....	29
2.2.4	Microbiology .....	29
2.2.5	PCR .....	30
2.2.6	Immunoassay .....	30
2.2.7	Other Infectious Disease .....	30
2.2.8	Syndromic PoC .....	30
2.2.9	Biomarkers Molecular Diagnostics .....	30
2.2.10	Biomarkers Other .....	31
2.2.11	Limitations .....	31
2.3	Methodology .....	32
2.3.1	Methodology .....	32

2.3.2	Sources .....	32
2.3.3	Authors.....	32
2.4	Perspective: Healthcare and the IVD Industry .....	34
2.4.1	Global Healthcare Spending .....	34
2.4.2	Spending on Diagnostics .....	36
2.4.3	Important Role of Insurance for Diagnostics.....	37
3	Sepsis – Current Science .....	38
3.1	What is Sepsis? .....	39
3.1.1	Organ Damage .....	40
3.1.2	Neonatal sepsis .....	40
3.1.3	Prognosis .....	41
3.2	Diagnosis .....	42
3.2.1	Infection Identification .....	42
3.2.2	Biomarkers .....	42
3.2.3	Differential diagnosis .....	46
3.2.4	The Cytokine Storm – Diagnostic Needs .....	46
3.3	Causes of Sepsis .....	47
3.3.1	Sepsis Progression .....	48
3.3.2	The Cytokine Storm – COVID and Other Situations.....	49
3.4	Prevalence.....	49
3.4.1	Impact of COVID on Sepsis Prevalence.....	51
4	Industry Overview .....	52
4.1	Players in a Dynamic Market .....	53
4.1.1	Academic Research Lab.....	54
4.1.2	Diagnostic Test Developer .....	54

4.1.3	Instrumentation Supplier .....	55
4.1.4	Chemical/Reagent Supplier.....	55
4.1.5	Pathology Supplier.....	55
4.1.6	Independent Clinical Laboratory .....	56
4.1.7	Public National/regional Laboratory .....	56
4.1.8	Hospital Laboratory .....	57
4.1.9	Physicians Office Lab (POLs) .....	57
4.1.10	Audit Body .....	58
4.1.11	Certification Body .....	58
5	Market Trends.....	60
5.1	Factors Driving Growth .....	61
5.1.1	Increasing Prevalence .....	61
5.1.2	Antimicrobial Resistance.....	62
5.1.3	Increasing Diagnosis.....	63
5.1.4	Multiplex Diagnostics Impacts.....	63
5.1.5	The Aging World .....	63
5.1.6	Developing World Impact .....	66
5.2	Factors Limiting Growth .....	67
5.2.1	The Cost Curve Shrinks the Market.....	67
5.2.2	The Diagnostics Dilemma.....	68
5.2.3	Adoption Lag and Cost Control .....	68
5.3	Instrumentation, Automation and Diagnostic Trends.....	69
5.3.1	Traditional Automation and Centralization .....	69
5.3.2	The New Automation, Decentralization and Point Of Care .....	69
5.3.3	Instruments Key to Market Share .....	71

5.3.4	Bioinformatics Plays a Role .....	71
5.3.5	PCR Takes Command .....	72
5.3.6	Next Generation Sequencing Fuels a Revolution .....	73
5.3.7	NGS Impact on Pricing.....	74
5.3.8	Whole Genome Sequencing, A Brave New World .....	74
5.3.9	Companion Diagnostics Blurs Diagnosis and Treatment.....	74
5.3.10	Shifting Role of Diagnostics .....	76
5.3.11	The Next Five Years .....	78
6	Sepsis Diagnostics - Recent Developments .....	79
6.1	Recent Developments – Importance and How to Use This Section .....	80
6.1.1	Importance of These Developments.....	80
6.1.2	How to Use This Section.....	80
6.2	SeptiCyte® RAPID Validated .....	80
6.3	Cepheid Group B Strep Test Addresses Neonatal Sepsis .....	82
6.4	DeepUll Inks Financing Deal.....	82
6.5	Sequencing-Based Approach Shows Promise for Sepsis Dx .....	83
6.6	VolitionRx Studies Cancer, Sepsis Tests.....	84
6.7	Cytovale Prepping Sepsis Test for FDA Submission .....	85
6.8	Great North R & I to Develop POC Sepsis Dx .....	88
6.9	Pathogenomix Developing Sepsis Testing Platform .....	91
6.10	Gradientech Launches Study of AST System.....	96
6.11	Sepsis Test Developers Accelerate Plans.....	99
6.12	Immunexpress Receives Clearance for Sepsis Assay .....	104
6.13	Prenosis, Roche Partner on Sepsis Detection .....	105
6.14	Presymptom Health Developing Test for Sepsis.....	106

6.15	Ortho Clinical Diagnostics Interleukin-6 Reagent Pack.....	110
6.16	Cytovale to Enter Sepsis Testing Market .....	110
6.17	Baebies Awarded \$11.6M to Develop Diagnostic Platform to ID Sepsis .....	115
6.18	Personalized Medicine in Sepsis.....	116
6.19	Point-of-care Device can Diagnose Sepsis in 30 Minutes .....	118
6.20	SpeeDx Developing Respiratory Virus Host-Response Test.....	119
6.21	Scanogen Developing Blood Infection Test with Sepsis Application.....	124
6.22	Inflammatix Developing New Sepsis Dx .....	127
6.23	Immunexpress, Biocartis to Roll Out Sepsis Test .....	132
6.24	Sepset Biosciences Using COVID-19 Patient Samples to Validate Sepsis Test	135
6.25	Immunexpress to Develop Sepsis Test .....	138
6.26	DNAe Developing POC Sequencing for Sepsis.....	139
6.27	NGS technique offers quick, accurate diagnosis of Sepsis.....	144
6.28	Portable device diagnoses sepsis faster .....	146
7	Profiles of Key Companies .....	148
7.1	Abbott Laboratories.....	149
7.2	Abionic .....	151
7.3	Accel Diagnostics .....	152
7.4	Accelerate Diagnostics .....	154
7.5	ADT Biotech .....	155
7.6	Anatolia Geneworks .....	156
7.7	Axis-Shield Diagnostics Ltd.....	157
7.8	Baebies.....	158
7.9	Beckman Coulter Diagnostics .....	160
7.10	Becton, Dickinson and Company .....	161

7.11	Biocartis .....	163
7.12	BioFire Diagnostics (bioMérieux) .....	164
7.13	bioMérieux Diagnostics.....	166
7.14	Bio-Rad Laboratories, Inc. ....	169
7.15	Bruker .....	172
7.16	Cube Dx .....	174
7.17	Curetis N.V. / Curetis GmbH.....	175
7.18	Cytovale.....	177
7.19	Deepull Diagnostics .....	178
7.20	DNAe .....	179
7.21	EKF Diagnostics Holdings .....	180
7.22	GeneFluidics .....	182
7.23	GenMark Dx (Roche).....	183
7.24	Grifols .....	185
7.25	Immunexpress.....	186
7.26	Inflammatix .....	187
7.27	LightDeck Diagnostics .....	188
7.28	Linear Diagnostics .....	189
7.29	Luminex Corp (DiaSorin) .....	190
7.30	Mobidiag (Hologic).....	192
7.31	NanoDx .....	193
7.32	Nanomix.....	194
7.33	Qiagen .....	195
7.34	Response Biomedical .....	198
7.35	Roche Molecular Diagnostics .....	199

7.36	SeLux Diagnostics .....	201
7.37	Septec .....	202
7.38	Siemens Healthineers .....	203
7.39	Sphingotec.....	205
7.40	T2 Biosystems.....	206
7.41	Thermo Fisher Scientific Inc.....	208
7.42	Vela Diagnostics.....	211
8	Sepsis Global Diagnostic Markets Overview.....	212
8.1	Sepsis Diagnostics – Global Market Overview by Country .....	213
8.1.1	Table – Global Market by Country.....	213
8.1.2	Chart - Global Market by Country.....	214
8.2	Global Sepsis Diagnostics Markets Overview by Assay .....	215
8.2.1	Table – Global Market by Assay.....	215
8.2.2	Chart – Global Market by Assay – Segments Growth.....	216
8.2.3	Chart – Global Market by Assay – Share by Year .....	217
8.2.4	Chart – Global Market by Assay .....	218
8.2.5	Chart – Global Market by Assay – Base Year .....	219
8.2.6	Chart – Global Market by Assay – Final Year.....	220
8.3	Global Sepsis Diagnostics Markets Overview by Cause .....	221
8.3.1	Table – Global Market by Cause .....	221
8.3.2	Chart – Global Market by Cause – Segments Growth .....	222
8.3.3	Chart – Global Market by Cause – Share by Year .....	223
8.3.4	Chart – Global Market by Cause.....	224
8.3.5	Chart – Global Market by Cause – Base Year.....	225
8.3.6	Chart – Global Market by Cause – Final Year .....	226

8.4	Global Sepsis Diagnostics Markets Overview by Product.....	227
8.4.1	Table – Global Market by Product.....	227
8.4.2	Chart – Global Market by Product – Segments Growth.....	228
8.4.3	Chart – Global Market by Product – Share by Year.....	229
8.4.4	Chart – Global Market by Product .....	230
8.4.5	Chart – Global Market by Product – Base Year .....	231
8.4.6	Chart – Global Market by Product – Final Year.....	232
8.5	Global Sepsis Diagnostics Markets Overview by Lab .....	233
8.5.1	Table – Global Market by Lab.....	233
8.5.2	Chart – Global Market by Lab – Segments Growth.....	234
8.5.3	Chart – Global Market by Lab – Share by Year.....	235
8.5.4	Chart – Global Market by Lab.....	236
8.5.5	Chart – Global Market by Lab – Base Year.....	237
8.5.6	Chart – Global Market by Lab – Final Year.....	238
8.6	Global Sepsis Diagnostics Markets Overview by Place.....	239
8.6.1	Table – Global Market by Place.....	239
8.6.2	Chart – Global Market by Place – Segments Growth.....	240
8.6.3	Chart – Global Market by Place – Share by Year .....	241
8.6.4	Chart – Global Market by Place .....	242
8.6.5	Chart – Global Market by Place – Base Year .....	243
8.6.6	Chart – Global Market by Place – Final Year.....	244
9	Sepsis Diagnostic Market – by Assay .....	245
9.1	Sepsis Diagnostic - Microbiology .....	246
9.1.1	Table Sepsis Diagnostic Microbiology – by Country.....	246
9.1.2	Chart - Sepsis Diagnostic Microbiology Growth .....	247

9.2	Sepsis Diagnostic - PCR.....	248
9.2.1	Table Sepsis Diagnostic PCR – by Country .....	248
9.2.2	Chart - Sepsis Diagnostic PCR Growth .....	249
9.3	Sepsis Diagnostic – Immunoassay .....	250
9.3.1	Table Sepsis Diagnostic Immunoassay – by Country .....	250
9.3.2	Chart - Sepsis Diagnostic – Immunoassay Growth .....	251
9.4	Sepsis Diagnostic – Infectious Disease Other.....	252
9.4.1	Table Sepsis Diagnostic Infectious Disease Other – by Country .....	252
9.4.2	Chart - Sepsis Diagnostic – Infectious Disease Other Growth .....	253
9.5	Sepsis Diagnostic – Biomarker MDx .....	254
9.5.1	Table Sepsis Diagnostic Biomarker MDx – by Country .....	254
9.5.2	Chart - Sepsis Diagnostic – Biomarker MDx Growth .....	255
9.6	Sepsis Diagnostic – Biomarker Other .....	256
9.6.1	Table Sepsis Diagnostic Biomarker Other – by Country .....	256
9.6.2	Chart - Sepsis Diagnostic – Biomarker Other Growth.....	257
10	Global Sepsis Diagnostics Markets – By Cause .....	258
10.1	Sepsis Diagnostic - GastroIntestinal .....	259
10.1.1	Table Sepsis Diagnostic GastroIntestinal – by Country.....	259
10.1.2	Chart - Sepsis Diagnostic GastroIntestinal Growth .....	260
10.2	Sepsis Diagnostic – Respiratory COVID-19 .....	261
10.2.1	Table Sepsis Diagnostic Respiratory COVID-19– by Country .....	261
10.2.2	Chart - Sepsis Diagnostic Respiratory COVID-19 .....	262
10.3	Sepsis Diagnostic – Respiratory Other .....	263
10.3.1	Table Sepsis Diagnostic Respiratory Other – by Country.....	263
10.3.2	Chart - Sepsis Diagnostic – Respiratory Other Growth .....	264

10.4	Sepsis Diagnostic – Neonatal.....	265
10.4.1	Table Sepsis Diagnostic Neonatal – by Country .....	265
10.4.2	Chart - Sepsis Diagnostic – Neonatal Growth.....	266
10.5	Sepsis Diagnostic – Other Cause .....	267
10.5.1	Table Sepsis Diagnostic Other Cause – by Country .....	267
10.5.2	Chart - Sepsis Diagnostic – Other Cause Growth .....	268
11	Global Sepsis Diagnostics Markets – By Product.....	269
11.1	Sepsis Diagnostic - Instrumentation .....	270
11.1.1	Table Sepsis Diagnostic Instrumentation – by Country.....	270
11.1.2	Chart - Sepsis Diagnostic Instrumentation Growth .....	271
11.2	Sepsis Diagnostic – Consumables.....	272
11.2.1	Table Sepsis Diagnostic Consumables – by Country .....	272
11.2.2	Chart - Sepsis Diagnostic Consumables .....	273
11.3	Sepsis Diagnostic – Software & Service .....	274
11.3.1	Table Sepsis Diagnostic Software & Service – by Country .....	274
11.3.2	Chart - Sepsis Diagnostic – Software & Service Growth.....	275
12	Global Sepsis Diagnostics Markets – By Lab.....	276
12.1	Sepsis Diagnostic – In Lab.....	277
12.1.1	Table Sepsis Diagnostic In Lab – by Country .....	277
12.1.2	Chart - Sepsis Diagnostic In Lab Growth.....	278
12.2	Sepsis Diagnostic – Point of Care.....	279
12.2.1	Table Sepsis Diagnostic Point of Care – by Country .....	279
12.2.2	Chart - Sepsis Diagnostic Point of Care .....	280
13	Global Sepsis Diagnostics Markets – By Place .....	281
13.1	Sepsis Diagnostic - Hospital .....	282

13.1.1	Table Sepsis Diagnostic Hospital – by Country .....	282
13.1.2	Chart - Sepsis Diagnostic Hospital Growth .....	283
13.2	Sepsis Diagnostic – Other Place .....	284
13.2.1	Table Sepsis Diagnostic Other Place – by Country .....	284
13.2.2	Chart - Sepsis Diagnostic Other Place .....	285
14	Appendices.....	286
14.1	United States Medicare System: Clinical Laboratory Fees Schedule .....	287
14.2	The Most Used IVD Assays.....	386
14.3	The Highest Grossing Assays .....	390

## Table of Tables

Table 1 sepsis biomarkers - Established and potential.....	43
Table 2 Market Players by Type.....	54
Table 3 Five Factors Driving Growth .....	61
Table 4 Three Factors Limiting Growth.....	67
Table 5 Seven Key Diagnostic Laboratory Technology Trends .....	69
Table 6 - Global Sepsis Diagnostics Market by Country/Region.....	213
Table 7 Global Market by Assay .....	215
Table 8 Global Market by Cause .....	221
Table 9 Global Market by Product .....	227
Table 10 Global Market by Lab.....	233
Table 11 Global Market by Place .....	239
Table 12 Sepsis Diagnostic Microbiology by Country .....	246
Table 13 Sepsis Diagnostic PCR by Country.....	248
Table 14 Sepsis Diagnostic Immunoassay by Country .....	250
Table 15 Sepsis Diagnostic Infectious Disease Other by Country .....	252
Table 16 Sepsis Diagnostic Biomarker MDx by Country .....	254
Table 17 Sepsis Diagnostic Biomarker Other by Country.....	256
Table 18 Sepsis Diagnostic GastroIntestinal by Country .....	259
Table 19 Sepsis Diagnostic Respiratory COVID-19 by Country.....	261
Table 20 Sepsis Diagnostic Respiratory Other by Country .....	263
Table 21 Sepsis Diagnostic Neonatal by Country.....	265
Table 22 Sepsis Diagnostic Other Cause by Country.....	267

Table 23 Sepsis Diagnostic Instrumentation by Country .....	270
Table 24 Sepsis Diagnostic Consumables by Country .....	272
Table 25 Sepsis Diagnostic Software & Service by Country .....	274
Table 26 Sepsis Diagnostic In Lab by Country .....	277
Table 27 Sepsis Diagnostic Point of Care by Country .....	279
Table 28 Sepsis Diagnostic Hospital by Country .....	282
Table 29 Sepsis Diagnostic Other Place by Country .....	284
Table 30 Clinical Lab Fee Schedule .....	287
Table 31 The Most Common Assays .....	386
Table 32 Largest Revenue Assays .....	391

## Table of Figures

Figure 1 Sepsis Survival graph .....	27
Figure 2 Percentage of Sepsis Patients with Comorbidity .....	28
Figure 3 Global Healthcare Spending.....	35
Figure 4 The Lab Test Pie .....	36
Figure 5 Sepsis Clinical Progression .....	48
Figure 6 The Road to Diagnostics.....	53
Figure 7 Deaths From Drug Resistant Infections 2050 .....	62
Figure 8 The Changing Age of The World's Population.....	64
Figure 9 Health Care Consumption by Age .....	65
Figure 10 Cancer Incidence - Age at Diagnosis .....	65
Figure 11 Growth in Health Care Spending Developing World .....	66
Figure 12 Centralized vs. Decentralized Laboratory Service .....	70
Figure 13 A Highly Multiplexed Syndromic Testing Unit .....	70
Figure 14 The Real Cost to Sequence the Human Genome.....	73
Figure 15 The Codevelopment Process.....	75
Figure 16 Comparing MDx Diagnostic and Traditional Testing .....	76
Figure 17 Growth rates of Sepsis Diagnostics.....	78
Figure 18 Global Market Share Chart .....	214
Figure 19 Sepsis Diagnostics Market Segment Shift Base vs Final year .....	218
Figure 20 Sepsis Diagnostics Market by Assay Base Year .....	219
Figure 21 Sepsis Diagnostics Market by Assay Final Year.....	220
Figure 22 Sepsis Diagnostics Market Segment Shift Base vs Final year .....	224
Figure 23 Sepsis Diagnostics Market by Cause Base Year.....	225

Figure 24 Sepsis Diagnostics Market by Cause Final Year .....	226
Figure 25 Sepsis Diagnostics Market Segment Shift Base vs Final year .....	230
Figure 26 Sepsis Diagnostics Market by Product Base Year .....	231
Figure 27 Sepsis Diagnostics Market by Product Final Year .....	232
Figure 28 Sepsis Diagnostics Market Segment Shift Base vs Final year .....	236
Figure 29 Sepsis Diagnostics Market by Lab Base Year .....	237
Figure 30 Sepsis Diagnostics Market by Lab Final Year .....	238
Figure 31 Sepsis Diagnostics Market Segment Shift Base vs Final year .....	242
Figure 32 Sepsis Diagnostics Market by Place Base Year .....	243
Figure 33 Sepsis Diagnostics Market by Place Final Year .....	244
Figure 34 Sepsis Diagnostic Microbiology Growth .....	247
Figure 35 SEPSIS Diagnostics Syndromic POC Panel Growth .....	249
Figure 36 Sepsis Diagnostic Immunoassay Growth .....	251
Figure 37 Sepsis Diagnostic Infectious Disease Other Growth .....	253
Figure 38 Sepsis Diagnostic Biomarker MDx Growth .....	255
Figure 39 Sepsis Diagnostic Biomarker Other Growth .....	257
Figure 40 Sepsis Diagnostic GastroIntestinal Growth .....	260
Figure 41 SEPSIS Diagnostics Respiratory COVID-19 .....	262
Figure 42 Sepsis Diagnostic Respiratory Other Growth .....	264
Figure 43 Sepsis Diagnostic Neonatal Growth .....	266
Figure 44 Sepsis Diagnostic Other Cause Growth .....	268
Figure 45 Sepsis Diagnostic Instrumentation Growth .....	271
Figure 46 SEPSIS Diagnostics Consumables .....	273
Figure 47 Sepsis Diagnostic Software & Service Growth .....	275
Figure 48 Sepsis Diagnostic In Lab Growth .....	278

Figure 49 SEPSIS Diagnostics Point of Care.....280

Figure 50 Sepsis Diagnostic GastroIntestinal Growth .....283

Figure 51 SEPSIS Diagnostics Other Place.....285