

Point of Care Diagnostics 2010 and Beyond: Rapid Testing at a Crossroads

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Abstracts

As Kalorama Information's lead diagnostic analyst finds, the point of care concept is at a crossroads: the technologies needed to make rapid testing a reality are here. But is healthcare ready? The drive for wellness and the attention surrounding healthcare reform will surely focus attention on rapid diagnostics. However, according to Shara Rosen, RT, M.B.A., there are many challenges which must be overcome for point of care solutions to fit, and those companies willing to pivot strategies and best adjust to changes in the healthcare marketplace may be rewarded.

This report, *Point of Care Diagnostics 2010: Rapid Testing at a Crossroads* represents the most current analysis of the role of Point of Care Diagnostics in today's in vitro industry. Other reports have looked at products, companies and market forecasts, as this report does. But in her analysis Shara Rosen takes a bold look into the markets, technologies, and trends in decentralized testing with a special focus on the economics of rapid test use in critical care and emergency medicine. The report includes:

Markets for POC Diagnostics (Diabetes, Cardiac markers, Clinical Chemistry/Critical Care, Hematology, Coagulation,
Drugs of Abuse/Therapeutic Drug Monitoring, Infectious Diseases,
Pharmacodiagnostics, Sepsis, Oncology, Women's health / Pregnancy/Fertility)
By Venue Revenue Estimates for Hospital POC, Physician POC and Other Venue

Review of Products in the Market

Forecasts to 2013



Markets and Forecasts for Self-Testing (OTC)

The role of EMR in the Point of Care Market

Possible Effects of Healthcare Reform

POLs, Home Monitoring, Alternate Samples and Other Trends

Successful Strategies of POC Companies

Profiles of Over 100 Companies Competing in this Market

There are many factors in the growth of POC testing- increasing numbers of diagnosed diabetics, people with cardiovascular disease, and other chronic conditions. It is also expected to play a role in a trend in health care to evaluate provider organizations for quality in care delivery. While this quality imperative is most apparent in pay-for-performance systems, it also provides a framework by which public funds can be used more rationally. This is an especially relevant technology given the U.S. healthcare reform efforts.

All countries are feeling the brunt of aging populations and an increased burden of chronic disease management. Employers and insurance companies are interested in improving the health of customers, and there are some innovative tactics developing in this area. The report is conservative in its predictions and offers a calculated look into the future, based on events currently taking place.

The report offers a quantitative assessment of specific markets in US dollars for 2008 and forecasted out to 2013. These data are provided in order to set the status quo of tests and technologies. However the report concentrates on how these will impact the economics of healthcare over the near term and longer when possible.

As part of Kalorama Information's comprehensive coverage, the following companies are discussed:

23andMe

3M Health Care



77 Elektronika

| A. Menarini |
|---|
| A/C Diagnostics |
| Abaxis, Inc. |
| Abbott Diagnostics |
| ABTECH Scientific |
| Accumetrics |
| ACIST Medical |
| Acrongenomics Inc. |
| Adeza Biomedical |
| ADIATEC |
| ADIATEC |
| Aerscher Diagnostics |
| |
| Aerscher Diagnostics |
| Aerscher Diagnostics AgaMetrix, Inc. |
| Aerscher Diagnostics AgaMetrix, Inc. Alfa Scientific |
| Aerscher Diagnostics AgaMetrix, Inc. Alfa Scientific Alfa Wassermann |
| Aerscher Diagnostics AgaMetrix, Inc. Alfa Scientific Alfa Wassermann Alverix Inc. |



| Animas/J&J |
|--------------------------|
| ANP Technologies |
| Antigen Discovery Inc. |
| Apollo Hospitals |
| Arkray |
| Arrayit Diagnostics |
| AspenBio Pharma |
| Astron Clinica |
| AT First Diagnostic |
| Audit Diagnostics |
| Axis-Shield plc |
| Bayer Diabetes Care |
| Beckman Coulter |
| Becton Dickinson |
| Bedfont Scientific |
| Biohit Oy |
| BiolQ |
| bioLytical Labs |
| Biomagnetics Diagnostics |
| Biomerica, Inc. |



bioMérieux

| Bionime Corp. |
|------------------------------|
| Bio-Rad Laboratories |
| BIOSAFE Medical Technologies |
| Biosite/Inverness |
| Boditech Med |
| BodyTel Scientific |
| Branan Medical Corp |
| Burnet Institute |
| Calypte Biomedical |
| Careside Medical |
| Carolina Liquid Chemistries |
| Celerus Diagnostics |
| Chelsea Technologies |
| Chembio Diagnostic |
| Chempaq A/S |
| Chemtron Biotech |
| Cholestech Corp. |
| Claros Diagnostics |
| |



| CLX Medical, Inc. |
|--------------------------------|
| Combimatrix |
| Common Sense, Ltd. |
| Commonwealth Labs |
| Connectyx Technologies |
| ContraVac, Inc. |
| Decision Biomarkers |
| DexCom, Inc. |
| Diabetech, LP |
| Diabetes Sentry |
| Diaglobal GmbH |
| Diagnostic Devices |
| Diagnostics for All |
| Diagnostics for the Real World |
| Diazyme Laboratories |
| Digital Bio Tech |
| Diversa Limited |
| DNA Direct, Inc. |
| DNAFORM |

Point of Care Diagnostics 2010 and Beyond: Rapid Testing at a Crossroads

DxNA



Echo Therapeutics

| EKF-diagnostic GmbH |
|----------------------|
| Enfora |
| Enigma Diagnostics |
| Enterix Inc. |
| Entra Health |
| Epocal, Inc. |
| EPS Bio Technology |
| ESA Biosciences |
| eScreen, Inc. |
| ExpressMD Solutions |
| EyeMarker Systems |
| Flexsite Diagnostics |
| Focus Diagnostics |
| Fora Care |
| GE Healthcare |
| GenBio |
| Gene Smart Wellness |
| Genexel-Sein Inc. |



| Gentag Inc. |
|------------------------------|
| Genzyme Diagnostics |
| Global Detection & Reporting |
| Glucometrics, Inc. |
| Google, Inc. |
| Guided Therapeutics |
| Hai Kang Life Corp. |
| Hain Lifescience GmbH |
| HandyLab, Inc. |
| HealthPia America |
| HealthPort |
| Helena Laboratories |
| Hema Diagnostic Systems |
| Hema Metrics |
| HemoCue AB |
| Hero Network Network |
| HMM GmbH |
| Hoana Medical |
| Home Access Health |

Home Diagnostics



Horiba ABX

| Idaho Technology |
|-------------------------------|
| <u>.</u> |
| IDenta Corp |
| Identigene |
| IDEXX Laboratories |
| incentaHEALTH LLC |
| Innovative Biosensors |
| Instrumentation Laboratory |
| Insulet Corporation |
| Integrity Applications |
| Intel Corporation |
| International Technidyne |
| Inverness Medical Innovations |
| Knome |
| Lab Express |
| LifeAssays AB |
| Lifescan |
| LifeSign LLC |
| LifeStat |
| |



| Lifestream Technologies, Inc. |
|-------------------------------|
| Lifestyle Choices |
| Luminex |
| Luminous Medical |
| MACHEREY-NAGEL |
| Masimo Corp |
| Matritech |
| M-Biotech |
| Medical Automation Systems |
| MedMira Inc. |
| Medtronic Inc. |
| Menssana Research, Inc. |
| Meretek Diagnostics Inc. |
| Meridian Bioscience |
| Micromem Technologies |
| Micronics Inc. |
| MicroPhage, Inc. |
| MinuteClinic |
| Mitsubishi Kagaku latron |
| |

MP Biomedicals



| Multilyte Limited |
|----------------------------|
| MycroLab Pty |
| Nanogen |
| Nanomix, Inc. |
| Nanosphere, Inc. |
| National Jewish Health |
| Navigenics, Inc. |
| Network Biosystems |
| Neuroptix Corp |
| Nihon Kohden |
| Noninvasive Medical Tech |
| Nova Biomedical |
| OPTI Medical Systems |
| OraSure Technologies |
| Orion Diagnostica |
| OrSense Ltd. |
| Ortho Clinical Diagnostics |
| OvumOptics, Inc. |
| Oxford Biosensors |



| Oxonica Diagnostics |
|--------------------------------|
| Phadia AB |
| Philips Handheld Immunoassays |
| PlaCor, Inc. |
| PointCare Technologies |
| Polymedco |
| Practice Fusion |
| PreMD Inc. |
| PrimeraDx |
| Probe Scientific Ltd |
| Prometheus Laboratories |
| Psynomics |
| QBC Diagnostics |
| Qiagen |
| Q-linea |
| Quadraspec |
| QualSec, Inc |
| QuantRx Biomedical Corporation |
| Quidel Corp |
| |



Radiometer A/S

| Raman spectroscopy |
|----------------------------------|
| Rapid Pathogen Screening |
| Rennesens GmbH |
| Response Biomedical |
| Rite Aid |
| Roche Diagnostics |
| Royal Philips Electronics |
| Safeway, Inc. |
| Screening Devices Canada |
| SEMOFS |
| Sentinel Bioactive Paper Network |
| SeraCare Life Sciences |
| Serotec |
| Siemens Healthcare Diagnostics |
| SIENCO |
| Smiths Detection |
| Smiths Medical MD |
| Soar BioDynamics |
| |



| Solei Systems, Inc |
|-----------------------------|
| Solianis Monitoring |
| SpectraScience, Inc. |
| Sphere Medical Ltd. |
| SpheroSense Technologies |
| Stanbio Laboratory |
| StatSure Diagnostic Systems |
| STD Test Express |
| STMicroelectronics |
| Synova Healthcare |
| Sysmex Corp |
| T2 Biosystems |
| Taidoc Technology |
| TelCare |
| Telus Corporation |
| Textronics, Inc. |
| Thermo Fisher Scientific |
| Tosoh Corp |
| Trinity Biotech |
| TwistDx, Ltd. |



| Tyrian Diagnostics |
|----------------------|
| UnitedHealth Group |
| Veralight, Inc. |
| Veredus Laboratories |
| VeriChip Corporation |
| Via Medical Corp |
| Vital Diagnostics |
| Vivacta Limited |
| Walgreens |
| Wal-Mart Stores |
| Webahn Inc. |
| Ypsomed |
| |



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Physician Office Labs

United Kingdom

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Hematology

Coagulation

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Decentralized Coagulation Testing - OTC

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Allergy

Infectious Diseases

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Beckman Coulter Inc.

Becton, Dickinson and Company (BD)

bioMerieux Inc.

Bio-Rad Laboratories Inc.

GE Healthcare

Instrumentation Laboratory

Inverness Medical Innovations

Lifescan Inc.



Nova Biomedical

Ortho Clinical Diagnostics (OCD)

Qiagen N.V.

Quidel Corporation

Radiometer A/S

Roche Diagnostics

Diabetes

Cardiac Markers

Clinical Chemistry

Critical Care

Siemens Healthcare Diagnostics

Cardiac Markers

Diabetes Care

Blood Gases

Urinalysis

Sysmex Corporation

TOSOH Corporation

'New Frontier' POC COMPANIES

3M Health Care

77 Elektronika Kft.

Abaxis, Inc.

A/C Diagnostics

Accumetrics

ACIST Medical Systems, Inc.

AgaMetrix, Inc.

Alfa Wassermann Diagnostic Technologies, LLC (AWDT)

American Bio Medica Corp

Audit Diagnostics

Axis-Shield plc

Biohit Oy

BioIQ

Biomerica, Inc.

Biosite Incorporated

B.R.A.H.M.S. AG

Calypte Biomedical Corporation

Chembio Diagnostic Systems, Inc.

Chempaq A/S



Cholestech Corporation

Concateno plc

DexCom, Inc.

Diabetech, LP

Diazyme Laboratories

EKF-diagnostic GmbH

ESA Biosciences Inc.

Hain Lifescience GmbH

HandyLab, Inc.

Helena Laboratories USA

Hema Diagnostic Systems (HDS)

HemoCue AB

HemoSense, Inc.

Home Diagnostics, Inc.

Horiba ABX S.A.

Insulet Corporation

International Technidyne Corp (ITC)

Masimo Corporation

Matritech

Medical Automation Systems, Inc.

MedMira Inc.

Medtronic Inc.

A. Menarini Diagnostics

Meridian Bioscience

MP Biomedicals LLC

Nanosphere, Inc.

OPTI Medical Systems, Inc.

OraSure Technologies, Inc.

Phadia AB

Philips Handheld Immunoassays

Polymedco, Inc.

QBC Diagnostics, Inc.

Response Biomedical Corp

Serotec (AbD Serot

Smiths Medical MD, Inc. (formerly Deltec, Inc.)

Stanbio Laboratory

Taidoc Technology Corp.

Trinity Biotech plc

Via Medical Corporation



Vital Diagnostics

Other Players

Acrongenomics Inc.

Alfa Scientific Designs, Inc.

Amic AB

Astron Clinica

AspenBio Pharma, Inc.

AT First Diagnostic, LLC

bioLytical Laboratories Inc.

Biomagnetics Diagnostics Corporation

Bionime Corporation

BodyTel Scientific, Inc.

Burnet Institute

Celerus Diagnostics

Chelsea Technologies Group Ltd

Claros Diagnostics

CLX Medical, Inc.

ContraVac, Inc.

Decision Biomarkers Inc.

Diabetes Sentry Products Inc.

Diaglobal GmbH

Diagnostic Devices, Inc.

Diagnostics for All (DFA)

Diagnostics for the Real World (DRW)

Digital Bio Technology/ InCyto

Diversa Limited (formerly Ambri Ltd.)

DNAFORM

DxNA

Echo Therapeutics, Inc. (previously Sontra Medical)

Enigma Diagnostics Limited

Enterix Inc.

Entra Health Systems

Epocal, Inc.

EUMED Biotechnology Co. Ltd.

eScreen, Inc.

EyeMarker Systems, Inc.

Flexsite Diagnostics, Inc.



Fora Care

GenBio

Gene Smart Wellness

Gentag Inc.

Glucometrics, Inc.

Guided Therapeutics, Inc.

Hai Kang Life Corporation

HealthPia America

Heidelberger-Medical-Marketing GmbH (HMM GmbH)

Hema Metrics

Hoana Medical, Inc.

Idaho Technology, Inc.

Identa Corporation

Identigene

Innovative Biosensors, Inc.

Integrity Applications Ltd.

Intel Corporation

LifeAssays AB

LifeSign LLC

Lifestyle Choices Ltd

Luminous Medical, Inc.:

M-Biotech

Menssana Research, Inc.

Micromem Technologies Inc.

Micronics Inc.

MicroPhage, Inc.

Multilyte Limited

MycroLab Pty Ltd.

Nanomix, Inc.

National Jewish Health

Network Biosystems

Neuroptix Corporation

Noninvasive Medical Technologies, Inc.

OrSense Ltd.

OvumOptics, Inc.

Oxonica Diagnostics

PlaCor, Inc.

PointCare Technologies

Probe Scientific Ltd



Prometheus Laboratories Inc.

Q-linea

Quadraspec

QualSec, Inc

QuantRx Biomedical Corporation

Quotient Diagnostics

Rapid Pathogen Screening

Rennesens GmbH

Screening Devices Canada, Inc.

Sentinel Bioactive Paper Network

Sphere Medical Ltd.

SIENCO

Smiths Detection

Solei Systems, Inc.

Solianis Monitoring AG

SpheroSense Technologies Inc.

STD Test Express

Surface Enhanced Micro Optical Fluidic Systems

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