



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*

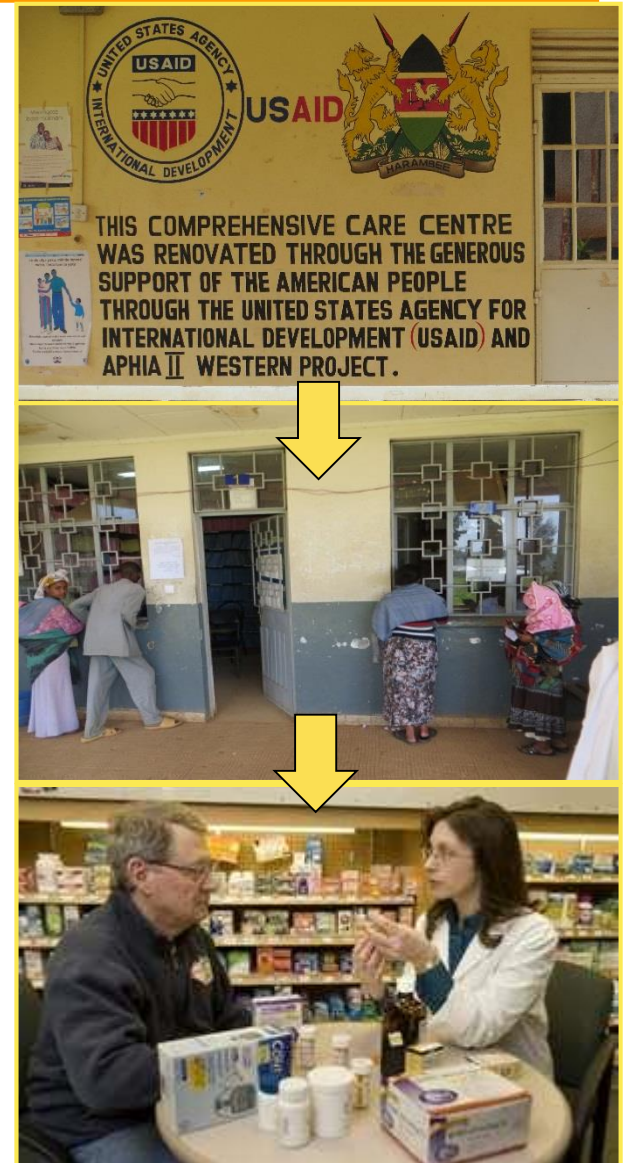
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POCT Advancements in Developing Markets Will Help to Drive Disruptive Change in Developed Markets

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



The Testing Situation Today In Resource Limited Settings

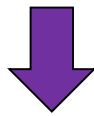
- ❑ Health care workers in resource-limited settings lack access to rapid diagnostic test results to make treatment decisions during the clinical visit
- ❑ Only an estimated 45% of those who need testing in sub-Saharan Africa get it
- ❑ Many persons who are tested do not return to the clinic (lost to 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 encounter¹”



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

Point of Care Testing – More Than Just a Technology Solution

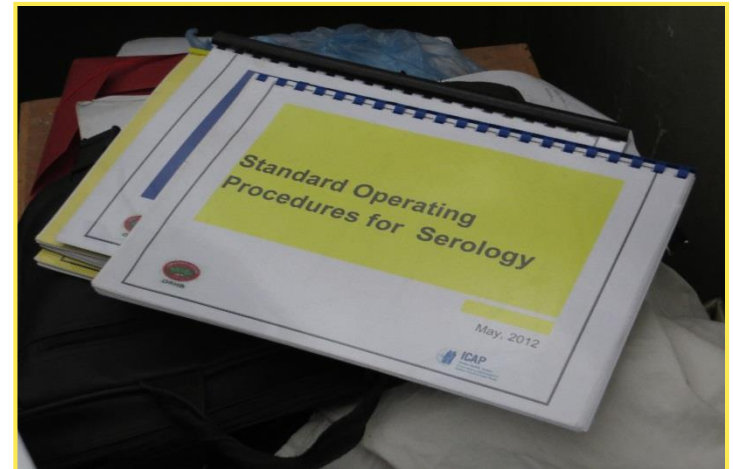
Better designed POC instrument systems are not the only options being evaluated. Other considerations:

- 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

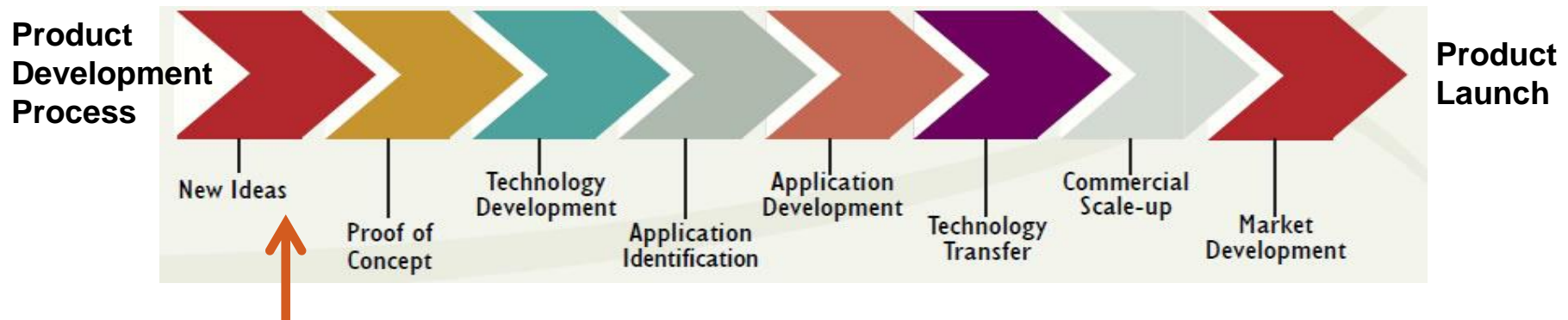
POCT must be thought of as a combination of technology solutions and business process considerations



Koladeba HC, Northern Ethiopia
Bushofitu HC, Ethiopia



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



Brazil



Ethiopia



South Africa



Kenya

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:

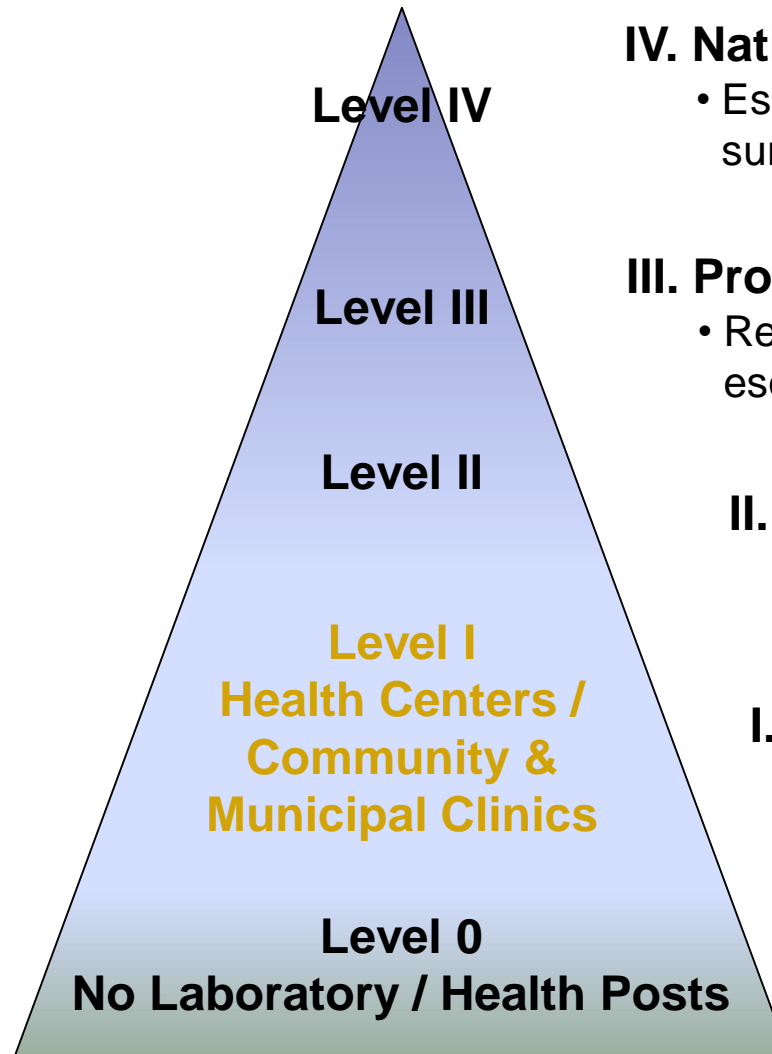
Policy Makers	<ul style="list-style-type: none">• Leverage technology revolution• Manage disease burden at primary care location• Expand infrastructure
Clinicians	<ul style="list-style-type: none">• Add treatment decision tools• Prevent loss to follow up
Laboratorians	<ul style="list-style-type: none">• Improve testing services
Patients	<ul style="list-style-type: none">• Demand local services• Seek better care



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

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

Laboratory System Profiles: Level I is the Target Setting



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	Maternal / Neonatal	Febrile	Respiratory	EDD
<ul style="list-style-type: none"> ● HIV antibody ● HIV CD4 ● HIV Viral load ● CBC ● Liver function ● Creatinine ● TB+ ● TB MDR/XDR 	<ul style="list-style-type: none"> ● Pre-eclampsia ● CBC ● Glucose ● Syphilis ● HPV ● HIV p24 ● HIV antibody ● Hepatitis ● Serum iron 	<ul style="list-style-type: none"> ● Malaria / G6PD ● Pneumonia ● Dengue ● Typhoid 	<ul style="list-style-type: none"> ● Pneumonia ● Influenza ● RSV ● TB Identification ● TB MDR/XDR ● CBC 	<ul style="list-style-type: none"> ● Amoebiasis ● Campylobacter ● E. Coli ● Shigellosis ● Cholera ● Cryptosporidium
<h2>Neglected IDs</h2> <ul style="list-style-type: none"> ● Schistosomiasis ● Leishmaniasis ● Japanese Encephalitis ● Trypanosomiasis 				

Key: Diagnostic platform required to perform test

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

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



Design Requirements: Site Readiness to Adopt New POCT

Readiness to adopt New POC Platform

as estimated from an infrastructure score

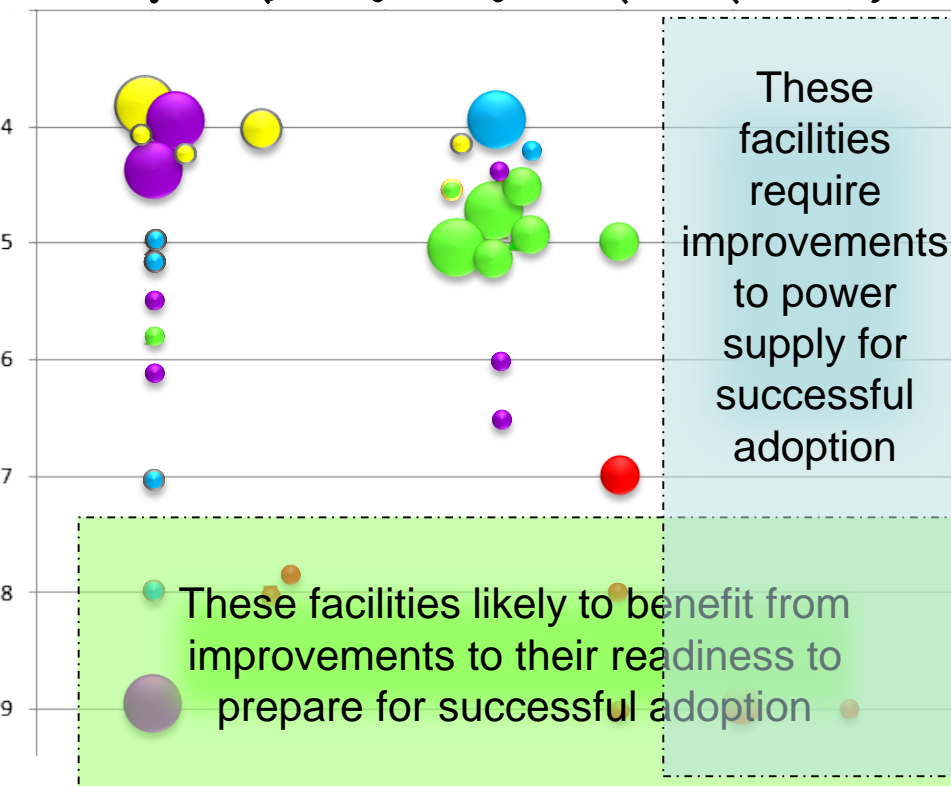
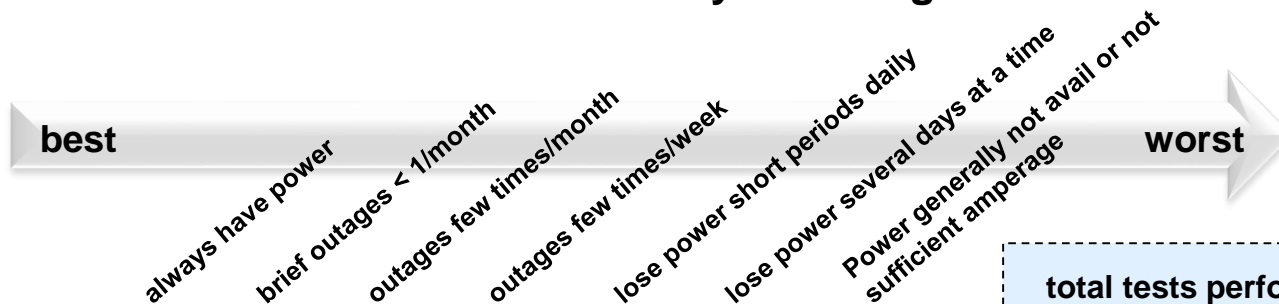
most ready

Score includes:

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

least ready

Power Availability Rating



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

Communications and Reporting: Fast-Paced Changes



Paper Based

100%

Cellular

80%

Internet

66%

Lab LIS

30%

Pos Patient ID

0%

Today

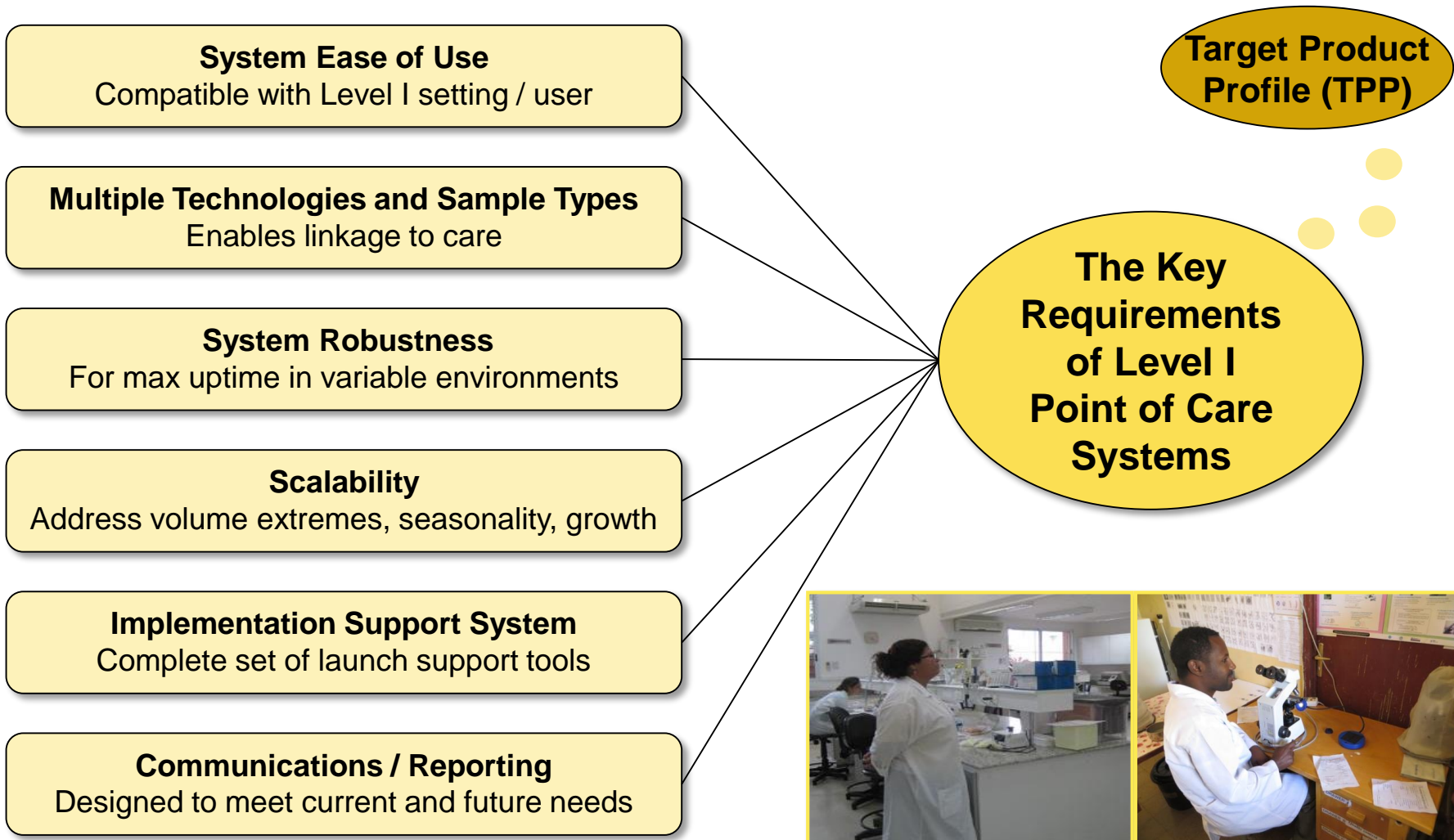
**% Survey Responses with Indicated
Communications Capability**

Future

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 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

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?



**Sponsoring Agencies –
Bushofitu Hosp / ART
Clinic, Ethiopia**

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?

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)						
HIV Test	Period	South Africa		WHO Africa Region	WHO Global Statistics	
		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	

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



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

Steady State / Static Market Model

Target Markets

Countries / Regions	RSA SSA Brazil	China India
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

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

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:

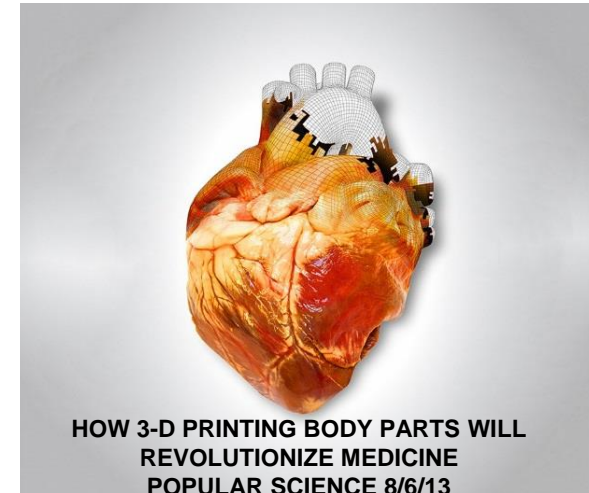
- Disaster response / homeland security
- High Technology and Silicon Devices:
(e.g., Cisco, Intel, Apple)
- Bus Models & Information:
(e.g., Microsoft, Google)
- Big Data:
(e.g., GE, McKesson)



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



DIAGNOSTIC APPLICATIONS?

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

