Point of Care Testing in Molecular Diagnostics: What it Takes to Win?

2016 Financial Analyst Briefing

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DISCLOSURES

• THIS PRESENTATION HAS BEEN PREPARED SOLELY FOR INFORMATIONAL PURPOSES

• THE INFORMATION REPRESENTS THE PERSONAL VIEWS OF THE PRESENTER
Richard S. Creager, PhD

- PhD in Microbiology
- > 35 years IVD Experience
- > 150 commercial products (510k, PMA)
- Senior Executive/GM for Fortune 500 IVD companies
- Former SVP of MDx IVD company
- Former CSO leading IVD company
- Current, IOI Partners/NaviDx
Agenda

• Molecular Diagnostics Point of Care Market
• Customer Requirements
• Market Barriers
• Point of Care Systems: Current and Future
• Summary
Molecular Diagnostics POC Attracting Attention

More Than $1B in Acquisitions, Investments, Financings, and Public Offerings Since 2009
Molecular Diagnostics Market

2015 Global MDx Market size: $6B

Point of Care Represents ~ 20% of Total MDx Market Today

Global MDx Market

MDx POC $1.2B

CLIA Waived
MDx POC
$0.05B

Testing Location

- Hospital Labs
- CLIA High Complexity Labs
- Reference Labs

Sources: Grand View Molecular POC 2015 report
MDx POC Share of Total MDx Market

2015 Global MDx Market size: $6B USD

- Retail Clinics & Pharmacies
- Student Health Clinics
- Neighborhood Ambulatory Care Clinics
- Physician Offices (GPs & Specialists)
- CLIA Waived Labs
- CLIA Moderately Complex Labs
- Hospital Clinics
- Hospital Floor (Near Patient Bedside)
- Emergency Rooms
- Intensive Care Units
- Rural Health Clinics
- Nursing Homes, Assisted Living Residence
- Hospital Labs
- Moderately Complex Labs
- Highly Complex Labs
- Reference Labs

Only $50M of the $1.2B MDx POC is CLIA Waived
~ 100% of CLIA Waived POC is Respiratory Testing (Flu & Strep)

Source: Grand View Molecular POC 2015 report
Global MDx POC Market Growth

MDx POC Market Expected To Triple By 2024
Infectious Disease and Oncology Assays will Dominate

Source: Grand View Molecular POC 2015 report
MDX POC Market Drivers

Patient Focused Drivers

- Rapid results impacts patient treatment decisions
- Personalized medicine (new therapies, the right antibiotic, etc.)

Economic Drivers

- Healthcare Reform – more covered patients
- Ageing Populations - treatment in non-hospital settings (assisted living, nursing care, at-home care, etc.)
- New Healthcare Delivery Models (retail, self-testing, etc.)
- Healthcare Decentralization (China, India, rural USA, etc.)
- Epidemics, Pandemics, Emerging Pathogens (SARS, Zika, Ebola, Chikungunya)
- Faster Results: Reduce length of hospital stays, reduce time in ERs

Patient & Economic Benefits are Key Drivers
What Customers Want

- Equivalent Performance to Core Lab Systems
- Few System Repairs (<1/year)
- To Electronic Medical Record
- To Lab Information System
- Developed Markets: 15 – 30 C
- Emerging Markets: 14 – 40 C
- Developed Markets: 110/220 v
- Emerging Markets: Battery Operated
- Developed Markets: Refrigerator
- Emerging Markets: Room Temperature

- Less than 30 Minutes Required
- Less than 15 Minutes Preferred
- CLIA Waived
- Sample to Answer
- Less than 2 Minutes Hands on Time
- To Electronic Medical Record
- To Lab Information System
- Developed Markets: 15 – 30 C
- Emerging Markets: 14 – 40 C
- Developed Markets: 110/220 v
- Emerging Markets: Battery Operated
- Developed Markets: Refrigerator
- Emerging Markets: Room Temperature

- Cost Effective Tests
- Cost Effective Tests
- Power
- Power
- Easy to store reagents
- Easy to store reagents

- Weigh <10 lb.
- Weigh <10 lb.
- Operating Conditions
- Operating Conditions
- Operating Conditions
- Operating Conditions
- Operating Conditions

- Consolidate Tests on One Device
- Consolidate Tests on One Device
- One System
- One System
- One System
- One System
- One System

Improved Patient Management: Core Lab Quality, Cost, Easy To Use, and Fast Results are Key Drivers for Adoption
Key Development Challenges

1st systems announced in early 2000s
• Moderate Complexity
• Biofire
• Nanosphere Verigene
• Cepheid GeneXpert
• Hospital Based

Long Product Development Process
• 2 – 4 Years per Assay
• 3 – 7 Years for Instrument

Regulatory Process Complex
• 510(k)
• CLIA Waivers

Selling, Marketing, & Support
• Replacing less expensive alternative technologies

Development is a Long & Expensive Process
Regulated Product Development

Phase 1: Concept
  - User Needs

Phase 2: Feasibility
  - Design Input

Phase 3: Development

Phase 4: Design Output Verification

Phase 5: Design Transfer
  - Commercialization
  - FDA Submission/Clearance

Phase 6: Clinical Validation

2 to 4 years (Assays)

Average Cost is $2M - $5M per Assay

Long Process: Missteps and Do-Overs
CLIA WAIVER TESTING

By CLIA Definition, Waived Tests are:

• Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible

• Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

*Clinical Laboratory Improvement Amendments of 1988; FDA Consensus Guidance of 2005
POC Product Design Requirements

- Demonstrate analytical performance & clinical performance for the device’s intended use
- Human Factors engineering
- Prepare CLIA waiver equivalent (simple and accurate)
- Require the device tested at POC sites by POC users (non-lab professionals)

POC Regulatory Requirements Equivalent to Core Lab Systems
Clinical Studies Tend to be Large, Complex, & Expensive

- Large # of Patients
- Multiple Sample Types
- High Amount of Resources
- At least 3 unskilled operators at each site
  - Clinical studies take 6 – 12 months
  - Costs from $500k to $2M

Influenza virus
(1,000 – 2,000 patients)

Chlamydia/Gonorrhea
(5,000 – 7,000 patients)

Some tests require multiple sample types
(e.g. urine, endocervical, vaginal, urethral, fecal, throat)

3 POC sites, e.g. ED, physician’s office, nurse’s station, etc.

Method comparison and precision & reproducibility studies

Clinical Studies
## Regulatory Review

<table>
<thead>
<tr>
<th>FDA Clearance</th>
<th>CE Mark</th>
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<tbody>
<tr>
<td>• Recommended: pursue CLIA waiver, in parallel with 510(k)</td>
<td>• Class: CE Mark Class C device (POC)</td>
</tr>
<tr>
<td>• Class: Clearance Class II device (CT/NG, Flu A/B, Strep A)</td>
<td>• Review Time: ~ 2 – 4 months</td>
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<tr>
<td>• Review Time: ~3 - 6 months</td>
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US, China, Japan Review Times Longer than Europe
MDx POC Commercialization

POC Customer Segments
- Academic Hospitals ~ 1,000
- US Hospitals**
  ~ 4,600
- Retail Clinics (CLIA Waived)*
  ~ 2,400
- Physician Offices (CLIA WAIVED)
  ~ 100,000

Distribution Channels
- Market Development
- Large, Skilled Sales Force

Large, Skilled Sales Force
Market Development

Medical Affairs
Regulatory Affairs
Technical Support

Scientific Affairs

Commercial Success Requires Adequate Staff Sales and Support

Sources: * Accenture, Nov, 2015, ** AHA, 2016
Today’s Products

Moderate Complexity

- Slower test times: ~ 1 – 2 hours
- Skilled operators
- Tend to be large/heavy (10 – 55 lbs.)
- Limited menu (except Cepheid, Diasorin)
- Hospital-based

CLIA-Waived

- Fast test times: ~ 8 – 20 minutes
- Non-skilled operators
- Light weight/portable (7 – 8 lbs.)
- New customer segments
- Strong distribution channels
- Limited menu

Simplicity (CLIA-Waived): Expanding Market Penetration
Up and Coming Products

- Promise fast test times: ~ 10 - 30 minutes
- Non-skilled operators
- Most ultra-light weight/portable (1 – 5 lbs.)
- Launching 2017 - 2018

Smaller, Faster, Lighter with Potential of Broad Market Reach
What Will it Take to Win in MDx POC?

The Right Product/Technology:
- Core Lab Quality Results, Easy, Fast, Simple (CLIA-Waived), Reliable

Cost-Effective
- (displace inexpensive lateral flow devices)

Scalable Platform:
- Match test volume needs for each test setting

Broad Menu in Infectious Disease

Distribution Channels

Marketing, Sales, & Support
Summary

MDx POC market

Significant upside potential

A lot of players

Major IVD companies & new entrants

Significant hurdles

Expensive ($2M - $5M/assay; $50M - $100M/system)

- Menu (>10 – 15 years for full menu)
- Complex clinical studies & regulatory approvals
- Requires adequate marketing & sales staff
- Pricing (Margins) as more players enter market
Thank You!

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