



SUPPLIER SUMMIT

**USAID Global Health
Supply Chain Program
Supplier Summit
February 21-23, 2017**

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USAID Global Health Supply Chain Program

Laboratory Instrument & Inventory Forecast



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Laboratory Session Overview

Overall goal is strengthen the relationship between suppliers and GHSC-PSM through the sharing of strategic information and priorities to support an uninterrupted supply of quality laboratory products the are delivered on time.

Session I:

- Share information regarding laboratory product technical specifications, supply chain, registration preferences, import license requirements, and both installation and post-installation challenges
- To improve awareness and common understanding of strategic priorities amongst key stakeholders in the supply chain

Session II:

- Ensure smooth & on time delivery through sharing forecasted commodity demand
- Discussion on reagent rental vs direct purchase scheme.



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Diagnostic Products: The “First and Third 90”

Suppliers and GHSC-PSM together can support PEPFAR countries as they strive to meet these goals



Fast-Track Targets

by 2020

90-90-90

HIV treatment

500 000

New HIV infections or fewer

ZERO

Discrimination

by 2030

95-95-95

HIV treatment

200 000

New HIV infections or fewer

ZERO

Discrimination

Strategic Priorities

USAID Diagnostic Strategic Objectives

- Coordinated network approach that includes the following:
 - ✓ **Coordination** and alignment of instrument management strategies among **global stakeholders**
 - ✓ Real-time **data collection** and **sharing** and **use** to inform **maintenance** strategies and **informed instrument placement** to improve utilization
 - ✓ Negotiated **network-wide pricing** agreements that leverage a **reagent rental approach**
 - ✓ Improved monitoring of adherence to contract terms, and **active monitoring of vendor performance**

Operational approaches to achieving strategic objectives

- Improved procurement planning including more regular quantifications, delivery schedule planning, and country insights into consumption
- Better communication and collaboration throughout the PSM supply chain including with the suppliers, field offices, and technical teams at HQ
- New e-catalog with SKU numbers that are easier for the field to select
- Develop understanding of the registration requirements by product type for each destination – in partnership with suppliers
- Strengthen relationships with suppliers
- Optimized procurement modalities including:
 - IDIQ for EID/VL commodities
 - BPA with wholesalers
 - LTA/IDIQ for “hot list” commodities

PSM operational improvements for supply chain management between HQ and the field offices

- Instrument procurement questionnaire for the Field offices
- Quantification of consumables & reagents by most updated software tool (ForLab)
- Optimization of lab equipment networks in country (LabEQIP)
- Technical advisors/lab manager in the Field Offices with technical support from lab specialists at HQ
- Systematic procurement process followed by fair bid evaluation process
- Development of country supply plans

Areas for improvement along the supply chain

Planning and Forecasting

- Coordination amongst key stakeholders in country and at HQ with respect to planning and forecasting reagents/VL/consumables

Procurement

- Suppliers require constant follow up to ship out at quarter/year end

Freight Forwarding

- Staggered deliveries
- Delivery lead-time
- Shipments require pickup co-ordination

Customs

- Waiver arrangements

In Country Logistics

- Cool chain or dry ice requirements for many products
- Arranging the transit to the multiple health facilities and labs in-country

Viral Load (VL) and Early Infant Diagnosis (EID)

- VL – A quantitative test to determine the amount of HIV in a sample of blood
- EID – A qualitative test to determine the HIV status of a infant under 24 months of age

Current Vendors



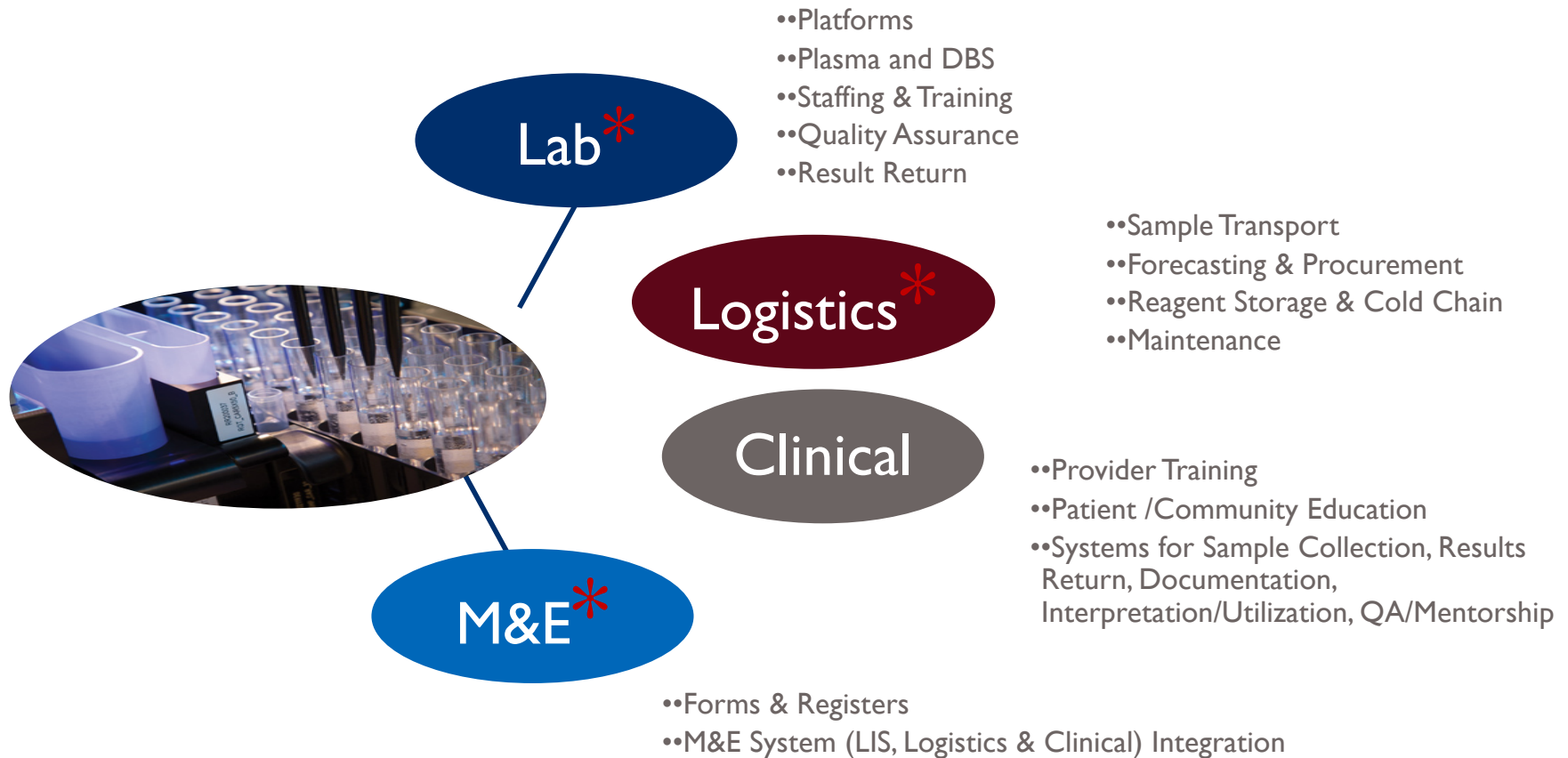
Diagnostics



HOLOGIC®



Components of Successful VL/EID Scale Up



* PSM focus

VL and EID procurement concerns (demand)

Concerns

- Alignment of instrument deployments with commodity needs-- Awareness of Minimal requirements to test
- Information in changed SOP
- Commodities and software roll-out – Not aligned with updated technology

Solutions

- Supplier need to provide starter kit details
- Ensuring forecasts account for changes in commodity and are communicated to HQ
- Provide guidance on forecasting best practices which include such modifications
- Updated technology will be in use

VL and EID procurement concerns (supply)

Concerns

- To get right commodity at right place in right condition
- Lack of pricing transparency in RFP responses
- High level of instrument failures

Solutions

- Manufacturer need to allow their distributor for cool goods in country business
- Clear requirements in the next RFP such that bids will be considered invalid if not provided per specifications
- Manufacturer \ Seller need to provide clear operational manual to buyer.

PEPFAR VL/EID scale-up strategy: network approach

- Understanding the national laboratory network and supportive systems (agnostic of disease type or program area) to inform efficient and effective program growth and instrument expansion.
 - Requires baseline mapping of the laboratory network and systems, identification of functional instruments, and current utilization rates.
- An all-inclusive per test cost structure spread across all instruments of the same brand within the network and available to all stakeholders to include:
 - Cost options that account for existing instruments with new contract models (e.g. Leasing and rentals) that facilitate network expansion
 - Inclusive service and maintenance
 - Data solutions for patient result transmission, instrument/user performance
 - Additional technology & support (training, barcoding, sample processing);

Recommended approaches moving forward

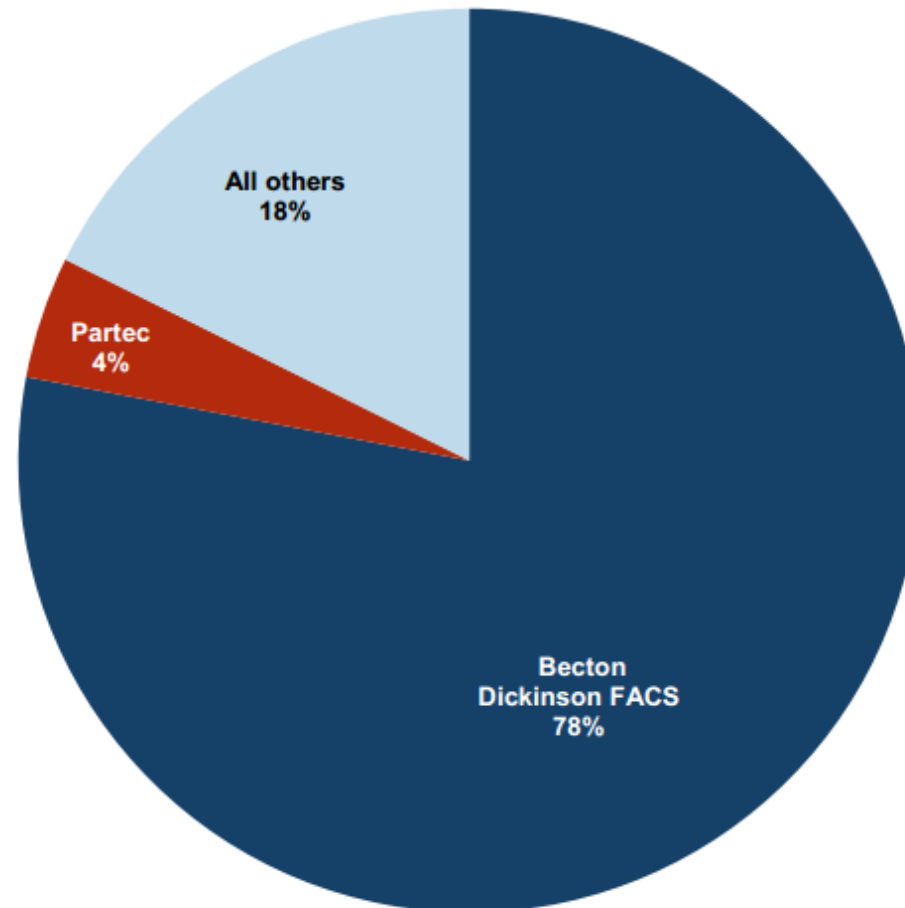
- Seek a systems/network approach where possible
- Pursue reagent rental/leasing over purchase
- Leverage data to negotiate contract terms and best fit solutions for existing instruments
 - Reagent bundling (S&M) for existing instruments
 - Amortizing instruments in reagent costs
- Development of and adherence to supply plans. (National quantification / forecast / supply plan development)
- Ensuring back-up laboratory contingency plans
- Revisit and renegotiate agreements bi-annually

Set yourself up for competition!

CD4

CD4 – Quantitative or semi-quantitative test measuring the level of CD4 cells in the blood. As the level decreases, the person will develop opportunistic infections. Changes in CD4 counts are an indication of whether ART is working.

Flow cytometry suppliers : Market Dynamics



Current vendors



CD4 trends and strategies

With the implementation of “test and treat”, CD4 is not as useful a measure for HIV program clinicians as Viral Load.

Over time we will see a shift to **increasing** demand for Viral Load and **decreasing** demand for CD4



As fewer CD4 machines are demanded GHSC-PSM will begin developing instrument disposal strategies

Point of Care (POC)

POC - Tests designed to be at or near site, where patient is located, that do not need permanent dedicated space and performed outside the physical facilities of clinical laboratories. GHSC-PSM is primarily interested in VL & EID POC moving forward.

WHO framework for ASSURED criteria for POC

A: Affordable

S: Sensitive – few false negatives

S: Specific – few false positives

U: User-friendly – simple, 3-4 steps, minimal training

R: Rapid, robust

E: Equipment free – or minimal equipment

D: Deliverable to end users, w/ internet connectivity

Key Strategy

GHSC-PSM plans to leverage the software, LabEQIP, in coordination with UNITAID, CHAI, EGPAF in order to develop an appropriate “network strategy” for POC machine placement

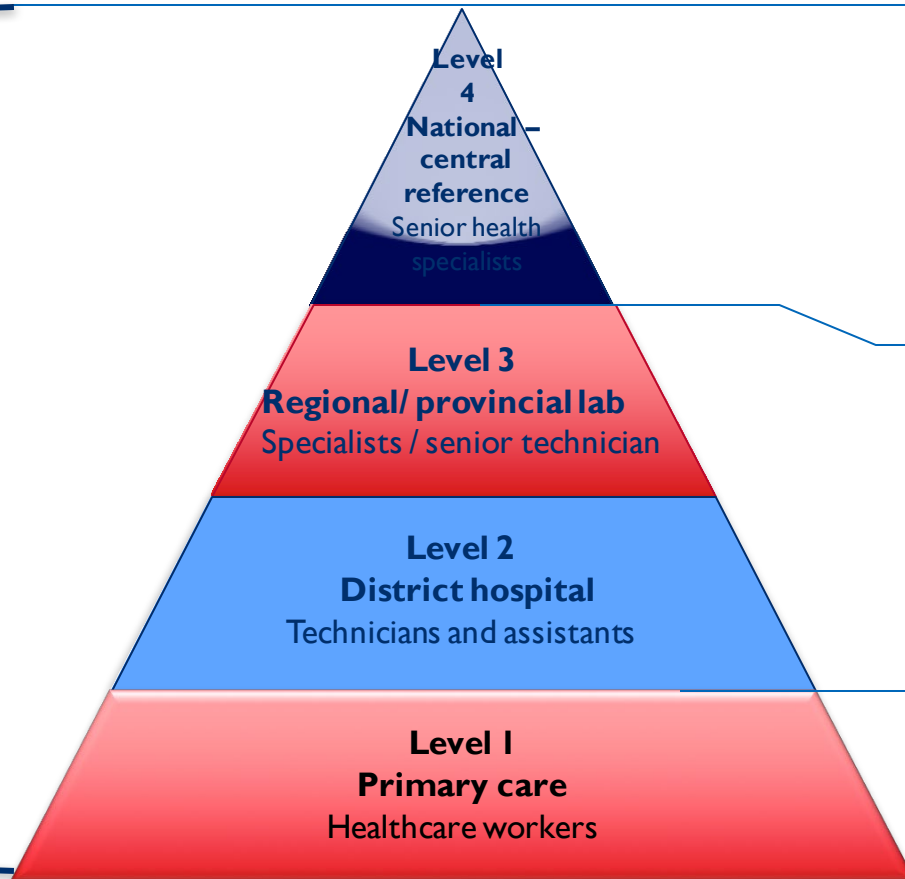
Tiered Lab System

Diagram of tiered laboratory system

Type of staff required

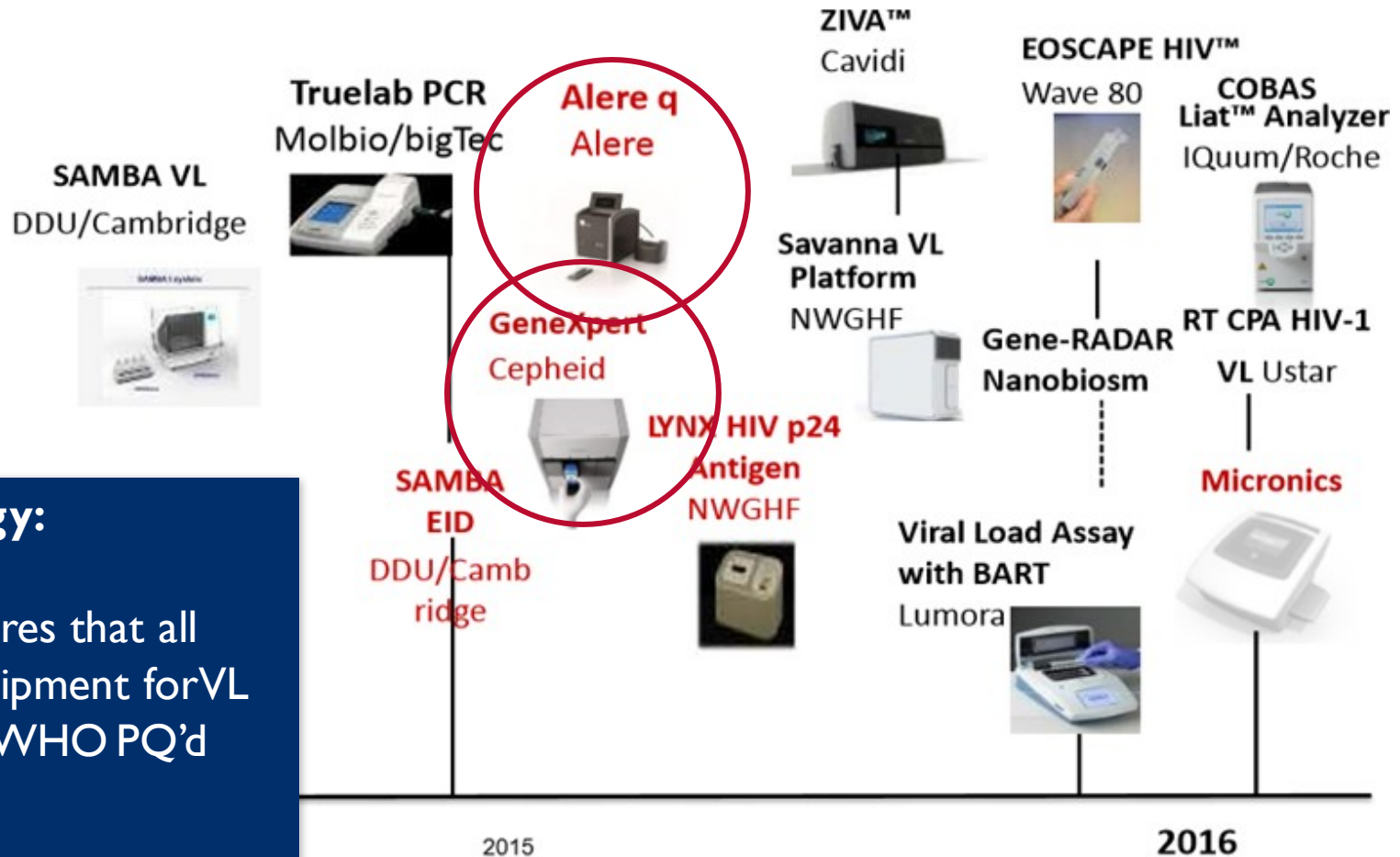
Description

NETWORK APPROACH SPANS ALL LEVELS



- Require large throughput and large number of patient samples
 - Require large upfront investment
 - Centralized testing can be a challenge when where patient specimens must be transported over long distances
 - Follow-up is typically 2-4 weeks
- Small instrumentation to achieve the same functionality as ones in a larger lab but at a lower test throughput
 - Flexible rapid and easy to implement diagnostics, with appropriate-sized machines for peripheral settings
- Typically low throughput
 - POC systems intended for resource-limited settings are generally designed for minimal laboratory infrastructure

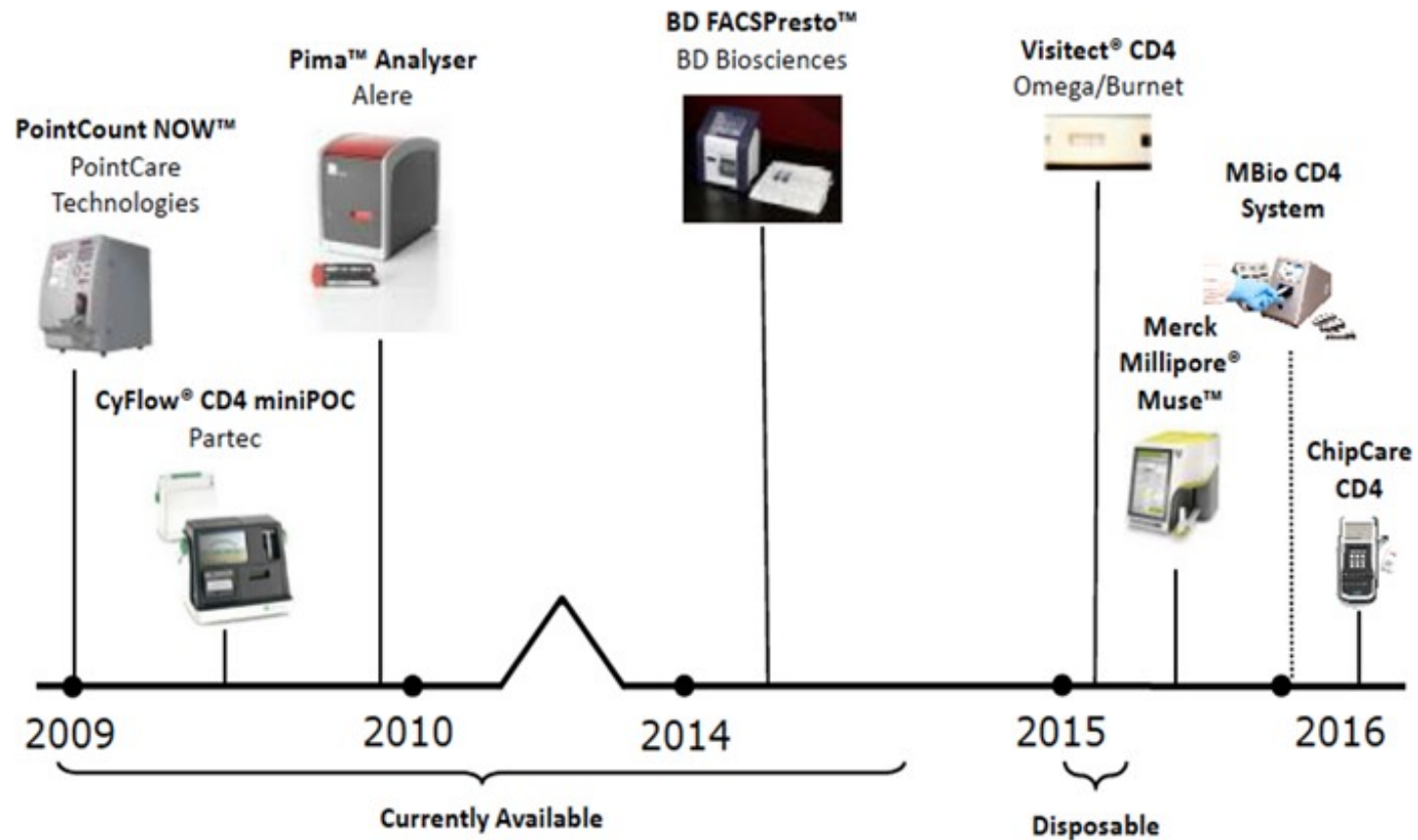
POC Viral Load and EID Instrument



Key Strategy:

USAID requires that all large lab equipment for VL and EID are WHO PQ'd

POC CD4 Instrument



POC challenges and opportunities

- Issues associated with lack of sufficient infrastructure to support the equipment
- Lack of QA & proficiency test
- Need for maintenance of machines that are not functioning
- Need for national level planning - to strategically place machines purchased by multiple donors and coordinate all stakeholders who are procuring
- Lack of trained staff operating machines
- Service contracts
- Country specific legal constraints
- Lot-to-Lot Evaluation of reagents – need controls for new POC machines

POC strategic challenges and opportunities

Challenge

- Neglected infrastructure
- Lack of quality assurance and proficiency tests
- Long down times waiting for machine maintenance
- Deployment of instruments in coordination with multiple stakeholders
- Lack of trained staff
- National level planning

Opportunity

- Work with MOH or partners to upgrade
- Address with RFX/contracts
- Address with contracting and supplier performance M&E
- Leverage software such as LABEQIP
- Include 'service' provisions in contract
- Support technical assistance to countries

Ongoing manufacturer engagement

PEPFAR, GF, and UNITAID involvement - purpose

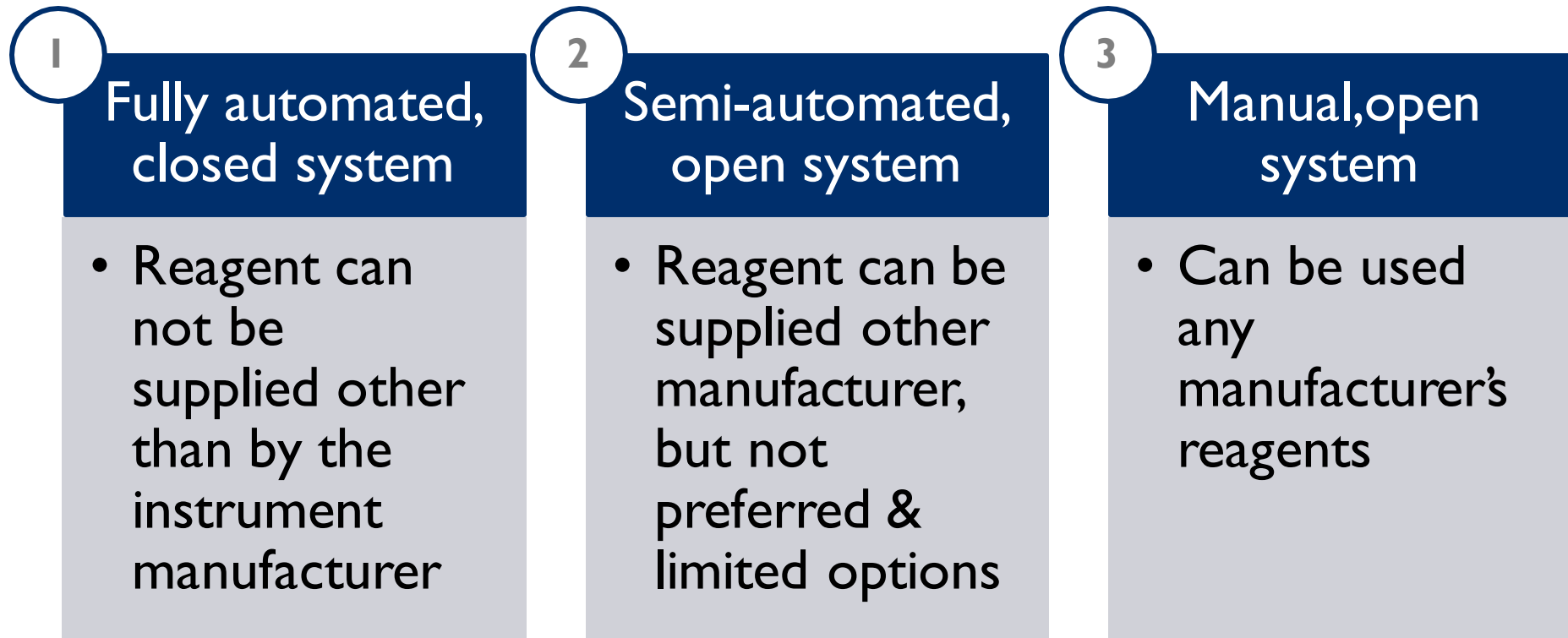
- Quarterly meetings to address country specific challenges;
- Protocol enhancements and technology updates;
- Development of responsive maintenance strategies;
- VMI (vendor management inventory);
- National or regional contracts - Reagent rental/leasing options and bundling for legacy equipment;
- Strengthening local vendor capacity – alignment with in-country scale-up ambitions;
- Improved visibility and coordination;
- POC integration, procurement and maintenance strategy development.

Hematology and Clinical Chemistry Analyzer

Hematology – General blood tests such as complete blood count (CBC)

Clinical Chemistry – Other bodily fluid tests such as blood glucose, electrolytes, enzymes, hormones, lipids, other metabolic substances, and proteins

Hematology & Clinical Chemistry Analyzer Models



Current vendors



Analyzer strategic challenges and opportunities

Challenge

- Short shelf life of calibrator & control for far delivery points in-country
- Service & maintenance of geographically wide network
- Reagent upgrades over time
- Protocol upgrades over time

Opportunity

- Order will be placed in advanced as per customer AMC & looking forward for upgraded version of reagent with better shelf life
- Bulk Annual service contract
- Upgraded reagent marketing
- Annual training contract

General Laboratory Instruments

Laboratory – A place to conduct tests

General Lab Instruments

- Ancillary equipment (freezers, centrifuges, incubators, water bath, UPS , desktop, printer etc.)
- Specialized equipment (biosafety cabinets, autoclaves, filtration systems, ventilation systems, etc.)



General Lab Instruments challenges and opportunities

Challenge

- Lack of local customer support – if purchased from a wholesaler
- Lack of predictable pricing across distributors/countries for same product
- Long delivery lead times
- High level of vendor and instrument diversity
- Long down times waiting for machine maintenance
- Customer Product preference (SSJs) i.e. lack of significant comparative data if offer alternative items
- Aligning instrument capacity with site level demand and readiness

Opportunity

- Scope of service center business
- Scope of getting constant business

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Inventory & Forecast : Session II



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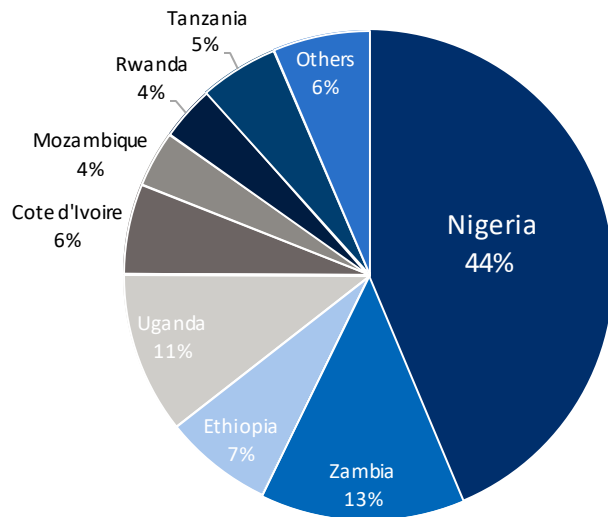
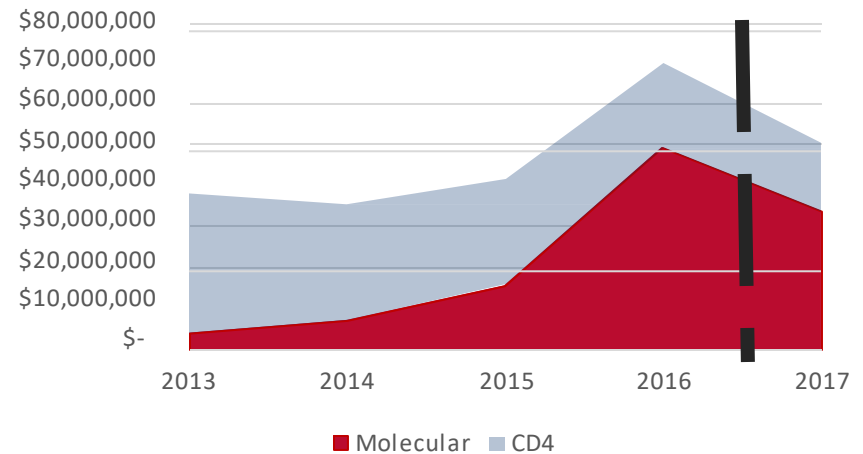
Agenda

- Inventory & Forecasting
- Calendar of sourcing events Fiscal Year 2017
- Overview Of QA/QC
- Supplier Discussion + Q &A



GHSC-PSM molecular & CD4 reagent spend

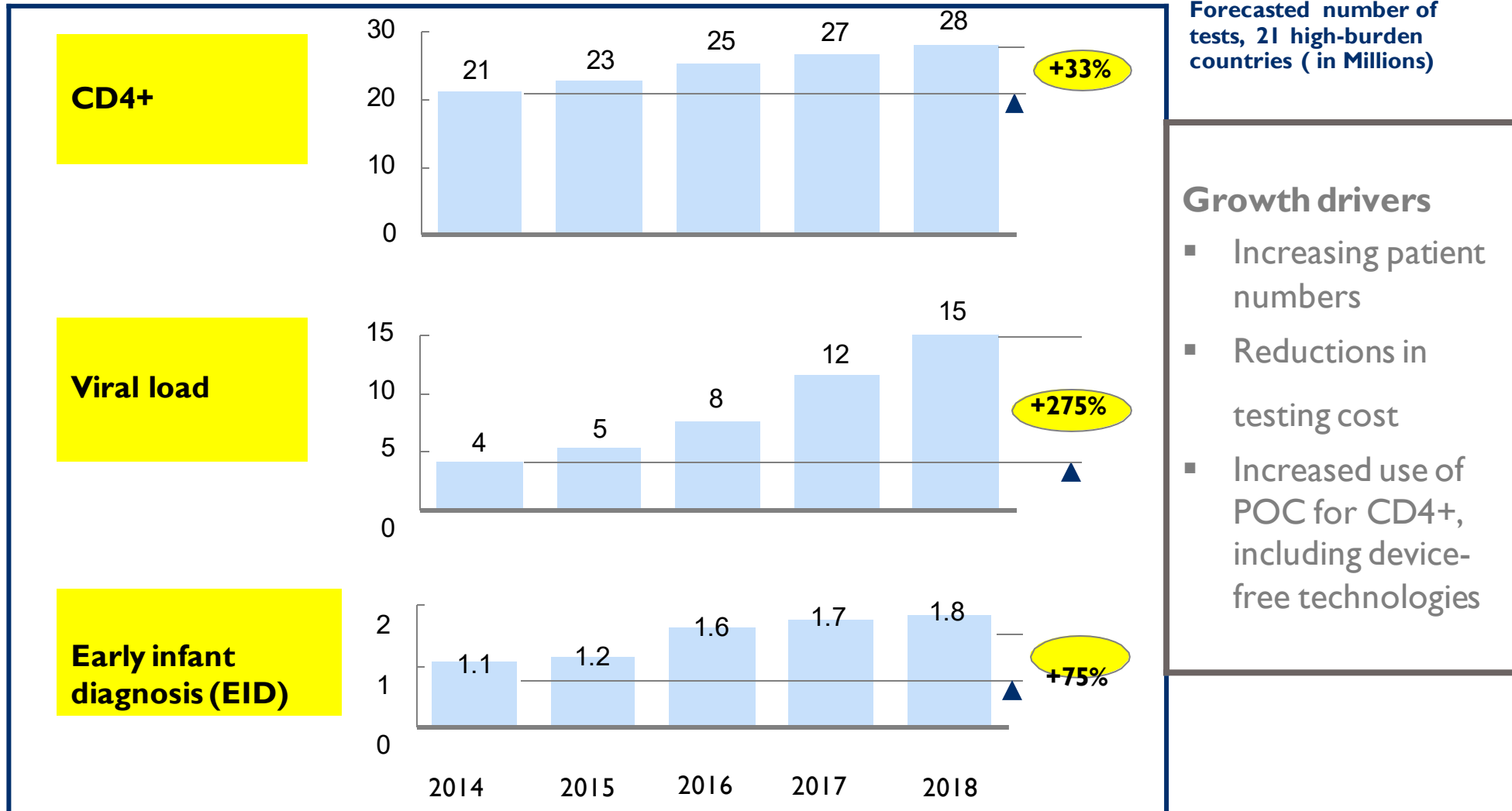
- 2017 data represented by supply plan data. Supply Plans have been received from most countries.
- 2017 supply plan submission countries represent **93% of 2016 spend**, and 80% of 2013 – 2016 spend.



COUNTRY	2016 SPEND
Nigeria	\$30.0 M
Zambia	\$9.4 M
Uganda	\$7.4 M
Ethiopia	\$5.0 M
Cote d'Ivoire	\$4.2 M
Tanzania	\$3.6 M
Mozambique	\$2.6 M
Rwanda	\$2.6 M
Others	\$4.4 M

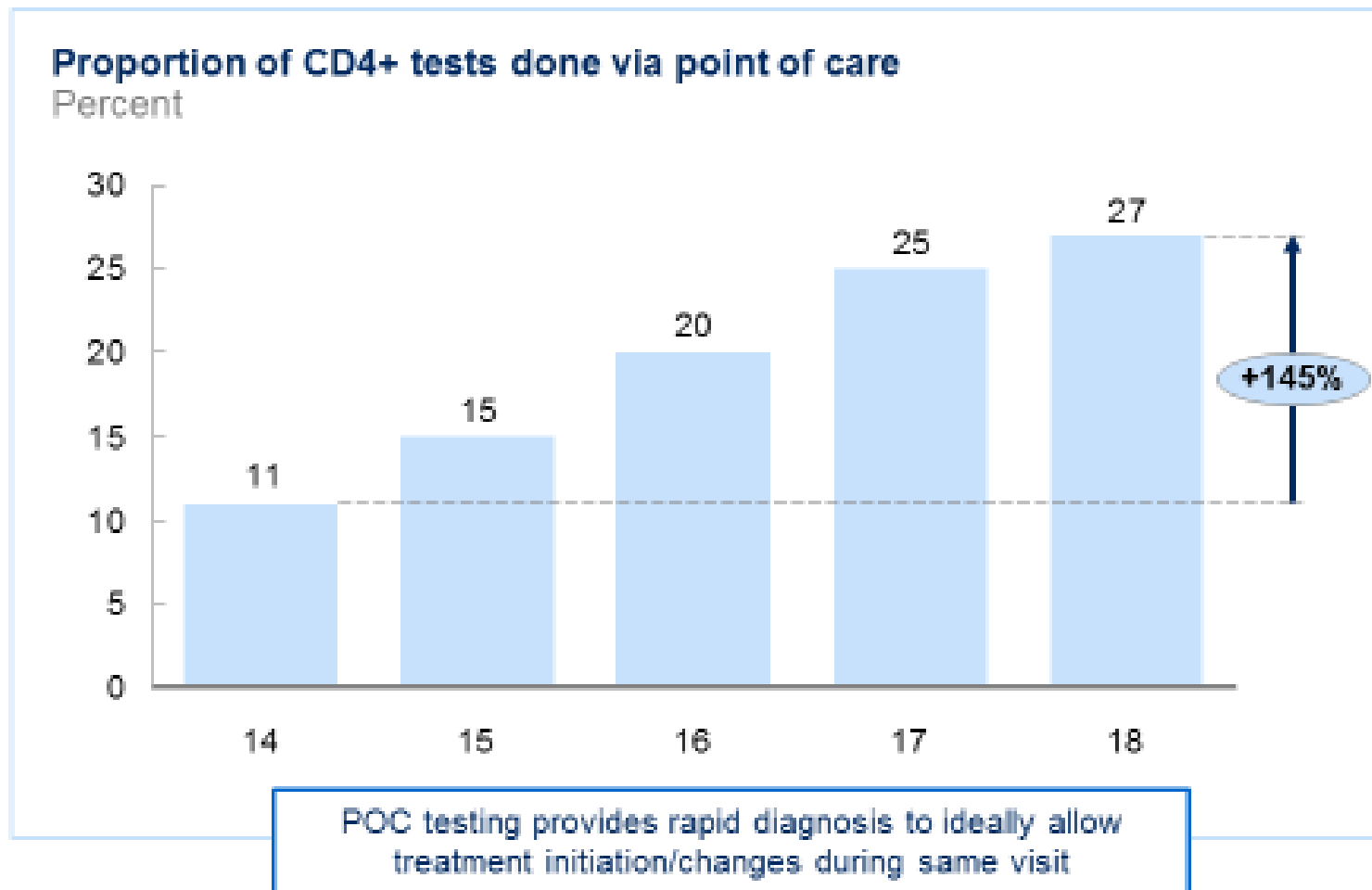
Advanced Testing Methods

All three of the more advanced testing methods are forecast to have significant growth, especially viral load



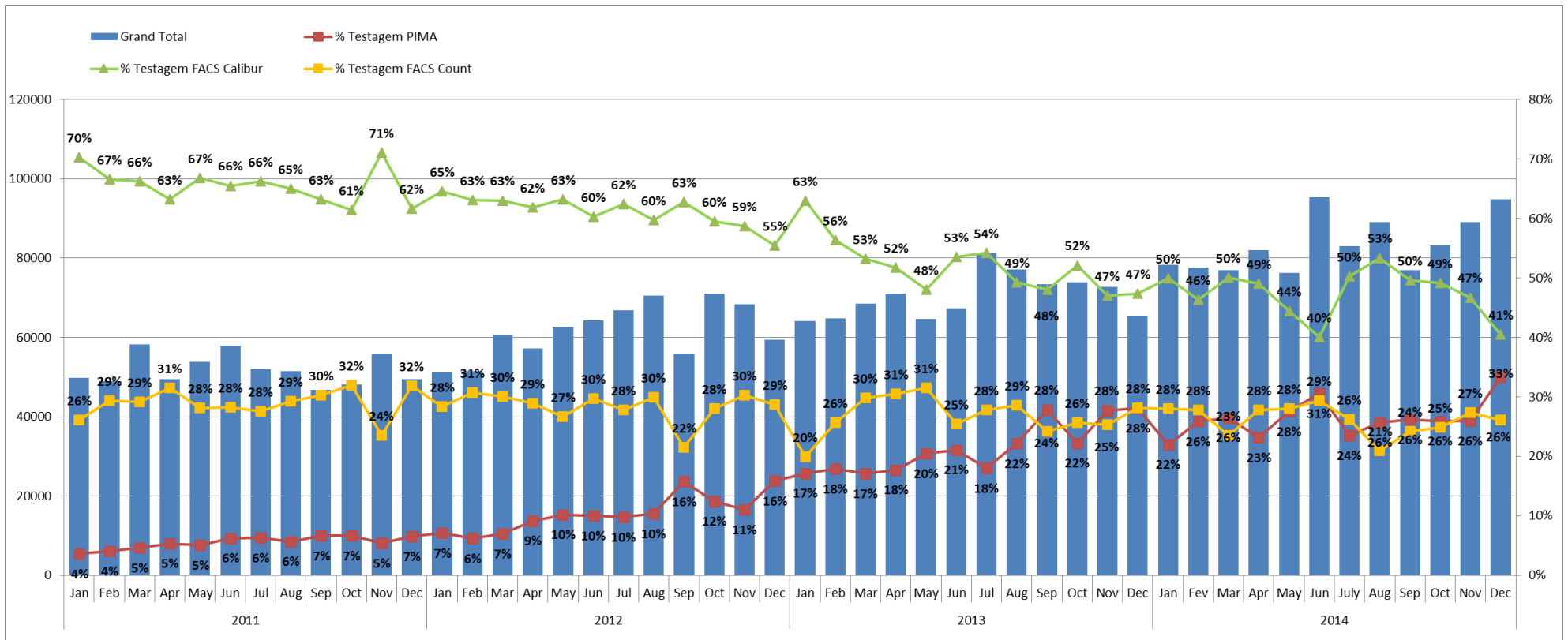
Source: CHAI Survey of 21 LMICs

Point of care testing expected to increase significantly in CD4+ market



Source: CHAI Survey of 21 LMICs

Conventional vs. POC commodity shifts



Calendar of Sourcing event Fiscal 2017

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Lab Data Challenges

1. Cost Data

- Lab data is always subject of changes. So budget prediction is big challenge. Historical information till Jan 2017.

2. Commodity Categories

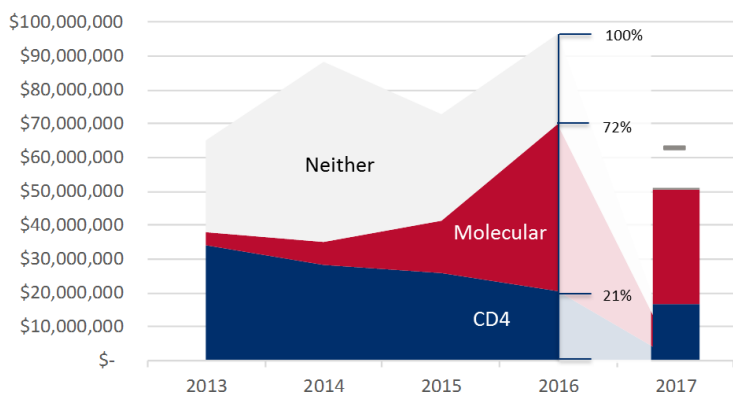
- Complete Functional + Intervention Mapping of Products to product.
- We have some information around intervention category, and have used that to build this deck

3. Country Forecasts + Data

- PSM is in the process of implementing country forecasting processes in the countries
- PSM is in the process of receiving country plans for Q1 2017

Lab Spend by Intervention Type: Molecular Products Showing Rapid Growth

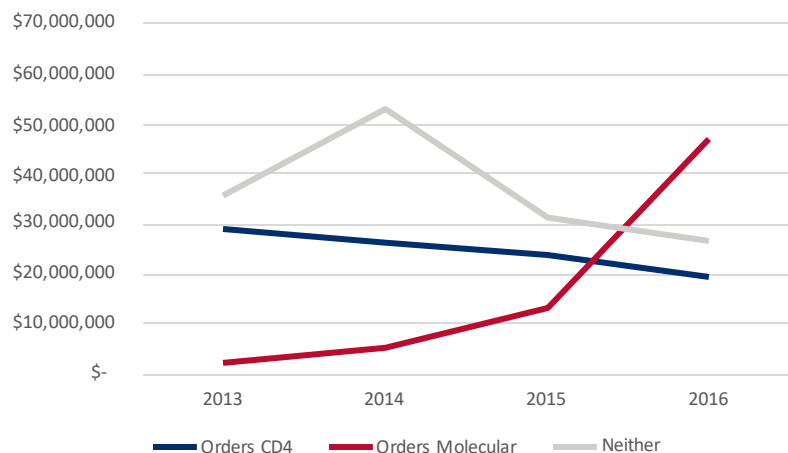
Spend by Type of Commodity*



Molecular (Viral Load Quant/Adult, and EID products)spend is expected to continue to outpace CD4 spend in 2017.

PSM has country forecast data from countries representing 90%+ of historical spend, shown in 2017. Total Molecular + CD4 Spend may decrease from 2016 peak.

Spend Trend

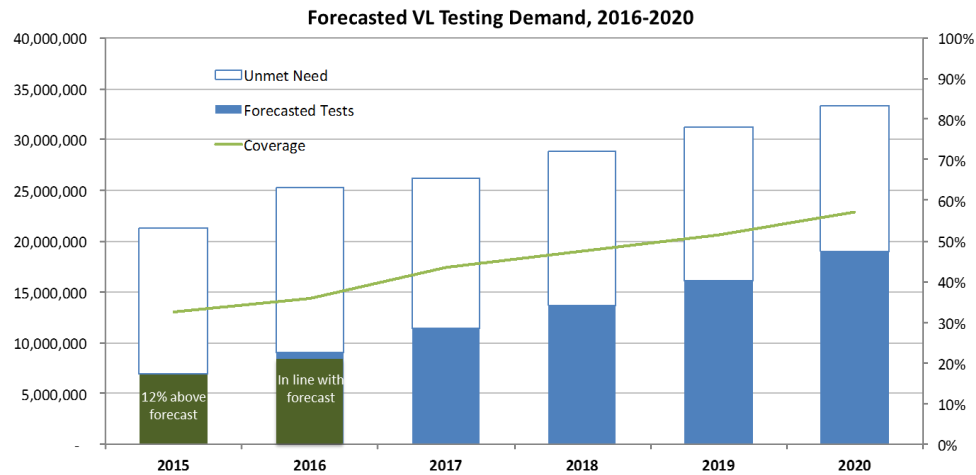


Viral Load spend shows rapid growth in past four years, tripling spend from 2015 to 2016.

*Source: PSM analysis; SCMS and PSM data YTD; weighted average cost price for most recent year data is used to calculate costs. Neither refers to products that can not be exclusively mapped to Molecular or CD4 categories – may cover both or neither.

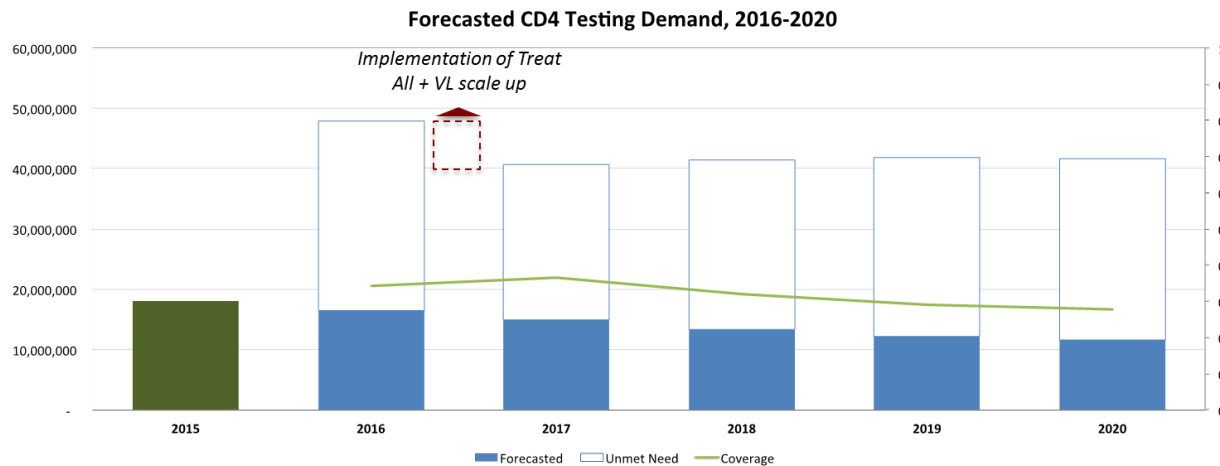
Long Term Forecast: Forecasted 2017 to be Another Year of VL/EID Growth and Roughly Flat CD4 Tests Among 21 LMICs

Forecast provided by Clinton Health Access Initiative at December 2016 WHO Diagnostics Forecasting Event. Note – metric may be in tests run, rather than procurement of products.



Viral load testing is expected to grow rapidly at a Compound Annual Growth Rate (CAGR) of 30% through 2020

*Source: CHAI Survey of 21 LMICs



CD4 testing is expected to remain roughly flat (CAGR of -8%) as countries increase patient initiation targets and scale up viral load monitoring

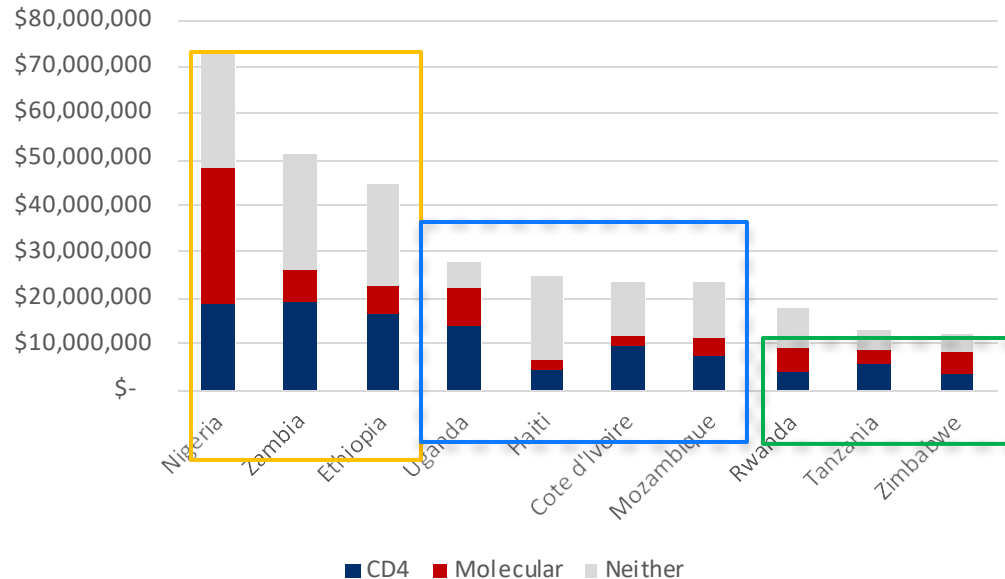
*Source: CHAI Survey of 21 LMICs

The Majority of Lab Procurement Including VL/CD4/EID is Conducted Through Local Procurement

- Targeted Local Procurements (TLP) represent an increasing percent procurements, growing from 63% in 2012 to +80% in 2015.
- Volumes procured by each country vary and can largely be divided in (H/M/L).

This slides is subject of discussion: need feedback from Jason & Mary Lyn

Total 2013 – 2016 Intervention Spend (\$)*



- **High-volume country** (>\$40 4yr): Nigeria, Zambia, Ethiopia
- **Mid-volume country** (\$20M-\$40M 4yr): Uganda, Cote D'Ivoire, Mozambique, Haiti*
- **Lower-volume country** (<\$20M 4yr): Rwanda, Tanzania, Zimbabwe + 16 others

*Source: 2017 Country Forecast; Plan Team Analysis; 2016 amount is approximated based on YTD orders. Pending further updates from Country Plans

In Dec-2016, Source team reached out to Nigeria, Mozambique, and Rwanda country offices. Sessions with Zambia and Ethiopia are in progress.

Overview Of QA/QC

QA/QC Eligibility

- ISO 9001:2000
- ISO 13485
- ISO 13488
- CE01847/SRA/USFDA

Supplier Discussion

Major challenges and opportunities

Challenges

Viral load scale up requires accurate forecasts, an optimized instrument network, and functioning machines

Disparate local market, inconsistent pricing and service level do not satisfy country requirements

Lack of training and management in machine performance and utilization

Changing clinical needs and evolution of laboratory technology

Opportunities

- Enhance Country Supply Planning
- Optimize Networks
- Negotiate reagent rental agreements
- Negotiate continuous support for legacy equipment

- Negotiate transparent pricing & volume discounts through HQ-supported procurement
- Optimize service & supply terms
- Optimize supplier portfolio & increase market competition

- Improve data management capability
- Request periodical performance reports

- Offer diverse intervention options (VL/EID/CD4) and conditions (POC/Lab)

Discussion session: What are the challenges and opportunities not captured in the summary above?

Scope of Framework Agreements

1. Establish Global Framework Agreement with all eligible suppliers for Viral Load, Early Infant Diagnosis, and CD4.
2. Equipment/supply procurement through reagent rental (strongly preferred) or direct purchase options. Solicit all-inclusive price per test.
3. Emphasis on good quality network for installation, training, maintenance, local support, and supply chain of reagents/samples.
4. Each respondent may be contacted for negotiations on prices and services, to match or remain below recent historical prices and/or stay in line with other global pricing strategies.
5. Terms and conditions will be discussed and agreed with each manufacturer.
6. Second-round tender will be conducted to obtain best offers in price and service.
7. Firm orders for eligible items will be made against the resulting Framework Agreement. Individual order quotations will be evaluated for adherence to the framework agreement with GHSC-PSM.
8. Amendments may be added to address global or country-specific requirements
9. Set up communication mechanism for frequent engagements between vendors and PSM. Leverage ARTMIS capability. Examples include a quarterly demand forecast from PSM to suppliers, and a performance report (number of machines/tests) from suppliers to PSM.

Reagent Rental Scheme

- Risk sharing between PSM and vendors with potential premiums paid for value added
- Increase consumption efficiencies and accurate projections
- Maintenance obligation to vendors tied to contracts
- Reduction of downtime and increase of consumption products
- Training of end-users on preventative maintenance
- Reachable engineers linked to local distributors network
- Retirement of non-functional or obsolete equipment

Key Takeaways

Takeaways!

- Seek a systems/network approach where possible to inform network maintenance and expansion
- Planning and procurement must be coordinated among agencies / donors in country
- Reagent rental / bundling of services (including connectivity) into contracting is priority
- Development of and adherence to criteria for placement of additional machines or higher throughput platforms
- Integration of POC platforms into current networks
- Data is key to asset management. Contractual requirements for data sharing (downtime / protocols / specimen type / etc.)
- We are working with stakeholder to address issues – but, we need your input!

Supplier Q & A

Acknowledgements

- Mr. Jay Heavner, Strategic Engagement Director, GHSC-PSM
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- Ms. Catherine (Cat) Dame, Demand Planning Analyst, GHSC-PSM

Archana Bharti, GHSC-PSM

abharti@ghsc-psm.org

Shadrack Were, GHSC-PSM

swere@ghsc-psm.org

Appendix

Adoption of global standards for identification and data capture and exchange

- Implement global standards for:
 - Product and location identification
 - Packaging, presentation, and data capture
 - Data exchange of orders, shipment status and delivery notification
- Goal is to achieve:
 - End to end data visibility
 - Supply chain efficiency
 - Supply chain security

For more information, we suggest you attend the following sessions:

- Implementation of GSI Global Standards for Product Identification
- Data Exchange with GHSC