

HIV Viral Load Testing Market Analysis

September 2012
Laboratory Services Team
Clinton Health Access Initiative



Agenda

Background on Viral Load Testing

Growth of Global Viral Load Market

Factors Impacting Scale-up

Integration of Conventional and Point Of Care Testing

Global Viral Load Market Forecast

Preliminary CD4 and Early Infant Diagnosis Forecast

Upcoming Point of Care Project

Providing high-quality diagnostics is essential in the fight against HIV

- People living in resource-limited settings (RLS) are disproportionately affected by the AIDS epidemic
- Rural populations are hit hardest
- Most testing and monitoring is relatively expensive, and requires laboratory infrastructure and skilled staff, which limits access to centralized locations
- There is a need to offer testing and monitoring near the point of care to improve access and patient outcomes

An opportunity exists for widespread scale-up of cost-efficient viral load testing in developing countries

Viral load monitoring has become the standard of care for monitoring patients receiving ART in much of the world

- Providing an early sign of non-adherence or treatment failure
- Prolonging duration of first-line drug regimen
 - Preventing unnecessary switches in treatment
 - Reducing the need for more expensive 2nd-line ART
- Supporting migration to 2nd line treatment in a timely manner
 - Reducing the spread of highly resistant virus
- Confirming viral suppression in pregnant woman
 - Lowering the risk of mother-to-child transmission

CID (2007) 44:128-34; Trop Med Int Health (2011) 15:251-58; JID (2010) 201: S16-S25; JID (2010) 201: S73-S77; AIDS Res Treat (2011) 2011:1-7; Infect Dis (2008) 8:89; Antivir Ther (2007) 12:83-88; J Acquir Defic Syndr (2006) 41:323-31

WHO's 2010 recommendations note viral load testing only as resources permit

- Viral load should be used in a targeted approach to confirm suspected treatment failure based on immunological and/or clinical criteria
- Viral load should be used in a routine approach, measured every 6 months, with the objective of detecting failure earlier than possible with immunological and/or clinical criteria

While the need for viral load testing is well documented, current high cost and complexity has limited WHO's ability to make stronger recommendations for wider scale up

World Health Organization. Antiretroviral therapy for HIV infection in adults and adolescents: recommendation for a public health approach; 2010 Revision. World Health Organization. Technical brief on viral load technologies; June 2010.

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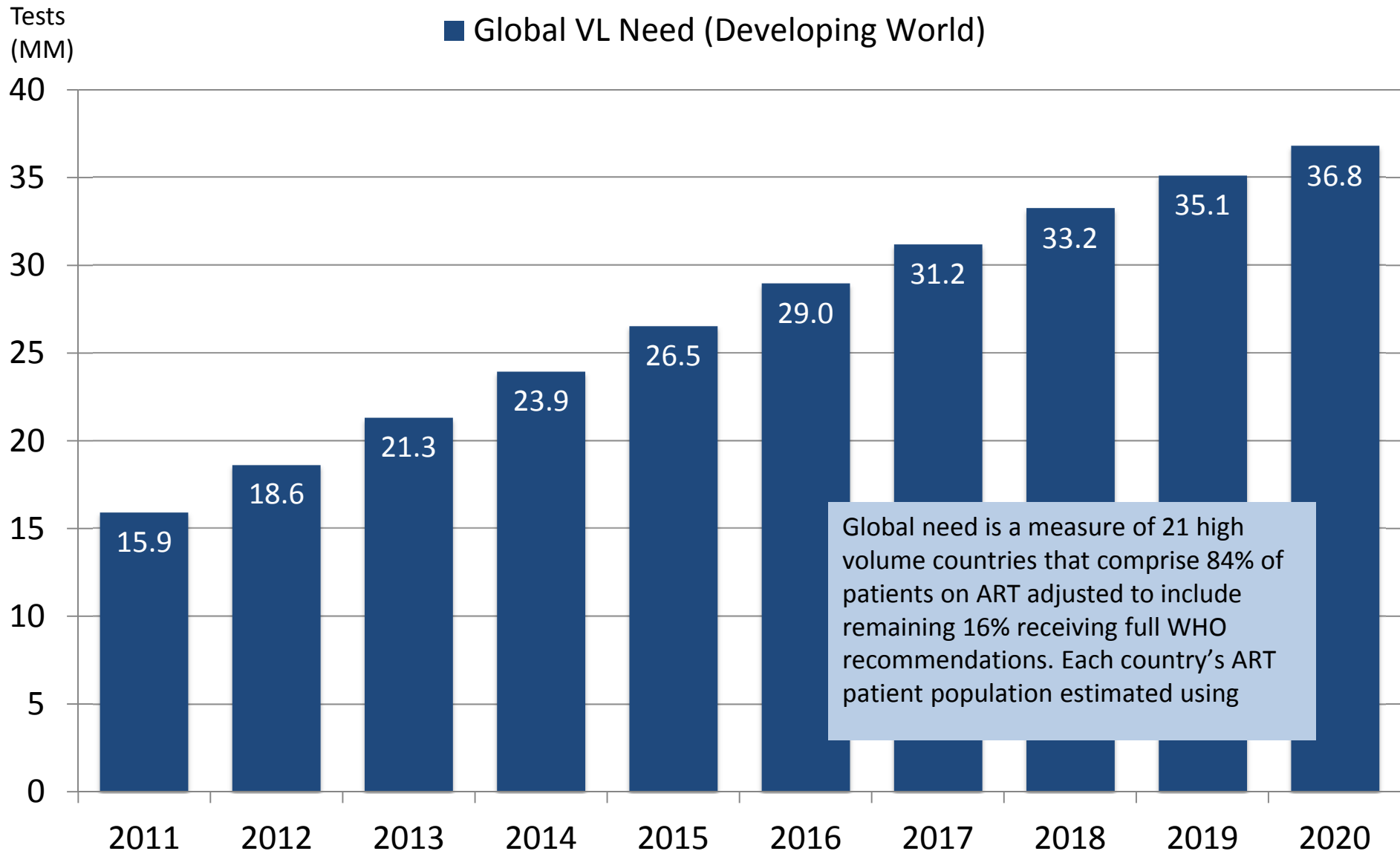
Methodology of global VL forecast (Part 1)

- Need of VL testing volume measured at 21 high volume countries that comprise ~84% of patients on ART. Total need adjusted to include remaining ~16%.
- Global need in the developing world defined as all lower income countries (LIC), lower middle income countries (LMIC), and upper middle income countries (UMIC), as defined by World Bank income classifications.
- Each country's ART patient population estimated using projections for 2011-2020
- Each country's patient population segmented using two dimensions:
 - Type of facility
 - Provincial or district hospital labs
 - Large urban clinics within 15 minutes to lab
 - Small rural clinics greater than 15 minutes to lab
 - Type of VL test
 - Baseline VL screening
 - Routine post-ART VL monitoring
 - VL testing for patients with suspected treatment failure
- To estimate number of patients in each category of facility (Labs, <15 minutes from lab, >15 minutes from lab) proxies used where necessary:
 - Percent of population living in urban areas
 - Overall coverage rate of patients in need of ART

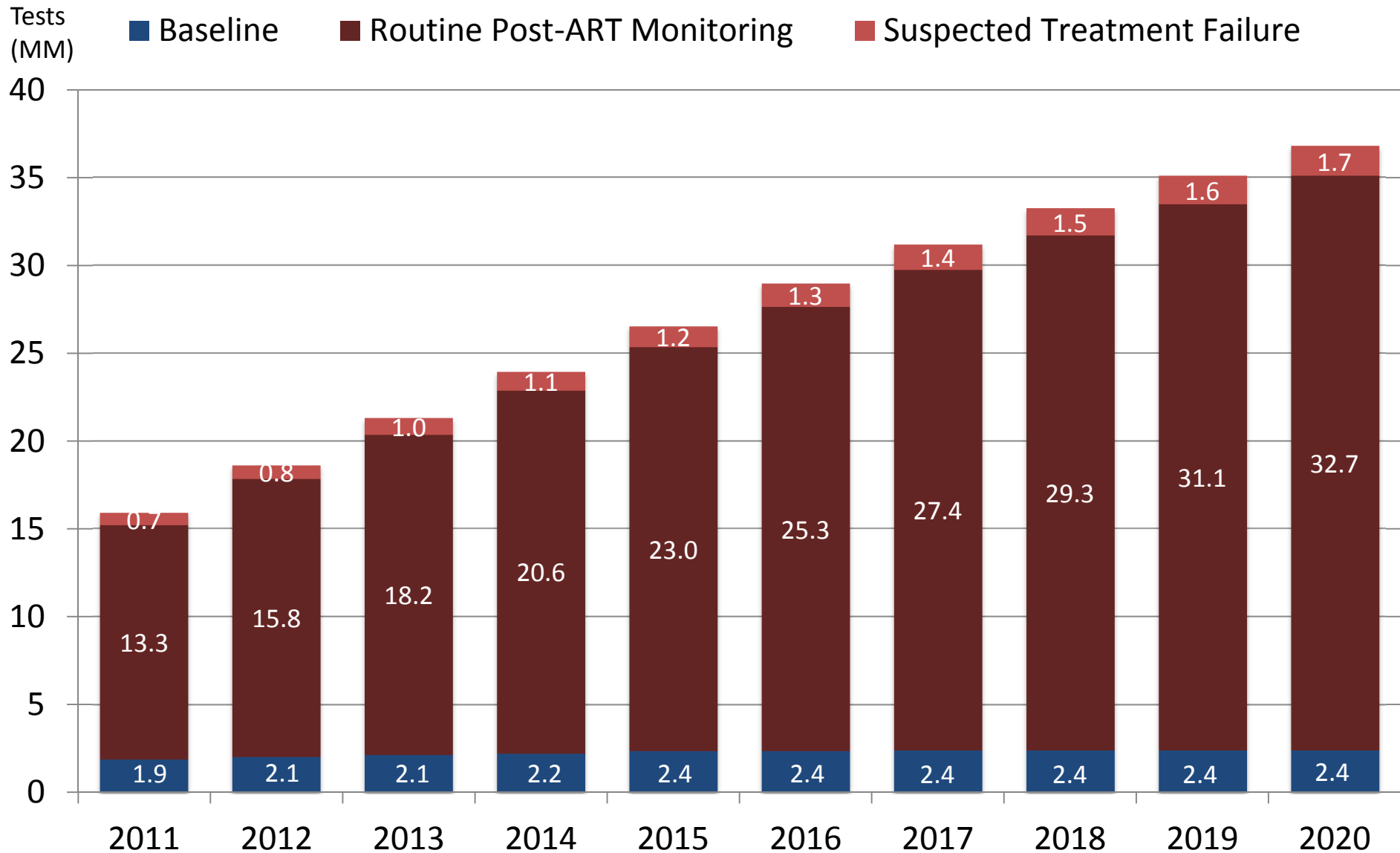
Methodology of global VL forecast (Part 2)

- Uptake of new products based on experience from existing products and key assumptions:
 - ~1m tests in the first year for a new product
 - New products focus on ~6 major countries in Year 1, then 4-6 additional countries/year
 - POC products likely to be adopted only at facilities without conventional VL on-site
 - New products capture 10% of POC VL market in first year, and grow 5-10% each year
 - POC uptake schedule based on 1 device-based product available in 2013, 2 device-based products available in 2014, and 3 device-based products available in 2015
 - Initially, multiple POC products can all continue to grow, but eventually a few (2-3) will take the majority of the market
- Impact of POC adoption on conventional VL testing volumes forecasted:
 - Assumed conventional VL testing has 30% of potential district hospital volumes, and 15-25% of potential clinic volumes, all through referral to reference hospitals
 - The remainder of potential testing volumes are currently not being met
 - In the absence of POC, these percentages would continue to grow by ~2.5% each year
 - After POC adoption, new products will gradually take conventional market share, growing by ~5% each year

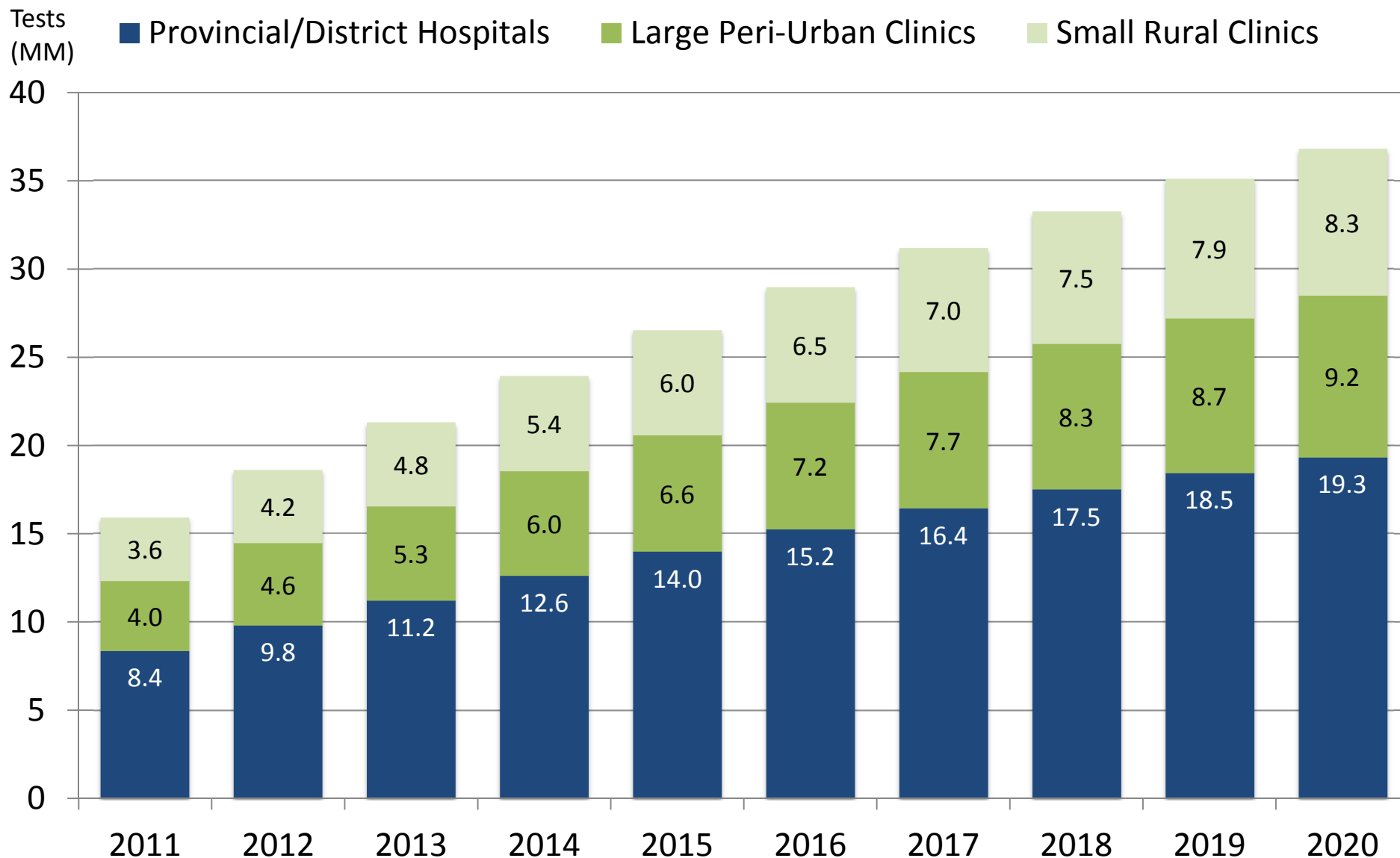
Global need for viral load testing is expected to grow significantly in 2011-2020, based on ART scale-up trends and WHO guidelines



Routine VL monitoring twice per year for ART patients will remain the largest component of testing need



There is growth potential in various settings including urban and rural clinics which, are largely without access to conventional viral load



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Scale-up of viral load testing will depend on many factors, and will vary significantly across countries

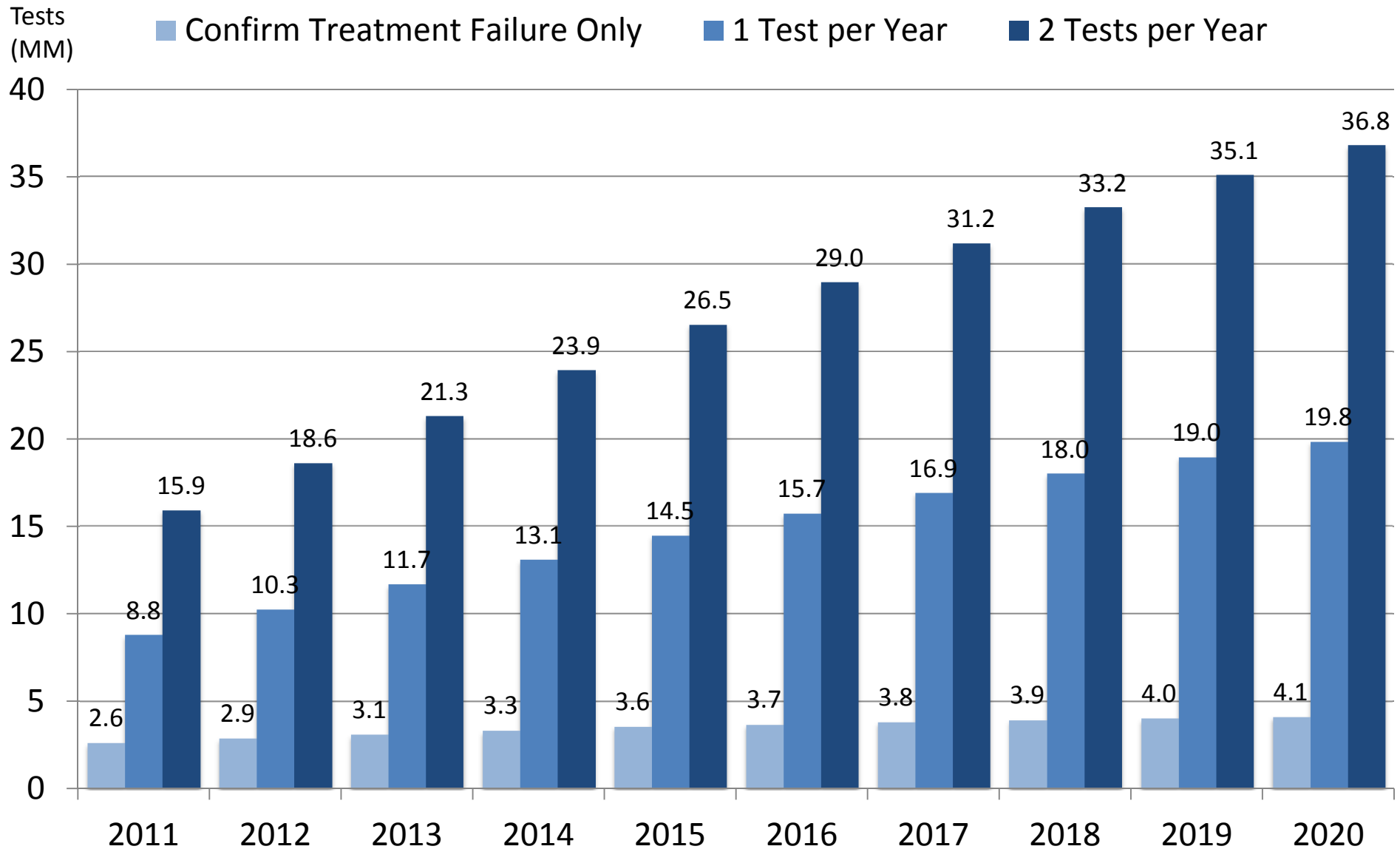
- **Demand-side factors impacting scale-up**
 - Ministry of Health buy-in and political climate
 - Infrastructure availability
 - Time to conduct evaluations and registrations
 - Rate of site-by-site training and implementation
 - Funding availability for diagnostics

- **Supply-side factors impacting scale-up**
 - Initial capital expenditure for new diagnostic platforms
 - Wastage and price per test result
 - Ease of use and robustness
 - Distribution and service
 - Assay performance

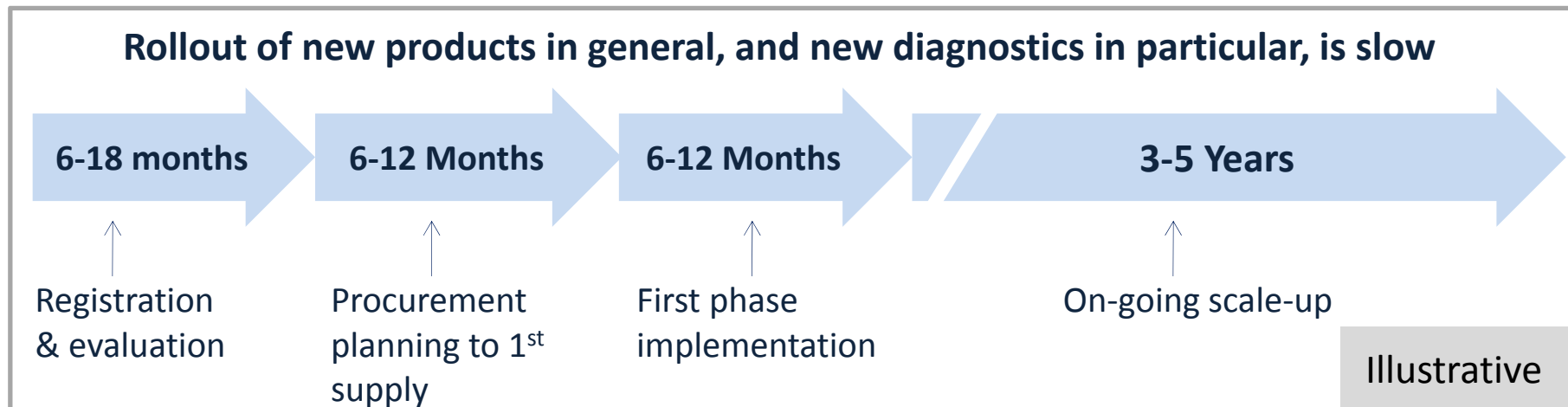
The speed of implementation will also vary significantly across countries

- Current conventional VL coverage:
 - South Africa, Brazil, Botswana, Thailand, and China have already reached significant coverage with conventional VL, and comprise ~80% of global volumes
 - A few other countries have achieved modest conventional VL volumes in the public sector (e.g. Rwanda, Namibia, Nigeria), but access remains low
 - Others have VL laboratories, but they are used mainly in the private sector or for research purposes (e.g. Ethiopia, Uganda, India, Lesotho)
 - Most of the remaining countries in the forecast lack significant public sector VL testing (e.g. Cameroon, Cote d'Ivoire, Mozambique, Swaziland, Tanzania, Zambia, Zimbabwe)
- Assumptions about conventional VL scale-up projections:
 - In the past year, Kenya and Malawi have begun to make investments in VL capacity
 - In addition, a few countries already have VL equipment and intend to scale up testing in the next 1-2 years if funding permits (e.g. Ethiopia, Zimbabwe, Nigeria)
- Assumptions about POC VL scale-up projections:
 - Many countries have plans to evaluate and pilot new POC VL technologies in 2012, or and as products become available
 - Certain countries are established early adopters of new POC technology (e.g. Mozambique, Zimbabwe, Malawi, Uganda)

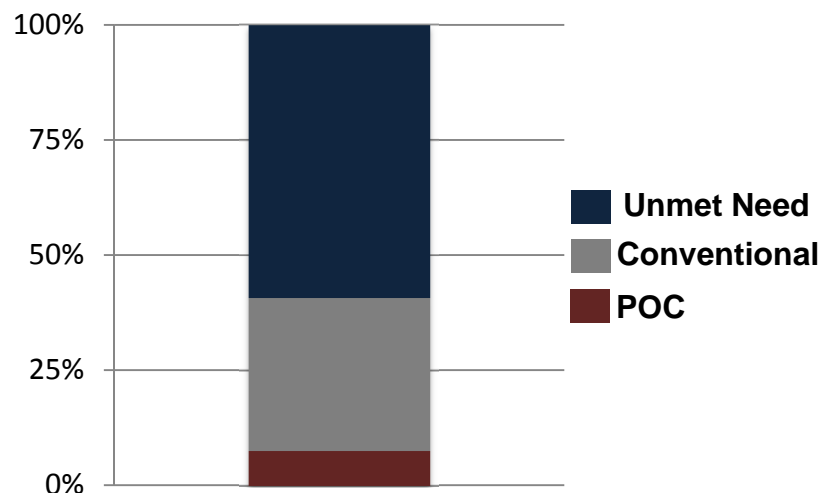
Alternative scenarios: Actual need will depend on testing levels in country guidelines and level of investment



Demand side factors impacting scale up: Slow roll out of diagnostics historically



CD4 market in 7 high volume countries in East and Southern Africa*



Despite approval and early adoption, uptake has been slow

*Representing approximately 35% of the CD4 market in developing countries

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Conventional and new technologies are needed to provide full access to viral load testing

Point of care (POC) is a diagnostic test that is performed near the patient or treatment facility, has a fast turnaround time, and may lead to a change in patient management

JID (2012) S2:1-12

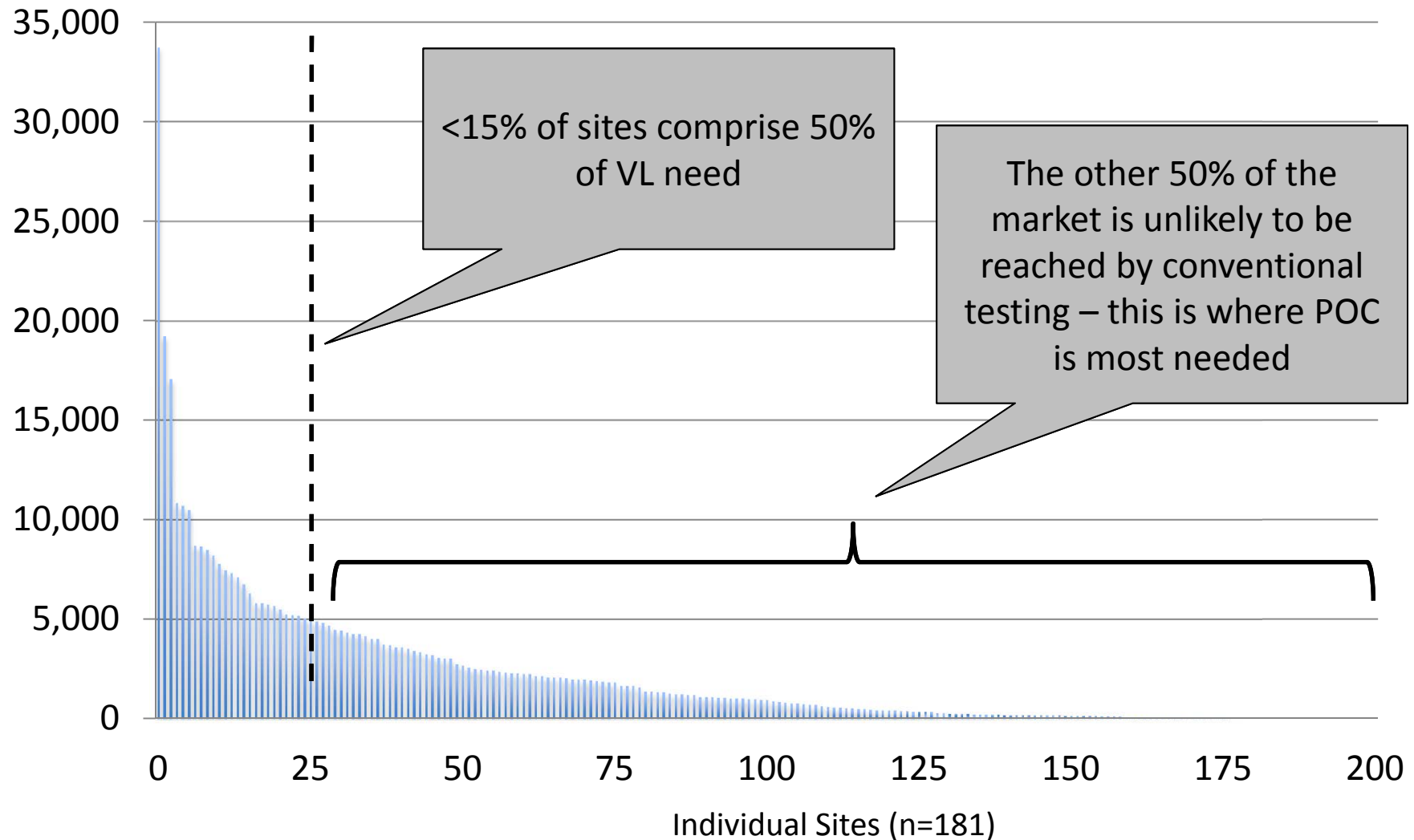
- POC will be required to provide access to rural communities in RLS settings
- POC CD4 diagnostics lead to higher patient retention and better patient outcomes
 - Patient loss cut
 - Time to ART initiation reduced
 - Dramatic increase in the rate of ART initiation

Lancet (2011) 378:1572-79; Bull World Health Organization (2010) 88:675-80

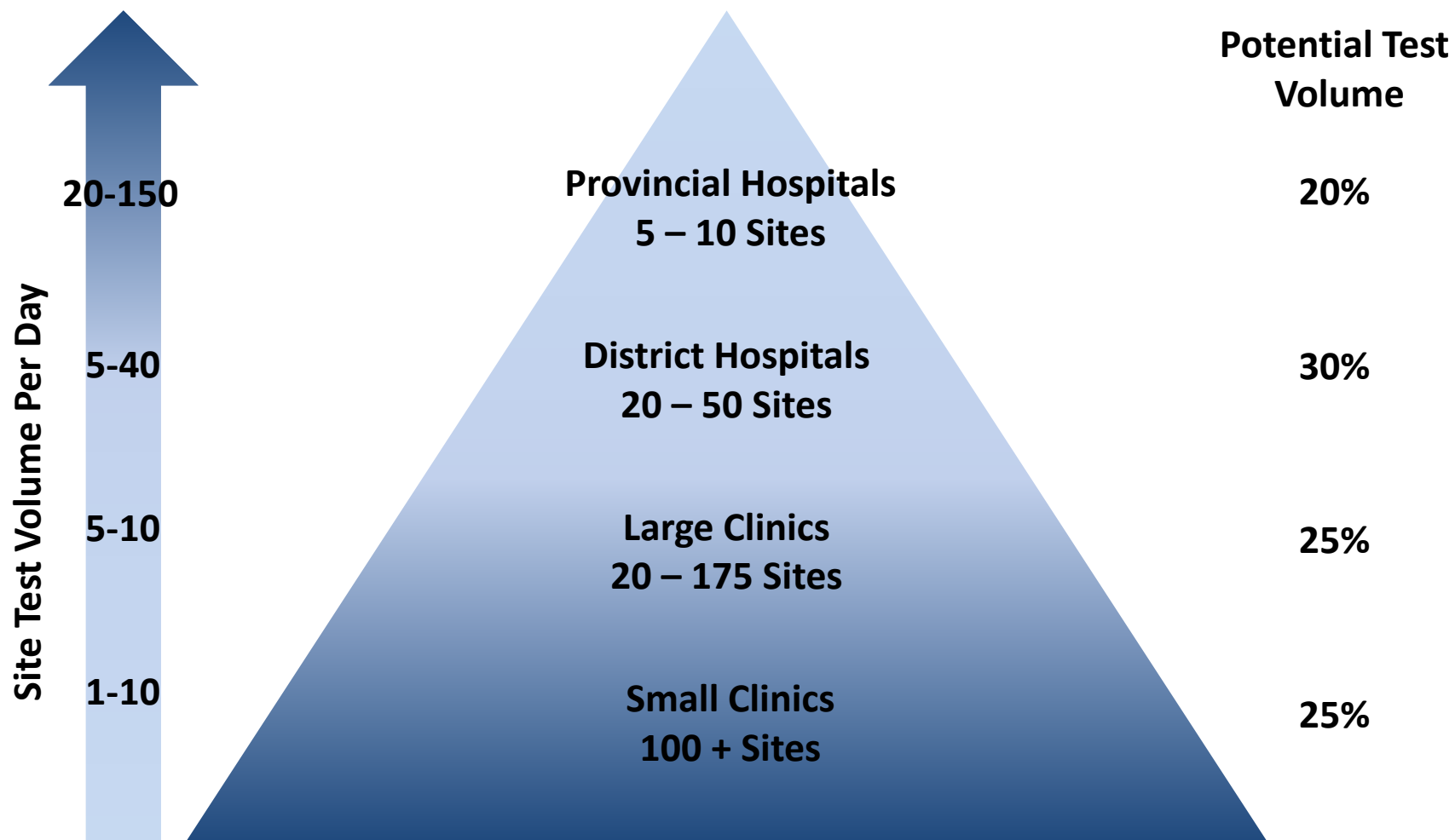
In most countries, a few large provincial and district hospitals comprise most of the VL testing need

Number of Tests Needed per Site per Year

Example Country: VL Testing Need at ART Sites without VL On-Site (as per WHO GL)



Strategic deployment of conventional and POC diagnostics are needed to accelerate widespread access to viral load testing



Approximate values based on average number of sites and range across 9 African countries
Number of tests per year are based on patient test needs

Agenda

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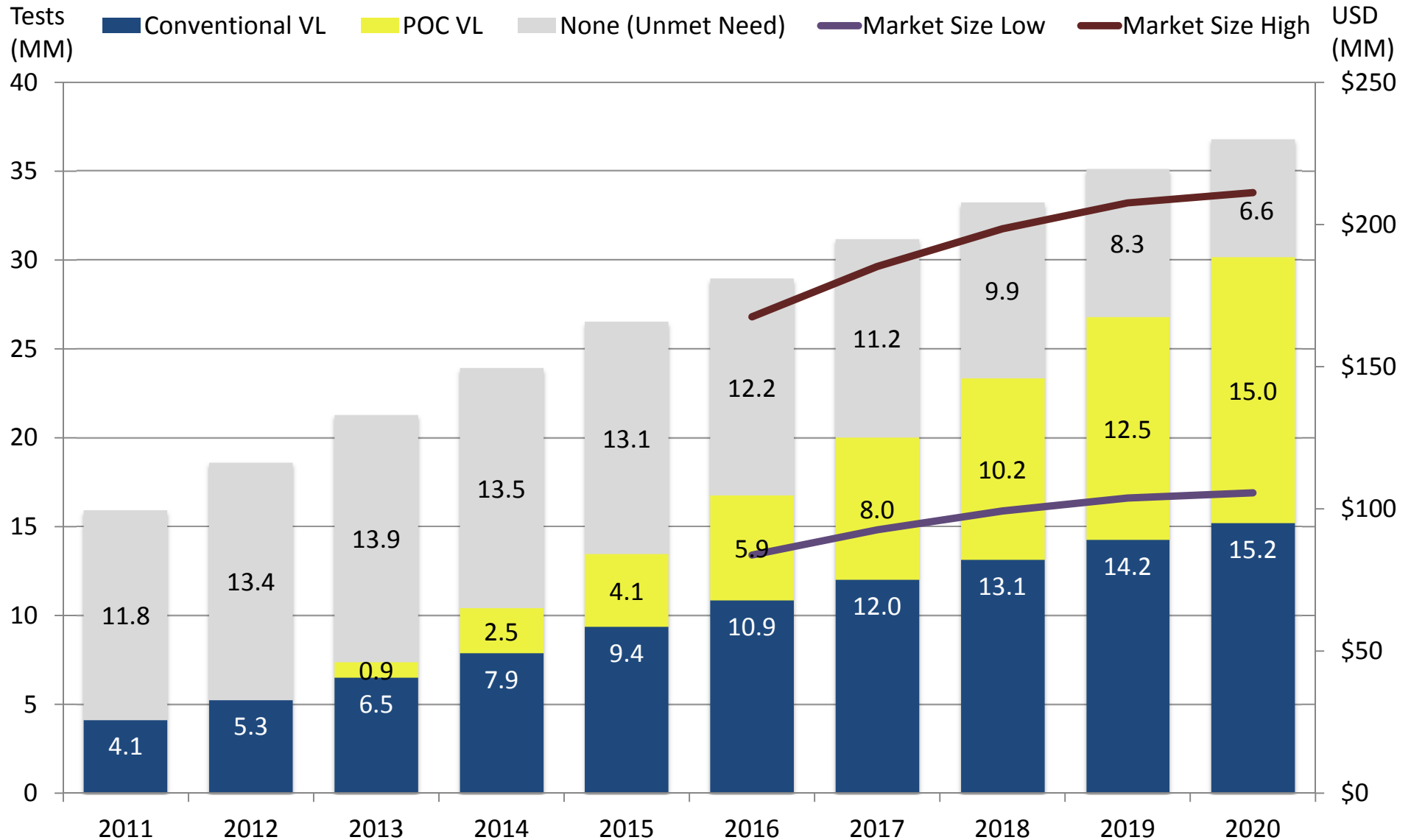
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As access improves, POC and conventional VL markets will both grow



Market size in USD estimated with \$10 per test in 2016 and \$7 per test in 2020 and linear price reductions between. Market size high refers to 2 tests per year in countries as shown in the bar graphs. Market size low refers to 1 test per year in countries.

Conclusions - VL

- The upside potential for viral load testing is large and could exceed \$200MM by 2020.
- Conventional VL and new technologies such as POC diagnostics will be essential to provide broad patient access.
- Scale-up will be impacted by demand-side factors from WHO recommendations in 2013 to in-country validation/adoption and the international funding climate.
- Market penetration and growth will also depend on supply-side factors such as price per test-result, assay performance and the strength of distribution and service networks.

Agenda

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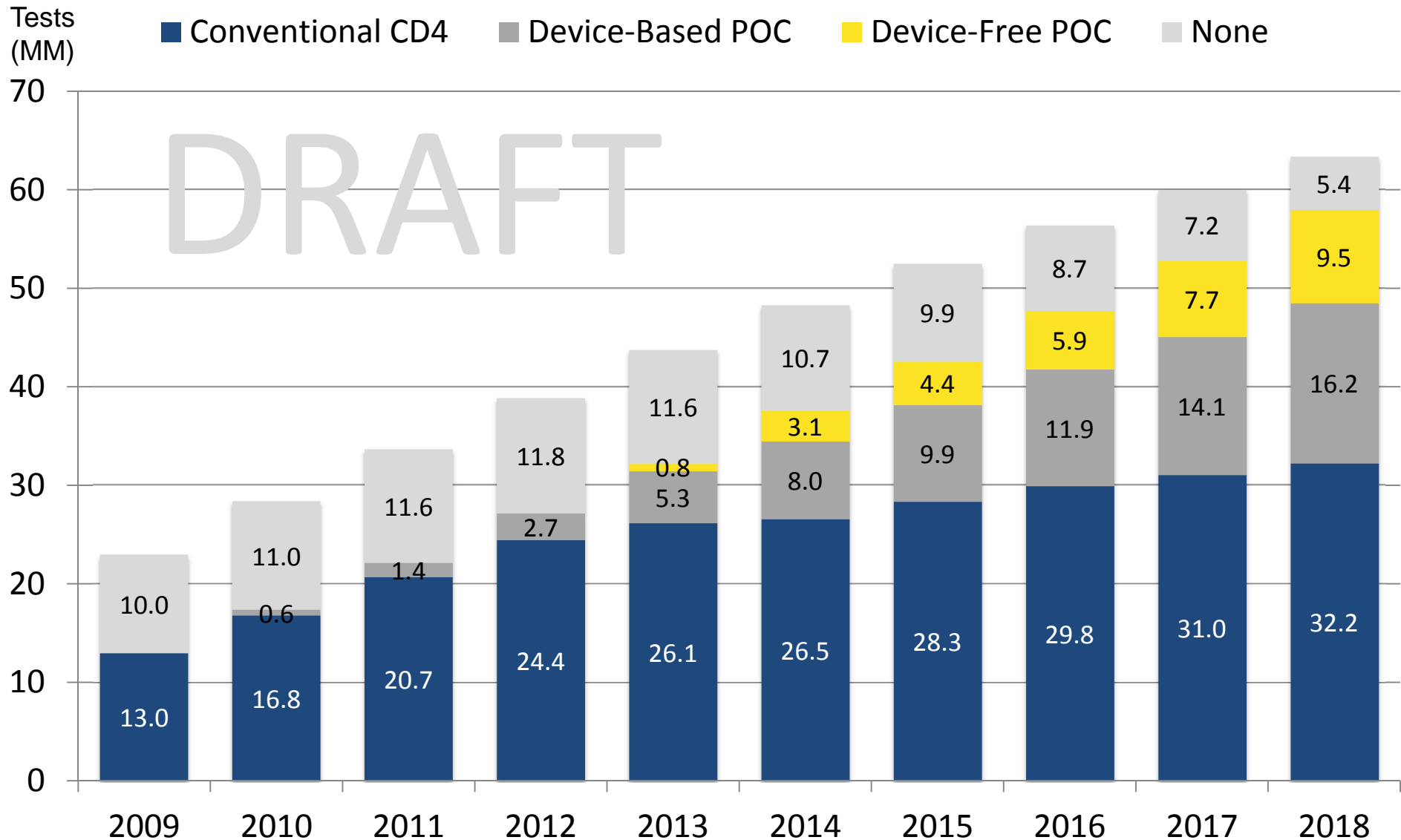
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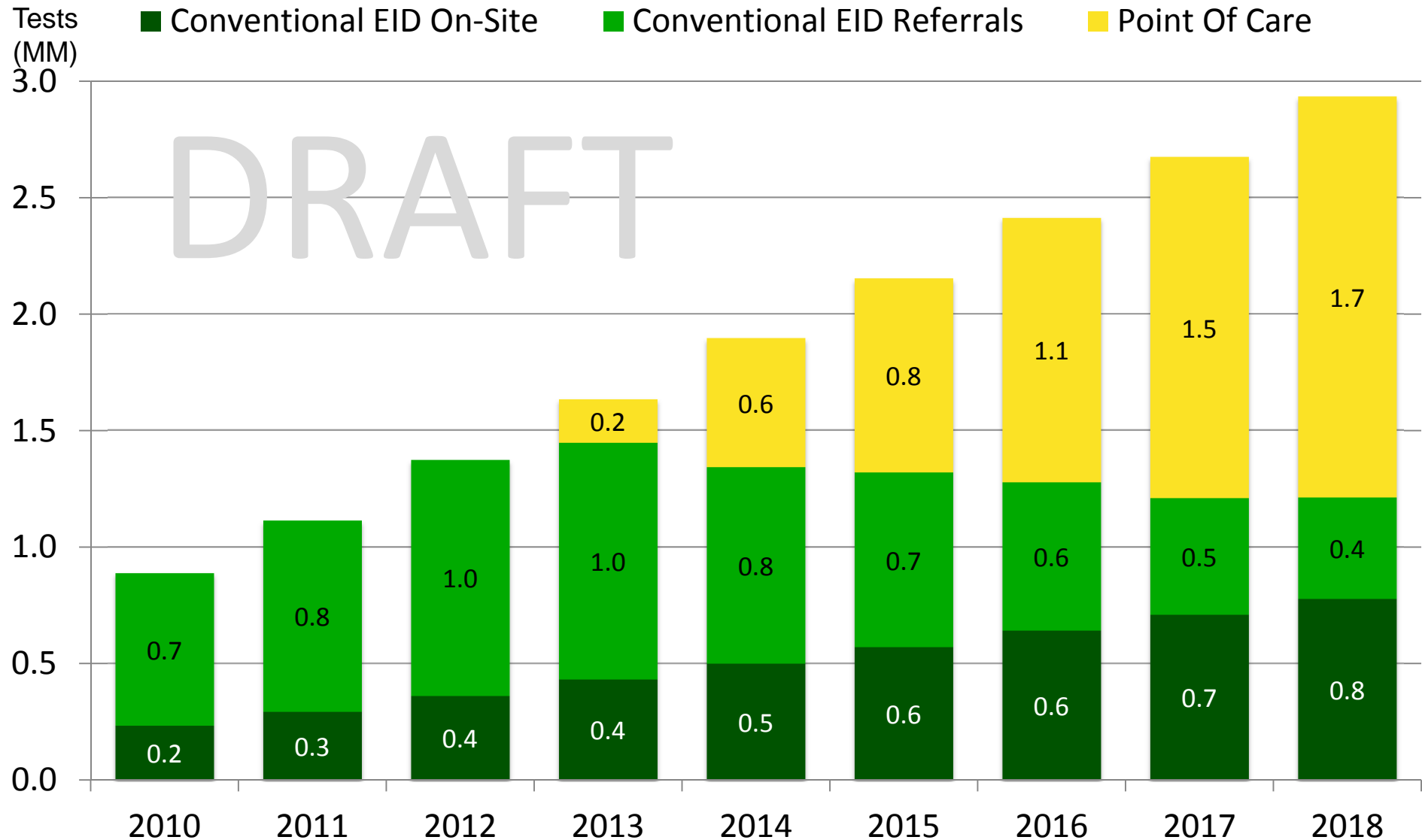
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Draft POC CD4 Forecast - Device-Based POC, Device-Free POC, and conventional CD4 markets will all continue to grow



Draft POC EID Forecast – Modest POC growth scenario with minimal conventional cannibalization



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A new POC project in 7 high volume countries in Africa

CHAI, UNICEF, and UNITAID are together committed to:

- Creating and sustaining a **healthy competitive market** for POC diagnostics where
 - The most patients have access to diagnostics
 - There continues to be innovation for increased value
 - New products can easily enter the market
- Signaling commitment to the POC market through **uptake**
- **Growing the demand side** of the market
- Accelerating **normative guidance** on the use of HIV POC diagnostics
- Supporting the **entry and uptake** of new, quality products
- Achieving **substantial public health impact**

Components necessary for smooth, rapid uptake of new diagnostics



Thank you.