

Enabling POC Diagnostics through Standard Setting

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Agenda

- **Point of Care Initiative**
- **Standards Activities**
 - **Product**
 - **Interface**
 - **Regulatory**
 - **Business**

Point-of-Care Diagnostics Initiative

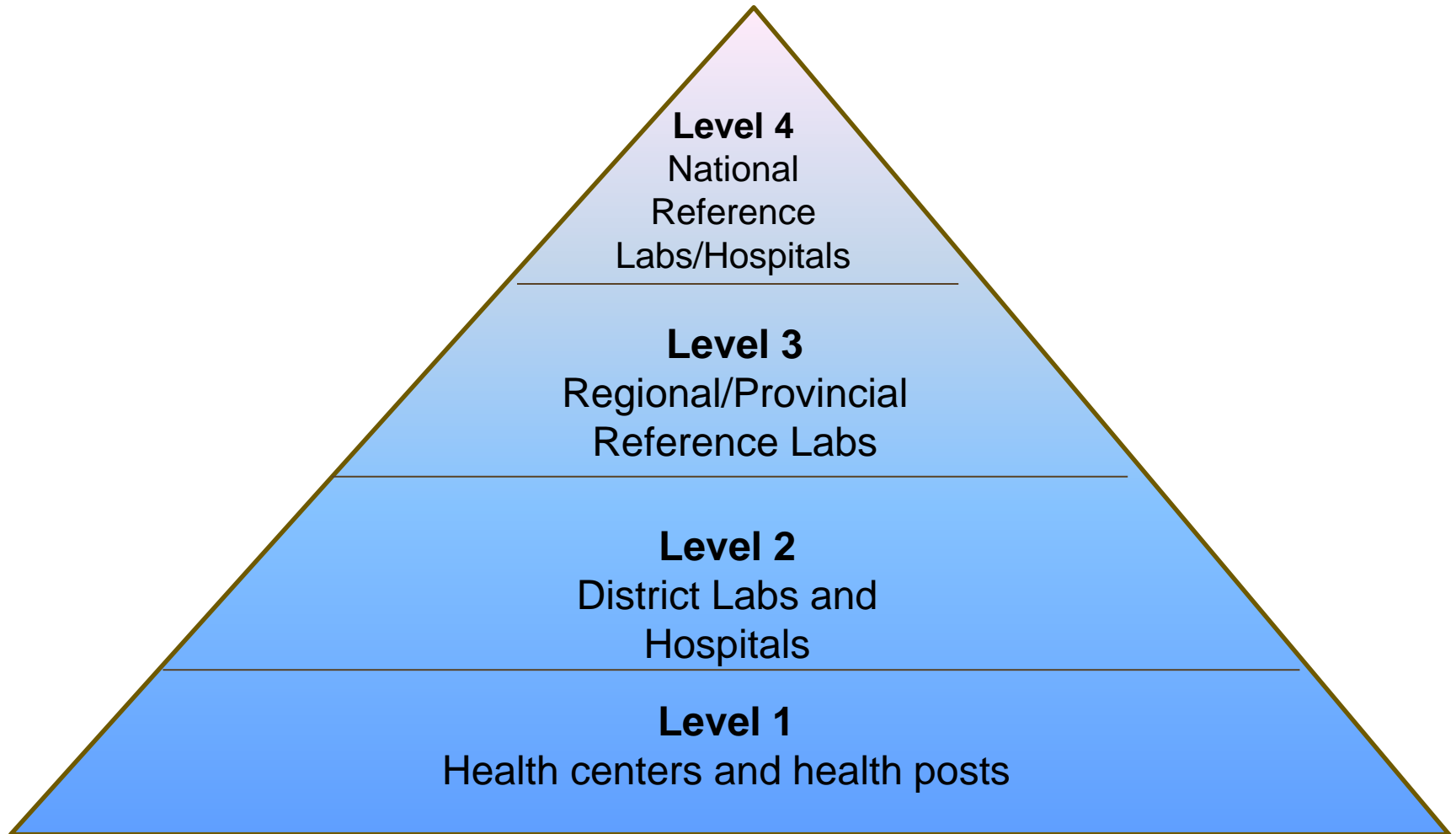


What is Point-of-Care (POC)?

- **Point-of-Care Testing:**

Testing that is performed near or at the site of patient care with the result leading to possible change in the course of care of the patient. Testing that is performed outside a central laboratory environment, generally nearer to, or at the site of the patient. Also referred to as “near-patient” testing, or “point-of-need testing.

Defining the Target Use Setting



Access to a New Diagnostic Depends on the Level of Infrastructure Available

Advanced/
Moderate

Minimal

None



- Hospitals and urban clinics
- Electricity, clean water, well-equipped laboratories, trained clinicians

- Health clinics (Africa), rural clinics (Asia, Latin America)
- No reliable electricity or clean water, no laboratory, minimal expertise

- Village or community
- No electricity, clean water, physical infrastructure, or trained staff



How POC platforms can increase access to diagnostics...

Access to Care by Infrastructure Category*			
Region	Access to no infrastructure	Access to minimal infrastructure	Access to moderate/advanced infrastructure
Africa	25%	47%	28%
Asia	13%	29%	58%

Potential Coverage 28% - 58%

Current - Diagnostic Tools

Potential Coverage 75% - 87%

Mid Term Goal - POC Platform with Moderate Impact

Potential Coverage 87% - 93%

Far Term Goal - POC Platform with Significant Impact

POC Dx RFP Timeline

Grand Challenges
in Global Health



Grand Challenges Canada™
Grands Défis Canada™

BOLD IDEAS FOR HUMANITY.™

- **GCGH Diagnostics RFP Announced: 12/1/2009**
- **GCGH Diagnostics LOIs due: 2/16/2010**
 - 700+ LOIs submitted
- **Date LOIs were selected: 4/30/2010**
 - ~60 LOIs invited to submit full proposals
- **Proposals were due: 7/19/2010**
- **Awards made Q2 2011**
- **GCC Diagnostics RFP Announced: 5/3/2010**
- **GCC Diagnostics LOIs due: 7/12/2010**
 - 200+ LOIs submitted
- **Date LOIs were selected: 8/30/2010**
 - 24 LOIs invited to submit full proposals
- **Proposals were due: 11/30/2010**
- **Awards made Q2 2011**

POC Dx Initiative Goals

- **Develop an open point of care instrument platform capable of delivering optimum performance**
- **Establish interoperability standards to encourage menu expansion by competing companies/sources**
- **Reduce barriers to entry into the GH markets by eliminating the need for expensive instrument development**
- **Achieve a harmonized regulatory environment**

Diagnostics Platform Standards Initiative

Grand Challenges in Global Health



1: Sample Collection & Preparation

2. Molecular Recognition & Detection

3. Signal Transduction & Readout

4. Enabling technologies for diagnostics

5. Implementation research



Technology Investments



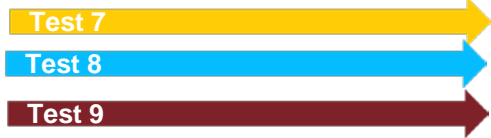
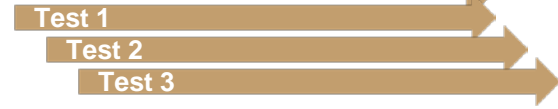
Standards Go/NoGo

Prototype & Test Development

System Integrator I



System Integrator II



Science and Technical Advisory Group (STAG)
Standards Setting Activity

Phase 1 (3 yr)
Sub-components

Phase 2 (3 yr)
Integration

Global Health Challenges

- **Delivery**
 - Poorly defined Target Product Profiles
 - Limited product menu
 - Understanding of what tests are needed
- **Technical**
 - Interoperability
 - Technology requirements
- **Regulatory**
 - Inefficient regulatory systems
- **Business**
 - Poor ROI's
 - FTO requires significant royalty stacking
 - Lack of efficient distribution channels in developing world
 - Unclear funding structure

POC Dx Initiative

Our Hypothesis

- An effective, agreed upon set of standards would have a transformative impact on the performance, health impact and costs of Point of Care Diagnostics
- These standards might include: technical, interface, product performance, quality, logistics, business, IP,
- These standards would need to be supported by an appropriate regulatory and business regime

Evolution of Standards Nomenclature

- **Standards Nomenclature**
 - **Platform/System Related:**
 - **Product/Assay Standards**
 - **Interface/Instrument Standards**

 - **Market Related:**
 - **Regulatory Standards**
 - **Business Standards**

Product Standards

- **Target Product Profiles**
- **Target Menu**
- **Throughput & Turn Around Time (TAT)**
- **Human Factors - Ease of Use**
- **Reagent/Assay Stability**
- **Instrument Robustness/Durability (MTBF)**
- **Quality Assurance and Quality Control**
- **Data Management**
- **Biosafety**

Interface Standards

- **Define the physical interface parameters**
- **Define the instrument performance requirements**
- **Determine power allocation/location**
- **Provide maximum flexibility for assay/technology innovation**
- **Enable use of a wide range of divergent technologies**
- **Encourage/Attract private industry to leverage the open platform**

Instrument Concepts

Concept 1: Full Service Processor



Concept 2: Stand-Alone Dedicated Processors



Concept 3: Handheld Devices



Regulatory Standards

- **Establish Globally Harmonized Standards – Implemented Locally/Regionally**
- **Develop Regional Capacity and Processes**

What goals do we have for a high-performing regulatory and quality assurance system?

Overall objective

Increase the supply of affordable, quality-assured diagnostic products

Goals

- 1** Avoid harm from low-quality Dx
 - Limit use of low-quality diagnostics in developing markets**
 - Improve appropriate use of resources
 - Protect against harm from inaccurate diagnosis
- 2** Insure fast, efficient, affordable process
 - Minimize barriers for good diagnostics**
 - Reflect agreed upon standards set by the larger stakeholder community
 - Regulatory body operates quickly, efficiently, and cost-effectively
- 3** Guide product development
 - Provide guidance/feedback to manufacturers for good products**
 - Characteristics of good products and appropriate burden of proof
 - Incentives/ motivations aligned with product value
- 4** Inform procurement
 - Provide actionable information to procurers about quality and performance of diagnostic tests**
- 5** Provide for sustainability
 - Designed to move toward long-term sustainability**
 - Appropriate matching of cost and value for each player in the system
 - Encourages engagement from LMIC manufacturers and NRAs

What standards are needed to achieve our goals?

- Risk-based classification – ~3 tiers
- Quick process – 30-90 days
- Common technical document accepted by all authorities
- Evidence of performance accuracy – risk-based, ranging from:
 - Lab-based evaluation by certified third-party lab
 - 2-3 well-designed and powered clinical trials / demonstration studies in diverse populations / geographies
- Mutually recognized site inspection criteria
 - Likely according to ISO 13485 standard
- Quality testing – risk-based, ranging from lot release testing to periodic product testing
- Marketing and advertising controls on claims
- System for post-market validation (at site of use), reporting, and notification
- Legal framework for enforcement of corrections and recalls

Need a system that can implement these standards through a process that is globally harmonized and recognized

Business Standards

- **Establish Innovative Business Models**
 - Delivery Logistics
 - Instrument Service
- **Establish a Royalty Free Environment**
- **Avoid Royalty Stacking**
- **Create Access to a Reasonable Return on Investment**
- **Establish Reliable Revenue Structure**

Industry Partnerships

- **Goal:** to improve the investment proposition of global health for for-profits and thereby increase the value of their contributions
- **Approach:** Mitigate risks, increase rewards and incentives, improve the policy environment

Private companies are critical and integral to the success of each of our strategies to achieve their goals

Thank You

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