

POINT OF CARE TESTING
**Evaluating the return to evidence
based medicine, novel technologies
and the competitive landscape**
By Biophoenix

Biophoenix

Biophoenix is a biomedical consultancy based in the heart of England, UK, which was founded by Dr Sreten Bogdanovic and Dr Beata Langlands. Established with support from the UK Department of Trade and Industry (DTI) in 1994, Biophoenix provides detailed, accurate, market and technical information to support decision-making by biotechnology-based enterprises in the healthcare industry. In doing so, Biophoenix relies on its comprehensive in-house bioindustry database and a wide network of contacts. Biophoenix also audits biotechnology-based enterprises with regard to the risk of intellectual property litigation on behalf of several Lloyds of London insurers. Further information is available on the internet at www.biophoenix.com.

Dr Langlands holds a PhD in biochemistry from the University of Glasgow, UK, and has worked as an immunologist, a project leader with a new biotechnology company based at Warwick University in the UK, and as a university lecturer. Biophoenix has researched and written over 50 in-depth management/market reports.

Copyright © 2010 Business Insights Ltd

This Management Report is published by Business Insights Ltd. All rights reserved. Reproduction or redistribution of this Management Report in any form for any purpose is expressly prohibited without the prior consent of Business Insights Ltd.

The views expressed in this Management Report are those of the publisher, not of Business Insights. Business Insights Ltd accepts no liability for the accuracy or completeness of the information, advice or comment contained in this Management Report nor for any actions taken in reliance thereon.

While information, advice or comment is believed to be correct at the time of publication, no responsibility can be accepted by Business Insights Ltd for its completeness or accuracy.

Table of Contents

Point of Care Testing

Executive summary	14	
Market overview	14	
POC testing in diabetes	15	
Fertility-related tests	16	
Hemostasis testing	17	
Cardiology tests	18	
Infectious disease tests	19	
Drugs of abuse testing	20	
Clinical chemistry and other rapid tests	21	
Company profiles	22	
Market analysis and forecasts	23	
Chapter 1	Market overview	26
Summary		26
The shift to POC diagnostic testing		27
Locations for POC testing		28
Background on IVD technologies		28
Clinical chemistry		28
Immunoassays		29
Nucleic acid testing		31
Technologies for POC testing		33
Lateral-flow tests		34
Next-generation lateral-flow devices		37
Electrochemical enzymatic tests		38
Advances in microfluidics		39
Data management and connectivity		40
Market drivers		42
Market restraints		44
Regulation of in vitro diagnostic tests (US)		44

CLIA	46
------	----

Chapter 2 POC testing in diabetes 50

Summary	50
Diabetes diagnostics and monitoring	51
Meter systems for blood glucose monitoring	54
Increasing performance requirements	63
Examples of POC device manufacturers	64
Roche Diagnostics	64
Arkray	65
Home Diagnostics	65
Abbott Diabetes Care	66
Nova Biomedical	66
Epocal	67
Diagnostic Devices	67
HemoCue	67
Luminous Medical	68
Health-Chem Diagnostics	68
Continuous glucose monitoring systems	68
Examples of POC device manufacturers	69
DexCom	69
Medtronic MiniMed	69
Abbott Diabetes Care	70
HbA1c testing	70
Examples of POC device manufacturers	72
Diazyme Laboratories	72
HemoCue	72
Bio-Rad Laboratories	73
Siemens	73
Trinity Biotech	74

Chapter 3 Fertility-related tests 76

Summary	76
Introduction	77
Pregnancy (hCG) tests	77
Detection of hCG variants	83
Ovulation tests	84
OTC pregnancy test kits	84
Examples of manufacturers of pregnancy tests	85
Inverness Medical Innovations	85

Swiss Precision Diagnostics	87
Church & Dwight	88
Siemens Healthcare Diagnostics	88
Applied DNA Technologies	89
Quidel	89
BTNX	89
Germaine Laboratories	90
Other fertility-related tests	90

Chapter 4 Hemostasis testing 94

Summary	94
Introduction	95
Hemostasis modulation	96
Use of anticoagulants	96
Use of antiplatelets	97
Hemostasis testing	98
Coagulation testing	98
Prothrombin time	98
Activated partial thromboplastin time	100
Activated coagulation time	101
Guidelines on POC coagulation testing (US)	102
Examples of manufacturers of POC tests	103
Abbott Laboratories	103
Axis-Shield	104
Siemens	104
Instrumentation Laboratory	105
Haemoscope	105
Helena Point of Care	106
Inverness Medical Innovations	107
International Technidyne	108
Roche Diagnostics	108
Akers Biosciences	109
Platelet function tests	110
POC testing	112
Examples of manufacturers of POC tests	112
Helena Point of Care	112
Siemens Healthcare Diagnostics	112
Accumetrics	113

Chapter 5 Cardiology tests 118

Summary	118
----------------	------------

Overview of cardiovascular disease	119
Lipids associated with atherosclerosis	120
Lipid management guidelines (US)	121
Laboratory lipid profiling	122
Mail-in fingerstick tests	123
Point-of-care lipid tests	124
Routine assay methods	126
Examples of manufacturers of CLIA waived tests	127
AccuTech	127
Inverness Medical Innovations	128
Polymer Technology Systems	129
Abaxis	130
Cardiac protein biomarker diagnostics	130
Biomarkers of necrosis	131
Biomarkers of hemodynamic stress	132
Biomarker panels for risk stratification	133
The need for POC testing	134
Examples of manufacturers of POC tests	135
Siemens	135
Inverness Medical Innovations	136
ELITech Group	137
Roche Diagnostics	138
Response Biomedical	139
Abbott Point of Care	139

Chapter 6 Infectious disease tests 142

Summary	142
Introduction	143
POC testing	143
Rapid immunoassays	144
Nucleic acid testing	148
Sexually-transmitted diseases	150
HIV	150
Chlamydia	153
HPV	154
HSV-2	155
Trichomonas vaginalis	155
Gonorrhea	156
Respiratory infections	156
Influenza A and B	157
Influenza A swine flu	161
RSV	163
Strep A	163
Legionella	164
M. tuberculosis	164

Gastrointestinal infections	165
H. pylori	165
C. difficile	166
Parasites	166
Other infections/conditions	167
Enteroviral meningitis	167
Infectious mononucleosis	168
Hepatitis C	168
Strep B	169
MRSA	170
Sepsis	170
Malaria	171
Acute conjunctivitis	172
Platelet-associated bacteria	172
Periodontal disease	173
Urine infection	173

Chapter 7 Drugs of abuse testing 176

Summary	176
Introduction	177
Point-of-care urine-based testing	177
Commonly abused prescription drugs	178
Opioids	178
Central nervous system depressants	179
Stimulants	180
Psychoactive drugs	180
Methadone	181
Illicit drugs	181
Methamphetamine	181
Cocaine	182
Heroin	183
Phencyclidine	184
Cannabinoids	184
POC testing sites	185
CLIA waived DOA rapid tests	186
Examples of POC DOA test manufacturers	191
Inverness Medical Innovations	191
Nanogen	192
Bio-Rad Laboratories	193
Siemens Healthcare Diagnostics	193
Instant Technologies	193
NOVX Systems	194
Detection of DOA in oral fluids	194

POC technology/products	227
Banyan Biomarkers Inc	228
Company description	228
POC technology/products	228
BioHelix Corporation	228
Company description	229
POC technology/products	229
Bio-Rad Laboratories Inc	230
Company description	230
POC technology/products	230
BiOracle Ltd	231
Company description	231
POC technology/products	232
Calypte Biomedical Corporation	232
Company description	233
POC technology/products	233
Cepheid	233
Company description	233
POC technology/products	234
Diazyme Laboratories	235
Company description	235
POC technology/products	235
ELITech Group	236
Company description	236
POC technology/products	237
Enigma Diagnostics Ltd	238
Company description	238
POC technology/products	238
GeneEx Inc	239
Company description	239
POC technology/products	239
Health-Chem Diagnostics LLC	239
Company description	240
POC technology/products	240
Helena Laboratories Corporation	240
Company description	241
POC technology/products	241
Home Diagnostics Inc.	242
Company description	242
POC technology/products	242
International Technidyne Corporation	243
Company description	243
POC technology/products	243
Inverness Medical Innovations Inc	244
Company description	244

POC technology/products	245
Meso Scale Diagnostics LLC	246
Company description	247
POC technology/products	247
Micronics	247
Company description	248
POC technology/products	248
Molecular Vision Ltd	248
Company description	249
POC technology/products	249
NOVX Systems Inc	249
Company description	250
POC technology/products	250
OraSure Technologies Inc	251
Company description	251
POC technology/products	251
Phadia AB	252
Company description	252
POC technology/products	252
PointCare Technologies Inc	253
Company description	253
POC technology/products	254
Polymer Technology Systems Inc	254
Company description	254
POC technology/products	255
Princeton BioMeditech Corporation	255
Company description	255
POC technology/products	256
Qualigen Inc	257
Company description	257
POC technology/products	257
Quidel Corporation	257
Company description	258
POC technology/products	258
Rapid Pathogen Screening Inc	259
Company description	259
POC technology/products	260
Response Biomedical Corporation	260
Company description	260
POC technology/products	261
Roche Diagnostics Corporation	261
Company description	262
POC technology/products	262
Siemens Healthcare Diagnostics Inc	264
Company description	264

POC technology/products	264
Trinity Biotech Plc	266
Company description	266
POC technology/products	266
Verax Biomedical Inc	267
Company description	267
POC technology/products	267

Chapter 10 Market analysis and forecasts 270

Summary	270
Outlook for the POCT market	271
Forecasts for individual POCT market sectors	273
Glucose monitoring	273
HbA1c testing	274
Pregnancy/fertility testing	274
Infectious disease testing	274
Lipid profiling	275
Cardiac marker testing	275
Coagulation testing	276
Drugs of abuse testing	276
Automated urine/blood analysis	277
Cancer screening	277
Penetrating the healthcare system	277
POCT in retail health clinics	278
POCT in physicians office labs	279
Future POCT technologies	279

Appendix 281

Research methodology	281
Glossary	281

List of Figures

Figure 1.1:	Approaches to overcoming limitations of traditional PCR-based assays	33
Figure 1.2:	A representative basic lateral flow immunoassay (LFI) device	35
Figure 1.3:	Schematic of an electrochemical glucose biosensor with meter display	38
Figure 1.4:	Schematic of a lab-on-a-chip device	40
Figure 1.5:	Drivers & restraints for the POCT market	43

Figure 2.6:	Patient potential for type 2 diabetes	51
Figure 2.7:	Causes of inaccurate glucose test results	54
Figure 6.8:	Infectious disease tests CLIA waived (%), Nov 2006 - Oct 2009	144
Figure 6.9:	GeneXpert system for PCR-based DNA testing	149

List of Tables

Table 2.1:	Glucose monitoring products 2006-09	56
Table 2.2:	Glucose monitoring products 2006-09 (ctd 1)	57
Table 2.3:	Glucose monitoring products 2006-09 (ctd 2)	58
Table 2.4:	Glucose monitoring products 2006-09 (ctd 3)	59
Table 2.5:	Glucose monitoring products 2006-09 (ctd 4)	60
Table 2.6:	Glucose monitoring products 2006-09 (ctd 5)	61
Table 2.7:	HbA1c testing products	72
Table 3.8:	Pregnancy and ovulation tests	78
Table 3.9:	Pregnancy and ovulation tests (ctd 1)	79
Table 3.10:	Pregnancy and ovulation tests (ctd 2)	80
Table 3.11:	Pregnancy and ovulation tests (ctd 3)	81
Table 5.12:	Lipid profiling tests	126
Table 6.13:	Infectious disease tests – Strep A infection	145
Table 6.14:	Infectious disease tests – H. pylori infection	146
Table 6.15:	Infectious disease tests – Infectious mononucleosis	147
Table 6.16:	Infectious disease tests – HIV infection	147
Table 6.17:	Infectious disease tests – influenza A/B infection	148
Table 6.18:	Infectious disease tests – urinary infection	148
Table 7.19:	Drugs of abuse (DOA) test systems and analytes	188
Table 7.20:	Drugs of abuse (DOA) test systems and analytes (ctd 1)	189
Table 7.21:	Drugs of abuse (DOA) test systems and analytes (ctd 1)	190
Table 8.22:	Automated urine analyzers/reagents	203
Table 8.23:	Automated urine analyzers/reagents (ctd 1)	204
Table 8.24:	Automated urine analyzers/reagents (ctd 2)	205
Table 8.25:	Blood chemistry analyzers/reagents	207
Table 8.26:	Blood chemistry analyzers/reagents (ctd 1)	208
Table 8.27:	Immunological Fecal Occult Blood (FOB) tests	213
Table 9.28:	Abbott Laboratories sales to external customers (\$m), 2006-08	221
Table 9.29:	Cepheid product sales by market (\$ thousands), 2007-08	234
Table 9.30:	Inverness Medical Innovations sales (\$ thousands), 2007-08	245
Table 9.31:	Quidel POC diagnostic revenues (\$ thousands), 2007-08	258
Table 10.32:	POCT market forecast by application, 2008-13	271
Table 10.33:	POCT market forecast by region, 2008-13	272