Diagnostic Test Service Commercialization in Multiplex and Esoteric Testing: A Roadmap to Diagnostics in the 21st Century

Description: Test services, once the norm in the diagnostics industry, then abandoned for reagent sales, are now making a comeback.

IVD companies have established cGMP and CLIA-registered labs by which they offer their proprietary tests to physicians, hospitals and reference labs. These tests are outside the oversight of the traditional FDA and CE Mark test commercialization avenue in the U.S. and Europe and so are thought to come to market by what may seem to be the back door.

Kalorama has been watching this trend, and in her unique report, Kalorama Information's diagnostic analyst Shara Rosen covers the increasing trend in diagnostics towards servicing of tests in addition to selling test kit products and where this fits into the IVD industry today.

Information in this report includes
- Current market and forecast for diagnostics test services
- Detailed Analysis of the Esoteric Test Market (Clinical Chemistry, Immunoassays, Radioimmunoassays, Coagulation, Histology/Cytology, Nucleic Acid Assays, Flow Cytometry)
- Review of Current Products on the Market
- Test Service Revenue Breakdown for Major Companies
- Evaluation of Test Services Products on the Market According to Five Checkpoints
- Strategies for Success In Test Service Commercialization
- Company Profiles

The report covers Clinical test services offered by reference laboratories, hospital laboratory outreach programs, direct to consumer web-based companies, and CLIA-registered company labs. The report describes the lay of the land for test services when they were first launched in the mid 1980s, the status quo in 2008 and a peek into the future.

What are the market factors driving test servicing? What companies are best suited for this strategy now and in the future? What are the best strategies, who has been most successful and where is this trend headed in the future? What are the areas of IVD most likely to be impacted by this trend? This report answers these questions and more. Rosen's report will not only describe the market as it is today, but provide a clear picture - a roadmap - to how diagnostics will be practiced in this century.

Shara Rosen is Kalorama's lead diagnostic analyst and is the author of the Worldwide Market for In Vitro Diagnostics, 6th Edition., Physician Office Lab Markets, Point of Care Diagnostics and several other important diagnostic studies. This study is the result of her research and analysis and interviews with experts in the field.

Contents:
- CHAPTER ONE: EXECUTIVE SUMMARY
  - Scope and Methodology
  - Market Trends
  - Clinical Chemistry
  - Coagulation tests
  - Flow Cytometry
  - Histology/Cytology
  - Infectious Diseases
  - Keys to Success
- CHAPTER TWO: INTRODUCTION
  - Background
  - The U.S. Versus Europe
  - ASRs
  - Hospital Outreach and National Reference Lab Services
  - Lab Outreach Testing
CHAPTER THREE: MARKET OVERVIEW/ SUPPLY ANALYSIS

Background
Market Analysis, revenue estimates 2007 - 2012
Testing Markets
ISC and ISH
Market and Growth
Market Share
Lab Launches and Acquisitions
Market Leaders
Evaluation of Lab Tests
Uniqueness
Need
Reimbursed
Incumbent
Recognized
Peer Reviewed
Competition from FDA Cleared Products
Cost
Competitive Technologies
Pathwork
  BRCA analysis
  Mammastatin
Limited Use of Molecular Testing for Colon Cancer.
TDT
Ovarian Cancer Testing
Future Leaders?
HIV Testing
Mental Illness
Test Services on the Horizon

CHAPTER FOUR: MARKET TRENDS/ DEMAND ANALYSIS

The Commercialization of Multiplexed and Complex Analyses
Opportunity Pricing and margins are attractive
Demand for Esoteric Tests

CHAPTER FIVE: MARKET BARRIERS FOR TEST SERVICES

Regulatory affairs
Can the FDA Regulate New test Modalities?
IVD MIA s
Pending LDT Legislation
Reimbursement Imperative
Physician Uptake
Connectivity, a Force to Consider
The In Vivo - In Vitro Diagnostic Paradigm
Social media and Internet-Based Services

CHAPTER SIX: TESTS AND COMPANIES TO WATCH

23andMe, Inc.
Key Comment
Details

Affymetrix
Key Comment
Details

Agendia B.V.
Key Comment
A RUP Laboratories
Key Comment
Details

Athena Diagnostics, Inc.
Key Comment
Details

Atherotech
Key Comment
Details

AviaraDx (formerly Arcturus Biosciences)
Key Comment
Details

Biomedical Diagnostics, LLC/Abviva, Inc.
Key Comment
Details

Biophysical Corporation
Key Comment
Details

Caris MPI
Key Comment

Clariant Inc. (formerly ChromaVision
Key Comment
Detail

Clinical Data, Inc
Key Comment
Details

CombiMatrix Molecular Diagnostics (CMDX)
Key Comment
Details

Consumer Genetic
Key Comment
Details

Corgenix Medical Corporation
Key Comment
Details

Correlogic Systems, Inc
Key Comment
Details

deCode Genetics Inc.
Details

DiagnoCure
Key Comment
Details

DNA Direct, Inc.
Key Comment
Details
Key Comment
Details

Nymox Pharmaceuticals
Details

Oncolab, Inc.
Key Comment
Details

Panacea Pharmaceuticals, Inc.
Key Comment
Details

Pathway Diagnostics Corporation
Key Comment
Details

Pathwork Diagnostics (formerly Predicant Biosciences)
Key Comment
Details

Perceptronix Medical Inc.
Key Comment
Details

Power3 Medical Products, Inc.
Key Comment
Details

Precision Therapeutics, Inc.
Key Comment
Details

Prometheus Laboratories Inc.
Key Comment
Details

Psynomics Incorporated
Key Comment
Details

Quest Diagnostics Incorporated
Key Comment
Details

Rational Therapeutics
Key Comment
Details

Rosetta Genomics Ltd.
Key Comment
Details

Signature Genomic Laboratories, LLC
Key Comment
Details

Smart Genetics
Key Comment
Details

Specialty Laboratories
Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

Product Name: Diagnostic Test Service Commercialization in Multiplex and Esoteric Testing: A Roadmap to Diagnostics in the 21st Century
Web Address: http://www.researchandmarkets.com/reports/2860897/
Office Code: SCD23GQS

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF)</td>
<td>USD 1500</td>
</tr>
<tr>
<td>Single User:</td>
<td></td>
</tr>
<tr>
<td>Hard Copy:</td>
<td>USD 3900 + USD 57 Shipping/Handling</td>
</tr>
<tr>
<td>Electronic (PDF)</td>
<td>USD 7000</td>
</tr>
<tr>
<td>Enterprisewide:</td>
<td></td>
</tr>
</tbody>
</table>

* Shipping/Handling is only charged once per order.

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: Mr ☐ Mrs ☐ Dr ☐ Miss ☐ Ms ☐ Prof ☐
First Name: ___________________________________________ Last Name: _______________________________________
Email Address: * __________________________________________
Job Title: ___________________________________________
Organisation: ___________________________________________
Address: ___________________________________________
City: ___________________________________________
Postal / Zip Code: _______________________________________
Country: ___________________________________________
Phone Number: ___________________________________________
Fax Number: ___________________________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code: ______________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:
(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World