CATALYSIS
FOUNDATION FOR HEALTH

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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POCT Advancements in Developing Markets Will Help to Drive Disruptive Change in Developed Markets

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

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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

Variability Seen in Level I Environments

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[1]"

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

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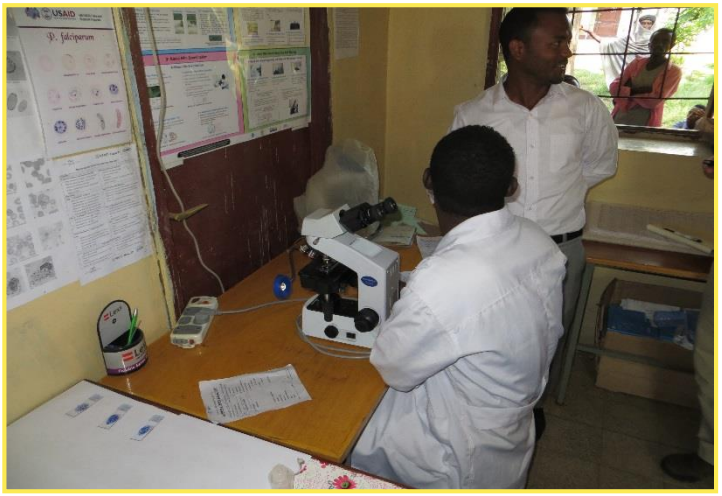
Point of Care Testing – More Than Just a Technology Solution

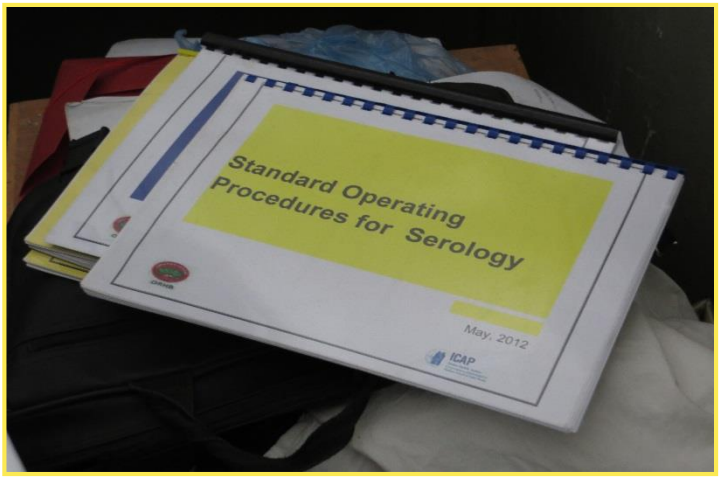
Better designed POC instrument systems are not the only options being evaluated. Other considerations:

- 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



Koladeba HC, Northern Ethiopia
Bushofitu HC, Ethiopia



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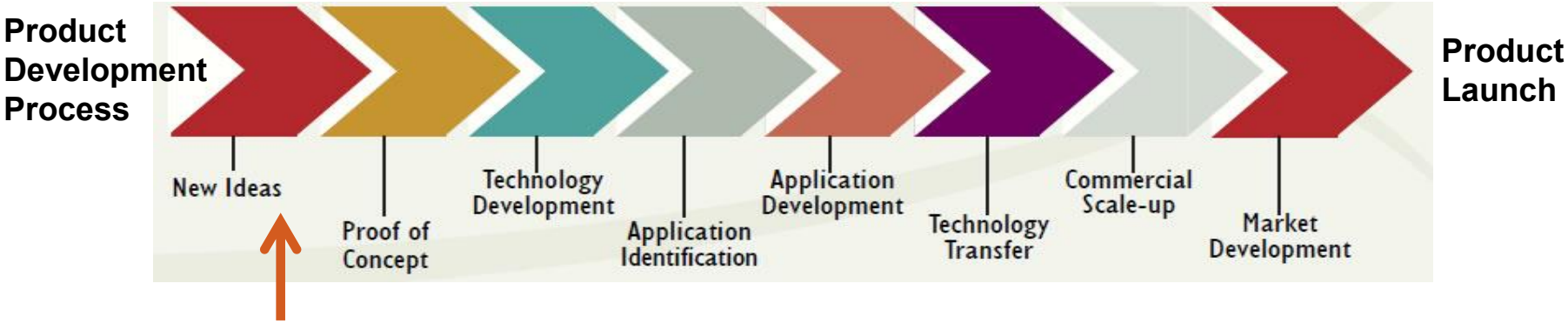
Establish Needs and Requirements: A First Priority in the Product Development Process



- 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

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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

Brazil

Ethiopia

South Africa

Kenya

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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

Primary Care Reception Policlinico Helio Pellegrino - Rio de Janeiro, Brazil

Momentum is building for POCT as one solution for improving access and linkage to healthcare

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Laboratory System Profiles: Level I is the Target Setting

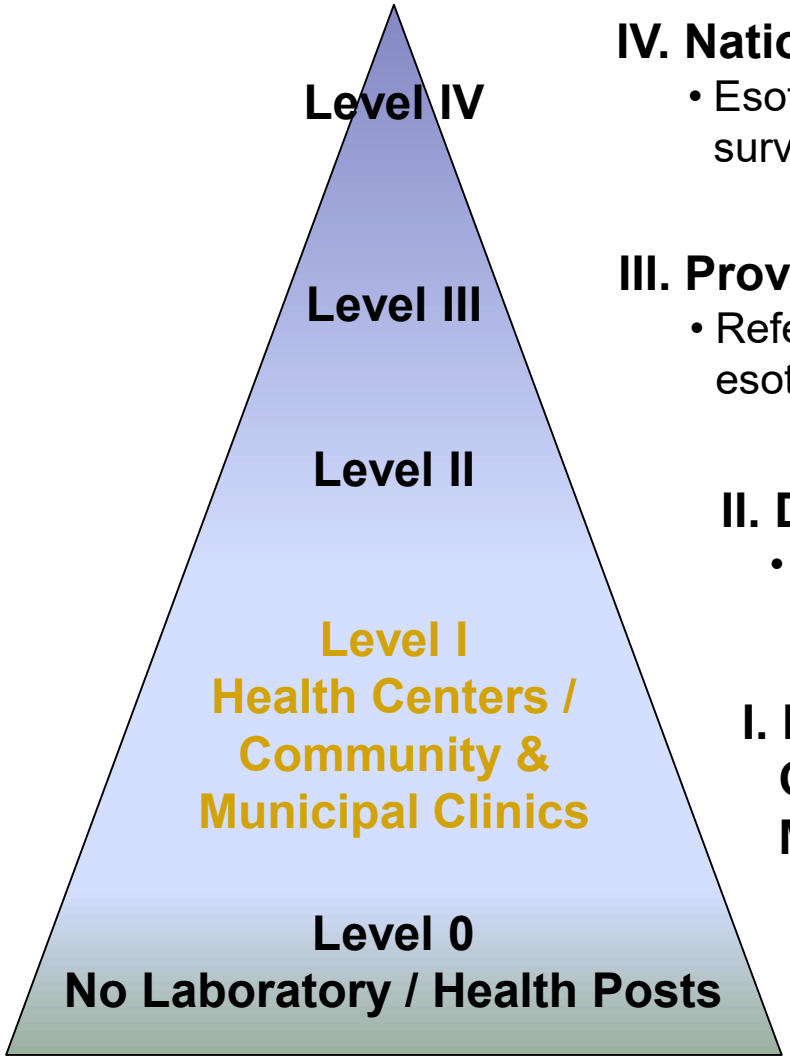
IV

III

II

I

0



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

Example: Broad Menu Desired at Level I Facilities

HIV

- HIV antibody
- HIV CD4
- HIV Viral load
- CBC
- Liver function
- Creatinine
- TB+
- TB MDR/XDR

Maternal / Neonatal

- Pre-eclampsia
- CBC
- Glucose
- Syphilis
- HPV
- HIV p24
- HIV antibody
- Hepatitis
- Serum iron

Febrile

- Malaria / G6PD
- Pneumonia
- Dengue
- Typhoid

Respiratory

- Pneumonia
- Influenza
- RSV
- TB Identification
- TB MDR/XDR
- CBC

EDD

- Amoebiasis
- Campylobacter
- E. Coli
- Shigellosis
- Cholera
- Cryptosporidium

Neglected IDs

- Schistosomiasis
- Leishmaniasis
- Japanese Encephalitis
- Trypanosomiasis

Key: Diagnostic platform required to perform test

Cell counting | Chemistry analysis | NAT | Lateral flow / Immunoassay

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Sample High Impact Test Menu for Level I Health Centers

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

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

HIV Diagnosis and ART Initiation		
HIV 1/2 Ab rapid test	Kidney function panel	CBC
HIV CD4	Liver function panel	
TB case detection	HIV viral load	
TB Diagnosis and First Line Drug Resistance		
TB Dx + first line Rx resistance markers		
Malaria Diagnostic and Drug Susceptibility		
Malaria species determination + G6PD (genetic marker)		
Maternal Health (core menu varies by country)		
HIV 1/2 Ab Rapid test	CBC w Hematocrit	Syphilis
HIV CD4	Malaria RDT	Glucose

Introduction Menu Requires

- ❑ 4 technology types and several sample types

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Design Requirements: Site Readiness to Adopt New POCT

Readiness to adopt New POC Platform

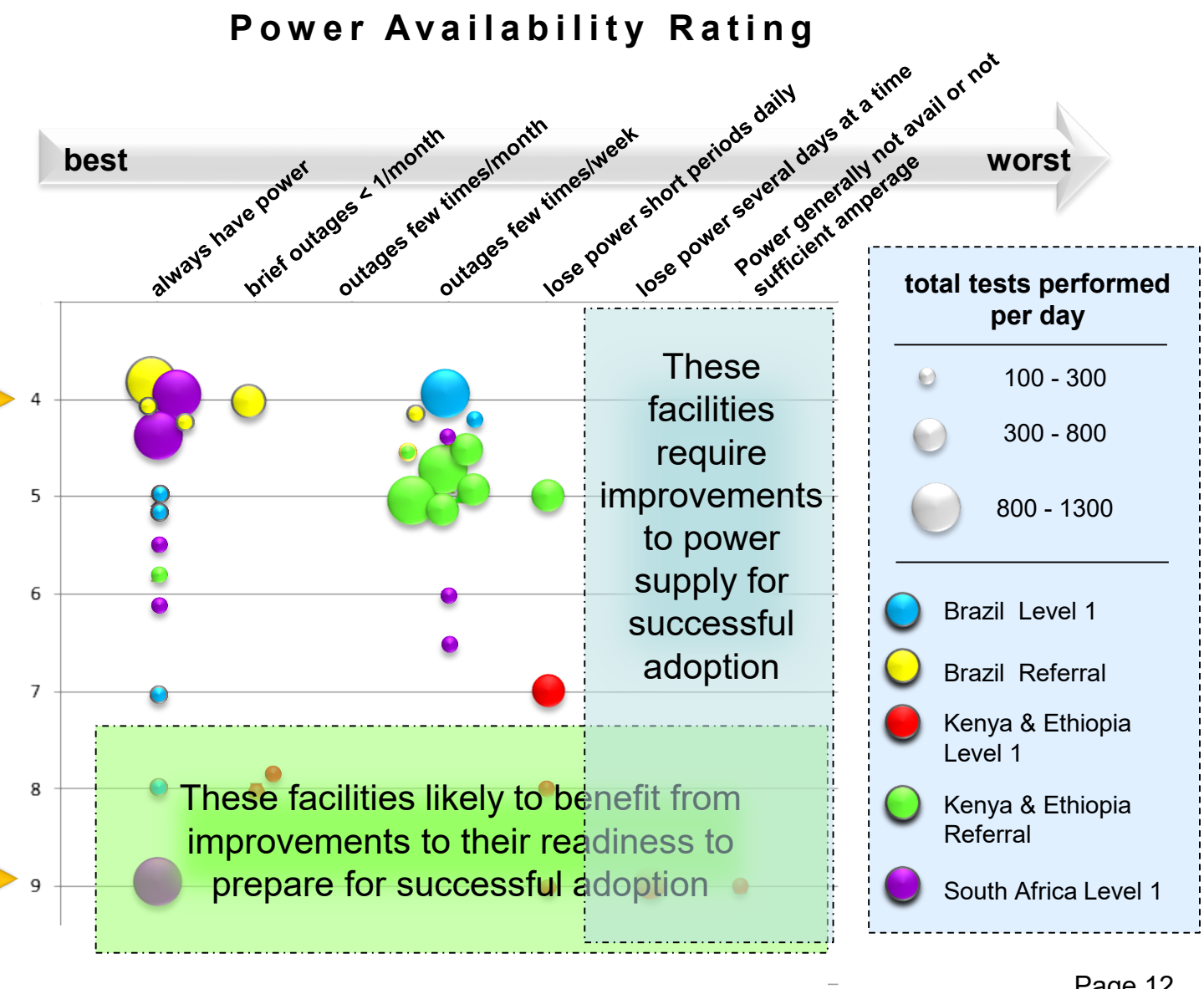
as estimated from an infrastructure score

most ready

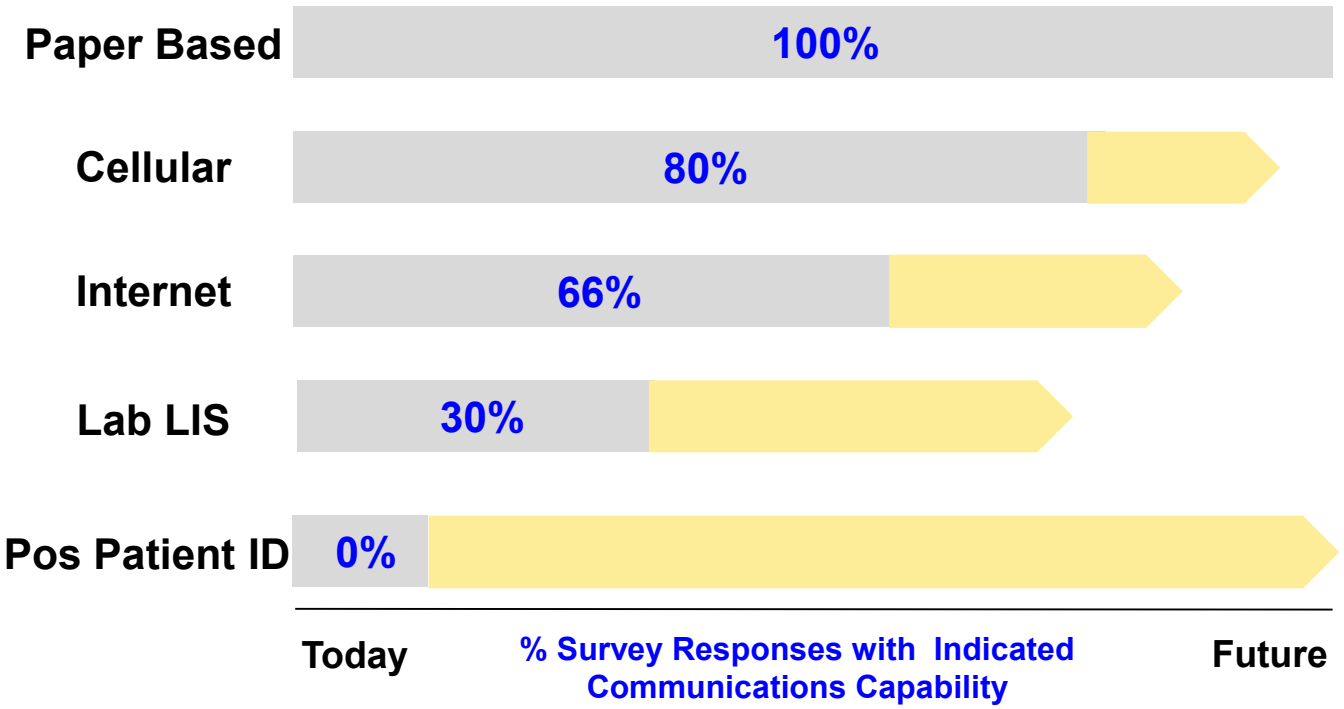
Score includes:

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

least ready



Communications and Reporting: Fast-Paced Changes



Communications capabilities must be designed to:

- ❑ Accommodate current paper-based systems and future IT-driven systems, and
- ❑ Help drive future system placements

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Summary Market Research Learnings: Requirements for a POC System at Level I Laboratories

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 Key Requirements of Level I Point of Care Systems

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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

USAID-sponsored VCT Center, Matayos Health Center, Busia, Kenya

Sponsoring Agencies – Bushofitu Hosp / ART Clinic, Ethiopia

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?

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

	Level 1				Level II	
	Likely to Adopt		Potential Additional Sites		Potential Additional Sites	
Country	Setting	Number	Setting	Number	Setting	Number
Kenya	**Health Cntr**	**1,025**	Medical Clinics	2,969	District Hosp	131
	Medical Cntr	**17**			Subdist. Hosp	132
					Other Hosp	233
					Nursing Homes	187
					Maternity Homes	47
South Africa	**Community Health Cntr**	**265**	Primary Health Cntr	3,466	Dist. Hospitals	264
Brazil	**Municipal / Health Cntr**	**33,241**			General Hospitals	5,200
					Polyclinics	6,000
India	**Community Health Cntr**	**4,809**	Primary Health Centers	23,887	Taluk Hospitals	1000's
					Private Path. Labs	1000's
China	**Community Health Cntr**	**7,861**	Community Health Stations	24,999	Tier 1 Hosp	5,636
	Subdist. Health Cntr	**667**				
	Township Health Cntr	**37,295**				
Total All Sites		**85,180**		**55,321**		**>17,830**
Potential System Placements		**170,360**		**110,642**		**>35,660**

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

Target	Period	South Africa	% of Global	WHO African Region	% of Global	WHO Global Statistics	% of Global
Population							
Total Pop. (000s)	2011	50.5	0.7%	857,382	12.4%	6,941,907	100.0%
Urban %	2011	62%		38%		52%	
HIV							
Prevalence (000s)	**2011**	**5,600**	**16.5%**	**23,800**	**70.0%**	**34,000**	**100.0%**
Incidence (000s)	**2011**	**378**	**15.1%**	**1,837**	**73.5%**	**2,500**	**100.0%**
Malaria							
Prevalence (000s)	2010	18	0.0%	179,304	63.3%	283,369	100.0%
Incidence (000s)	2011	10		20,168		23,826	100.0%
Tuberculosis							
Prevalence (000s)	2011	501	5.8%	2,246	25.9%	8,677	100.0%
Incidence (000s)	2011	344	6.0%	1,367	23.7%	5,772	100.0%
Maternal Health							
Live Births (000s)	2011	1,065	0.6%	32,581	19.3%	168,688	100.0%

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

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

		South Africa		WHO Africa Region	WHO Global Statistics
HIV Test	Period	Actual	% on ART	Potential Volumes	Potential Volumes
CD4	2011	3,758	67%	15,971	22,816
Viral Load	2011	1,533	90%	5,568	7,298
EID PCR	2011	294	17%	1,068	1,399

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The Missing Piece: A Sustainable Business Model
Why is This Approach Unique?

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

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Detailed Quantitative Inputs for Model: Enable Scenarios, Sensitivities, and Future Model Flexibility

Steady State / Static Market Model

Target Markets

Countries / Regions	RSA, China, SSA, India, Brazil
Health Systems	Public, Private
Health Sites	Level 1, Level 2
Health Conditions	HIV AIDS, Maternal Health, Tuberculosis, Malaria

Product Offerings

Instrument	Modules / Bays, Up-time, % Utilization, Expected Life, COGS
Panels	Test Menu, Assay Types, Run-times, COGS
Services	Maintenance, Service/Support, Training

Market Delivery

Supply Chain	1 vs. Many Mfrs, Components, Mark-ups
Distribution Channel	Government, Distributor, NGO, Direct
Pricing	Products, Public, Private (Multiplier)
Market Share	Products, Public & Private, Tender/Competitive

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

Worldwide POC Market						
Segment	2009	2010	2011	2016	CAGR% 2011-2016	% of Market (2016)
Glucose Monitoring	7,760	7,650	7,503	7,600	0.3	46.0
Blood Chemistry and Electrolytes	2,185	2,210	2,251	2,850	4.8	17.2
Cardiac Markers	619	802	1,025	2,010	14.4	12.2
Pregnancy and Fertility	793	815	851	1,050	4.3	6.3
Drug and Alcohol	503	490	498	565	2.6	3.4
Infectious Disease	391	284	412	687	10.8	4.2
Cholesterol	367	372	387	470	4.0	2.8
Hemoglobin / Hemostasis	360	375	409	585	7.4	3.5
Tumor Marker	196	203	215	350	10.2	2.1
Urine Chemistry	215	233	258	370	7.5	2.2
Total	13,389	13,434	13,809	16,537	3.7	100.0

Worldwide POC Market Share (2011)		
	Estimated Market Size	
Region	%	$M
North America	55.1	7,605
Europe	29.7	4,095
Asia	11.8	1,633
ROW	3.4	476
Total	100	13,809

- 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

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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

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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

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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?

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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

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