

### 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



## LIQUID BIOPSY MARKETS BY CANCER TYPE AND BY USAGE TYPE WITH **IMPACT OF COVID-19 PANDEMIC.** INCLUDING EXECUTIVE AND CONSULTANT GUIDES AND CUSTOMIZED FORECASTING AND ANALYSIS 2021-2025



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. Liquid Biopsy Market - Strategic Situation Analysis & Impact of COVID-19.....20
- ii. Guide for Executives, Marketing, Sales and Business Development Staff .....23
- iii. Guide for Management Consultants and Investment Advisors .....25
- 1. Introduction and Market Definition .....26
  - 1.1 What is Liquid Biopsy? ..... 27
  - 1.2 The Sequencing Revolution ..... 28
  - 1.3 Market Definition ..... 30
    - 1.3.1 Revenue Market Size ..... 30
  - 1.4 Methodology ..... 31
    - 1.4.1 Authors ..... 31
    - 1.4.2 Sources ..... 32
  - 1.5 A Spending Perspective on Liquid Biopsy ..... 33
    - 1.5.1 An Historical Look at Clinical Testing ..... 34
- 2. Market Overview .....36
  - 2.1 Players in a Dynamic Market ..... 37
    - 2.1.1 Academic Research Lab ..... 38
    - 2.1.2 Diagnostic Test Developer..... 38
    - 2.1.3 Genomic Instrumentation Supplier ..... 38
      - 2.1.3.1 Cell Separation and Viewing Instrumentation Supplier ..... 39

- 2.1.4 Pharmaceutical/Reagent Supplier ..... 39
- 2.1.5 Independent Testing Lab..... 39
- 2.1.6 Public National/regional lab ..... 40
- 2.1.7 Hospital lab ..... 40
- 2.1.8 Physician Lab ..... 40
- 2.1.9 Audit Body ..... 41
- 2.1.10 Certification Body..... 41
- 2.2 Using Biopsies ..... 43
  - 2.2.1 Cancer ..... 43
  - 2.2.2 Precancerous conditions ..... 44
  - 2.2.3 Inflammatory conditions ..... 44
- 2.3 Biopsy Sites ..... 45
- 2.4 The Situation Today – Biopsy Analysis..... 47
- 2.5 Evidence of Cancer - Liquid Biopsy Technology ..... 48
  - 2.5.1 The Big Picture on Liquid Biopsy Technology ..... 48
  - 2.5.2 The Role of CTCs ..... 50
    - 2.5.2.1 Types of CTCs..... 51
    - 2.5.2.2 CellSearch Detection- Ultimate Sensitivity ..... 52
    - 2.5.2.3 Epic Sciences Detection- Imaging Takes the Lead..... 53
    - 2.5.2.4 Maintrac Detection – The Microscope..... 53
    - 2.5.2.5 Other Methods ..... 55
  - 2.5.3 ctDNA – Going Mainstream? ..... 56
  - 2.5.4 Exosomes and Micro Vesicles – New Kid on the Block..... 57
  - 2.5.5 The Multiple Play..... 60

- 2.6 Cancer Treatment Protocol Under Siege ..... 62
  - 2.6.1 Issues to Liquid Biopsy Adoption – Double Diagnostics ..... 62
  - 2.6.2 The Cancer Screening Market Opportunity ..... 63
    - 2.6.2.1 GRAIL – What Is It? ..... 64
  - 2.6.3 Cancer Management vs. Diagnosis ..... 65
    - 2.6.3.1 The Role of Risk Assessment ..... 65
    - 2.6.3.2 Managing Therapy ..... 66
    - 2.6.3.3 Monitoring Disease – What Is It? ..... 66
  - 2.6.4 Phases of Adoption – Looking into The Future ..... 67
  - 2.6.5 The Promise of Liquid Biopsy ..... 68
- 2.7 Structure of Industry Plays a Part ..... 70
  - 2.7.1 Hospital Testing Share ..... 70
  - 2.7.2 Economies of Scale ..... 70
    - 2.7.2.1 Hospital vs. Central Lab ..... 71
  - 2.7.3 Physician Office Lab's ..... 72
  - 2.7.4 Physician's and POCT ..... 72
- 3. Market Trends ..... 74
  - 3.1 Factors Driving Growth ..... 75
    - 3.1.1 Non Invasive Game Changer ..... 75
    - 3.1.2 Lower Cost ..... 76
    - 3.1.3 Greater Accuracy ..... 76
    - 3.1.4 Wide Range of Potential Uses ..... 76
    - 3.1.5 Aging Population ..... 76
  - 3.2 Factors Limiting Growth ..... 78

- 3.2.1 Lower prices..... 78
- 3.2.2 Lack of Standards..... 79
- 3.2.3 Protocol Resistance..... 79
- 3.2.4 Initial Adoption Cost..... 79
- 3.2.5 COVID-19 ..... 79
- 3.3 Instrumentation and Automation..... 81
  - 3.3.1 Instruments Key to Market Share ..... 81
  - 3.3.2 Bioinformatics Plays a Role ..... 81
- 3.4 Diagnostic Technology Development..... 82
  - 3.4.1 Next Generation Sequencing Fuels a Revolution..... 83
  - 3.4.2 Impact of NGS on pricing..... 84
  - 3.4.3 Pharmacogenomics Blurs Diagnosis and Treatment..... 84
  - 3.4.4 CGES Testing, A Brave New World ..... 85
  - 3.4.5 Biochips/Giant magneto resistance based assay..... 86
- 4. Liquid Biopsy Recent Developments.....87
  - 4.1 Recent Developments – Importance and How to Use This Section..... 88
    - 4.1.1 Importance of These Developments ..... 88
    - 4.1.2 How to Use This Section..... 88
  - Liquid Biopsy NGS Panels - Diverse Test Claims ..... 88
  - CMS Colon Cancer Screening Memo Bodes Well for Assays ..... 94
  - Natera Liquid Biopsy Test Coverage to Expand ..... 96
  - Freenome Closes Financing to Support Early Cancer Detection Trial ..... 97
  - C\$2.6M Liquid Biopsy Initiative ..... 98
  - NeoGenomics, Inivata Partner for Lung Cancer Liquid Biopsy ..... 100

Liquid Biopsy Shows Promise as Screen for Cancers ..... 100

Inivata launches RaDaR™ for the detection of residual disease and recurrence ..... 101

Liquid Biopsy Assay Detects 50+ Types of Cancer..... 102

Liquid Biopsy Study Confirms Concordance with Tissue Biopsy ..... 104

Guardant Health Liquid Biopsy Expands Medicare Coverage ..... 106

Aethlon Medical Lands Grant for Exosome Isolation Device ..... 108

Biolidics to Develop Liquid Biopsy Breast Cancer Test..... 108

Liquid Biopsy Equal to Tissue to Indicate Immunotherapy Response ..... 109

Exact Sciences buys Genomic Health..... 111

Multi-Gene Liquid Biopsy Breast Cancer Panel..... 113

Bio-Techne receives FDA breakthrough device for prostate cancer liquid biopsy..... 113

Thrive to Develop Earlier Detection of Multiple Cancer Types ..... 115

Guardant Health Liquid Biopsy Test to be Covered by EviCore..... 117

Liquid biopsy combines Illumina's 'ultradeep' sequencing with Grail's machine learning. 118

Biocept Partnership Offering for Liquid Biopsy Adds Several Key Services ..... 120

Natera Commercializes Tumor Whole Exome Sequencing from Plasma ..... 120

Sienna Buys Liquid Biopsy & Exosome Isolation Technology ..... 122

Inivata Completes £39.8M Series B Funding Round..... 123

Bio-Rad Clinical ddPCR Test, Diagnostic System Get FDA Clearance..... 124

CellMax, Medigen Biotech Partner in Colorectal Cancer Clinical Trials ..... 125

Biodesix Acquires Integrated Diagnostics ..... 126

Predicine, Kintor Pharmaceuticals Partner on Clinical Trials, CDx ..... 127

Bio-Techne to Acquire Exosome Dx for Up to \$575M ..... 127

GRAIL Announces Data on Detection of Early-Stage Lung Cancers ..... 129



Precision for Medicine Acquires ApoCell ..... 131

NeoGenomics to Acquire Genoptix for Cash, Stocks ..... 131

PGDx Liquid Biopsy Assay to be Used in Cancer Drug Study ..... 133

Liquid Biopsy IDs More NSCLC Mutations in Study of Guardant Test..... 134

Inivata Gets Draft Medicare Coverage Determination for Lung Cancer Test..... 136

5. Profiles of Key Players ..... 138

Abbott Diagnostics..... 139

AccuraGen Inc..... 141

Acuamark Diagnostics..... 142

Admera Health, LLC..... 143

Agena Bioscience, Inc..... 145

Agilent..... 147

Amoy Diagnostics Co., Ltd. .... 149

Anchor Dx ..... 150

ANGLE plc ..... 151

ApoCell, Inc. .... 153

ArcherDx, Inc. .... 154

Asuragen..... 155

AVIVA Biosciences ..... 157

Baylor Miraca Genetics Laboratories ..... 158

Beckman Coulter, Inc. .... 159

Becton, Dickinson and Company..... 161

BGI Genomics Co. Ltd ..... 163

Bioarray Genetics..... 165

Biocartis .....	166
Biocept, Inc.....	167
Biodesix Inc. ....	168
BioFluidica .....	169
bioMérieux Diagnostics.....	170
Bioneer Corporation.....	172
Bio-Rad Laboratories, Inc.....	174
Bio-Techne .....	176
Bioview .....	178
Bolidics.....	180
Boreal Genomics.....	181
Caris Molecular Diagnostics .....	182
CellMax Life.....	183
Cepheid (now Danaher) .....	184
Chronix Biomedical .....	186
Circulogene .....	187
Clinical Genomics .....	188
Cynvenio.....	189
Cytolumina Technologies Corp. ....	190
CytoTrack.....	191
Datar Cancer Genetics Limited.....	192
Diagenode Diagnostics .....	193
Diagnologix LLC.....	194
Enzo Life Sciences, Inc. ....	195

Epic Sciences.....	197
Epigenomics AG.....	198
Eurofins Scientific .....	199
Exosome Diagnostics.....	202
Exosome Sciences .....	204
Fluidigm Corp .....	205
Fluxion Biosciences .....	207
Foundation Medicine.....	208
Freenome .....	209
GeneFirst Ltd. ....	210
Genetron Health (Beijing) Co., Ltd.....	211
Genomic Health .....	212
GILUPI Nanomedizin .....	214
Grail, Inc. ....	215
Guardant Health .....	217
HansaBiomed .....	218
HeiScreen .....	219
Helomics .....	221
Horizon Discovery .....	223
iCellate .....	225
Illumina .....	226
Incell Dx.....	228
Inivata.....	229
Integrated Diagnostics.....	230

Janssen Diagnostics .....	231
MDNA Life SCIENCES, Inc.....	232
MDx Health .....	233
Menarini Silicon Biosystems .....	235
Millipore Sigma.....	236
Miltenyi Biotec.....	237
miR Scientific .....	238
Molecular MD .....	239
Myriad Genetics/Myriad RBM .....	240
NantHealth, Inc. ....	242
Natera .....	244
NeoGenomics .....	246
New Oncology .....	248
Novogene Bioinformatics Technology Co., Ltd. ....	249
Oncocyte.....	251
OncodNA.....	252
Oxford Nanopore Technologies.....	253
Perkin Elmer .....	255
Personal Genome Diagnostics .....	257
PrecisionMed .....	258
Promega .....	259
Qiagen Gmbh .....	261
Quidel.....	263
Rarecells SAS.....	265

RareCyte .....	267
Resolution Biosciences, Inc .....	268
Roche Molecular Diagnostics .....	269
Screecell .....	271
Siemens Healthineers .....	272
simfo GmbH .....	274
Singlera Genomics Inc. ....	275
SRI International .....	276
Sysmex Inostics.....	278
Tempus Labs, Inc. ....	279
Thermo Fisher Scientific Inc. ....	280
Thrive Earlier Detection .....	282
Trovagene.....	283
Volition.....	284
6. The Global Market for Liquid Biopsy Diagnostics .....	285
6.1 Global Market Overview by Country.....	286
6.1.1 Table – Global Market by Country.....	286
6.1.2 Chart - Global Market by Country .....	287
6.2 Global Market by Cancer - Overview .....	288
6.2.1 Table – Global Market by Cancer .....	288
6.2.2 Chart – Global Market by Cancer – Base/Final Year Comparison .....	289
6.2.3 Chart – Global Market by Cancer – Base Year .....	290
6.2.4 Chart – Global Market by Cancer – End Year.....	291
6.2.5 Chart – Global Market by Cancer – Share by Year .....	292

6.2.6 Chart – Global Market by Cancer – Segments Growth..... 293

6.3 Global Market by Usage - Overview ..... 294

6.3.1 Table – Global Market by Usage..... 294

6.3.2 Chart – Global Market by Usage – Base/Final Year Comparison ..... 295

6.3.3 Chart – Global Market by Usage – Base Year..... 296

6.3.4 Chart – Global Market by Usage – End Year ..... 297

6.3.5 Chart – Global Market by Usage – Share by Year..... 298

6.3.6 Chart – Global Market by Usage – Segments Growth ..... 299

7. Global Liquid Biopsy Diagnostic Markets – By Cancer .....300

7.1 Breast ..... 301

7.1.1 Table Breast – by Country ..... 301

7.1.2 Chart - Breast Growth ..... 302

7.2 Colorectal ..... 303

7.2.1 Table Colorectal – by Country ..... 303

7.2.2 Chart - Colorectal Growth..... 304

7.3 Cervical ..... 305

7.3.1 Table Cervical – by Country ..... 305

7.3.2 Chart - Cervical Growth ..... 306

7.4 Lung ..... 307

7.4.1 Table Lung – by Country ..... 307

7.4.2 Chart - Lung Growth ..... 308

7.5 Prostate ..... 309

7.5.1 Table Prostate – by Country ..... 309

7.5.2 Chart – Prostate Growth ..... 310

- 7.6 Other..... 311
  - 7.6.1 Table Other – by Country ..... 311
  - 7.6.2 Chart - Other Growth..... 312
- 8. Global Liquid Biopsy Diagnostic Markets – by Usage .....313
  - 8.1 Screening ..... 314
    - 8.1.1 Table Screening – by Country ..... 314
    - 8.1.2 Chart - Screening Growth..... 315
  - 8.2 Diagnostic ..... 316
    - 8.2.1 Table Diagnostic – by Country ..... 316
    - 8.2.2 Chart - Diagnostic Growth..... 317
  - 8.3 Therapy..... 318
    - 8.3.1 Table Therapy – by Country..... 318
    - 8.3.2 Chart - Therapy Growth ..... 319
  - 8.4 Monitor ..... 320
    - 8.4.1 Table Monitor – by Country ..... 320
    - 8.4.2 Chart - Monitor Growth..... 321
- Appendices .....322
  - I. United States Medicare System: 2020 Clinical Laboratory Fees Schedule ..... 322
  - II. COVID-19 Approved Assays ..... 370

Table of Tables

Table 1 Medicare Clinical Lab Expenditures Actual & Forecast 2014 to 2024 (\$Billion) ..... 35

Table 2 Market Players by Type ..... 37

Table 3 Biopsy Sites ..... 45

Table 4 Advantages of Liquid Biopsy in Screening Market ..... 64

Table 5 Outlook - Phases of Liquid Biopsy Adoption by Year..... 67

Table 6 Five Factors Driving Growth ..... 75

Table 7 Factors Limiting Growth ..... 78

Table 8 Key Diagnostic Laboratory Technology Trends ..... 82

Table 9 Next Generation Sequencing Technologies – Speed and Cost ..... 83

Table 10 - Global Market by Region ..... 286

Table 11 Global Market by Cancer ..... 288

Table 12 Global Market by Usage..... 294

Table 13 Breast by Country ..... 301

Table 14 Colorectal by Country ..... 303

Table 15 Cervical by Country ..... 305

Table 16 Lung by Country ..... 307

Table 17 Prostate by Country ..... 309

Table 18 Other by Country..... 311

Table 19 Screening by Country ..... 314

Table 20 Diagnostic by Country ..... 316

Table 21 Therapy by Country..... 318



Table 22 Monitor by Country ..... 320

Table 23 2020 Clinical Lab Fee Schedule ..... 322

Table 24 COVID -19 Approved Assays ..... 370

Table of Figures

Figure 1 Medicare Clinical Lab Expenditures 2014 to 2024 (\$Million) ..... 34

Figure 2 Comparison of Liquid Biopsy Classes ..... 49

Figure 3 Characteristics of Different Vesicle Types ..... 60

Figure 4 Percentage of World Population Over 65 ..... 77

Figure 5 Global Market Density Chart ..... 287

Figure 6 Global Market by Cancer - Base vs. Final ..... 289

Figure 7 Global Market by Cancer Base Year ..... 290

Figure 8 Global Market by Cancer End Year ..... 291

Figure 9 Cancer Share by Year ..... 292

Figure 10 Cancer Segments Growth ..... 293

Figure 11 Global Market by Usage - Base vs. Final ..... 295

Figure 12 Global Market by Usage Base Year ..... 296

Figure 13 Global Market by Usage End Year ..... 297

Figure 14 Usage Share by Year ..... 298

Figure 15 Usage Segments Growth ..... 299

Figure 16 Breast Growth ..... 302

Figure 17 Colorectal Diagnostics Growth ..... 304

Figure 18 Cervical Growth ..... 306

Figure 19 Lung Growth ..... 308

Figure 20 Prostate Growth ..... 310

Figure 21 Other Growth ..... 312

Figure 22 Screening Growth ..... 315

Figure 23 Diagnostic Growth ..... 317

Figure 24 Therapy Growth..... 319

Figure 25 Monitor Growth..... 321