



Adams Business Associates.

Tel: 44-(0)1494-465244

Email: aba@a-b-a.co.uk

DIAGNOSTICS BUSINESS ANALYSIS SERIES:

PERSONALISED MEDICINE & POINT-of-CARE TESTS, POCT ABA 310

**By ADAMS BUSINESS ASSOCIATES
March 2017.**



March 2017

ABA 310



Personalised Medicine & Point-of-Care Tests, POCT

March 2017

CONTENTS LIST

1. Introduction & Purpose for Business Analysis of Point-of-Care Diagnostics	1
2. POCT Technologies	13
2.1. Technology Overview	13
2.2. Office Laboratory Tests – Classical Chemistries	14
2.3. Lateral Flow Tests	15
2.4. Microarray Tests	17
2.5. Biosensor Tests	19
2.6. Molecular Diagnostics, MDx	21
2.7. Platform Developments	25
2.8. Point-of-Care Medical Devices	31
2.9. Technology Development	33
2.10. Comparative Technology Development Status	37
3. Manufacturing Considerations	39
3.1. Commercial Issues for Manufacture	39
3.2. Lateral Flow Manufacture for POCT	41
3.3. Microarray Manufacture for POCT	44
3.4. Microspheres & Beads Manufacture for POCT	47
3.5. Microfluidics for POCT Use	49
3.6. Manufacturing Guidelines for POCT	51
4. Regulatory & Reimbursement Impact	53
4.1. Regulatory & Reimbursement Dynamics	53
4.2. Regulatory Systems & POCT	57
4.3. Reimbursement for POCT	66



5. Diagnostics Market Segments	72
6. Applications & Market Quantification	78
7. Non-Invasive Testing & Impact of Non-Clinical POCT Applications	97
7.1. Non-Invasive Testing Dynamics	97
7.2. Non-Invasive Testing Value to the User & Patient	101
7.3. Non-Invasive Testing Technologies	103
7.4. Non-Invasive Testing Business Areas & Implementation Issues	106
7.5. Impact of Non-Clinical POCT testing	108
8. Commercial Positions in POCT	112
8.1. Companies & Profiles	112
8.2. Market Trends & Commercial Activities in 2015/2016	131
9 Companion Diagnostics, Personalised Medicine & POCT	134
9.1 Definitions	134
9.2 Research Funding for Personalised & Stratified Medicine	137
9.3 Commercial Collaborations	141
9.4 Future Development of POCT for Personalised Medicine & Companion Diagnostics	144
10 Strategic Marketing Implications for POCT	146
10.1 Marketing Philosophy	146
10.2 Implementation of POCT	148
10.3 Strategic Tools & Their Use in POCT	153
10.4 Generic Strategic Marketing Strategies Applied to POCT	159



FIGURES

1. Introduction & Purpose for Business Analysis of Point-of-Care Diagnostics	1
Figure 310.1. Further Reports for ABA Global Library for Life Science Research	1
Figure 310.2. ABA Global Library for Life Science Research Reports – Third Editions 2016	2
Figure 310.3. Diagnostics Procedure Implementation Rationale	3
Figure 310.4. Biological Cascade for Life Sciences	5
Figure 310.5. Basic Features of the Technology S-Curve	8
Figure 310.6. Technology S-Curve for the IVD Sector in 2016	8
Figure 310.7. Market Drivers for POCT IVDs, 2016 & 2007	10
Figure 310.8. Healthcare Dynamics for POCT IVDs, 2016	11
Figure 310.9. Healthcare Dynamics for Medical Devices, 2016	12
2. Technologies	13
Figure 310.10. Dip Stick Test Profile Example	14
Figure 310.11. Lateral Flow Test Basic Format	15
Figure 310.12. Typical Microarray Test Result Format	17
Figure 310.13. Biosensor Type Product, Abbott i-Stat	20
Figure 310.14. Main MDx Technology Principles	23
Figure 310.15. Layout of a Lab-on-a-Chip Device	27
Figure 310.16. Interactive Scheme for Homecare & Patient Monitoring	30
Figure 310.17. Physiological POCT Parameters Measured by Medical Devices 2016	31
Figure 310.18. Thermo Fisher Bench Top Mass Spectrometer & Agilent Bench Top HPLC	32
Figure 310.19. POCT Technology Development S-Curve, 2016	37
3. Manufacturing Considerations	39
Figure 310.20. POCT Technology Business Financial Structure, 2016	39
Figure 310.21. POCT Lateral Flow Technology Manufacturing Processes, 2016	43
Figure 310.22. Microarray Technology Manufacturing Processes, 2016	46
Figure 310.23. MicroFluidics Manufacture General Scheme	50
Figure 310.24. POCT Platform Guidelines, 2016	51
Figure 310.25. Global Cleaning Equipment Technology Market, 2016	52



4 Regulatory & Reimbursement Impact _____ 53

Figure 310.26. Diagnostic Products & Electromedical Equipment _____ 57
Figure 310.27. Diagnostic Products – IVD Reagents & Instruments _____ 58
Figure 310.28. European IVD-MDD Product Classifications, 2013 _____ 60
Figure 310.29. Summary of Class Approval Procedures for CE Mark Assignment _____ 61
Figure 310.30. Summary of Laboratory & POCT Sample Pathways _____ 68

5 Diagnostic Market Segments _____ 71

Figure 310.31. Overview of Diagnostic Testing Laboratory & POCT Segments, 2016 _____ 74

6 Applications & Market Quantification _____ 72

Figure 310.32. Overview of IVD Diagnostic Testing Markets, 2016 _____ 79
Figure 310.33. Regional Distribution of Global POCT Market, 2016 _____ 80
Figure 310.34. European Regional Distribution of POCT, 2016 _____ 81
Figure 310.35. Common & Less Used POCT Tests, 2016 _____ 82
Figure 310.36. POCT Application Markets, 2007 _____ 83
Figure 310.37. POCT Application Markets, 2016 _____ 83
Figure 310.38. Global Professional Point-of-Care Testing Markets, 2016 in \$US _____ 85
Figure 310.39. Professional Point-of-Care Testing Market USA, 2016 in \$US _____ 86
Figure 310.40. POCT Application Products by Specified Segment, 2016 _____ 88
Figure 310.41. POCT Implementation Messages & Actions, UK NHS & Commercial, 2016 _____ 89
Figure 310.42. POCT Implementation Factors for POCT Cardiac Markets _____ 90
Figure 310.43. POCT Enhancing Factors for POCT Cardiac Markers – Strong Agreement _____ 91
Figure 310.44. POCT Barriers to Adoption by Different Groups for Cardiac Markers _____ 92
Figure 310.45. The Netherlands Market as an Implementation Example – April 2014 _____ 93
Figure 310.46. POCT Market Dynamics for Future Business Development, 2013-2020 _____ 96

7 Non-Invasive Testing & Impact of Non-Clinical POCT Applications _____ 97

Figure 310.47. Non-Invasive Sampling & Assays _____ 98
Figure 310.48. Non-Invasive Technologies for Diagnostics, History _____ 104
Figure 310.49. Overall Market Segment Structure for Veterinary Diagnostics, 2016 _____ 110
Figure 310.50. Global Veterinary Diagnostic Market – by Species, 2016 _____ 111



8 Commercial Positions in POCT _____ 105

Figure 310.51. Overview of Commercial Point-of-Care Test Companies, 2016 _____	113-116
Figure 310.52. Generalised Basis of Competition for Point-of-Care Test Companies, 2016 _____	118
Figure 310.53.1. Company Profile Summary – Abaxis Inc _____	119
Figure 310.53.2. Company Profile Summary – Abbott Diagnostics _____	120
Figure 310.53.3. Company Profile Summary – Alere Inc. _____	121
Figure 310.53.4. Company Profile Summary – bioMerieux _____	122
Figure 310.53.5. Company Profile Summary – Enigma Diagnostics _____	122
Figure 310.53.6. Company Profile Summary – Instrumentation Laboratories _____	123
Figure 310.53.7. Company Profile Summary – Radiometer _____	123
Figure 310.53.8. Company Profile Summary – OraSure Technologies _____	124
Figure 310.53.9. Company Profile Summary – Roche Diagnostics _____	125
Figure 310.53.10. Company Profile Summary – Life Scan _____	126
Figure 310.53.11. Company Profile Summary – Response Biomedical _____	127
Figure 310.53.12. Company Profile Summary – Menarini Diagnostics _____	128
Figure 310.53.13. Company Profile Summary – Nova Biomedical _____	129

9 Companion Diagnostics, Personalised Medicine & POCT _____ 134

Figure 310.54. European Funding for Personalised Medicine, 2013 _____	139
Figure 310.55. Companion Diagnostic Partnerships, 2009-2013 _____	142

10 Strategic Marketing Implications for POCT _____ 136

Figure 310.56 Point-of-Care Diagnostic Market in 2013/14 _____	148
Figure 310.57 Typical Key Elements in POCT Diagnostic Purchase Decisions _____	151
Figure 310.58 Economic Value of Health to USA Society, 2006 _____	152
Figure 310.59 Technology Basis of Competition Ranking for Diabetes Self-Test, 2016 _____	156
Figure 310.60 Technology Basis of Competition for Non-Invasive POCT Devices, 2016 _____	158