# Round Table 12:
# Ensuring the Quality of Point of Care Testing:
# Need for Innovative Approaches

"Current Strategies and Updates on Evaluation of New POCT for HIV and CD4"

ASLM2014
December 3, 2014
Cape Town, South Africa

CLINTON
HEALTH ACCESS
INITIATIVE

# Agenda

**Past Experience with POC Evaluations**

Strategies for Accelerated POC Product Approvals

Update on Recent POC Evaluations

Future POC Evaluation Plans

Other Aspects of Quality

# Alere™ Pima was the first POC CD4 diagnostic to gain widespread uptake

- Commercially available in Q4 2009
- CE marked in Q4 2009
- First independent evaluations in Q1 2010
- WHO pre-qualified in Q4 2011

# Several Pima evaluations were conducted all over the world

Basic and Translational Science

## Evaluation of the PIMA Point-of-Care CD4 Analyzer in VCT Clinics in Zimbabwe

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**Abstract:** Point-of-care (POC) CD4 testing was implemented at a stand-alone HIV voluntary testing and counseling centre in Harare, Zimbabwe. To validate the use of this new technology, paired blood samples were collected from 165 patients either by a nurse or a laboratory technician and tested using POC and conventional laboratory CD4 machines. Finger prick (capillary) blood was collected directly into the PIMA POC CD4 Analyzer cartridges and tested immediately, whereas venous blood collected into evacuated tubes was used for CD4 enumeration on a Becton Dickinson FACSCalibur. There was no significant difference in mean absolute CD4 counts between the POC PIMA and Becton Dickinson FACSCalibur platforms (+7.6 cells/μL; $P = 0.72$). Additionally, there was no significant difference in CD4 counts between the platforms when run by either a nurse (+18.0 cells/μL; $P = 0.49$), or a laboratory technicians (−3.1 cells/μL; $P = 0.93$). This study demonstrates that POC CD4 testing can be conducted in a voluntary testing and counseling setting for staging HIV-positive clients. Both nurses and laboratory technicians performed the test accurately, thereby increasing the human resources available for POC CD4 testing. By producing same-day results, POC CD4 facilitates immediate decision-making, patient management and referral and may help improve patient care and retention. POC CD4 may also alleviate testing burdens at traditional central CD4 laboratories, hence improving test access in both rural and urban environments.

**Key Words:** CD4, HIV, diagnosis, client-initiated testing, laboratory, PIMA, point-of-care, voluntary counseling and testing, VCT

(*J Acquir Immune Defic Syndr* 2010;00:000–000)

### BACKGROUND

CD4 T-lymphocyte count is an important qualifying test for antiretroviral treatment (ART) in HIV-positive individuals and is also used to monitor treatment efficacy.[1–3] The scale up of public ART programs globally[4] has led to an increased demand for CD4 count tests, especially to assess treatment eligibility. Despite expansion of laboratory infrastructure and services, access to CD4 testing remains a bottleneck to ART scale-up. In Zimbabwe, an estimated 380,000 adults are in need of ART[5] and, by the end of 2009, an estimated 215,000 were on ART within the public sector.[5] There is clearly a need to increase access to ART services and improving CD4 access may help.

In Zimbabwe, the "New Start" voluntary testing and counseling (VCT) centers (also known as client-initiated testing and counselling centers) are established by the Ministry of Health and Child Welfare in partnership with Population Services International (PSI) and provide free rapid HIV testing services to more than 360,000 clients nationwide on an annual basis. Clients testing positive at VCT centers are then referred to Opportunistic Infection (OI) clinics for HIV care and ART if eligible. After enrollment at the OI clinics, patients are scheduled for a CD4 count test. Due to high demand, delays in CD4 testing can occur for 2–3 weeks on average. There is substantial loss-to-follow-
diagnosis and registration
CD4 testing can result in f
return or who die before it
exacerbated in rural areas
creates a significant bottle
The recently develope
test system (Alere, Waltham
20 minutes of sample colle
blood. The test can be con
testing does not require labo
the use of the PIMA system
performance against com
testing. The ability of both
to run POC CD4 tests was

### Study Population

Newly diagnosed HI
ipants were recruited for the

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From the *National Microbiology Reference Laboratory, Harare, Zimbabwe; †Ministry of Health and Child Welfare, Harare, Zimbabwe; ‡Population Services International, Harare, Zimbabwe; and §Clinton Health Access Initiative, Harare, Zimbabwe.
Reagents and instruments were supported by UNITAID; programatic funding from Children's Investment Fund Foundation.
Accepted for presentation at the August 2010 XVIII International AIDS Conference in Vienna.
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## Accurate CD4 T-cell enumeration and antiretro
## drug toxicity monitoring in primary healthca
## clinics using point-of-care testing

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**Objective:** To evaluate the accuracy of point-of-care tests (POCTs) for CD4 cell, clinical chemistry and hemoglobin in primary healthcare clinics in Mozambique.

**Design and methods:** POCT and laboratory-based assays were conducted on adult HIV-positive patients enrolled consecutively at primary healthcare clinics in Mozambique. Patients were tested on-site with POCT CD4 (Pima), clinical chemistry (Reflotron) and hemoglobin (HemoCue) devices using finger prick blood. Results obtained on paired blood samples were used for agreement analysis (bias and limits of agreement). Repeatability analysis was also performed for POCT CD4 cell counting.

**Results:** Primary health nurses operating the Pima, Reflotron and HemoCue POCT devices produced results with low levels of bias for CD4$^+$ T-cell counts (−52.8 cells/μl), alanine aminotransferase (−0.2 U/l), aspartate aminotransferase (−4.0 U/l) and hemoglobin (0.95 g/dl). CD4$^+$ T-cell counts in paired specimens of finger prick and venous blood tested on the POCT CD4 device were in close agreement (bias −9 cells/μl, coefficient of variation 10.6%). The repeatability of POCT CD4 cell counting was similar to that observed with laboratory instruments (bias −6.2 cells/μl, coefficient of variation 10.7% vs. bias −5.7 cells/μl, coefficient of variation 7.5%).

**Conclusion:** Primary health clinic nurses generated accurate results for CD4$^+$ T-cell counts, liver enzymes and hemoglobin using simple POC devices on finger prick samples at decentralized antiretroviral therapy (ART) clinics. POC diagnostics to monitor ART at primary healthcare level is technically feasible and should be utilized in efforts to decentralize HIV care and treatment.



*AIDS* 2011, **25**:807–812

**Keywords: antiretroviral therapy, CD4$^+$ T-cells, decentralized, laboratory monitoring, low resource, point of care, primary healthcare**

### Introduction

The absence of laboratory infrastructure in remote rural areas is a barrier to the decentralization of antiretroviral therapy (ART). However, the recent development of point-of-care tests (POCTs) for CD4$^+$ T-cell enumeration and the availability of POCT devices for clinical chemistry and hemoglobin (Hb) may permit on-site

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## Evaluation of PIMA™® Point of Care technology for CD4 T Cell enumeration in Kenya

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**Abstract**

**Objective**

To evaluate the performance and validity of PIMA™ point of care CD4 T cell enumeration technology in Kenya.

**Methodology**

The PIMA™ device was evaluated against commonly available CD4 T cell enumeration technologies using paired blood samples taken from 1549 HIV positive patients.

**Results**

The mean difference between the BD FACSCalibur™ an
FACSCount™, which are the commonest platforms in Kenya, was
(+76.5 cells/μl, p<0.01).

Both the PIMA™ and the BD FACSCount™ platforms were p
PIMA™ having a mean difference of -6.9 cells/μl (p = 0.27) and a
cells/μl, and BD FACSCount™ having a mean difference of
(p=0.36) and a bias of -0.06 cells/μl.

There was no significant difference between BD FACSCount™ a
when the latter used capillary blood (-8.6 cells/μl, p=0. 0.11).
difference between BD FACSCalibur™ and PIMA™ was signifi
cells/μl, p<0.01).

There was a significant difference between PIMA™ and GUA
cells/μl, p=0. 04) but none with the PARTEC Cyflow™ (-10 cells/μl,

The differences between the PIMA™, BD FACSCount™ an
Cyflow™ platforms did not affect the final tally of patients
antiretroviral therapy.

The BD FACSCalibur™ platform significantly differed from bo
FACSCount™ and the PIMA™ platforms, and also classified more
being ineligible for antiretroviral therapy.

## Utility of the point of care CD4 analyzer, PIMA, to enumerate CD4 counts in the field settings in India

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# Several Pima evaluations were conducted which all produced the same result

| Country | Completed | Bias | Sensitivity | Specificity | Result |
|---|---|---|---|---|---|
| Country 1 | 2010 | -60 cells/µl | 100% | 93% | ✓ |
| Country 2 | 2010 | -52 cells/µl | 94% | 75% | ✓ |
| Country 3 | 2010 | +8 cells/µl | 95% | 88% | ✓ |
| Country 4 | 2011 | -6 cells/µl | 94% | 86% | ✓ |
| Country 5 | 2011 | -49 cells/µl | 93% | 74% | ✓ |
| Country 6 | 2011 | -29 cells/µl | 95% | 90% | ✓ |
| Country 7 | 2012 | -2 cells/µl | 91% | 91% | ✓ |
| Country 8 | 2012 | -9 cells/µl | 90% | 87% | ✓ |

# Agenda

Past Experience with POC Evaluations

**Strategies for Accelerated POC Product Approvals**

Update on Recent POC Evaluations

Future POC Evaluation Plans

Other Aspects of Quality

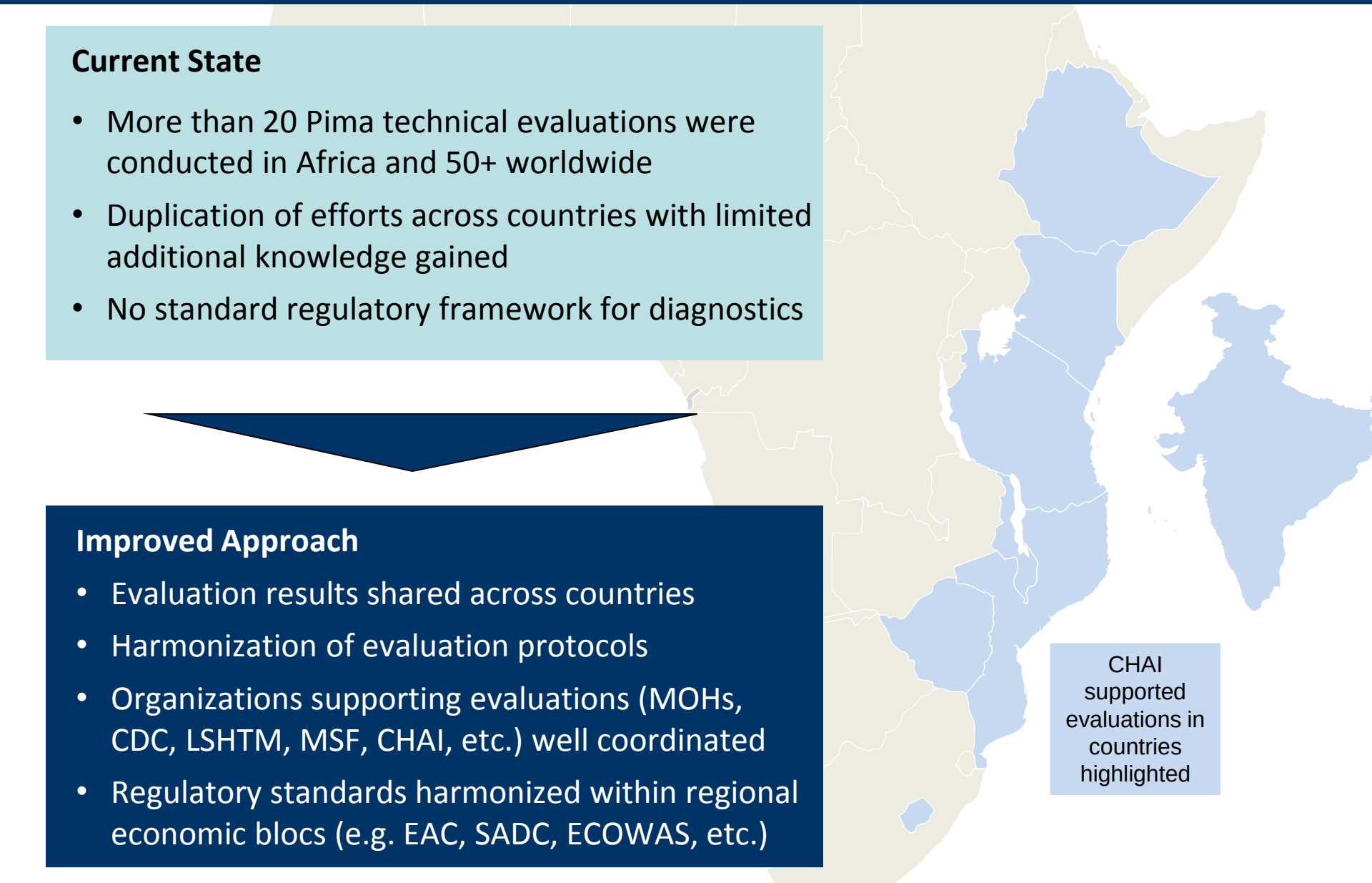
# Past experience suggests that multiple Pima evaluations delayed product uptake and did not provide significantly new information

**Current State**

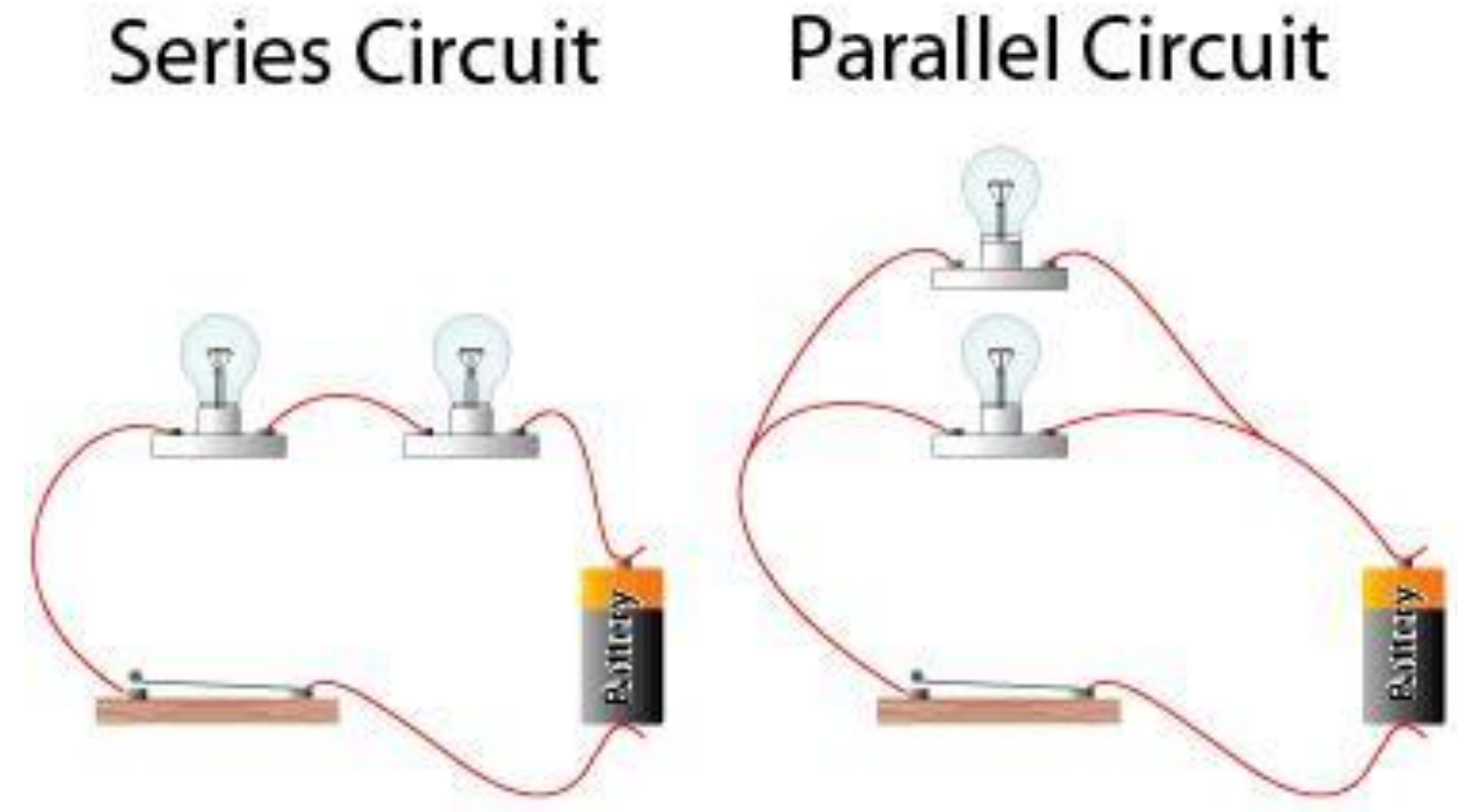
- More than 20 Pima technical evaluations were conducted in Africa and 50+ worldwide
- Duplication of efforts across countries with limited additional knowledge gained
- No standard regulatory framework for diagnostics

**Improved Approach**

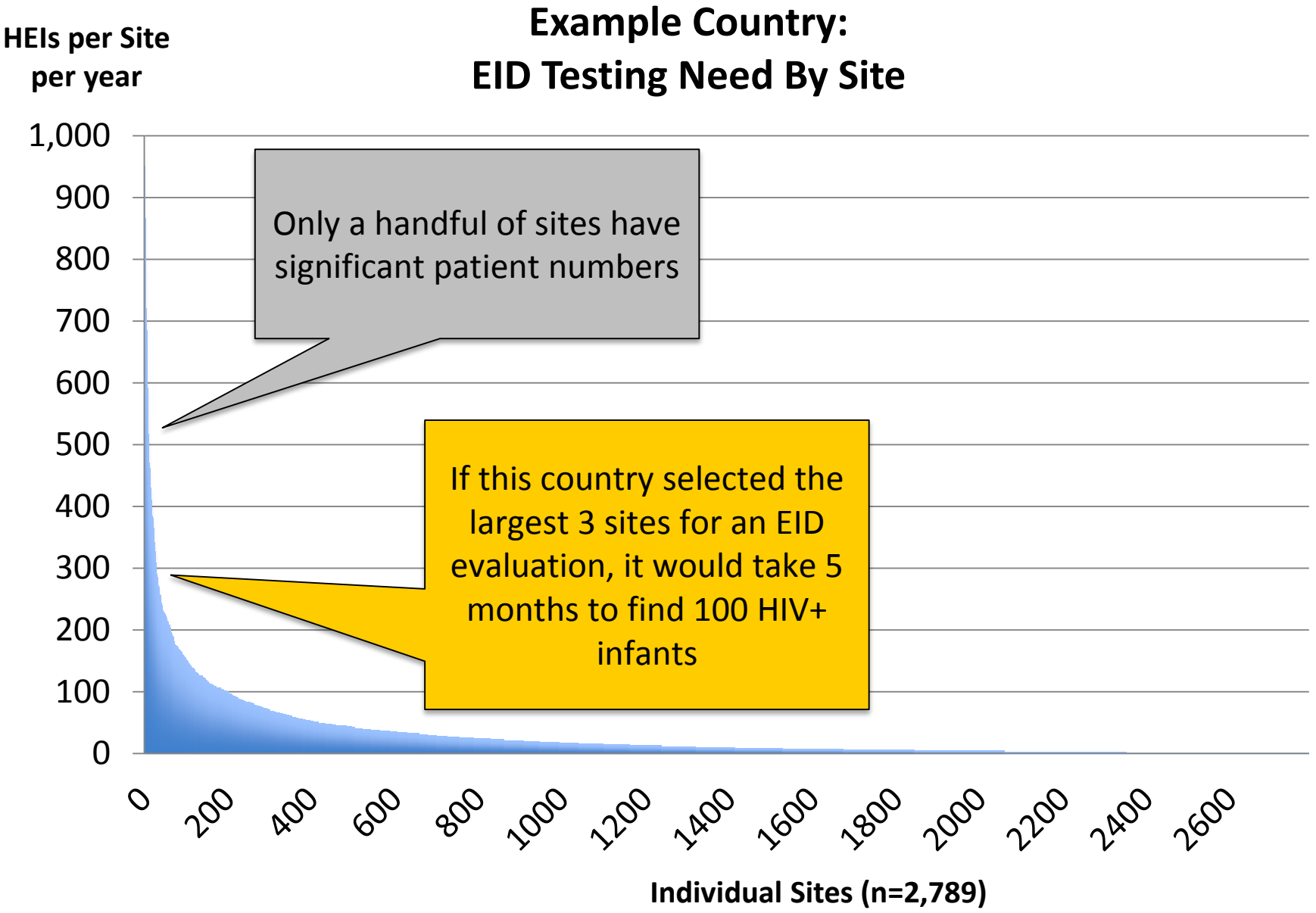
- Evaluation results shared across countries
- Harmonization of evaluation protocols
- Organizations supporting evaluations (MOHs, CDC, LSHTM, MSF, CHAI, etc.) well coordinated
- Regulatory standards harmonized within regional economic blocs (e.g. EAC, SADC, ECOWAS, etc.)



# How is regulatory harmonization like an electrical circuit?



# EID evaluations are particularly challenging to repeat in every country because of the time required to find the number of HIV+ infants required



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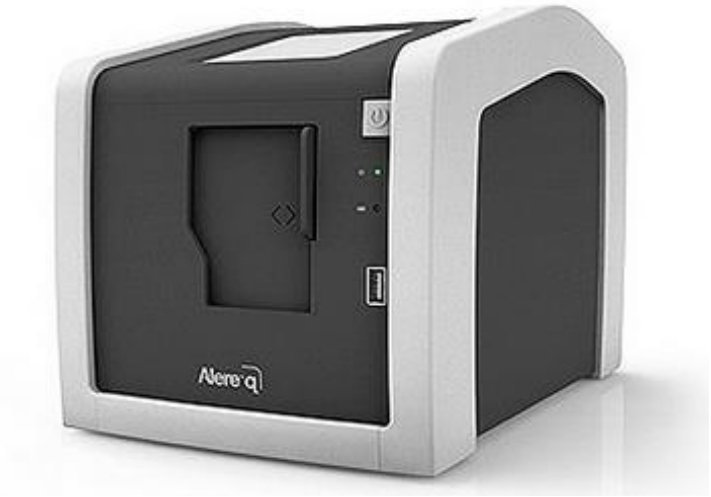
# POC EID evaluations are in their early stages, but at least one product has been shown to perform well in independent evaluation

| | Laboratory EID | | | | | |
|---|---|---|---|---|---|---|
| POC EID | Positive | Negative | POC EID Sensitivity (95% CI) | POC EID Specificity (95% CI) | Cohen Kappa (95% CI) | McNemar Test (*P*) |
| Positive | 64 | 1 | 98.5% | 99.9% | 0.981 | 0.500 |
| Negative | 1 | 761 | 91.7%; 99.9% | 99.3%; 100% | 0.960; 1.000 | 0.480 |

- Alere Q evaluated in Mozambique in 2013-2014 (Jani et al)
- 98.5% sensitivity
- 99.9% specificity

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# Other POC EID products appear promising in manufacturer-led evaluations

## Simple Amplification-Based Assay: A Nucleic Acid–Based Point-of-Care Platform for HIV-1 Testing

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***Background.*** A new nucleic acid–based assay (simple amplification-based assay [SAMBA]) for rapid visual detection of human immunodeficiency virus-type 1 (HIV-1) by dipstick is described. The assay was designed to be simple, stable, robust, self-contained, and capable of detecting a broad spectrum of HIV-1 subtypes and recombinant forms.

***Methods.*** The performance of the SAMBA HIV-1 test (amplification and detection chemistry) was evaluated using the World Health Organization HIV-1 RNA Genotype Reference Panel, with clinical samples representing various viral subtypes and recombinant forms common in sub-Saharan Africa. Sixty-nine randomly selected and blinded clinical samples that had undergone HIV-1 genotypic resistance analyses in a large London teaching hospital were also tested. These samples included 14 different viral subtypes or recombinant forms with viral loads of $78–9.5 \times 10^5$ copies/mL.

***Results.*** The sensitivity and viral subtype coverage of the SAMBA HIV-1 test were either comparable to or better than those of the commercially available nucleic acid–based HIV-1 diagnostic tests.

***Conclusions.*** The unique characteristics and competitive performance of the SAMBA HIV-1 test render it suitable for point-of-care and near-patient testing in both developed and developing countries.

Two-thirds of the estimated 33 million individuals infected with human immunodeficiency virus type 1 (HIV-1) worldwide live in sub-Saharan Africa, where three-quarters of the deaths from AIDS also occur [1]. One of the major interventions to limit HIV-1 infection and progression to AIDS has been the implementation of antiretroviral therapy (ART). The effectiveness of ART implementation, however, depends on the availability of simple, affordable, robust, and rapid tests for monitoring of therapy in patients. Plasma HIV-1 load measurement is essential to monitor response to treatment and viral escape, aiding clinicians' decisions on modification of treatment. Viral nucleic acid is also the best reliable marker for the early diagnosis of HIV-1 infection in infants with passively acquired maternal antibodies to the virus. However, currently available diagnostic assays for HIV-1 load [2–5] are not suitable and are unaffordable for resource-poor regions with a high prevalence of infectious diseases [6]. Most such assays are complex and time-consuming, and they require expensive instrumentation and dedicated laboratory space for sample preparation, amplification, and detection. The test reagents are also expensive and must

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## p24 Antigen Rapid Test for Diagnosis of Acute Pediatric HIV Infection

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**Abstract:** Currently, the majority of HIV-infected infants are found within limited-resource settings, where inadequate screening for HIV due to the lack of access to simple and affordable point-of-care tests impedes implementation of antiretroviral therapy. Here we report development of a low-cost dipstick p24 antigen assay using a visual readout format that can facilitate the diagnosis of HIV for infants in resource-poor conditions. A heat shock methodology was developed to optimize disruption of immune complexes present in the plasma of infected infants. The analytical sensitivity of the assay using recombinant p24 antigen is 50 pg/mL (2 pM) with whole virus detection as low as 42.5k RNA copies per milliliter plasma. In a blinded study comprising 51 archived infant samples from the Women and Infants Transmission Study, our assay demonstrated an overall sensitivity and specificity of 90% and 100%, respectively. In field evaluations of 389 fresh samples from South African infants, a sensitivity of 95% and specificity of 99% was achieved. The assay is simple to perform, requires minimal plasma volume (25 μL), and yields a result in less than 40 minutes making it ideal for implementation in resource-limited settings.

**Key Words:** carbon nanoparticles, HIV p24 assay, heat shock immune disruption, infant HIV, lateral flow diagnostic

(*J Acquir Immune Defic Syndr* 2010;55:413–419)

### INTRODUCTION

Approximately 1.5 million infants are born to HIV-infected women each year,[1] majority of whom are not tested for HIV until it is too late for optimal antiretroviral therapy (ART). Without treatment, the mortality rate in HIV-infected infants can be as high as 45% by the first birthday and 59% by the second.[2] Recent studies have demonstrated that early HIV diagnosis and prompt ART intervention can reduce infant mortality by 76% and HIV progression by 75%.[3] Such studies have contributed to a change in treatment guidelines by the World Health Organization to initiate ART therapy in infants as soon as they are diagnosed with HIV.[4]

Worldwide, there is vast disparity in health care provisions for HIV-infected infants in the developed world and those in resource-poor countries. In resource-limited countries, where 90% of the exposed infants are found, several obstacles such as limited screening programs for HIV and the lack of a simple and affordable point-of-care diagnostic currently impede the widespread implementation of ARTs. The current gold standard for HIV testing, DNA polymerase chain reaction (PCR), is not suited for implementation in these settings because of the long turn-around-times and inefficiencies involved in transporting samples to central laboratories and returning results to clinics. These inefficiencies lead to poor follow-up and low turn-outs for testing. Rapid antibody tests make diagnostic results available on the same visit, but cannot be used to diagnose infection as HIV exposed infants can retain maternal antibodies for up to 18 months.[4]

Various studies have highlighted the utility of HIV core p24 antigen detection for adult and pediatric screening,[5,6] prediction of disease progression,[7,8] and monitoring the effectiveness of ART.[9,10] An excellent overview of the work has been presented by Schupbach.[11] However, these studies have been carried out with enzyme-linked immunosorbent assay–based systems which are similar in complexity to PCR techniques in that they are time intensive and require

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*The authors Z.A.P. and R.E. contributed equally to this work.

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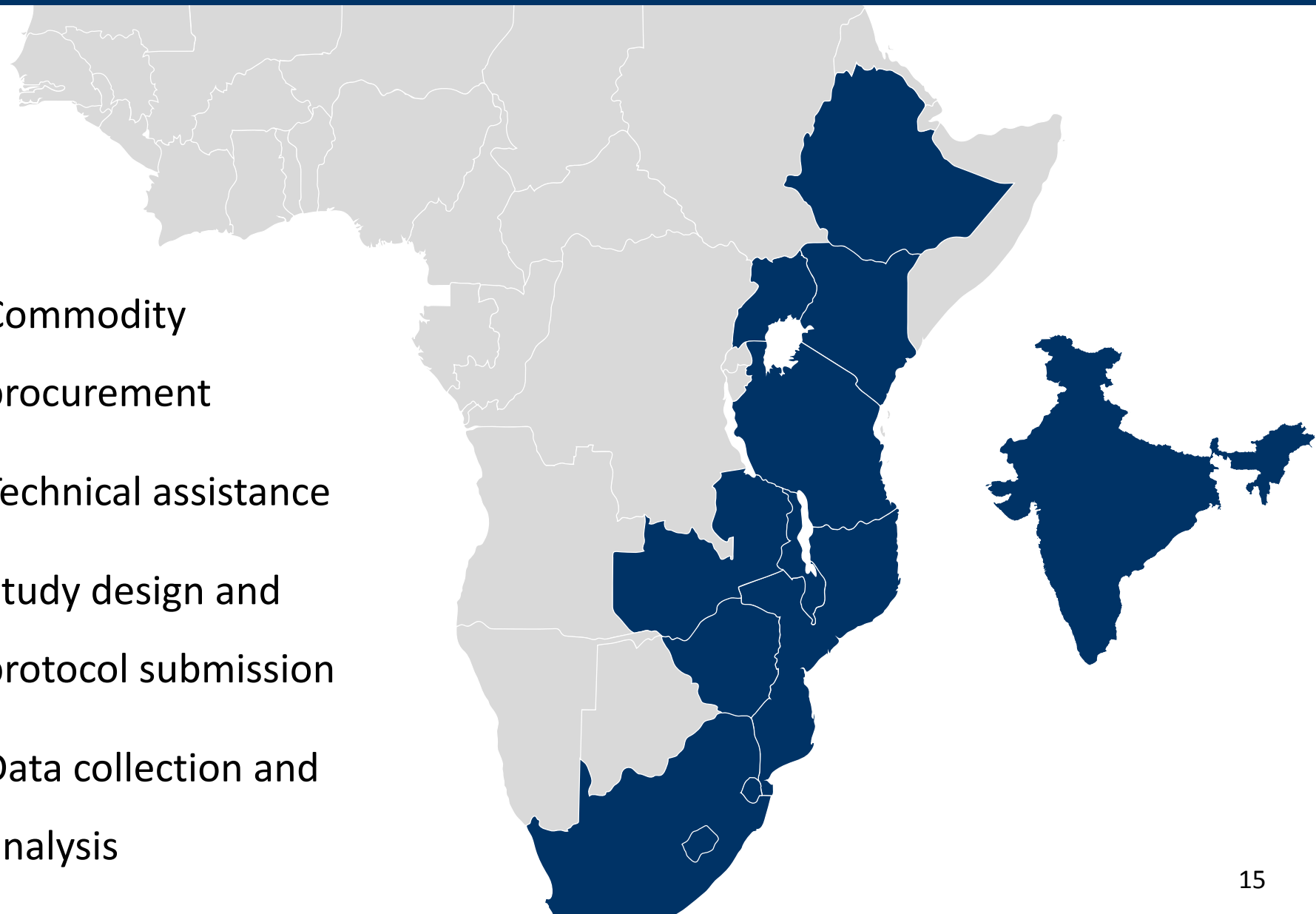
# CHAI will continue to provide support to local Principal Investigators to conduct evaluations when necessary to achieve regulatory approval



- Commodity procurement
- Technical assistance
- Study design and protocol submission
- Data collection and analysis

# To ensure testing quality, CHAI-supported evaluations will share common features

**CHAI-supported evaluations will be…**

- ✓ Independent from suppliers
- ✓ Conducted on finished products (not prototypes)
- ✓ Large enough to include adequate sample size
- ✓ Only conducted in-country when necessary for regulatory approval
- ✓ Conducted in field settings where the products will be used

# With funding from UNITAID and DFID, CHAI is supporting countries to evaluate new POC CD4, EID, and VL products as they become available

| Category | Product | Approximate Start Date | Regulatory Status |
|---|---|---|---|
| CD4 | BD FACS Presto | One evaluation ongoing; more planned in Q1 2015 | WHO-PQ |
| CD4 | Daktari | Planned in ~Q1 2015 | N/A |
| CD4 | Omega | When available | N/A |
| EID | Alere Q | One evaluation complete; more planned in Q1 2015 | CE mark pending |
| EID | Cepheid | Planned in ~Q1 2015 | N/A |
| EID | SAMBA | When available | N/A |
| EID | Northwestern p24 | When available | N/A |
| VL | Alere Q | When available | N/A |
| VL | Cepheid | Planned in ~Q1 2015 | N/A |
| VL | SAMBA | When available | N/A |

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# Ensuring testing quality goes far beyond evaluations

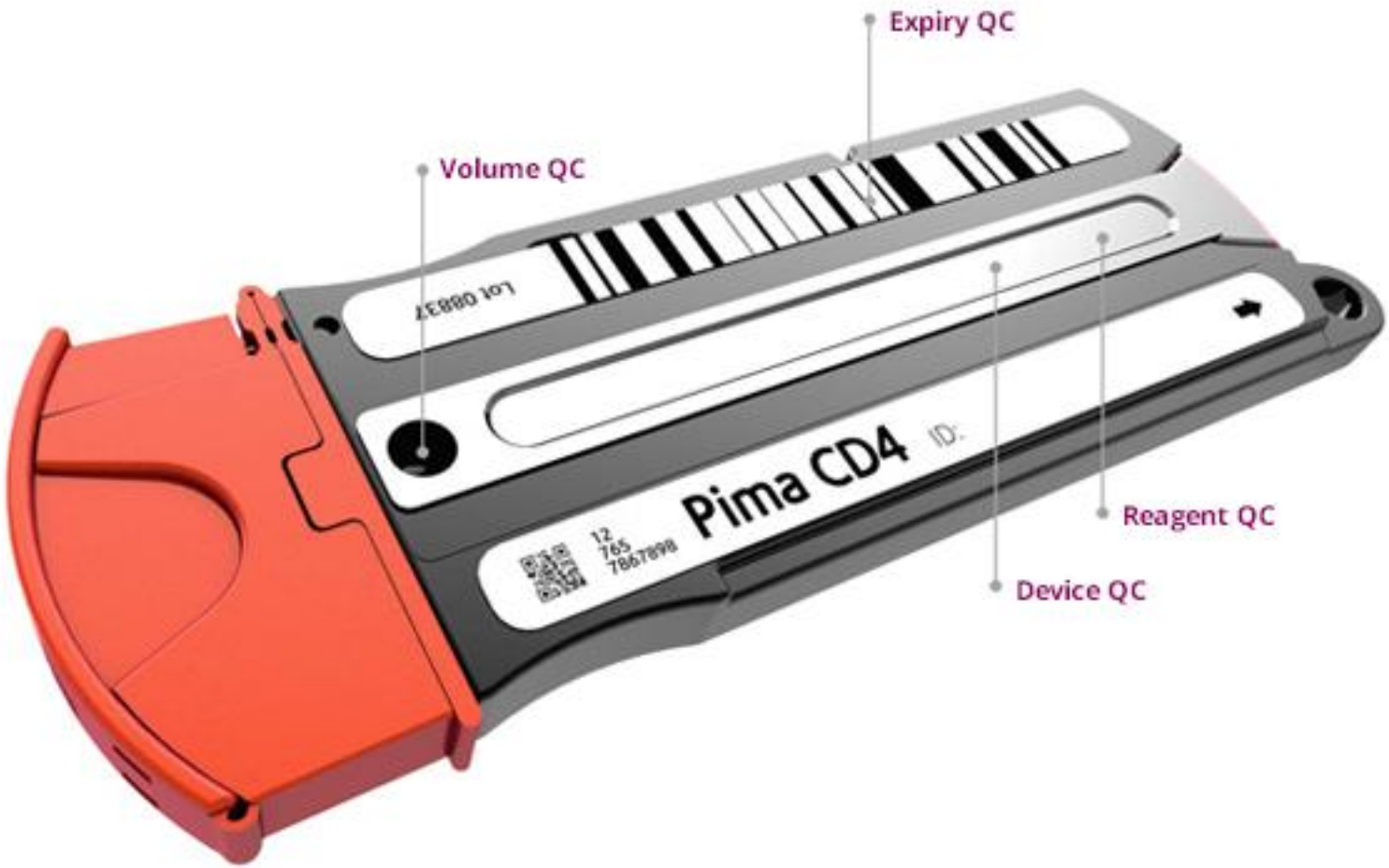

- Suppliers need to build quality into product design
- Particularly for POC, quality needs to be as automated as possible
- All products should have some form of internal QC on each test and/or daily checks

- All end users must be trained
- After initial training, end users need follow-up mentorship
- With high staff turnover, mechanisms are needed to identify sites in need of re-training

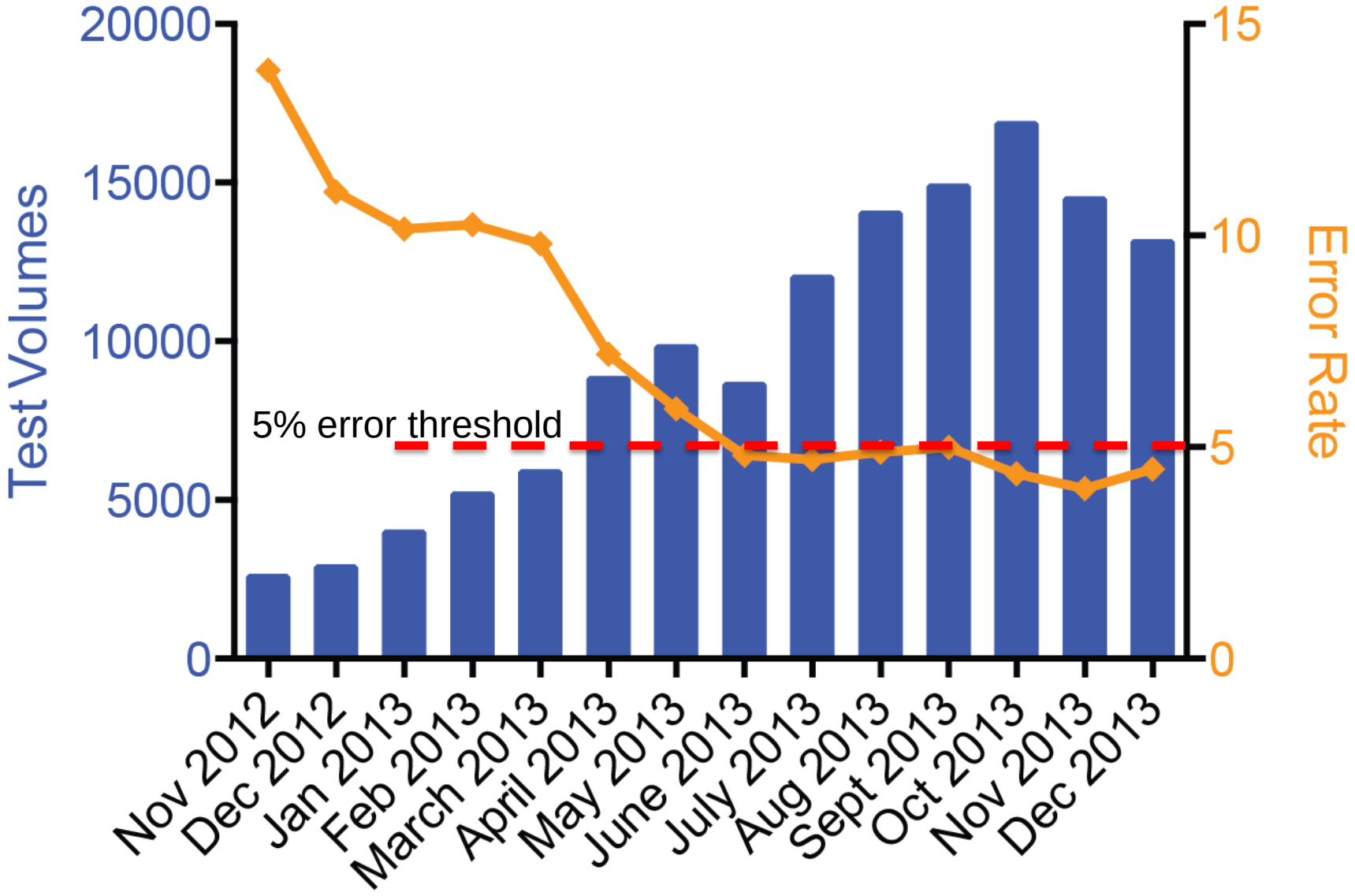
- All end users must perform daily QC before testing, if available
- QC should check devices, reagents, and testing procedure, if possible

- All sites should have some form of EQA, but this can take many forms:
- Proficiency testing (PT) either from 3rd party or in-country panels
- Data connectivity

# Quality must be addressed at the product development stage



# Example: Data connectivity can be used to monitor error rates in real-time, which are a good proxy for testing quality




Based on data available on connectivity

# Example: POC CD4 sites can perform as well or better than conventional CD4 sites in EQA programs

**EQA Performance - Absolute CD4**

| | PIMA | FACSCalibur | FACSCount |
|---|---|---|---|
| Oct-2011 | 100% (n=21) | 87.5% (n=17) | 92.7% (n=24) |
| A | 100.0% | 87.5% | 91.7% |
| B | 100.0% | 87.5% | 93.8% |
| Sep-2012 | 95.2% (n=42) | 93.3% (n=15) | 94.6% (n=25) |
| A | 95.2% | 93.3% | 96.0% |
| B | 95.2% | 93.3% | 93.3% |
| Mar-2013 | 95.8% (n=97) | 100% (n=12) | 95.2% (n=21) |
| A | 95.9% | 100.0% | 95.2% |
| B | 95.9% | 100.0% | 95.2% |
| **Average** | **97.0%** | **93.6%** | **94.2%** |

# All aspects of testing quality need to be addressed holistically



**Phase I: Plan HIV-related POCT Quality System**

- Engage leadership
- Establish national QA coordination team
- Define roles and responsibilities
- Define expected quality for POCT
- Conduct situational analysis
- Select and Assess sites
- Develop implementation plan
- Develop policies and incorporate QA into national plan
- Plan financial and human resources

**Phase II: Implement QA for POCT**

- Develop and Implement QA training and certification
- Conduct site supervision and drive accreditation
- Implement process control
- Generate QA-related Documentation
- Strengthen logistics for QA

# Thank You

- Ilesh Jani – INS Mozambique
- MOHs – Ethiopia, India, Jamaica, Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
- Trevor Peter, Lara Vojnov