Point of Care Testing (POCT): The Time is Now

Why emerging markets are driving advancements in POCT and how developed markets are likely to benefit

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Hypothesis

With focus increasing on POC technologies and their application to the needs of the developing world, it is time to consider the disruptive impact these investments will have in the coming years to help drive decentralization of testing services in developed world markets.
The Testing Situation Today In Resource Limited Settings

- Health care workers in resource-limited settings lack access to rapid diagnostic test results to make treatment decisions during the clinical visit.

- Only an estimated 45% of those who need testing in sub-Saharan Africa get it.

- Many persons who are tested do not return to the clinic (lost to follow up).

- Diagnostic systems available today were not designed for use in resource limited settings.

- Available test menus are not reflective of developing world needs.

- Advancements in POCT are needed.
Point of Care Testing (POCT) Definition

“Rapid testing turn-around and communication of results at the same location where patients visit and treatment is available to guide real-time clinical decisions during the clinical encounter”

Point of Impact (POI) Testing?

¹. Adapted from Pai et al. Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low-and Middle-Income Countries. PLOS Medicine 9: e1001306, Sept 2012
Better designed POC instrument systems are not the only options being evaluated. Other considerations:

- Compatibility with policies to expand local laboratory services
- Compliance with laboratory Monitoring and Quality standards
- Addresses training, distribution, service and support capabilities
- Satisfies communications requirements

POCT must be thought of as a combination of technology solutions and business process considerations
Establish Needs and Requirements: 
A First Priority in the Product Development Process

- Verify unmet needs: The search for common requirements:
  - Who is the customer? The user?
  - What are their pain points?
  - What is the use environment? Workflows?
  - Who are the key stakeholders?
  - What changes should be anticipated during the life of the product?

Clear understanding of needs will enable drafting of appropriate requirements and specifications documents.
Halteres Market Research: Verifying Market Needs and Requirements

- Kenya, Ethiopia, South Africa and Brazil (2012-2013)
  - Visited >60 facilities; Interviewed >170 individuals
- Primary focus was on Level I laboratory settings
  - Health Centers, Community Clinics
- Also visited upstream centers (hospitals, reference labs) to better understand the referral process and infrastructure
- Spoke to clinical and laboratory staff, Ministry of Health representatives and other medical / diagnostic experts
Key Market Findings: The Case for Point of Care Testing

- Uniform desire expressed by officials and practitioners to bring primary care services closer to the patient
- Rising expectations were evident from multiple stakeholder groups:

| Policy Makers | • Leverage technology revolution  
|               | • Manage disease burden at primary care location  
|               | • Expand infrastructure  
| Clinicians    | • Add treatment decision tools  
|               | • Prevent loss to follow up  
| Laboratorians | • Improve testing services  
| Patients      | • Demand local services  
|               | • Seek better care  

Momentum is building for POCT as one solution for improving access and linkage to healthcare
IV. National Ref. Labs / Hospitals
• Esoteric and referral testing; surveillance

III. Provincial Ref. Labs / Hospitals
• Referral testing; all testing except esoteric Dx

II. District Labs / Hospitals
• Referral testing; all routine Dx supporting Level I Centers

I. Lowest Level Labs / Health Centers, Community / Municipal Clinics
• Moderate infrastructure
• Primary care only; rapid tests, some manual serology, chemistry, microscopy

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Example: Broad Menu Desired at Level I Facilities

<table>
<thead>
<tr>
<th>HIV</th>
<th>Maternal / Neonatal</th>
<th>Febrile</th>
<th>Respiratory</th>
<th>EDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>- HIV antibody</td>
<td>- Pre-eclampsia</td>
<td>- Malaria / G6PD</td>
<td>- Pneumonia</td>
<td>- Amoebiasis</td>
</tr>
<tr>
<td>- HIV CD4</td>
<td>- CBC</td>
<td>- Pneumonia</td>
<td>- Influenza</td>
<td>- Campylobacter</td>
</tr>
<tr>
<td>- HIV Viral load</td>
<td>- Glucose</td>
<td>- Dengue</td>
<td>- RSV</td>
<td>- E. Coli</td>
</tr>
<tr>
<td>- CBC</td>
<td>- Syphilis</td>
<td>- Typhoid</td>
<td>- TB Identification</td>
<td>- Shigellosis</td>
</tr>
<tr>
<td>- Liver function</td>
<td>- HPV</td>
<td>-</td>
<td>- TB MDR/XDR</td>
<td>- Cholera</td>
</tr>
<tr>
<td>- Creatinine</td>
<td>- HIV p24</td>
<td>-</td>
<td>- CBC</td>
<td>- Cryptosporidium</td>
</tr>
<tr>
<td>- TB+</td>
<td>- HIV antibody</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>- TB MDR/XDR</td>
<td>- Hepatitis</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Serum iron</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

**Neglected IDs**

- Schistosomiasis
- Leishmaniasis
- Japanese Encephalitis
- Trypanosomiasis

**Key: Diagnostic platform required to perform test**

- Cell counting
- Chemistry analysis
- NAT
- Lateral flow / Immunoassay
Introduction Menu Requires

- 4 technology types and several sample types

Technologies
- RDT Serology
- Cell Analysis
- Nucleic Acids
- Chemistry

Sample Types
- Venous blood
- Finger stick
- Sputum
- Urine

<table>
<thead>
<tr>
<th>HIV Diagnosis and ART Initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1/2 Ab rapid test</td>
</tr>
<tr>
<td>HIV CD4</td>
</tr>
<tr>
<td>TB case detection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TB Diagnosis and First Line Drug Resistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB Dx + first line Rx resistance markers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Malaria Diagnostic and Drug Susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria species determination + G6PD (genetic marker)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maternal Health (core menu varies by country)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1/2 Ab Rapid test</td>
</tr>
<tr>
<td>HIV CD4</td>
</tr>
</tbody>
</table>
Design Requirements: Site Readiness to Adopt New POCT

**Power Availability Rating**

- **best**: always have power, brief outages < 1/month, outages few times/month, lose power short periods daily, sufficient amperage
- **worst**: Power generally not avail or not

**Score includes:**
- Physical lab facilities
- Clinical staff training
- Laboratorian training
- Mobile phone signal
- Computer utilization
- Internet

**Most ready**

**Least ready**

**total tests performed per day**

- 100 - 300
- 300 - 800
- 800 - 1300

- Brazil Level 1
- Brazil Referral
- Kenya & Ethiopia Level 1
- Kenya & Ethiopia Referral
- South Africa Level 1

These facilities require improvements to power supply for successful adoption.

These facilities likely to benefit from improvements to their readiness to prepare for successful adoption.
Communications and Reporting: Fast-Paced Changes

<table>
<thead>
<tr>
<th></th>
<th>Paper Based</th>
<th>Cellular</th>
<th>Internet</th>
<th>Lab LIS</th>
<th>Pos Patient ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today</td>
<td>100%</td>
<td>80%</td>
<td>66%</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>% Survey Responses with Indicated Communications Capability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Future</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Communications capabilities must be designed to:

- Accommodate current paper-based systems and future IT-driven systems, and
- Help drive future system placements
Summary Market Research Learnings:
Requirements for a POC System at Level I Laboratories

The Key Requirements of Level I Point of Care Systems

- **System Ease of Use**
  Compatible with Level I setting / user

- **Multiple Technologies and Sample Types**
  Enables linkage to care

- **System Robustness**
  For max uptime in variable environments

- **Scalability**
  Address volume extremes, seasonality, growth

- **Implementation Support System**
  Complete set of launch support tools

- **Communications / Reporting**
  Designed to meet current and future needs

Target Product Profile (TPP)
The Message: A New Generation of POC Diagnostics is Coming

- Funding from the Bill & Melinda Gates Foundation, UNITAID, FIND, TB Alliance, PEPFAR and others is supporting advancements in POCT

- Initially the focus is on developing world menu needs, but this will quickly morph into products for everywhere
  - E.g., non-communicables; surveillance

- And will support a new ICT infrastructure to deliver information and communications to sites where they have not been available before

Delivering multiple assay technologies on new POC platforms opens the door for developers to deliver new products to drive decentralization, but ........is there a market?
### Is There a Market for POCT in the Developing World? (Systems)

<table>
<thead>
<tr>
<th>Country</th>
<th>Likely to Adopt Setting</th>
<th>Number</th>
<th>Potential Additional Sites Setting</th>
<th>Number</th>
<th>Level II Potential Additional Sites Setting</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya</td>
<td>Health Cntr</td>
<td>1,025</td>
<td>Medical Clinics</td>
<td>2,969</td>
<td>District Hosp</td>
<td>131</td>
</tr>
<tr>
<td></td>
<td>Medical Cntr</td>
<td>17</td>
<td></td>
<td></td>
<td>Subdist. Hosp</td>
<td>132</td>
</tr>
<tr>
<td>South Africa</td>
<td>Community Health Cntr</td>
<td>265</td>
<td>Primary Health Cntr</td>
<td>3,466</td>
<td>Dist. Hospitals</td>
<td>264</td>
</tr>
<tr>
<td>Brazil</td>
<td>Municipal / Health Cntr</td>
<td>33,241</td>
<td></td>
<td></td>
<td>General Hospitals</td>
<td>5,200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Polyclinics</td>
<td>6,000</td>
</tr>
<tr>
<td>India</td>
<td>Community Health Cntr</td>
<td>4,809</td>
<td>Primary Health Centers</td>
<td>23,887</td>
<td>Taluk Hospitals</td>
<td>1000's</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Private Path. Labs</td>
<td>1000's</td>
</tr>
<tr>
<td>China</td>
<td>Community Health Cntr</td>
<td>7,861</td>
<td>Community Health Stations</td>
<td>24,999</td>
<td>Tier 1 Hosp</td>
<td>5,636</td>
</tr>
<tr>
<td></td>
<td>Subdist. Health Cntr</td>
<td>667</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Township Health Cntr</td>
<td>37,295</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total All Sites**: 85,180
**Potential System Placements**: 170,360

### Potential >300,000 instrument placement in 5 key countries

Is there potential for placement in all developing and developed countries?

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Is There a Market for POCT in the Developing World? (Tests)

- Defined patient populations
- Defined test menus and assay TPPs
- Confirmed need for MM’s of tests
- Challenges: Market access and sustainability

### Solution: For-profit business model supporting public / private consortia

### HIV Testing and Monitoring Market (Test Volume 000s, Annualized)

<table>
<thead>
<tr>
<th>HIV Test</th>
<th>Period</th>
<th>South Africa</th>
<th>WHO Africa Region</th>
<th>WHO Global Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Actual</td>
<td>% on ART</td>
<td>Potential Volumes</td>
</tr>
<tr>
<td>CD4</td>
<td>2011</td>
<td>3,758</td>
<td>67%</td>
<td>15,971</td>
</tr>
<tr>
<td>Viral Load</td>
<td>2011</td>
<td>1,533</td>
<td>90%</td>
<td>5,568</td>
</tr>
<tr>
<td>EID PCR</td>
<td>2011</td>
<td>294</td>
<td>17%</td>
<td>1,068</td>
</tr>
</tbody>
</table>
Integrated models for development of diagnostics for Level I/II health settings in emerging markets are lacking in program benchmarking and guidance.

Variability Seen in Level I Environments
**Detailed Quantitative Inputs for Model:**
Enable Scenarios, Sensitivities, and Future Model Flexibility

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### Steady State / Static Market Model

#### Target Markets

<table>
<thead>
<tr>
<th>Countries / Regions</th>
<th>RSA</th>
<th>SSA</th>
<th>Brazil</th>
<th>China</th>
<th>India</th>
</tr>
</thead>
</table>

#### Health Systems

<table>
<thead>
<tr>
<th></th>
<th>Public</th>
<th>Private</th>
</tr>
</thead>
</table>

#### Health Sites

<table>
<thead>
<tr>
<th></th>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
</table>

#### Health Conditions

<table>
<thead>
<tr>
<th></th>
<th>HIV AIDS</th>
<th>Maternal Health</th>
<th>Tuberculosis</th>
<th>Malaria</th>
</tr>
</thead>
</table>

#### Product Offerings

<table>
<thead>
<tr>
<th></th>
<th>Modules / Bays</th>
<th>Up-time</th>
<th>% Utilization</th>
<th>Expected Life</th>
<th>COGS</th>
</tr>
</thead>
</table>

#### Panels

<table>
<thead>
<tr>
<th></th>
<th>Test Menu</th>
<th>Assay Types</th>
<th>Run-times</th>
<th>COGS</th>
</tr>
</thead>
</table>

#### Services

<table>
<thead>
<tr>
<th></th>
<th>Maintenance</th>
<th>Service/Support</th>
<th>Training</th>
</tr>
</thead>
</table>

#### Market Delivery

<table>
<thead>
<tr>
<th></th>
<th>Supply Chain</th>
<th>1 vs. Many Mfrs</th>
<th>Components Mark-ups</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Distribution Channel</th>
<th>Government Distributor</th>
<th>NGO</th>
<th>Direct</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Pricing</th>
<th>Products</th>
<th>Public</th>
<th>Private (Multiplier)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Market Share</th>
<th>Products</th>
<th>Public &amp; Private</th>
<th>Tender/Competitive</th>
</tr>
</thead>
</table>

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Additional Food for Thought: Companies Will Think More Broadly Than Infectious Diseases: Significant Upside Opportunity

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose Monitoring</td>
<td>7,760</td>
<td>7,650</td>
<td>7,503</td>
<td>7,600</td>
<td>0.3</td>
<td>46.0</td>
</tr>
<tr>
<td>Blood Chemistry and Electrolytes</td>
<td>2,185</td>
<td>2,210</td>
<td>2,251</td>
<td>2,850</td>
<td>4.8</td>
<td>17.2</td>
</tr>
<tr>
<td>Cardiac Markers</td>
<td>619</td>
<td>802</td>
<td>1,025</td>
<td>2,010</td>
<td>14.4</td>
<td>12.2</td>
</tr>
<tr>
<td>Pregnancy and Fertility</td>
<td>793</td>
<td>815</td>
<td>851</td>
<td>1,050</td>
<td>4.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Drug and Alcohol</td>
<td>503</td>
<td>490</td>
<td>498</td>
<td>565</td>
<td>2.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Infectious Disease</td>
<td>391</td>
<td>284</td>
<td>412</td>
<td>687</td>
<td>10.8</td>
<td>4.2</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>367</td>
<td>372</td>
<td>387</td>
<td>470</td>
<td>4.0</td>
<td>2.8</td>
</tr>
<tr>
<td>Hemoglobin / Hemostasis</td>
<td>360</td>
<td>375</td>
<td>409</td>
<td>585</td>
<td>7.4</td>
<td>3.5</td>
</tr>
<tr>
<td>Tumor Marker</td>
<td>196</td>
<td>203</td>
<td>215</td>
<td>350</td>
<td>10.2</td>
<td>2.1</td>
</tr>
<tr>
<td>Urine Chemistry</td>
<td>215</td>
<td>233</td>
<td>258</td>
<td>370</td>
<td>7.5</td>
<td>2.2</td>
</tr>
<tr>
<td>Total</td>
<td>13,389</td>
<td>13,434</td>
<td>13,809</td>
<td>16,537</td>
<td>3.7</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Worldwide POC Market Share (2011)

<table>
<thead>
<tr>
<th>Region</th>
<th>%</th>
<th>$M</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>55.1</td>
<td>7,605</td>
</tr>
<tr>
<td>Europe</td>
<td>29.7</td>
<td>4,095</td>
</tr>
<tr>
<td>Asia</td>
<td>11.8</td>
<td>1,633</td>
</tr>
<tr>
<td>ROW</td>
<td>3.4</td>
<td>476</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>13,809</td>
</tr>
</tbody>
</table>

- Infectious Disease testing represents small but fast growing % of overall market
- Modeling shows significant ROW market upside potential (Level II-III, menu expansion, etc)
- Likely large opportunity in developed markets

* Source: BCC Research 2012
A Case for POCT in Developed Markets
“We’ve been hearing this for years - what’s different?”

- New POC technologies combined with improved business models will drive decentralization of testing

- POCT will support business models of new players:
  - Retail-Based Convenience Care (ObamaCare)
    - RediClinic / Wal-Mart
    - MinuteClinic / CVS
    - Healthcare Clinic / Walgreens
  - Multi-practice Clinics
    - Texas Health Group
  - Large Self Insured Employers
  - High Tech companies looking at devices for health, fitness and lifestyle management
    - Apple Healthbook and Passbook software

- Access to test results at the site of the treatment decision: more judicious use of Rx
  - E.g., antimicrobial drugs
Example: Urgent Care Clinics/Centers could be a major disrupter

- A 2010 Rand study stated that 20% of hospital emergency room visits could be treated at urgent care centers (UCCs)
- According to the Urgent Care Association of America:
  - An estimated 3 million patients per week visit UCCs
  - There are now as many as 10,000 UCCs in the US
- Growth should accelerate in 2014 when the Affordable Care Act adds 30 million Americans, many without doctors, to the health care system
- Hospitals are responding; Dignity Health, the fifth-largest hospital system in the US, bought U.S. HealthWorks, the second-largest urgent care chain (2012)
- Routine testing is conducted-- simple blood, urine and drug test
  - Additional opportunities to expand are under investigation
Other Developed Market Trends Likely to Impact POCT Adoption

- Opportunities for Cost Savings
  - Elimination of cold chain
  - Improved communications (source of inefficiencies and errors)
  - Less skilled / fewer employees running tests will increase profitability

- Interest from non-traditional sectors:
  - Disaster response / homeland security
  - High Technology and Silicon Devices: (e.g., Cisco, Intel, Apple)
  - Bus Models & Information: (e.g., Microsoft, Google)
  - Big Data: (e.g., GE, McKesson)

www.healthmap.org
The New World of Decentralized Diagnostics – Considerations

- Increased need for **Point of Impact** testing
  - Smaller labs and clinics (UCCs)
  - Both OTC and prescription drugs
  - Counseling and pharmacy services
  - Efficacy and adverse effects monitoring

- New players will bring new business models
  - “Test and shop” in Wal-Mart: pull through selling
  - “Pay for care” rapid clinics: convenience

- Big Dx manufacturers will see some erosion of their traditional business

- New POC manufacturers will see major new business opportunities
  - Rapid growth
  - Large global markets

It’s the cell phone market all over again…how will such disruptive change manifest itself in diagnostics?
Conclusion: Yes - Market Research Supports POCT Hypothesis

- Emerging Markets - Increasing adoption of POCT is being driven by:
  - Funding availability
  - Policy changes encouraging the re-allocation of health care dollars to improve impact at primary care
  - Rapid advancements in technology and infrastructure
  - Rising consumer expectations: improved healthcare access

- Developed Markets - Bright outlook aided by:
  - Parallel changes in healthcare policies (e.g., Affordable Care Act)
  - Disrupted access to testing and services (e.g., Urgent Care Clinics, Multi-Practice Clinics)
  - Advancements in other technologies (e.g., consumer digital health and wellness devices and social trends)

Hypothesis Supported: Advancements in POCT for developing markets will concurrently drive testing decentralization in developed markets