

# HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool

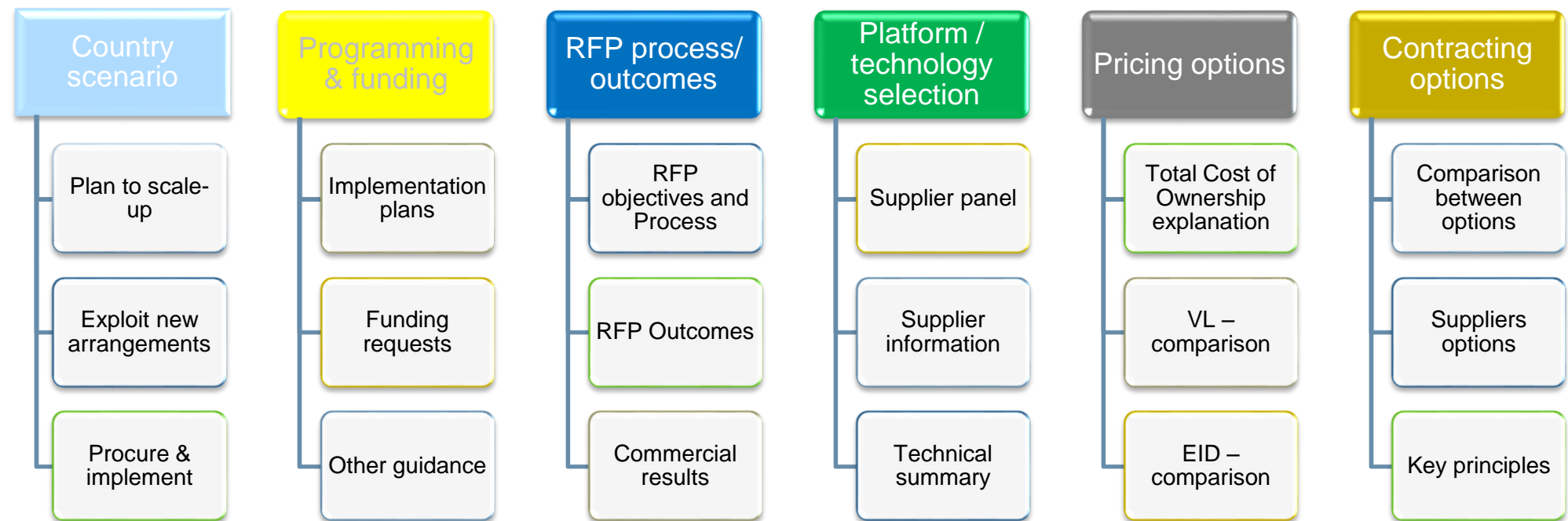
Version 2 April 2017

# HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool



Version 2 March 2017

Navigation diagram – Home page



This tool is being continually updated and the latest version of this tool can be downloaded from <https://www.theglobalfund.org/en/sourcing-management/health-products/viral-load-early-infant-diagnosis/>. We welcome receiving any comments or suggestions - contact details are provided on the webpage link above.

# Country scenario: Plan to introduce / scale-up VL or EID in my country

- Define testing algorithms and targets
- Analyze country context and existing testing capacity
- Assess utilization rate of existing testing platforms in country
- Review technology options
- Integrate sample transportation network
- Investigate costing scenarios
- Strengthen laboratory network/system
- Develop a phased implementation plan
- Prepare robust prioritized funding requests

# Country scenario: Exploit new commercial arrangements for my existing VL/EID technologies

- Map pricing offerings for reagents kits, equipment and services
- Understand options and opportunities for price breaks or committing volumes
- Compare added value services
- Consider cost of switching technologies

# Country scenario: Procurement and implementation of VL/EID

- Finalize product selection: analyser and corresponding reagent kits
- Consider Quality Assurance requirements
- Review pricing options
- Determine acquisition option
- Consider element of total cost of ownership
- Consider strengthening of lab system and infrastructure
- Evaluate Human Resources needs

# Global Fund/PEPFAR guiding principles for VL testing

## 1. Do no harm to existing programmes:

- Expanding viral load should not jeopardize scale-up of ART services to those currently eligible under WHO guidance.
- It is expected that not all countries will introduce or scale-up at the same rate.
- The introduction of virologic monitoring should not detract from Early Infant Diagnosis (EID) testing that uses the same platforms.

## 2. Analyse the impact of scale-up on existing budgets:

- The scale-up should have as little impact on overall laboratory and treatment budgets as possible.
- Careful consideration of a variety of trade-offs will need to be made including clinical monitoring protocols, machine placement and choice of technology
- Consideration of budgetary impacts for virologic testing should span several years, as initial costs may be higher, with benefits accruing later.
- The possibility to increase the budget for second-line antiretrovirals will need to be considered.

## 3. Optimize existing equipment and investments:

- Expanding the capacity for virologic monitoring can be supported by the optimal use of current diagnostics and platforms and maximizing previous investments.
- Innovative approaches to support laboratories, transfer specimens and communication of results should be adopted to support both previous and future investments.

## 4. Understand the current diagnostic marketplace:

- The introduction of additional technologies should take place in a rational manner,
- Comprehensive pricing information should be widely shared through the publication of the RFP outcomes

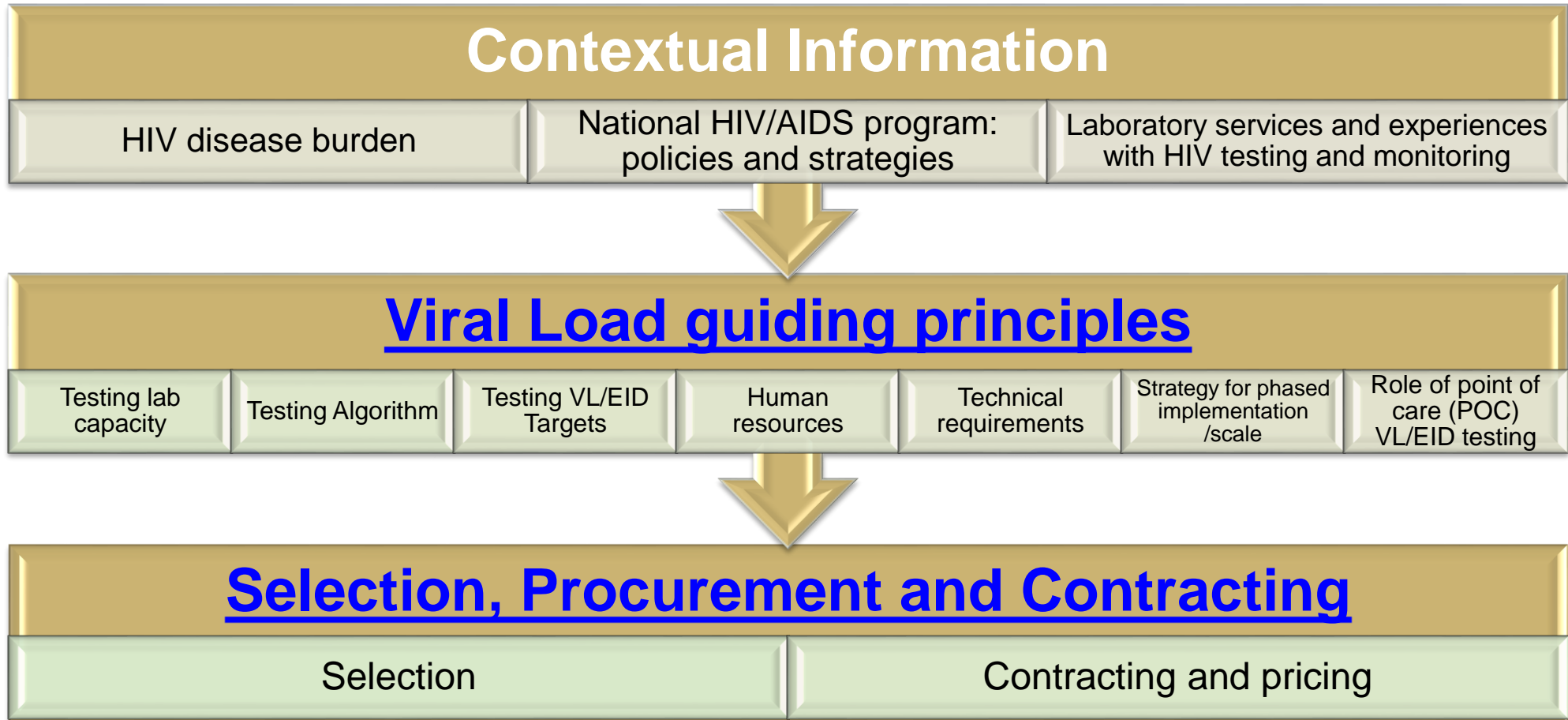
## 5. Develop a quality management/assurance programme that supports scale-up:

- The platforms, testing algorithms and lab systems should be embedded within an appropriate system for quality assurance at the global and national levels

## 6. Consider the context of the programme as introduction and scale-up take place:

- The expansion of viral load should take into consideration local HIV treatment guidelines and epidemiology.
- Virologic testing could be phased-in through prioritization of special populations or geographic areas.
- Additionally the role and amount of donor supported CD4 testing needs be considered both in the short and long term.

# Development of an implementation plan for VL/EID testing



Source: GF :“Programming of laboratory investments - with a focus on viral load testing: New Funding and Reprogramming:”

[http://www.theglobalfund.org/documents/psm/PSM\\_ProgrammingLaboratoryInvestmentViralLoadTesting\\_Guide\\_en/](http://www.theglobalfund.org/documents/psm/PSM_ProgrammingLaboratoryInvestmentViralLoadTesting_Guide_en/)

# Technology Selection Process

## Testing strategy

- Routine or targeted testing frequency
- VL & EID testing centralized vs decentralized approach

## Country Context

- Existing VL & EID testing capacity in country
- Regulatory requirements (national and donors policies)
- Quantification of testing target
- Capacity for sample transportation
- Availability of trained staff

## Features of analysers

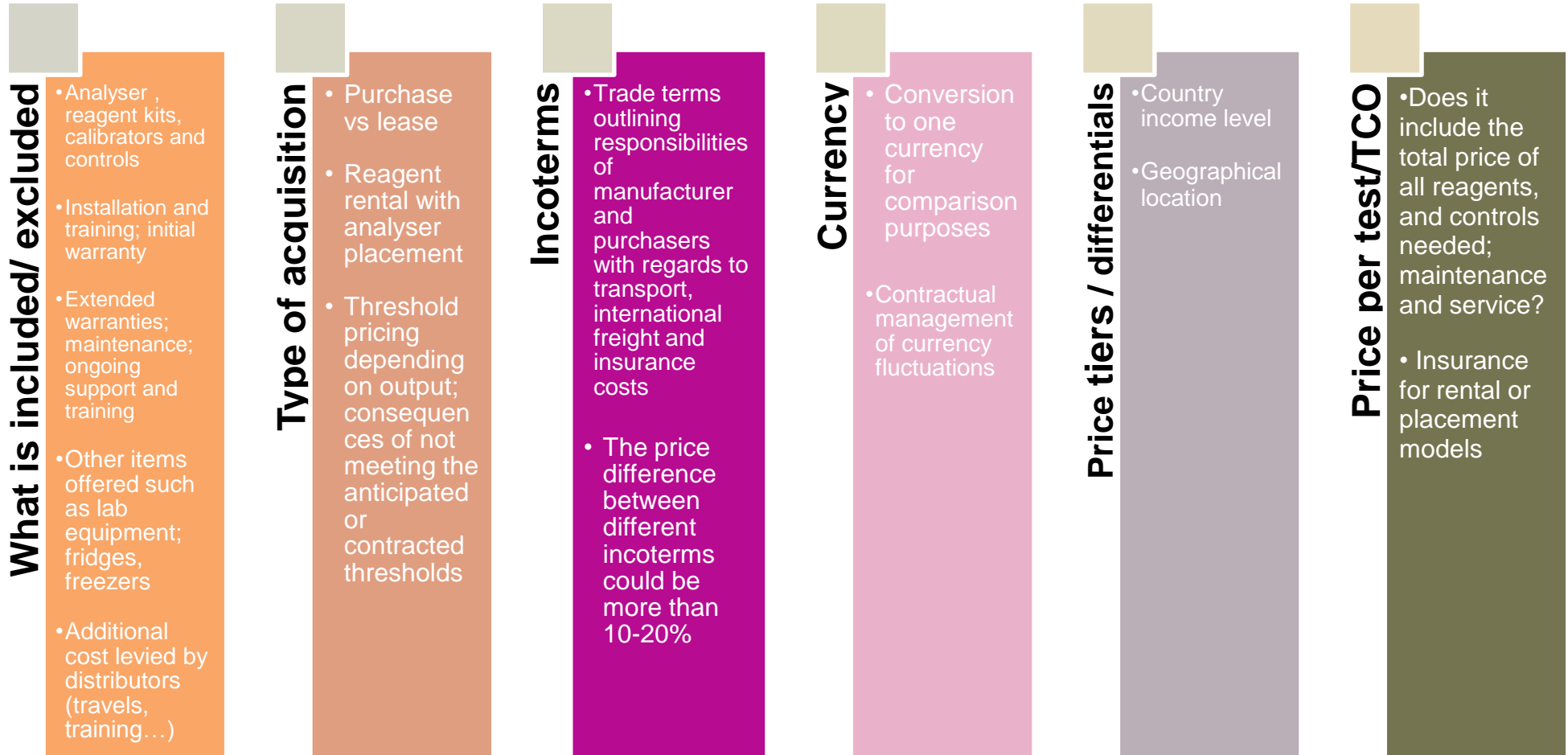
- Testing menu: VL and/or EID
- Sample type
- Number of tests per day.
- Automated/semi-manual/POC platform.
- Capacity for polyvalence
- Cold chain requirements for storage

## Commercial

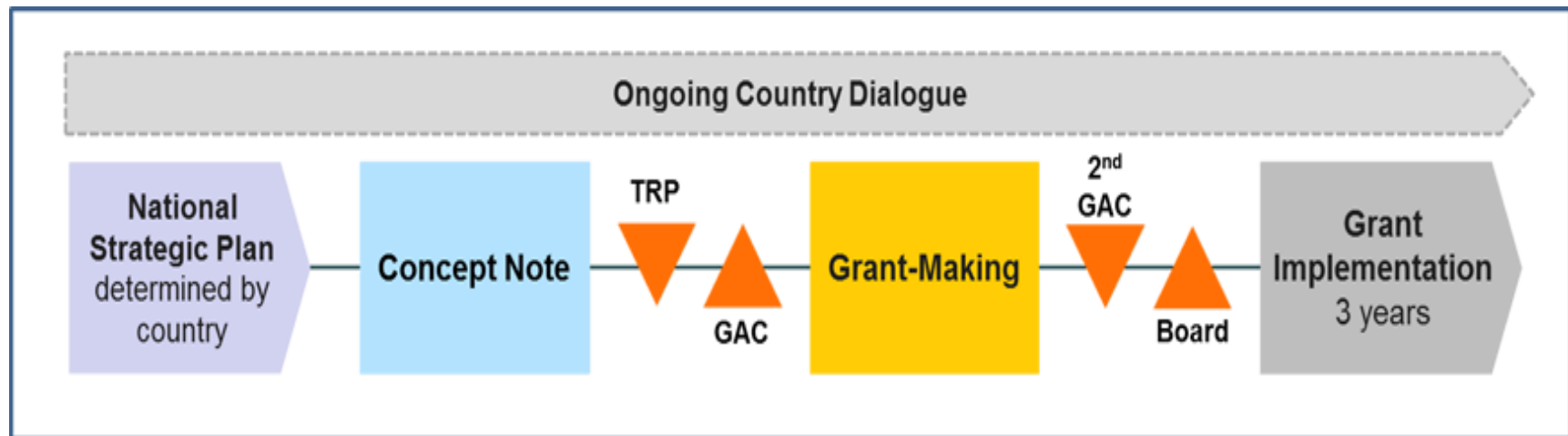
- Costs: analysers reagents, consumables, total cost of ownership
- Contractual offering and service level agreements including support, training, servicing



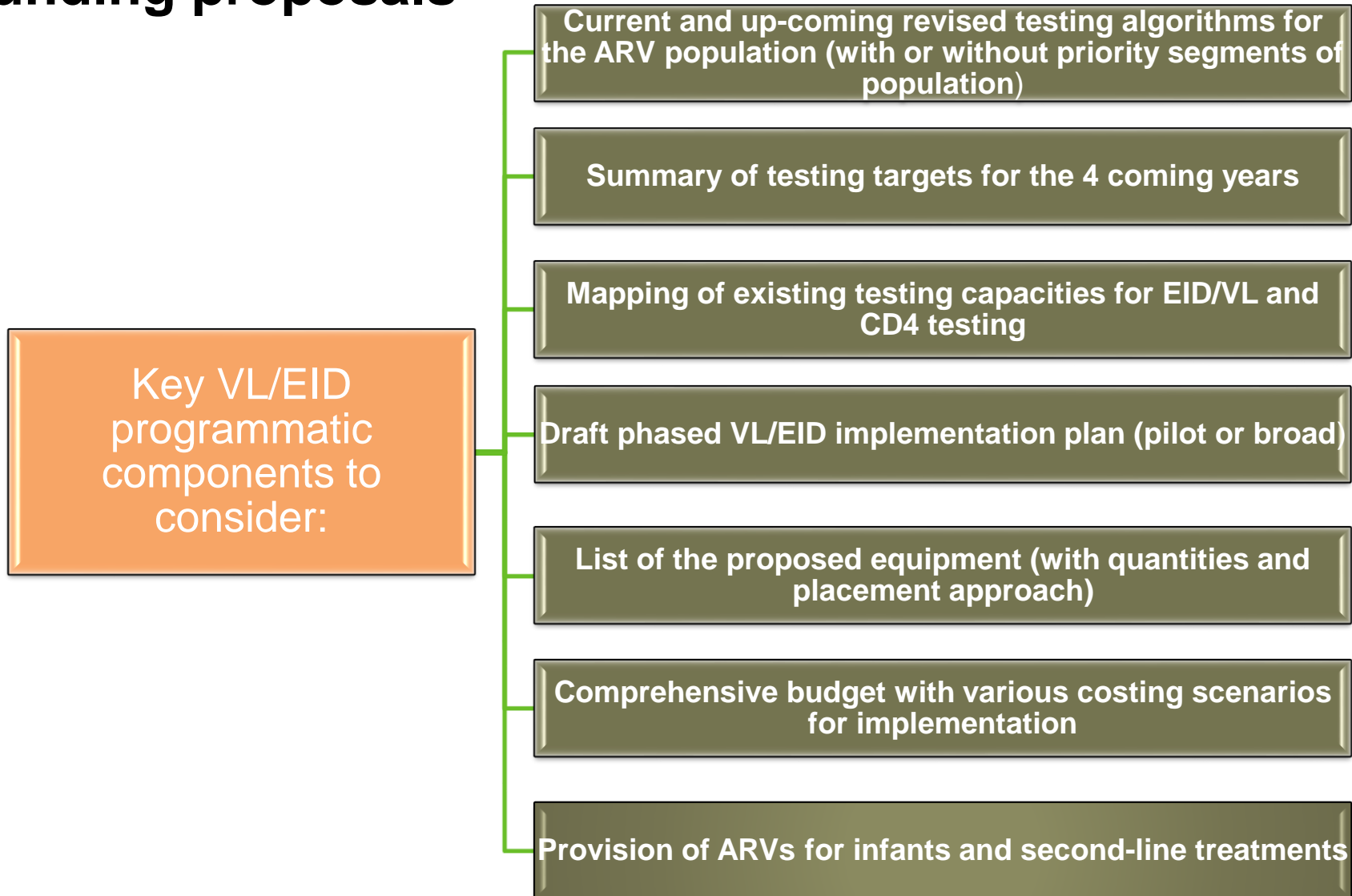
# Key elements to consider with respect to procurement, pricing and contracting



# VL/EID funding requests within grant life-cycle



# Funding proposals

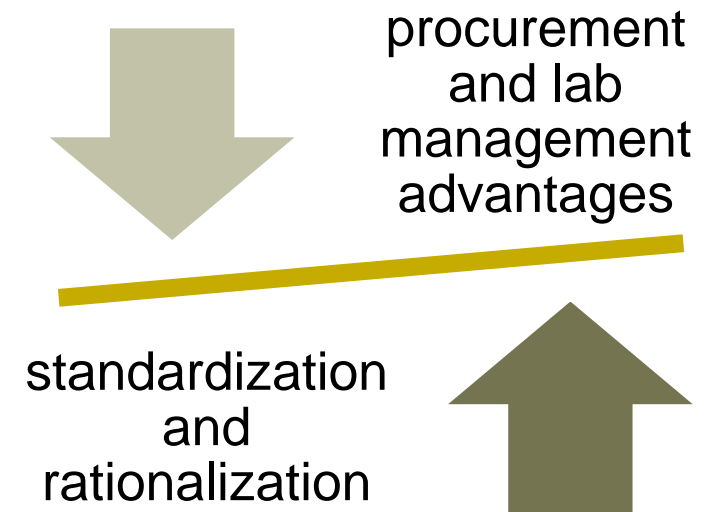
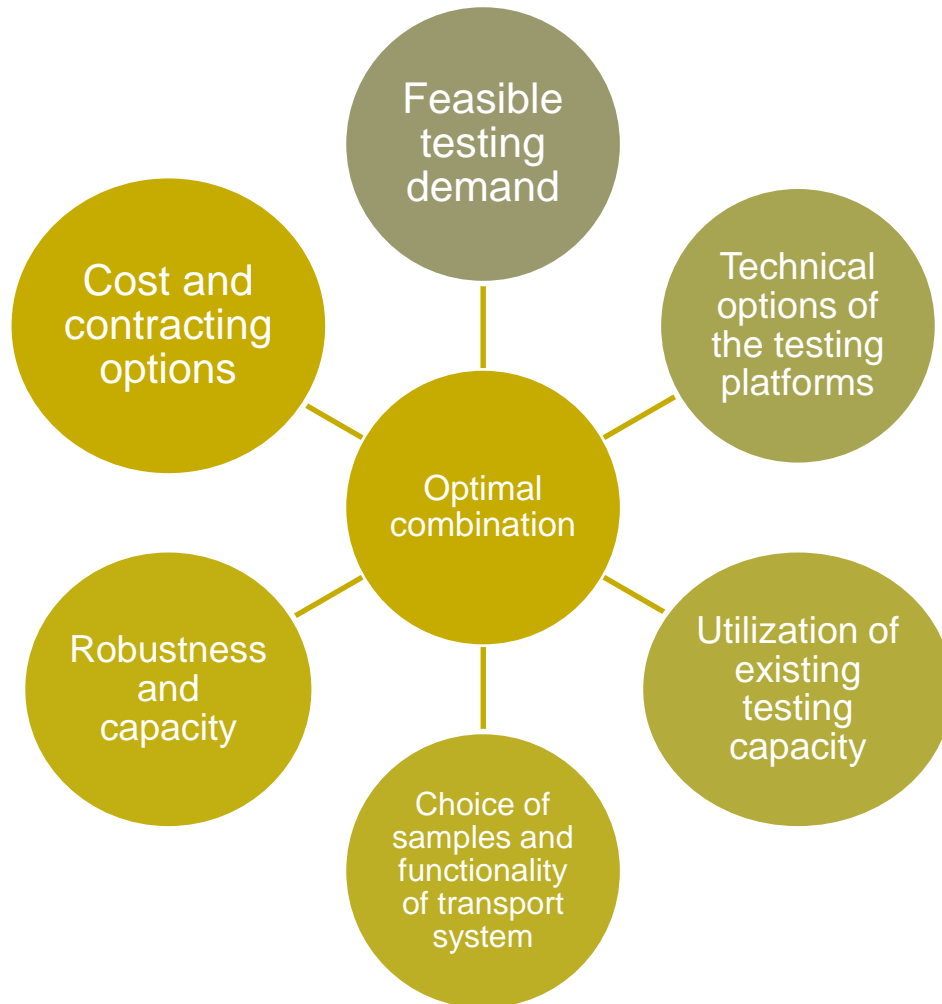


# Funding requests

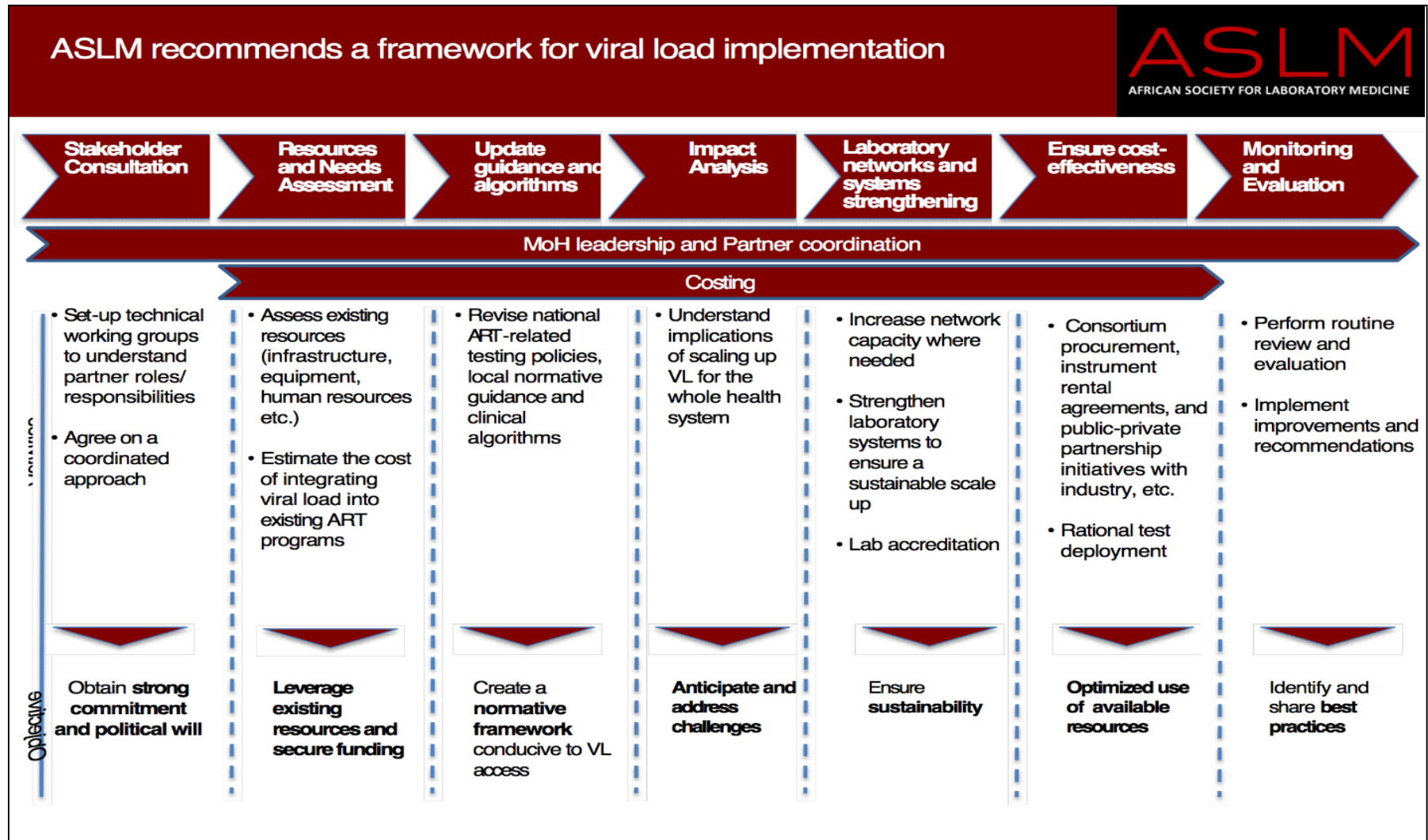
Key VL/EID technical components to consider:

- Selection of the appropriate technologies
- Needs and investments in laboratory infrastructure
- Needs for general lab equipment (fridges, freezers, centrifuges)
- Staff training
- Transportation system for the samples or referral system for the patients to reach the lab or sample collection facilities
- Results reporting system and Lab Information System
- Routine maintenance of equipment
- Supportive quality assurance systems

# A comprehensive approach for selection, procurement and contracting



# ASLM – VL implementation framework



# MSF: Guidance and Tool Kit



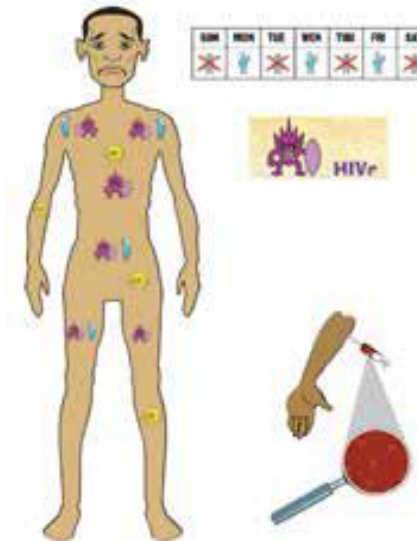
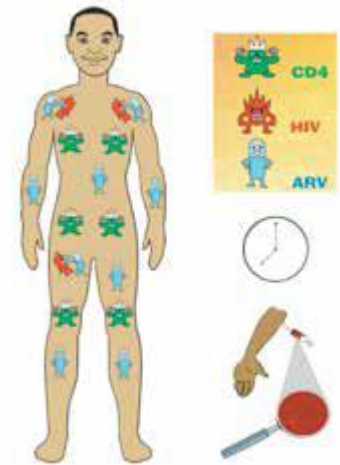
## PUTTING HIV TREATMENT TO THE TEST

A PRODUCT GUIDE FOR VIRAL LOAD AND POINT-OF-CARE CD4 DIAGNOSTIC TOOLS

[www.msfaaccess.org](http://www.msfaaccess.org)



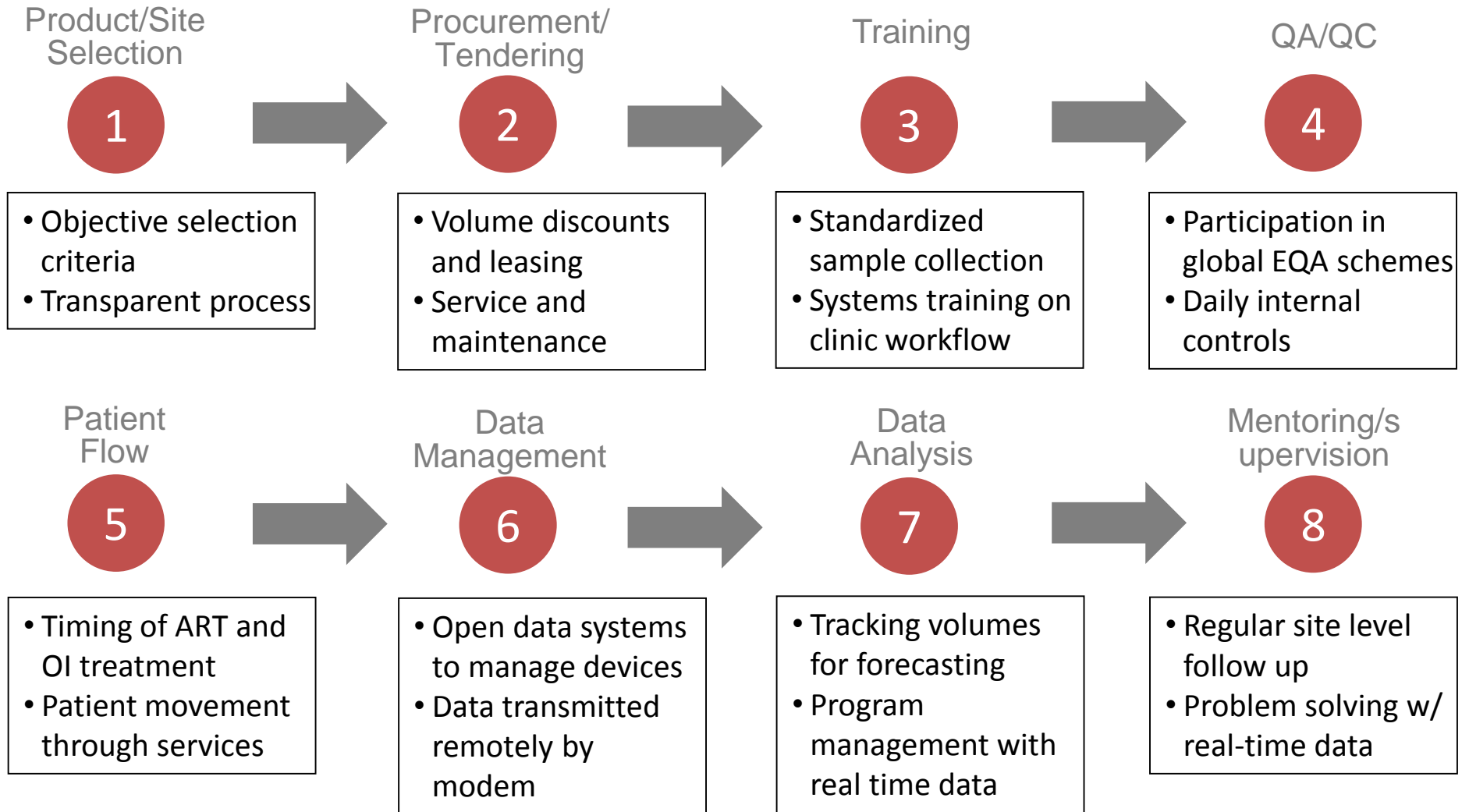
## MÉDECINS SANS FRONTIÈRES VIRAL LOAD TOOLKIT AN IMPLEMENTER'S GUIDE TO INTRODUCING HIV VIRAL LOAD MONITORING



<http://samumsf.org/blog/portfolio-item/viral-load-vl-toolkit/>

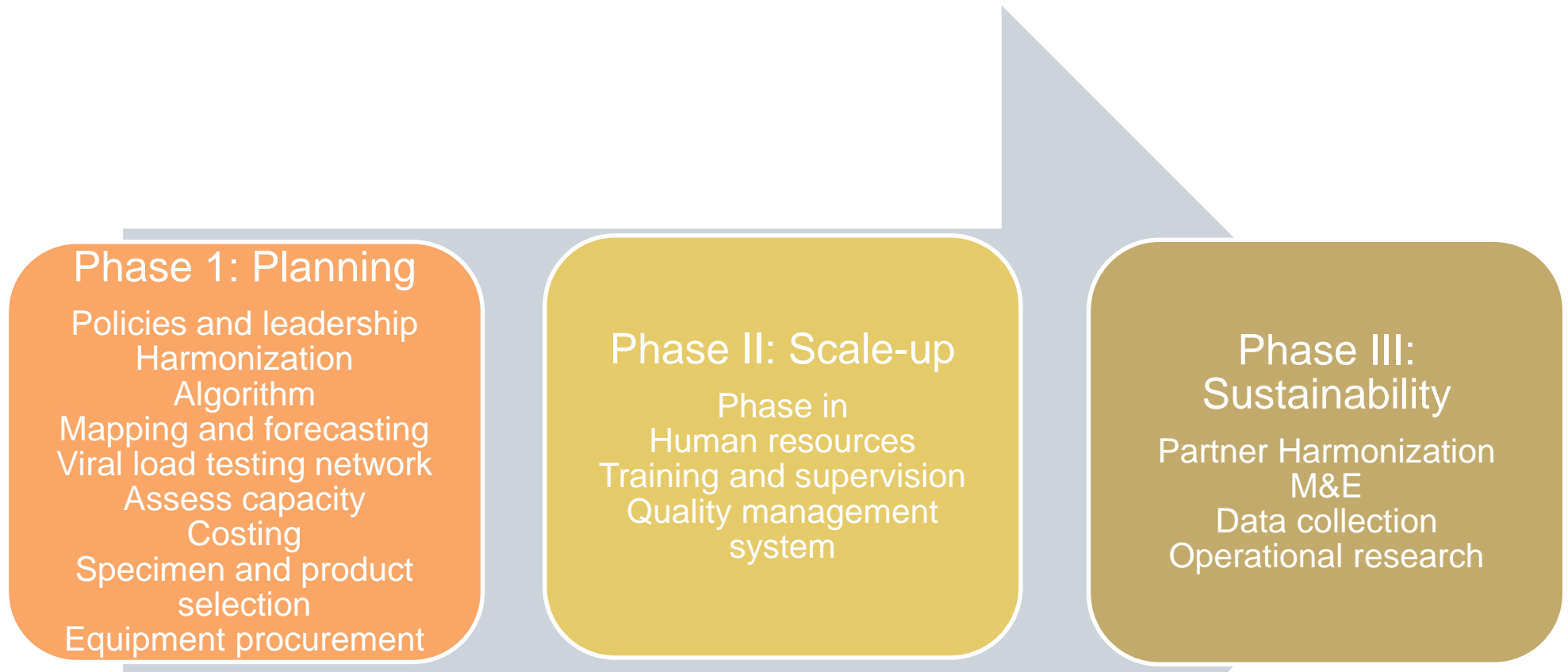
<http://www.msfaaccess.org/content/putting-hiv-treatment-test>

# UNITAID - Implementation: a number of processes required for new products





# WHO Guidance



Source: WHO: Technical and operational considerations for implementing HIV viral load testing: interim technical update. 2014

<http://www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/>

# References

## WHO

- Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2013.  
<http://www.who.int/hiv/pub/guidelines/arv2013/en/index.html>
- Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2014.  
[http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement\\_march2014/en/](http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/)
- WHO. Prequalification of Diagnostics programme public reports.  
[http://www.who.int/diagnostics\\_laboratory/evaluations/PQ\\_list/en/](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/)
- Manual for Procurement of Diagnostics and related Laboratory Items and Equipment. WHO. 2014.  
[http://www.who.int/entity/diagnostics\\_laboratory/procurement/131024\\_procurement\\_of\\_diagnostics\\_finalversion.pdf?ua=1](http://www.who.int/entity/diagnostics_laboratory/procurement/131024_procurement_of_diagnostics_finalversion.pdf?ua=1)

## African Society for Laboratory Medicine (ASLM)

- Viral Load Testing Consultation meeting. ASLM. 2013.
- <http://www.aslm.org/resource-centre/hiv-viral-load-testing/>

## UNITAID

- HIV/AIDS diagnostics technology landscape annual report with semi-annual update. UNITAID.  
<http://www.unitaid.eu/en/resources/publications/technical-reports>

## MSF

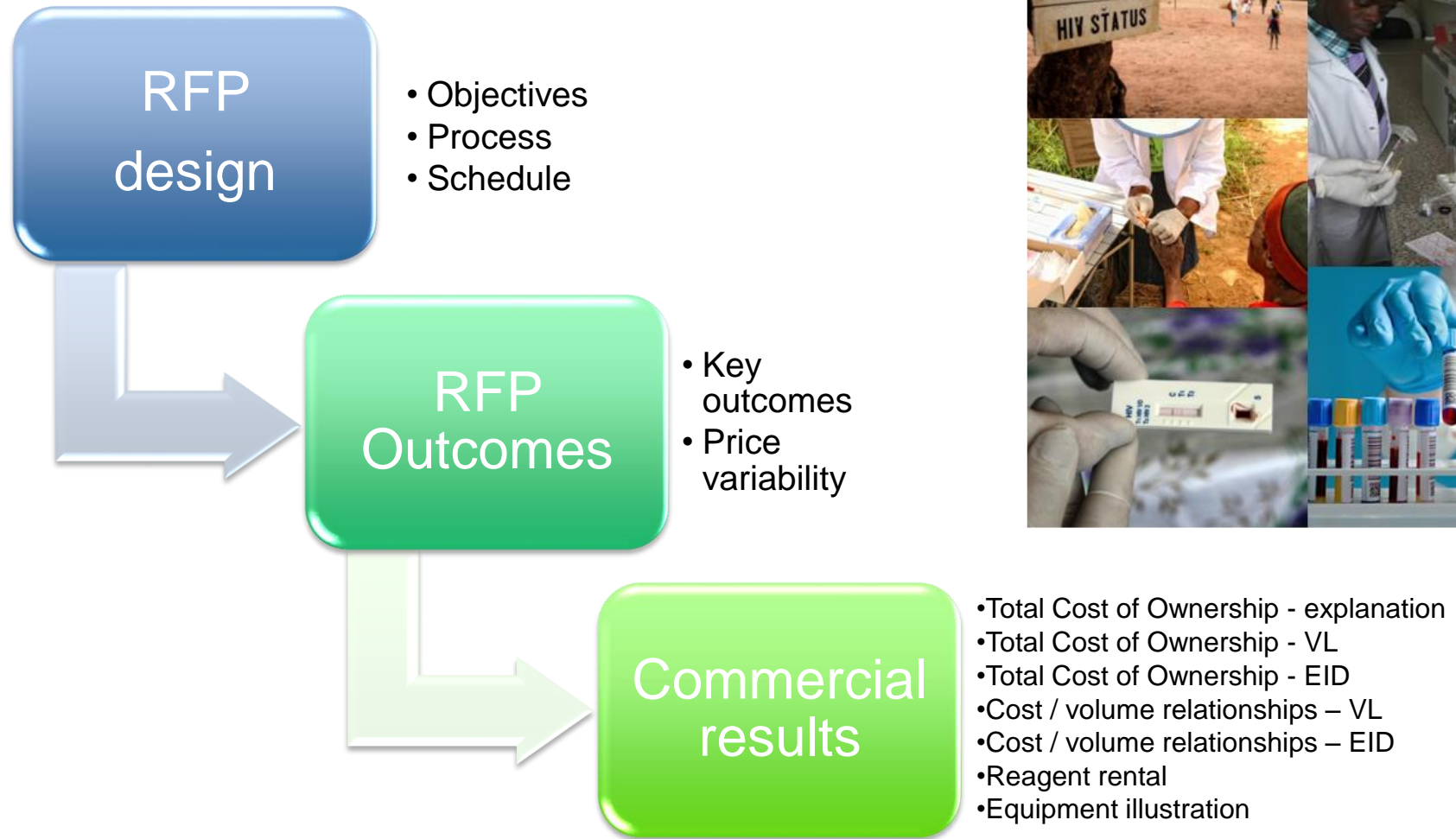
- Putting HIV Treatment to the Test : A Product Guide for Viral Load and Point-of-Care CD4 Diagnostic Tools. MSF. 2013
- <http://www.msfaccess.org/our-work/hiv-aids>

## The Global Fund

- Global Fund Information on Strengthening Systems for Health for Global Fund Applicants:  
<https://www.theglobalfund.org/en/resilient-sustainable-systems-for-health/>
- Global Fund's QA policy for Diagnostics;
- [http://www.theglobalfund.org/documents/psm/PSM\\_QADiagnostics\\_Policy\\_en/](http://www.theglobalfund.org/documents/psm/PSM_QADiagnostics_Policy_en/)

# Request for Proposal (RFP) - Tender for Viral Load and Early Infant Diagnosis

Navigation diagram



# Objectives of the Request for Proposal

1. To select a panel of manufacturers to enter into Framework Agreements to supply PRs through all procurement channels of Global Fund recipients
2. To improve transparency of cost and contracting elements to enable better selection, acquisition/procurement of analyzers, reagents and support services
3. Panel Suppliers are expected to enter into agreements that have the same terms, conditions and pricing with other public sector buyers



# RFP Process

## Eligibility

- Only bidders who were manufacturers of products in compliance with the Global Fund's Quality Assurance Policy on Diagnostics were eligible to participate

## Stage 1

- Preparation, submission, preliminary examination, screening and evaluation of proposals
- Invitation of selected bidders to participate in Stage 2

## Stage 2

- Discuss more detailed information and seek clarifications through dialogue and meetings
- Review of assumptions for total cost of ownership model
- Submission of Best and Final Offer (BAFO)

**New entrants in the market: The same 2-stage process will be followed for inclusion on the panel of suppliers after they meet the GF QA Policy requirements. It will be organized on an *ad-hoc* basis.**

## RFP Key Outcomes

Outcome: a range of credible, cost-effective, competitive options with more transparent pricing and contracting: viral load & EID

### Leveraged volumes

- ✓ Enables volumes to be leveraged and promotes maximum up-time and throughput

### Transparent contracting

- ✓ Guides new selection and establish contracting modalities and templates
- ✓ Benchmarks existing arrangements with forward-applicability in many cases
- ✓ Delivers Framework Contracts and Transaction Agreements

### Transparent costing

- ✓ Provides standardized costing enabling easier and more transparent decision-making
- ✓ Provides clear cost build-up to Total Cost of Ownership for a more meaningful and fair comparison

### Additional acquisition models

- ✓ Provides options of different acquisition models: purchase and reagent rental
- ✓ “Reagent rental” now available from many suppliers that is comparable with the equivalent “all in” bottom up price
- ✓ Identifies various value-added solutions

### Broader supplier base

- ✓ Includes 2 new offerings for lab-based systems (Hologic and Qiagen)
- ✓ Includes new entrants for lower throughput/-Point-of-Care offerings (Alere, Cepheid, DRW)
- ✓ Establishes process for new entrants with a clear target for pricing and contracting

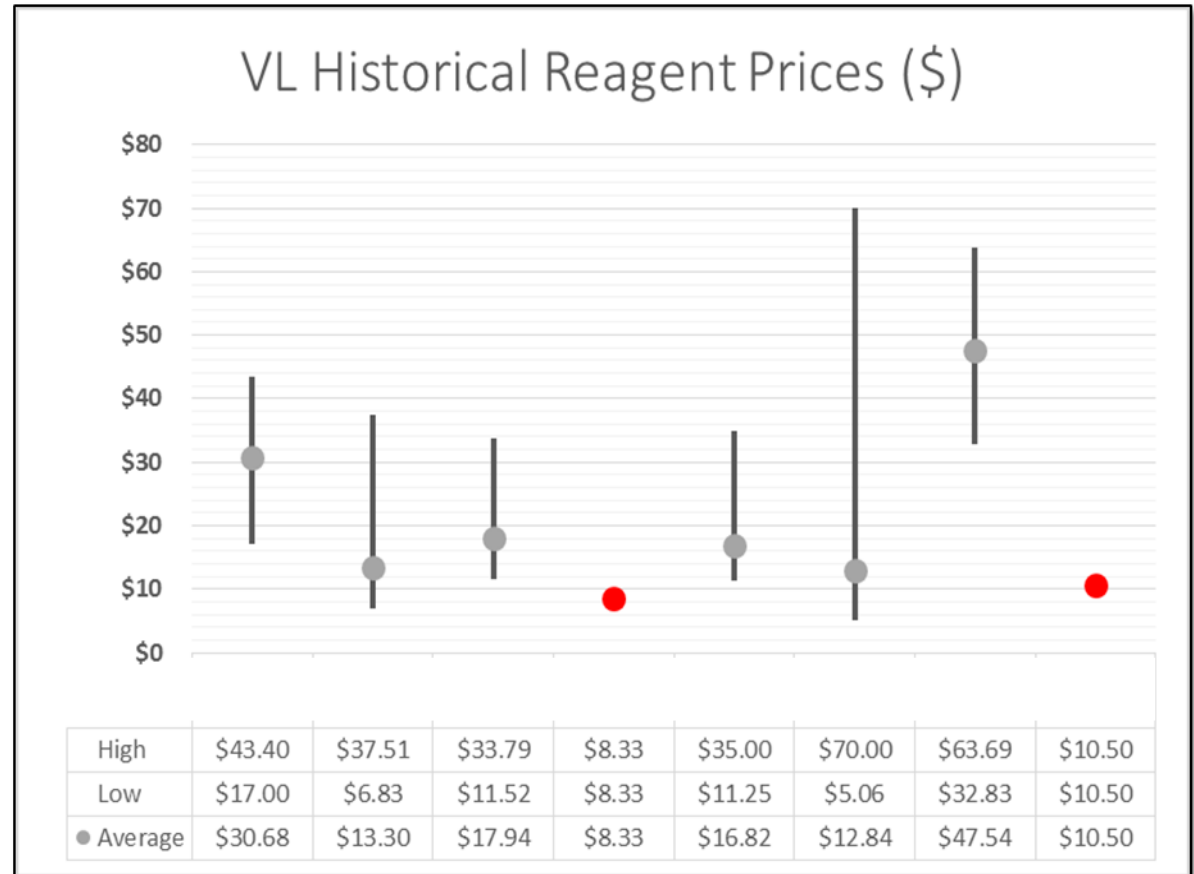
### Global visibility

- ✓ Enables better global visibility and framework for performance management (rather than fragmented country-level) and sustained delivery
- ✓ Includes agreement to make key elements of this RFP “available” in the public domain including TCO calculations

# Commercial outcomes

RFP outcomes will reduce prices paid and contractual variability

- Historically little visibility with arrangements country-by-country or even user/machine-by-machine
- Large range of prices paid, varying by country and over time
- New prices will reduce variability and be lower than average, resulting in savings (●)



Source: 2013/2014 Global Fund Procurement Data

## Global Fund's supplier panel (March 2017)

	Eligibility and Testing products	
	Regulatory status	Tests
Abbott	WHO PQ	VL, EID
Alere	WHO PQ	EID
Biocentric	CE mark	VL
BioMérieux	WHO PQ	VL
Cepheid	WHO PQ/CE mark	VL, EID
DRW	CE mark	VL, EID
Hologic	CE mark	VL
Qiagen	CE mark	VL
Roche	WHO PQ	VL, EID

Only Bidders who are manufacturers of products in compliance with the Global Fund Quality Assurance Policy on Diagnostics are eligible to be on the Supplier Panel (<https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>).



## Viral Load / EID platforms and tests

### ABBOTT



- Abbott RealTime m2000sp/m2000rt
- Test: Abbott RealTime HIV-1 qualitative
- Test: Abbott RealTime HIV-1 quantitative
- [www.abbottmolecular.com](http://www.abbottmolecular.com)

### ALERE



- Alere q
- Test: Alere q HIV-1/2 Detect assay
- [www.alerehiv.com](http://www.alerehiv.com)

### bioMERIEUX



- NucliSENS® EasyMAG®/EasyQ®
- NucliSENS® Mini MAG®/EasyQ®
- Test: NucliSENS EasyQ HIV-1 v2.0
- [www.biomerieux-diagnostics.com](http://www.biomerieux-diagnostics.com)

### BIOCENTRIC



- GenoXtract/FluoroCycler 96
- Generic HIV Charge Virale
- [www.biocentric.com/](http://www.biocentric.com/)

### CEPHEID



- GeneXpert® system
- Test: Xpert HIV-1 viral load & EID
- [www.cepheid.com](http://www.cepheid.com)

### DRW



- Samba I and Samba II
- Test: Samba Qual Whole Blood/Samba HIV SemiQ/ Samba II Qual Whole Blood/Samba II Semi Q
- [www.drw-ltd.com](http://www.drw-ltd.com)

### HOLOGIC



- Panther® system
- Test: Aptima HIV quant Dx
- [www.hologic.com](http://www.hologic.com)

### QIAGEN



- QIAasymphony SP, QIAasymphony AS, Rotor-Gene Q MDx 5plex HRM
- Test: Artus™ HIV-1 QS-RGQ RT-PCR System
- [www.qiagen.com](http://www.qiagen.com)

### ROCHE



- COBAS®AmpliPrep/COBAS® TaqMan®
- Test: CAP/CTM HIV-1 v2.0 Qual test
- Test: CAP/CTM HIV-1 v2.0
- [www.molecular.roche.com](http://www.molecular.roche.com)

# Abbott

## ABBOTT – YOUR EXPERIENCED PARTNER FOR SUCCESSFUL AND SUSTAINABLE SCALE-UP



Low reagent access price \$10.50 for any country committing to scale up HIV-1 testing with Abbott.\*

Same low reagent access price \$10.50 available for any combination of the pioneering assays: **HIV-1 Viral Load, HIV-1 Qualitative (Early Infant Diagnosis), MTB detection, HCV, HBV, HPV & CT/NG** – allowing you to consolidate and maximize the value of your investment.\*



Abbott offers a suite of practical tools designed to support scale up of testing, including resource calculators and efficiency tracking. These tools are making a difference in many country Partnerships and are part of Abbott's total solution for sustainable scale up.\*

\* See <https://www.abbottmolecular.com/gf-agreement-details-request.html> to request more details or ask your Abbott representative



# Alere™ q Molecular. Anytime, anywhere.

## Alere™ q platform

*Designed to operate in all manner of challenging settings.*


- Fully automated mobile, molecular point of care analyser
- Intuitive and unique cartridge system
- No operator sample manipulation required. Extraction, isolation, amplification and detection all fully integrated in single use cartridges

## Alere™ q HIV-1/2 Detect test

*Revolutionary point of care nucleic acid amplification test for detection and differentiation of HIV-1 groups M/N/O and HIV-2.*

- Molecular results at the point of care within **52 minutes**
- Suitable for testing infants and adults in resource limited settings
- 25µL of plasma and whole blood can be used
- For [Early Infant Diagnosis](#) / Acute Diagnosis / HIV molecular confirmation at the point of care



 **Watch the video**  
Hear from key opinion leaders

**Alere™ q HIV-1/2 Viral Load Plasma and Alere™ q Filovirus Detect**  
COMING SOON

## Connectivity & Support

*Unique offering of technical service, data connectivity, program management and ongoing training through our skilled Field Staff Support (FSS) program and connectivity solutions.*

- [FSS](#) available in 6 African countries
- [Alere™ DataPoint](#) software provides real-time visibility across all instruments out in the field

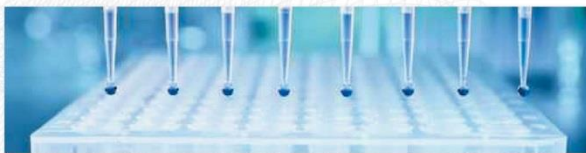
# BIOCENTRIC



In 2005, **Biocentric** has pioneered the access of HIV VL in **limited resources countries** by offering the **first HIV viral load tests kit working on open platforms.**

With an open platform, the laboratory is not limited to only one supplier. On the contrary, it has access to an unlimited menu of tests in virology, bacteriology, human genetics, plants...

Should a disease outbreak or a new antibiotic resistance occur in your country, an efficient screening and diagnostic can rapidly be operational on the open platform.



### Advantages :

- ✓ low plastic waste
- ✓ the system remains operational even during maintenance
- ✓ compact size



## UNIVERSAL ACCESS!

- 3 hours / run
- Up to 192 tests / day
- Personalized follow-up
- Large test range.....

HIV-1 VL  
 HIV-2 VL  
 HIV EID  
 DBS  
 HBV VL  
 MTB  
 CT/NG  
 HSV...

- On-site training
- A tailor-made logistics
- Dedicated Exel Apps to help prepare and organize
  - ✓ PCR runs
  - ✓ commercial orders

### GENERIC HIV CHARGE VIRALE KIT



### The open platform consists of :

4 independant extraction units each enabling up to 12 extractions/run

1 open real time thermocycler



Ready to use extraction cartridge

Disposable pipetting system  
Included in the extraction kit



# bioMérieux



## bioMérieux NucliSENS™ HIV Viral Load monitoring solution



### Extraction

**NucliSENS™  
miniMAG**

**NucliSENS™  
easyMAG**

**BOOM® technology**  
*(bioMérieux proprietary technology)*

**RNA target** : perfect correlation  
between plasma and whole blood

**Polyvalence Argene Molecular tests**

### Amplification / Detection

**NucliSENS™  
EasyQ**

**NucliSENS™  
EasyQ HIV-1 v2.0**

**WHO  
Prequalified**

**POWERED BY  
NucliSENTRAL™**

**LIS**

**CE MARKED DBS protocol  
for venous and  
capillary blood**

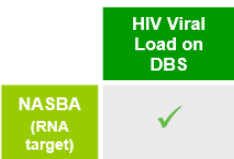


**EasyQ HIV-1 v2.0**  
*LoD (95% detection level), 1ml input volume*

**25 VQA cps/ml**  
*(corresponding to 14.4 IU/ml of v1.2)*  
  
*(1 IU = 1.74 cps)*

**EasyQ HIV-1 2.0**  
*Claimed LoD (95% detection level)*

<b>Dried blood spot</b> <i>(2 spots = 0.1 ml)</i>	<b>802 VQA cps/ml</b>
--	---------------------------



- ✓ **Increased Accessibility to HIV VL testing**
  - CE-marked protocol with DBS
- ✓ **High Flexibility**
  - Platforms that can adapt to the testing needs
  - Robust and easy-to-use
- ✓ **High Quality**
  - High sensitivity
  - CE-marked applications
  - Customer services

# CEPHEID

## Why Choose GeneXpert®?

**Modular:** There is a GeneXpert that's a perfect fit for your workload—in the laboratory or near patient. Same cartridge, same module, same sample type, same result. Centralised / decentralised testing, it's up to you. Consistent quality in all settings. Optimised transport with no requirement to compromise sample type.

**Expandable:** As your need grows you can add extra modules and GeneXpert will grow with you.

**Dependable:** GeneXpert is proven worldwide, with more than 14,000 modules operating, many in the very harshest environments.

**Totally Random Access:** The minimum batch size is just one sample.

- No waiting for a batch of 24/48/96 to fill.
- No waste of reagents with incomplete batches.

**Simple, Rapid, Secure:** Everything you need is in the cartridge. Easy-to-learn procedures ensure reliable performance and maintained quality even where staff changes are frequent. The closed cartridge avoids errors by preventing contamination

**True Integrated Molecular Platform:** Instant access to Cepheid's broad and fast-expanding cartridge menu.

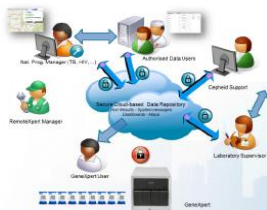
- Co-infection (TB, HCV)
- Women's Health, Healthcare-Associated Infection, Oncology, Critical Infectious Disease, & Virology



**Fair Pricing for All:** Cepheid's compassionate HBDC programme ensures that everyone gets the same price with discounts based on world-wide consumption.

**Cloud-based communications:** RemoteXpert® connects all of the GeneXperts in your network together and provides

- Informative dashboards for M&E
- Epidemiological monitoring
- Remote servicing capacity



# DRW



## SAMBA®

Simple, rapid and robust diagnostic system specifically designed for resource-limited settings  
 Two innovative nucleic acid-based rapid HIV diagnostics systems with the same proven chemistry:

- SAMBA I: batch process for use at near point-of-care
- SAMBA II: 'sample-in results-out' for use at point-of-care

Enabling "test and treat" for Viral Load monitoring or Early Infant Diagnosis:

- Viral Load: Overall concordance of >97% compared to centralised testing in clinical samples in Kenya, Malawi, Uganda and Zimbabwe
- Early Infant Diagnosis: Sensitivity of 98.5% and specificity of 99.8% in infants tested in Kenya, Uganda and Zimbabwe

### SAMBA I - Semi automated - Near Patient Testing - batch processing - 16-48 samples/day



SAMBAprep



SAMBAamp

#### HIGH THROUGHPUT

A combination of sample preparation and amplification/detection instruments give maximum flexibility with throughput suitable for regional and district hospitals

#### MINIMAL TRAINING

Designed to be easy to use with minimal training.

#### REAGENT STABILITY & OPERATING RANGE

Highly stable reagents with no cold storage or cold-chain transport needed, wide temperature operating range for instruments

#### UNIT DOSE CARTRIDGES

Reagents provided in ready-to-use cartridges.

### SAMBA II - Fully automated - Sample in-Results out - POC System - 4-16 samples/day



Assay Module



Tablet Module



Printer Module

#### SIMPLE TO USE

Easy to load cartridges - test can be started within 1 minute. Built-in camera scans assay type and sample ID. Results automatically analyzed and recorded.

#### EASY DATA TRANSFER CAPABILITY

Machine units controlled by tablet, test results can be sent via SMS or exported directly to a PC, 2G/3G/4G and WiFi capacity for cloud based Dashboard support (shortly available)

#### SAFE AND ACCESSIBLE RESULTS

Tablet stores 100,000 patient results, Bluetooth printer prints results on thermal paper with 10 year stability.

#### FLEXIBLE THROUGHPUT

One SAMBA II can process 4 samples per day. Up to 4 assay modules can be controlled by single tablet increasing throughput to 16-20 tests per day.



CE marked

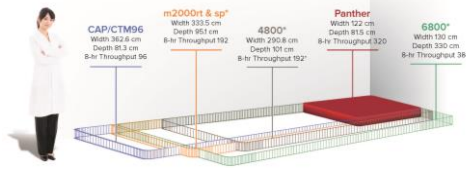
Flexible throughput covering POC and near POC use from 4-48 samples per day

# HOLOGIC

## The Aptima® HIV-1 Quant Dx Assay on the Panther® System



### General Purpose Lab Placement



- Small footprint delivering high throughput (320 samples/8hr day)
- Less electrical, weight, and size requirements vs. other systems
- No specialized molecular lab needed (no separate room)

**Suitable for decentralized settings**

### All-in Price Per Test

- All items needed for test included when kit is ordered
  - Assay Reagents, Calibrators, Controls
  - Fluids to run Panther
  - Tips and tubes (MTUs) used for reaction
  - Waste bags and cover for Panther
- Few plastics, consumables needed (only 2 tips and 1 tube/test)
- ONLY run calibrators/controls every 24hrs or 100 test kit

**Easy to manage inventory & minimal waste**



### Easy to Use System



- Direct loading of primary blood tubes (no sample prep)
- Sample to results automation with one instrument
- Intuitive functionality makes it easy to train staff
- Load any number of tubes (up to 120) at any time (no need to batch)

**Lower training requirements & minimizes risk of error**

**Aptima® HIV-1**  
Quant Dx Assay

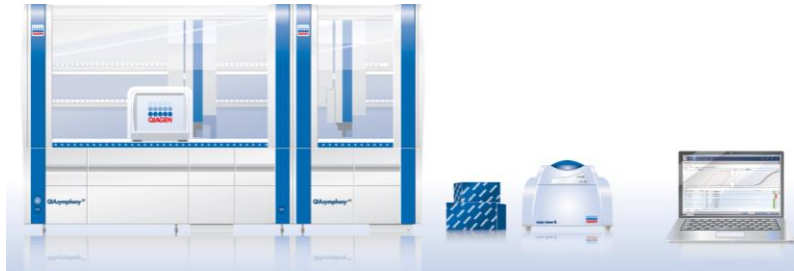


# QIAGEN



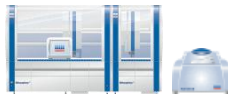
## The *artus* HI-virus-1 assays from QIAGEN

Automated or Manual flexible hardware solutions to build a future for your laboratory



Broad assay menu including:

- HIV-1
- HBV, HCV
- CMV, EBV, BKV
- HSV1/2, VZV
- CT/NG\*, GBS\*, *T. vaginalis*\*
- MRSA/SA\*, *C difficile*\*, VanR\*
- MTB, Respiratory Panel, Malaria
- Open channel for other tests



### **artus HI-Virus QS-RGQ Kit**

- LOD 34 cop/ml
- Linear range 45-45x10<sup>6</sup> cop/ml
- Sample type: plasma
- 24 or 72 rxn kits
- Automated extraction and assay set up, for medium to high throughput



### **artus HI-Virus RG Kit**

- LOD 30 cop/ml
- Linear range 54-45x10<sup>6</sup> cop/ml
- Sample type: plasma
- 24 or 96 rxn kits
- Manual extraction and assay set-up, for lower throughput

- ✓ Flexibility of batch size with no wastage
- ✓ Continuous sample loading\*
- ✓ Primary tube capability\*
- ✓ Integrated barcode reading\*
- ✓ Minimal hands on time
- ✓ Predefined assay runs
- ✓ Automatic transfer to assay setup\*
- ✓ Automated result interpretation
- ✓ Flexible hardware with a broad assay menu
- ✓ Easy LIMS integration

\* Only available on QS-RGQ automated solution

# ROCHE



## Roche Molecular Diagnostics *Trusted experience with the HIV-1 Global*



**Dual Target technology for reliable and secure results**



**Trusted company with the most clinically validated HIV-1 tests**



**Education & training programs from the scale-up experts**



**Fully automated system with comprehensive menu for maximum productivity**



**First-in-class service & support with in-country presence**



**Reagent ordering tools**

<http://molecular.roche.com/globalaccessprogram/Pages/default.aspx>

# Guidance: Selection of Testing Platforms

Consider VL/EID testing strategy and lab tiered system

Forecast of testing numbers for the next 4 years

Review technical options/ characteristics

Match throughput of equipment and testing targets

Check if VL/EID technology is validated for each sample type

Verify regulatory status and compliance with Global Fund's QA policy

Verify national equipment registration

Assess company capacity for in country distribution and servicing

Reagent kits: assess shelf-life and cold chain requirements for storage

Analyzers: assess maintenance requirements

Review pricing offers for analyzer, reagents and consumables.

Budget QA, lab infrastructure, training, sample transportation

# Guidance: Review characteristics of VL/EID testing platforms

Ease of use (automation, technical skills)	Analyzer capacity (number of tests per day), testing menu	Performance, sample type, detection of specific HIV subtypes
Reagents characteristics: cold chain and shelf-life	Polyvalence for TB, Hepatitis B and C, STIs	Data management: connectivity, back-up and data storage
Infrastructure requirements: power supply, climate control, dust	Instrument dimensions, ancillary equipment	Results reporting and lab management information system

# Comparison of technical options for VL - lab-based analyzers

	Detection target	Equipment for extraction	Equipment for amplification/detection	Sample type	Level of automation	Most stringent temperature requirement for at least one component	Shelf-life of reagents	Additional testing (TB, HCV & HBV)*	External Calibrators	Number of tests/day (8h per day)
<b>Abbott</b>	RNA	m2000sp	m2000rt	Plasma & Dry Blood Spot	High	Freezer (-20°C)	18 months	TB, HCV, HBV	Required on new lot or biannually	96-144
<b>Biocentric</b>	RNA	Open platform Or GenoXTract	Open platform or FluoroCycler	Plasma	Medium	Freezer	12 months	no	Not required	192
<b>bioMérieux automated</b>	RNA	EasyMag	EasyQ	Plasma & Dry Blood Spot	High	Fridge	18 months	no	Not required	144
<b>bioMérieux semi-automated</b>		MiniMag	EasyQ	Plasma & Dry Blood Spot	Medium					48
<b>Hologic</b>	RNA	Panther system		Plasma	High	Freezer	18 months	no	Required	320
<b>Qiagen automated</b>	RNA	QIA Symphony SP/QIA SymphonyAS	Rotor-Gene Q	Plasma	High	Freezer	17 months	HCV HBV	Not required	96
<b>Qiagen semi-automated</b>		manual	Rotor-Gene Q	Plasma	Medium					
<b>Roche</b>	RNA	Cobas Ampliprep	Cobas Taqman	Plasma	High	Fridge	12 and 22 months	HCV HBV	Not Required	144

\* Other assays beyond TB, HCV and HBV may be available – please consult company websites

## Comparison of technical options for EID - lab-based analyzers

	Detection target	Equipment for extraction	Equipment for amplification/detection	Sample type	Level of automation	Most stringent temperature requirement for at least one component	Shelf-life of reagents	External Calibrators	Number of tests/day (8h per day)
<b>Abbott</b>	Total Nucleic Acids	m2000sp	m2000rt	Plasma & Dry Blood Spot	High	Freezer	18 months	Not Required	144
<b>Roche</b>	DNA	Cobas Ampliprep	Cobas Taqman	Plasma & Dry Blood Spot	High	Fridge	12 and 22 months	Not Required	144

## Comparison of technical options for VL and EID - Point of Care (POC) options

	Detection target	Equipment for extraction	Equipment for amplification/detection	Sample type	Level of automation	Most stringent temperature requirement for at least one component	Shelf-life of reagents	Additional testing (TB, HCV & HBV)*	External Calibrators	Number of tests/day (8h per day)
<b>For EID ONLY</b>										
<b>Alere</b>	DNA	Alere q		Whole Blood	High	Room Temperature 4-30°C	9 months	no	Not required	8
<b>For EID and VL</b>										
<b>Cepheid</b>	RNA/ DNA	GeneXpert XVI	Plasma	High	Room Temperature 2-28°C. Transport refrigerated	12 months	TB HCV	Not required	80	
		GeneXpert IV							20	
		GeneXpert IV-2							10	
<b>DRW</b>	RNA/ DNA	Samba I	Plasma	Medium	Room temperature 2-37°C	12 months	no	Not required	16-48	
		Samba II	Plasma Whole Blood	High					4-16	

# Guidance: Regulatory status of VL/EID products

Global Fund list of HIV  
Diagnostic Products

<http://www.theglobalfund.org/en/sourcing/qa/diagnostics/>

WHO Pre-qualification for  
Diagnostic Products

[http://www.who.int/entity/diagnostics\\_laboratory/evaluations/150508\\_prequalified\\_products\\_list.pdf?ua=1](http://www.who.int/entity/diagnostics_laboratory/evaluations/150508_prequalified_products_list.pdf?ua=1)



# PRICING TABLES

## Baseline Information

- All quoted prices are EXWork
- Thresholds are annual unless indicated differently
- Thresholds are global (cumulative between orders from all eligible GF countries) unless indicated differently (per country)
- Some companies have restricted their offer to a list of specific countries, see the corresponding slides

# Pricing Table – ABBOTT

## Per Country Thresholds

<b>M200sp/m2000rt</b>	<b>STANDARD PURCHASE</b>				<b>REAGENT RENTAL</b>			
	<b>VIRAL LOAD</b>							
<b>PRICE BREAK</b>	Option not available							
<b>COMMITTED VOLUMES</b>								
Terms commitment	no commitment	3 years or more	3 years or more	3 years or more	no commitment	3 years or more	3 years or more	3 years or more
Thresholds	no commitment	no commitment	25 001-49 999	> 50 000	no commitment	no commitment	25 001-49 999	> 50 000
Cost of test	\$22,50	\$16,50	\$13,50	\$10,50	\$22,50	\$16,50	\$13,50	\$10,50
Control/Calibrator (CC)	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30
Consumables per test (C2)	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20
Test price + CC + C2	<b>\$25,00</b>	<b>\$19,00</b>	<b>\$16,00</b>	<b>\$13,00</b>	<b>\$25,00</b>	<b>\$19,00</b>	<b>\$16,00</b>	<b>\$13,00</b>
Equipment	\$170 000				\$8 450 per month for a 3y-5y contract - \$6 650 per month for a 5y-7y contract			
Service Maintenance/year	\$18 000				Included in price of equipment rental			
Warranty	12 months included				12 months included			
	<b>EARLY INFANT DIAGNOSIS</b>							
<b>PRICE BREAK</b>	Option not available							
<b>COMMITTED VOLUMES</b>								
Terms commitment	no commitment	3 years or more	3 years or more	3 years or more	no commitment	3 years or more	3 years or more	3 years or more
Threshold	no commitment	no commitment	25 001-49 999	> 50 000	no commitment	no commitment	25 001-49 999	> 50 000
Cost of test	\$22,50	\$16,50	\$13,50	\$10,50	\$22,50	\$16,50	\$13,50	\$10,50
Control/Calibrator (CC)	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30	\$0,30
Consumables per test (C2)	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20	\$2,20
Test price + CC + C2	<b>\$25,00</b>	<b>\$19,00</b>	<b>\$16,00</b>	<b>\$13,00</b>	<b>\$25,00</b>	<b>\$19,00</b>	<b>\$16,00</b>	<b>\$13,00</b>
Equipment	\$170 000				\$8 450 per month for a 3y-5y contract - \$6 650 per month for a 5y-7y contract			
Service Maintenance/year	\$18 000				Included in price of equipment rental			
Warranty	12 months included				12 months included			

# Pricing Table – ALERE

## Global Thresholds

ALERE Q	STANDARD PURCHASE					REAGENT RENTAL
	<b>VIRAL LOAD</b>					
	Option not available					
	<b>EARLY INFANT DIAGNOSIS</b>					
<b>PRICE BREAK</b>						
Thresholds	< 200 000	200-399 999	400-599 999	600-799 999	>800 000	Option not available
Cost of test	\$25,00	\$22,50	\$19,50	\$17,95	\$14,95	
Control/calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$25,00</b>	<b>\$22,50</b>	<b>\$19,50</b>	<b>\$17,95</b>	<b>\$14,95</b>	
Equipment	\$25 000					
Service Maintenance/year	\$0,00 included in price of reagents					
Warranty	12 months included. Extended warranty: \$2 500 per year					
<b>COMMITTED VOLUMES</b>						
Thresholds	< 200 000	200-399 999	400-599 999	600-799 999	>800 000	Option not available
Cost of test	\$25,00	\$22,50	\$19,50	\$17,95	\$14,95	
Control/calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$25,00</b>	<b>\$22,50</b>	<b>\$19,50</b>	<b>\$17,95</b>	<b>\$14,95</b>	
Equipment	\$25 000					
Service Maintenance/year	\$0,00 - included in price of reagents					
Warranty	12 months included. Extended warranty: \$2 500 per year					

## ALERE – List of Eligible Countries

- South Africa
- Lesotho
- Swaziland
- Botswana
- Namibia
- Mozambique
- Zimbabwe
- Zambia
- Malawi
- Angola
- Rwanda
- Tanzania
- Kenya
- Uganda
- Ethiopia
- Burundi
- DRC
- Cameroon
- Ivory Coast
- Chad
- Ghana
- Nigeria

# Pricing Table – BIOCENTRIC

## Global Thresholds

HIV Generic Charge Virale	STANDARD PURCHASE				REAGENT RENTAL							
	<b>VIRAL LOAD</b>											
<b>PRICE BREAK</b>												
Thresholds	< 100 000	100 000	300 000	900 000	Option not available							
Cost per test	\$15,01	\$14,43	\$13,90	\$13,05								
Control/Calibrators (CC)	\$2,19	\$2,10	\$2,03	\$1,90								
Consumables per test (C2)	\$0,60	\$0,60	\$0,60	\$0,60								
Test price + CC + C2	<b>\$17,80</b>	<b>\$17,13</b>	<b>\$16,53</b>	<b>\$15,55</b>								
Equipment	\$82 798											
Service Maintenance/year	\$8 300											
Warranty	12 months included. Extended warranty: \$4500 per year											
<b>COMMITTED VOLUMES</b>												
Thresholds	<100 000	300 000	900 000	1 000 000	< 100 000	300 000	900 000	1 000 000				
Cost per test	\$14,43	\$13,90	\$13,05	\$12,51	\$15,84	\$14,73	\$13,67	\$13,09				
Control/Calibrators (CC)	\$2,10	\$2,03	\$1,90	\$1,82	\$2,31	\$2,15	\$1,99	\$1,91				
Consumables per test (C2)	\$0,60	\$0,60	\$0,60	\$0,60	\$0,00	\$0,00	\$0,00	\$0,00				
Test price + CC + C2	<b>\$17,13</b>	<b>\$16,53</b>	<b>\$15,55</b>	<b>\$14,83</b>	<b>\$18,15</b>	<b>\$16,88</b>	<b>\$15,66</b>	<b>\$15,00</b>				
Equipment	\$82 798				Included in the price of reagents							
Service Maintenance/year	\$8 300				\$8 300							
Warranty	12 months included. Extended warranty: \$4500 per year				Included in the price of reagents							
	<b>EARLY INFANT DIAGNOSIS</b>											
	Option not available											

# Pricing Table – BioMERIEUX EasyMag/EasyQ

## Per Country Thresholds

EASYMAG/EASYQ	STANDARD PURCHASE		REAGENT RENTAL	
<b>VIRAL LOAD</b>				
<b>PRICE BREAK</b>				
Thresholds per country	< 180 000	> 180 000	Option not available	
Cost per test	\$18,41	\$13,35		
Control/Calibrator (CC)	\$0,00	\$0,00		
Consumables per test (C2)	\$1,59	\$1,15		
Test price + CC + C2	<b>\$20,00</b>	<b>\$14,50</b>		
Equipment	\$98 839			
Service Maintenance/year	\$12 700 (Silver option) \$14 227 (Gold option)			
Warranty	15 months included			
<b>COMMITTED VOLUMES</b>				
Thresholds per country	< 180 000	> 180 000	< 180 000	> 180 000
Cost per test	\$17,04	\$11,97		
Control/Calibrator (CC)	\$0,00	\$0,00		
Consumables per test (C2)	\$1,46	\$1,03		
Test price + CC + C2	<b>\$18,50</b>	<b>\$13,00</b>	<b>\$24,00</b>	<b>\$15,60</b>
Equipment	\$98 839		-	
Service Maintenance/year	\$12 700 (Silver option) \$14 227 (Gold option)		\$12 700 (Silver option) \$14 227 (Gold option)	
Warranty	15 months included		15 months included	
<b>EARLY INFANT DIAGNOSIS</b>				
Option not available				

# Pricing Table – BioMERICUX MiniMag/EasyQ

## Per country Thresholds

MiniMAG/EASYQ	STANDARD PURCHASE		REAGENT RENTAL	
<b>VIRAL LOAD</b>				
<b>PRICE BREAK</b>				
Thresholds per country	< 180 000	> 180 000	Option not available	
Cost per test	\$22,40	\$16,05		
Control/Calibrator (CC)	\$0,00	\$0,00		
Consumables per test (C2)	\$0,60	\$0,45		
Test price + CC + C2	<b>\$23,00</b>	<b>\$16,50</b>		
Equipment	\$53 729			
Service Maintenance/year	\$5 550 (Silver option) \$6 540 (Gold option)			
Warranty	15 months included			
<b>COMMITTED VOLUMES</b>				
Thresholds per country	< 180 000	> 180 000	< 180 000	> 180 000
Cost per test	\$20,45	\$14,80		
Control/Calibrator (CC)	\$0,00	\$0,00		
Consumables per test (C2)	\$0,55	\$0,40		
Test price + CC + C2	<b>\$21,00</b>	<b>\$15,20</b>	<b>\$26,00</b>	<b>\$17,10</b>
Equipment	\$53 729			
Service Maintenance/year	\$5 550 (Silver option). \$6 540 (Gold option)		\$5 550 (Silver option) \$6 540 (Gold option)	
Warranty	15 months included		15 months	
<b>EARLY INFANT DIAGNOSIS</b>				
Option not available				

# Pricing Table – CEPHEID GenXpert IV – 2

## Global Thresholds

GenXpert IV-2	STANDARD PURCHASE				REAGENT RENTAL
	<b>VIRAL LOAD</b>				
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Cost per test	\$16,80	\$16,08	\$15,30	\$14,75	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$16,80</b>	<b>\$16,08</b>	<b>\$15,30</b>	<b>\$14,75</b>	
Equipment	\$11 780 for the desktop configuration. \$12 280 for the laptop configuration				
Service Maintenance/year	\$450				
Warranty	24 months included. Extended warranty for 12 months: \$1 896. For 36 months up-front at time of purchase: \$4 500				
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE				
	<b>EARLY INFANT DIAGNOSIS</b>				
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Cost per test	\$17,95	\$17,43	\$16,65	\$16,08	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$17,95</b>	<b>\$17,43</b>	<b>\$16,65</b>	<b>\$16,08</b>	
Equipment	\$11 780 for the desktop configuration. \$12 280 for the laptop configuration				
Service Maintenance/year	\$450				
Warranty	24 months included. Extended warranty for 12 months: \$1 896. For 36 months up-front at time of purchase: \$4 500				
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE				



# Pricing Table – CEPHEID GenXpert IV

## Global Thresholds

GenXpert IV	STANDARD PURCHASE				REAGENT RENTAL
	VIRAL LOAD				
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Tcost per test	\$16,80	\$16,08	\$15,30	\$14,75	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$16,80</b>	<b>\$16,08</b>	<b>\$15,30</b>	<b>\$14,75</b>	
Equipment	\$17 000 for desktop configuration. \$17 500 for laptop configuration				
Service Maintenance/year	\$450				
Warranty	24 months included. Extended warranty for 12 months: \$2 898. For 36 months upfront at time of purchase: \$6 840				
<b>COMMITTED VOLUMES</b>					
SAME AS ABOVE					
<b>EARLY INFANT DIAGNOSIS</b>					
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Cost per test	\$17,95	\$17,43	\$16,65	\$16,08	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$17,95</b>	<b>\$17,43</b>	<b>\$16,65</b>	<b>\$16,08</b>	
Equipment	\$17 000 for desktop configuration. \$17 500 for laptop configuration				
Service Maintenance/year	\$450				
Warranty	24 months included. Extended warranty for 12 months: \$2 898. For 36 months upfront at time of purchase: \$6 840				
<b>COMMITTED VOLUMES</b>					
SAME AS ABOVE					

# Pricing Table – CEPHEID GenXpert XVI

## Global Thresholds

GenXpert XVI	STANDARD PURCHASE				REAGENT RENTAL
	VIRAL LOAD				
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Cost per test	\$16,80	\$16,08	\$15,30	\$14,75	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$16,80</b>	<b>\$16,08</b>	<b>\$15,30</b>	<b>\$14,75</b>	
Equipment	\$71 000 for desktop configuration. \$71 500 for laptop configuration				
Service Maintenance/year	\$1 800				
Warranty	24 months included. Extended warranty for 12 months: \$7 800. For 36 months up-front at time of purchase: \$18 504				
<b>COMMITTED VOLUMES</b>					
SAME AS ABOVE					
<b>EARLY INFANT DIAGNOSIS</b>					
<b>PRICE BREAK</b>					
Thresholds	< 500 000	500 000	1 000 000	1 500 000	Option not available
Cost per test	\$17,95	\$17,43	\$16,65	\$16,08	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$17,95</b>	<b>\$17,43</b>	<b>\$16,65</b>	<b>\$16,08</b>	
Equipment	\$71 000 for desktop configuration. \$71 500 for laptop configuration				
Service Maintenance/year	\$1 800				
Warranty	24 months included. Extended warranty for 12 months: \$7 800. For 36 months up-front at time of purchase: \$18 504				
<b>COMMITTED VOLUMES</b>					
SAME AS ABOVE					

# CEPHEID: List of Eligible Countries

Afghanistan	Dominica	Libya	Senegal
Albania	Dominican Republic	Lithuania	Serbia
Algeria	Ecuador	Macedonia	Seychelles
American Samoa	Egypt	Madagascar	Sierra Leone
Angola	El Salvador	Malawi	Solomon Islands
Antigua & Barbuda	Eritrea	Malaysia	Somalia
Argentina	Estonia	Maldives	South Africa
Armenia	Ethiopia	Mali	Sri Lanka
Azerbaijan	Fiji	Marshall Islands	St Kitts and Nevis
Bangladesh	Gabon	Mauritania	St Lucia
Belarus	Gambia (The)	Mauritius	St Vincent & Grenadines
Belize	Gaza Strip	Mexico	Sudan
Benin	Georgia	Micronesia	Sudan, South
Bhutan	Ghana	Moldova	Suriname
Bolivia	Grenada	Mongolia	Swaziland
Bosnia-Herzegovina	Guam	Montenegro	Syria
Botswana	Guatemala	Morocco	Tajikistan
Brazil	Guinea	Mozambique	Tanzania
Bulgaria	Guinea, Equatorial	Myanmar (Burma)	Thailand
Burkina Faso	Guinea-Bissau	Namibia	Timor-Leste
Burundi	Haiti	Nauru	Togo
Cabo Verde	Honduras	Nepal	Tokelau
Cambodia	India	Nicaragua	Tonga
Cameroon	Indonesia	Niger	Tunisia
Central African Republic	Iraq	Nigeria	Turkmenistan
Chad	Jamaica	Niue	Tuvalu
Chile	Jordan	Pakistan	Uganda
Colombia	Kazakhstan	Palau	Ukraine
Commonwealth of the Northern Mariana Islands	Kenya	Panama	Uruguay
Comoros	Kiribati	Papua New Guinea	Uzbekistan
Congo (Democratic Rep. of)	Korea, North	Paraguay	Vanuatu
Congo (Republic of the)	Kosovo	Peru	Venezuela
Cook Islands	Kyrgyzstan	Philippines	Vietnam
Costa Rica	Laos	Romania	Western Sahara
Côte d'Ivoire	Latvia	Russia	Yemen
Croatia	Lebanon	Rwanda	Zambia
Cuba	Lesotho	Samoa	Zimbabwe
Djibouti	Liberia	Sao Tome & Principe	

# Pricing Table – DRW Samba I

## Global Thresholds

SAMBA I	STANDARD PURCHASE						REAGENT RENTAL
<b>VIRAL LOAD</b>							
<b>PRICE BREAK</b>							
Thresholds	< 150 000	150000 - 300000	300 000 – 500 000	500 000 – 750 000	750 000 – 1M	>1 000,000	Option not available
Cost per test	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$37,40</b>	<b>\$28,80</b>	<b>\$24,60</b>	<b>\$21,60</b>	<b>\$19,40</b>	<b>\$17,80</b>	
Equipment	1 SambaPrep + 3 SambaAmp \$72 000 1 SambaPrep + 2 SambaAmp \$65 000 1 SambaPrep + 1 SambaAmp \$58 000						
Service Maintenance/year	\$0,00						
Warranty	12 months included. Extended warranty \$3 250 per year per SITE						
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE						
<b>EARLY INFANT DIAGNOSIS</b>							
<b>PRICE BREAK</b>							
Thresholds (per order)	< 150 000	150000 - 300000	300 000 – 500 000	500 000 – 750 000	750 000 – 1M	>1 000,000	Option not available
Cost per test	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	<b>\$37,40</b>	<b>\$28,80</b>	<b>\$24,60</b>	<b>\$21,60</b>	<b>\$19,40</b>	<b>\$17,80</b>	
Equipment	1 SambaPrep + 3 SambaAmp \$72 000 1 SambaPrep + 2 SambaAmp \$65 000 1 SambaPrep + 1 SambaAmp \$58 000						
Service Maintenance/year	\$0,00						
Warranty	12 months included. Extended warranty \$32 50 per year per SITE						
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE						

# Pricing Table – DRW Samba II

## Global Thresholds

SAMBA II	STANDARD PURCHASE						REAGENT RENTAL
<b>VIRAL LOAD</b>							
<b>PRICE BREAK</b>							
Thresholds (per order)	< 150 000	150000 - 300000	300 000 – 500 000	500 000 – 750 000	750 000 – 1M	>1 000,000	Option not available
Cost per test	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Control/Calibrator (CC)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables per test (C2)	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Equipment	\$24 800 if less than 200 Assay Modules, \$18 000 if more than 200 Assay Modules + \$1 750 for Tablet Module						
Service Maintenance/year	\$0,00						
Warranty	12 months included. Extended warranty \$3 250 per year per SITE						
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE						
<b>EARLY INFANT DIAGNOSIS</b>							
<b>PRICE BREAK</b>							
Thresholds (per country)	< 150 000	150000 - 300000	300 000 – 500 000	500 000 – 750 000	750 000 – 1M	>1 000,000	Option not available
Test	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Control/Calibrators	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Consumables	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	
Test price + CC + C2	\$37,40	\$28,80	\$24,60	\$21,60	\$19,40	\$17,80	
Equipment	\$24 800 if less than 200 Assay Modules, \$18 000 if more than 200 Assay Modules + \$1 750 for Tablet Module						
Service Maintenance/year	\$0,00						
Warranty	12 months included. Extended warranty \$3 250 per year per SITE						
<b>COMMITTED VOLUMES</b>	SAME AS ABOVE						

# Pricing Table – HOLOGIC

## Global Thresholds

<b>PANTHER</b>	<b>STANDARD PURCHASE</b>				<b>REAGENT RENTAL</b>			
	<b>VIRAL LOAD</b>							
<b>PRICE BREAK</b>								
Thresholds	< 250 000	250 000 – 500 000	500 000 – 1 000 000	1 000 000 – 2 000 000	< 250 000	250 000 – 500 000	500 000 - 1 000 000	1 000 000 - 2 000 000
Test	\$10,60	\$10,10	\$9,00	\$8,00	\$11,60	\$11,10	\$10,00	\$9,00
Control/Calibrators	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00
Consumables	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00	\$0,00
Test price + CC	<b>\$10,60</b>	<b>\$10,10</b>	<b>\$9,00</b>	<b>\$8,00</b>	<b>\$11,60</b>	<b>\$11,10</b>	<b>\$10,00</b>	<b>\$9,00</b>
Equipment	\$150 000				\$0, included in price of reagents			
Service Maintenance/year	\$27 000				\$0, included in price of reagents			
Warranty	12 month included. Extended warranty \$27 000 per year				\$0, included in price of reagents			
<b>COMMITTED VOLUMES</b>								
Thresholds		> 250 000				> 250 000		
Test		\$10,35				\$11,35		
Control/Calibrators		\$0,00				\$0,00		
Consumables		\$0,00				\$0,00		
Test price + CC		<b>\$10,35</b>				<b>\$11,35</b>		
Equipment	\$150 000				\$0,00, included in price of reagents			
Service Maintenance/year	\$27 000				\$0,00, included in price of reagents			
Warranty	12 months included. Extended warranty \$27 000 per year				\$0,00, included in price of reagents			

## HOLOGIC: List of Eligible Countries

- Angola
- Botswana
- Ethiopia
- Kenya
- Malawi
- Mauritius
- Mozambique
- Namibia
- Nigeria
- Rwanda
- South Africa
- Tanzania
- Uganda
- Zambia
- Zimbabwe

# Pricing Table – QIAGEN QIA Symphony RotorGene

Per country thresholds

QSRGQ	STANDARD PURCHASE					REAGENT RENTAL FOR 5 YEAR CONTRACT			
	<b>VIRAL LOAD</b>								
<b>PRICE BREAK</b>									
Thresholds	< 10 000	10 000	30 000	50 000	100 000	3 000*	5 000*	10 000*	20 000*
Cost per test	\$9,70	\$9,24	\$8,63	\$7,85	\$6,54	\$20,97	\$16,00	\$12,01	\$9,54
Control/Calibrator (CC)	\$0,77	\$0,73	\$0,70	\$0,65	\$0,54	\$1,08	\$1,03	\$0,97	\$0,80
Consumables per test (C2)	\$1,00	\$0,95	\$0,91	\$0,85	\$0,71	\$1,00	\$0,95	\$0,91	\$0,85
Test price + CC + C2	<b>\$11,47</b>	<b>\$10,92</b>	<b>\$10,24</b>	<b>\$9,35</b>	<b>\$7,79</b>	<b>\$23,05</b>	<b>\$17,98</b>	<b>\$13,89</b>	<b>\$11,19</b>
Equipment	\$100 000					\$0,00, included in price of reagents			
Service Maintenance/year	\$12 000					\$0,00, included in price of reagents			
Warranty	12 months included. Extended warranty \$3 000 per year					12 months included. Extended warranty \$3 000 per year			
	* Thresholds are indicated per laboratory								
<b>COMMITTED VOLUMES</b>									
Thresholds	< 10 000	10 000	30 000	50 000	100 000	3 000*	5 000*	10 000*	20 000*
Cost per test	\$8,08	\$7,07	\$7,19	\$6,54	\$5,45	\$19,35	\$14,46	\$10,57	\$8,23
Control/Calibrator (CC)	\$0,64	\$0,61	\$0,58	\$0,54	\$0,45	\$0,90	\$0,86	\$0,80	\$0,67
Consumables per test (C2)	\$0,84	\$0,80	\$0,76	\$0,71	\$0,59	\$0,84	\$0,80	\$0,76	\$0,71
Test price + CC + C2	<b>\$9,56</b>	<b>\$8,48</b>	<b>\$8,53</b>	<b>\$7,79</b>	<b>\$6,49</b>	<b>\$21,09</b>	<b>\$16,12</b>	<b>\$12,03</b>	<b>\$9,61</b>
Equipment	\$100 000					\$0,00, included in price of reagents			
Service Maintenance/year	\$12 000					\$0,00, included in price of reagents			
Warranty	12 months included. Extended warranty \$3 000 per year					12 months included. Extended warranty \$3 000 per year			
	* Thresholds are indicated per laboratory								
	<b>EARLY INFANT DIAGNOSIS</b>								
	Option not available								



# Pricing Table – QIAGEN RotorGene

Per country thresholds

Manual extraction/RG	STANDARD PURCHASE					REAGENT RENTAL FOR A 5 YEAR CONTRACT			
<b>VIRAL LOAD</b>									
<b>PRICE BREAK</b>									
Thresholds	<10 000	10 000	30 000	50 000	100 000	3 000*	5 000*	10 000*	20 000*
Cost per test	\$9,70	\$9,24	\$8,63	\$7,85	\$6,54	\$11,08	\$10,06	\$9,05	\$8,05
Control/Calibrator per test (CC)	\$0,77	\$0,73	\$0,70	\$0,65	\$0,54	\$0,90	\$0,86	\$0,81	\$0,67
Consumables per test (C2)	\$1,00	\$0,95	\$0,91	\$0,85	\$0,71	\$1,00	\$0,95	\$0,91	\$0,85
Test price + CC + C2	<b>\$11,47</b>	<b>\$10,92</b>	<b>\$10,24</b>	<b>\$9,35</b>	<b>\$7,79</b>	<b>\$12,98</b>	<b>\$11,87</b>	<b>\$10,77</b>	<b>\$9,57</b>
Equipment	\$7 500					\$0,00 – Included in price of reagents			
Service Maintenance/year	\$2 500					\$0,00 – Included in price of reagents			
Warranty	12 months included. Extended warranty \$225 per year					12 months included. Extended warranty \$225 per year			
* Thresholds are indicated per laboratory									
<b>COMMITTED VOLUMES</b>									
Thresholds	<10 000	10 000	30 000	50 000	100 000	3 000*	5 000*	10 000*	20 000*
Cost per test	\$8,08	\$7,70	\$7,19	\$6,54	\$5,45	\$9,46	\$8,52	\$7,61	\$6,75
Control/Calibrator per test (CC)	\$0,64	\$0,61	\$0,58	\$0,54	\$0,45	\$0,75	\$0,72	\$0,67	\$0,56
Consumables per test (C2)	\$0,84	\$0,80	\$0,76	\$0,71	\$0,59	\$0,84	\$0,80	\$0,76	\$0,71
Test price + CC + C2	<b>\$9,56</b>	<b>\$9,11</b>	<b>\$8,53</b>	<b>\$7,79</b>	<b>\$6,49</b>	<b>\$11,05</b>	<b>\$10,04</b>	<b>\$9,04</b>	<b>\$8,02</b>
Equipment	\$7 500					\$0,00 – Included in price of reagents			
Service Maintenance/year	\$2 500					\$0,00 – Included in price of reagents			
Warranty	12 months included. Extended warranty \$225 per year					12 months included. Extended warranty \$225 per year			
* Thresholds are indicated per laboratory									
<b>EARLY INFANT DIAGNOSIS</b>									
Option not available									

# Pricing Table – ROCHE CAP/CTM

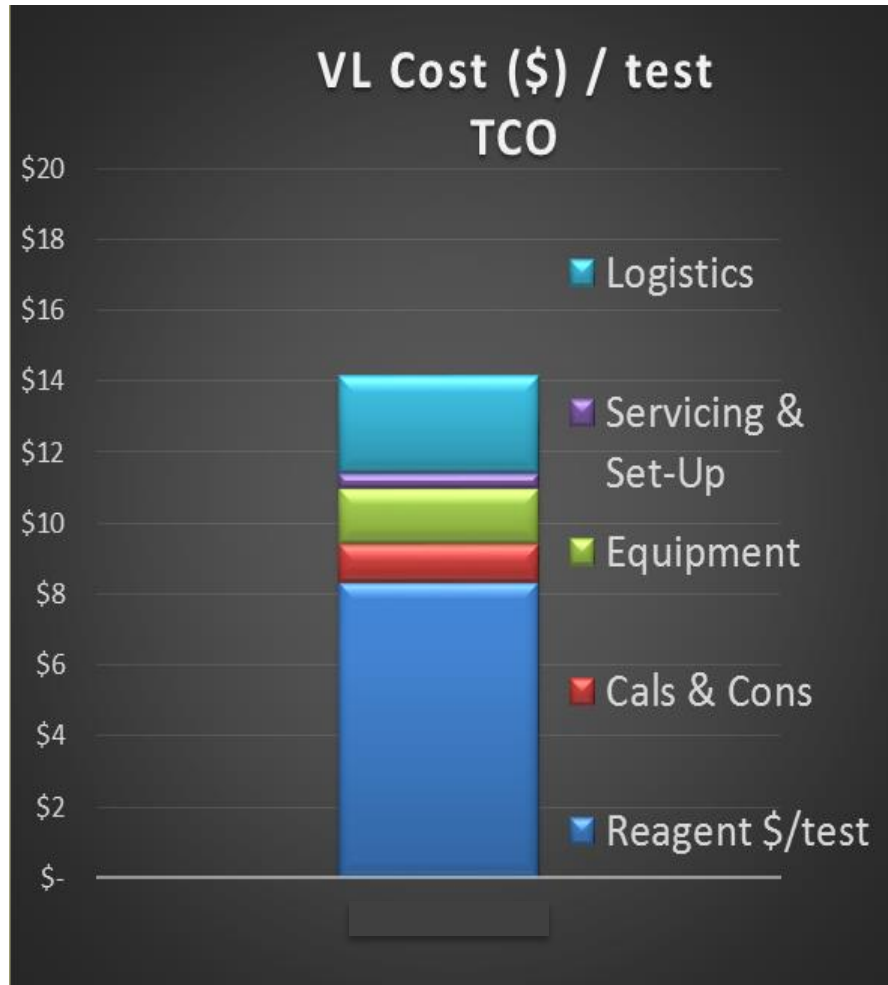
## Per country thresholds

CobasAmpliPrep/ CobasTaqman (CAP/CTM)	STANDARD PURCHASE	REAGENT RENTAL	HYBRID PROPOSAL
<b>VIRAL LOAD</b>			
PRICE BREAK		Option not available	
<b>COMMITTED VOLUME</b>			
Thresholds	None	> 25 000	> 25 000
Cost per test	\$8,33	\$8,33	\$8,33
Control/Calibrators (CC)	\$0,00	\$0,00	\$0,00
Consumables per test (C2)	\$1,07	\$1,07	\$1,07
Test price + CC + C2	<b>\$9,40</b>	<b>\$11,94 including equipment and maintenance</b>	<b>\$11,34 including equipment and maintenance</b>
Equipment	\$150 000	\$0 for equipment + \$2,00/test	\$45 000 for equipment +\$1,40/test
Service Maintenance	\$20 000/year	\$0,54/test	\$0,54/test
Warranty		12 months included	
<b>EARLY INFANT DIAGNOSIS</b>			
PRICE BREAK		NO OFFER	
<b>COMMITTED VOLUME</b>			
Thresholds	None	> 25 000	> 25 000
Cost per test	\$11,31	\$11,31	\$11,31
Control/Calibrators (CC)	\$0,00	\$0,00	\$0,00
Consumables per test (C2)	\$1,19	\$1,19	\$1,19
Test price + CC + C2	<b>\$12,50</b>	<b>\$15,04 including equipment and maintenance</b>	<b>\$14,44 including equipment and maintenance</b>
Equipment	\$150 000	\$0 for equipment + \$2,00/test	\$45 000 for equipment +\$1,40/test
Service Maintenance	\$20 000/year	\$0,54/test	\$0,54/test
Warranty		12 months included	

# ROCHE: List of Eligible Countries

Low Income Countries	Lower Middle Income	Upper Middle Income
Afghanistan	Angola	Botswana
Bangladesh	Armenia	Namibia
Benin	Cameroon	Palau
Burkina Faso	Cape Verde	St. Kitts
Burundi	Congo	St. Lucia
Cambodia	Cote D'Ivoire	St. Vincents
Central African Republic	Djibouti	South Africa
Chad	Egypt	
Comoros	Fiji	
Democratic People's Republic of Korea	Georgia	
DRC	Ghana	
Eritrea	India	
Ethiopia	Indonesia	
Gambia	Iraq	
Guinea	Kiribati	
Guinea Bissau	Laos	
Haiti	Lesotho	
Kenya	Mauritania	
Kyrgyzstan	Micronesia	
Liberia	Mongolia	
Malawi	Morocco	
Mali	Nigeria	
Mozambique	Pakistan	
Myanmar	Philippines	
Nepal	Moldova	
Niger	Samoa	
Rwanda	Sao Tome and Principe	
Sierra Leone	Senegal	
Somalia	Solomon Islands	
Tajikistan	Sri Lanka	
Togo	Sudan	
Uganda	Swaziland	
Tanzania	Timor Leste	
Zimbabwe	Tonga	
	Turkmenistan	
	Tuvalu	
	Ukraine	
	Uzbekistan	
	Vanuatu	
	Yemen	
	Zambia	

# Total Cost of Ownership (TCO) enables fair comparison



Logistics includes indicative freight/logistics/ agent fees/ country costs/ test averaged over countries

- Cost/ test for reagent/consumables kits
- Apportioned costs for equipment Freight, logistics, agents costs for equipment

Apportion set-up, training, installation and service cost as for equipment (unless included)  
Service & maintenance costs are for 3 years not covered by warranty

Apportion equipment cost as follows:

- Divide costs by total number of tests in a 3 year period to give a cost per test
- Total number of tests is daily capacity in an 8 hour day for 250 days / year for 3 years

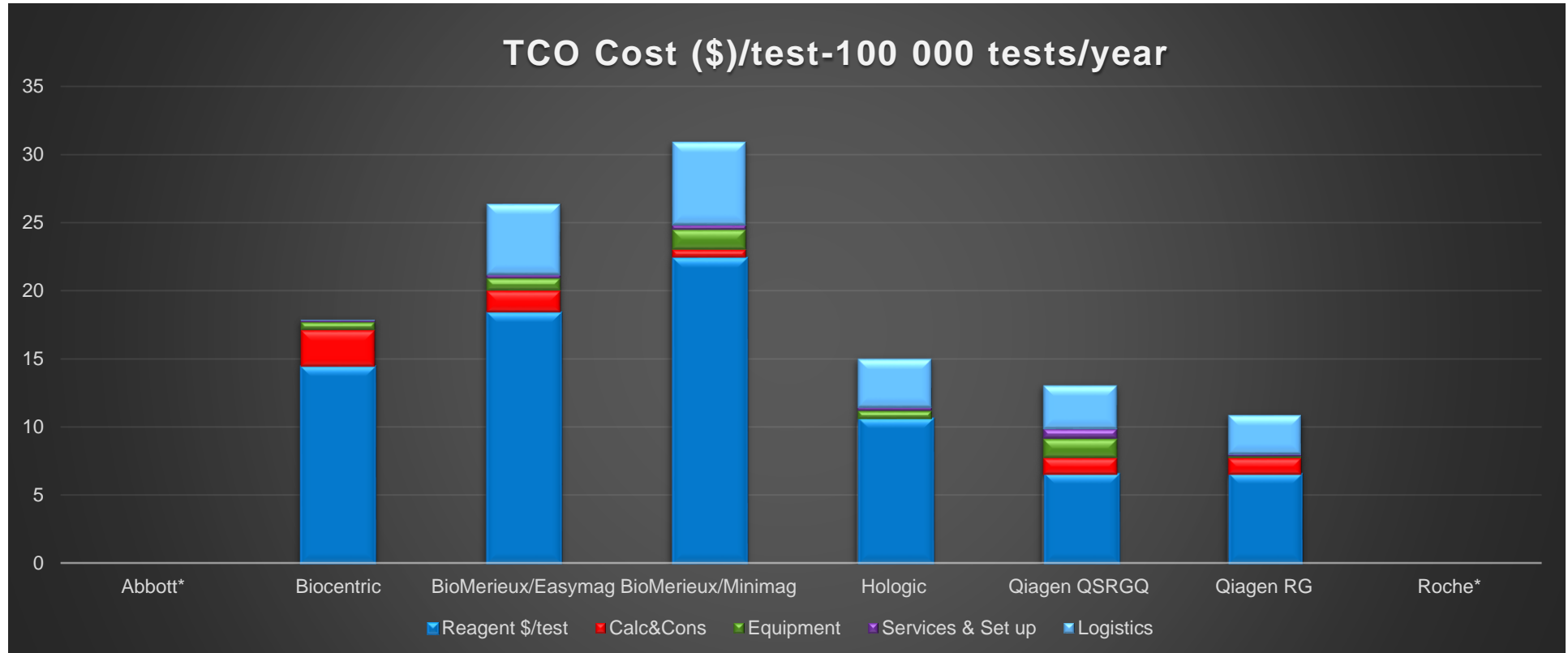
Controls / Calibration / Consumables / test based on supplier guidance

Reagent cost/ test (using given commercial model / volume)

TCO excludes “re-training” costs; upgrade costs; lab personnel time; lab facility costs; sample collection costs; opportunity costs around machine footprint; energy or other usage costs; end of life or recycling costs. TCO components on this slide are only indicative.

# TCO – **Viral Load** at 100 000 tests/year (Price Break) - Lab-based Analyzers

Graph provides indicative TCO price make-up for each supplier assuming 100 000 tests per year

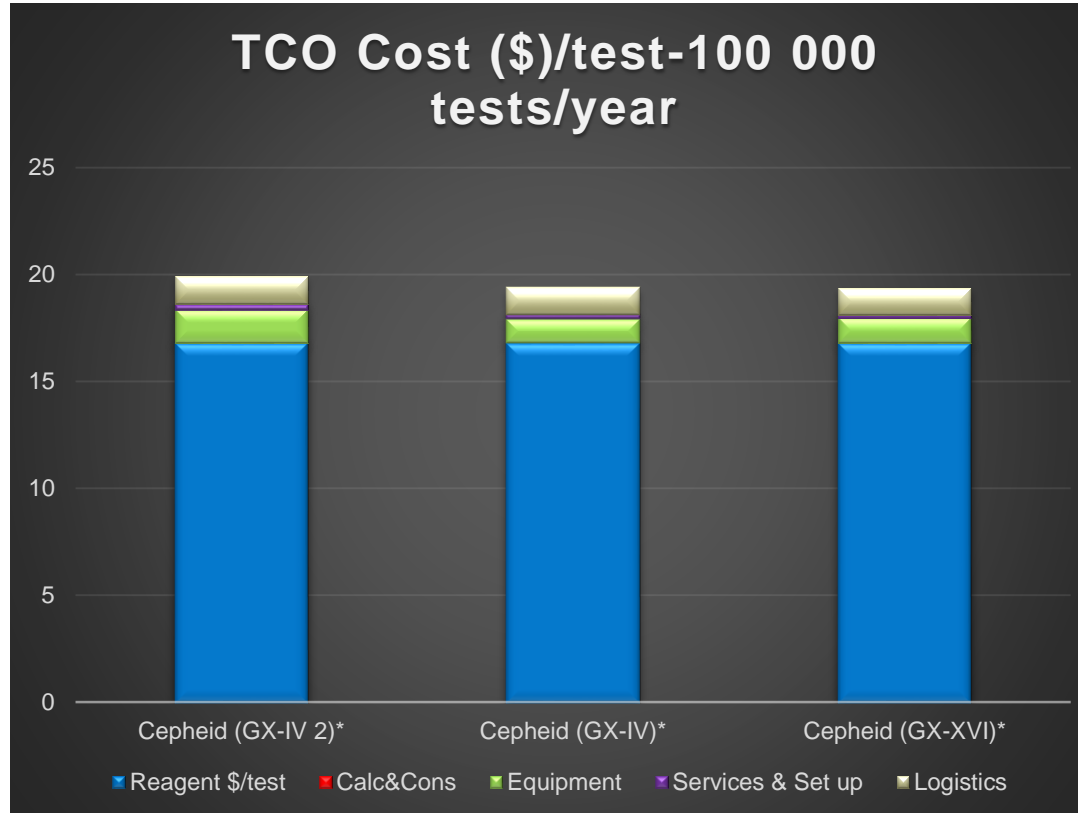


TCO as individual suppliers will have slightly different models; for example, logistics costs will vary between countries. Whilst the presented TCO numbers are illustrative, actual costs should not vary substantively from these numbers – and if a proposal submitted does so without proper justification, then an alternative supplier should be strongly considered

\*ABBOTT and ROCHE did not propose any offer for Price Break option (see further slides for their other offers)

# TCO - **Viral Load** at 100 000 tests/ year (Price Break) – POC analyzers

Graph provides indicative TCO price make-up for each supplier assuming 100 000 tests/year.

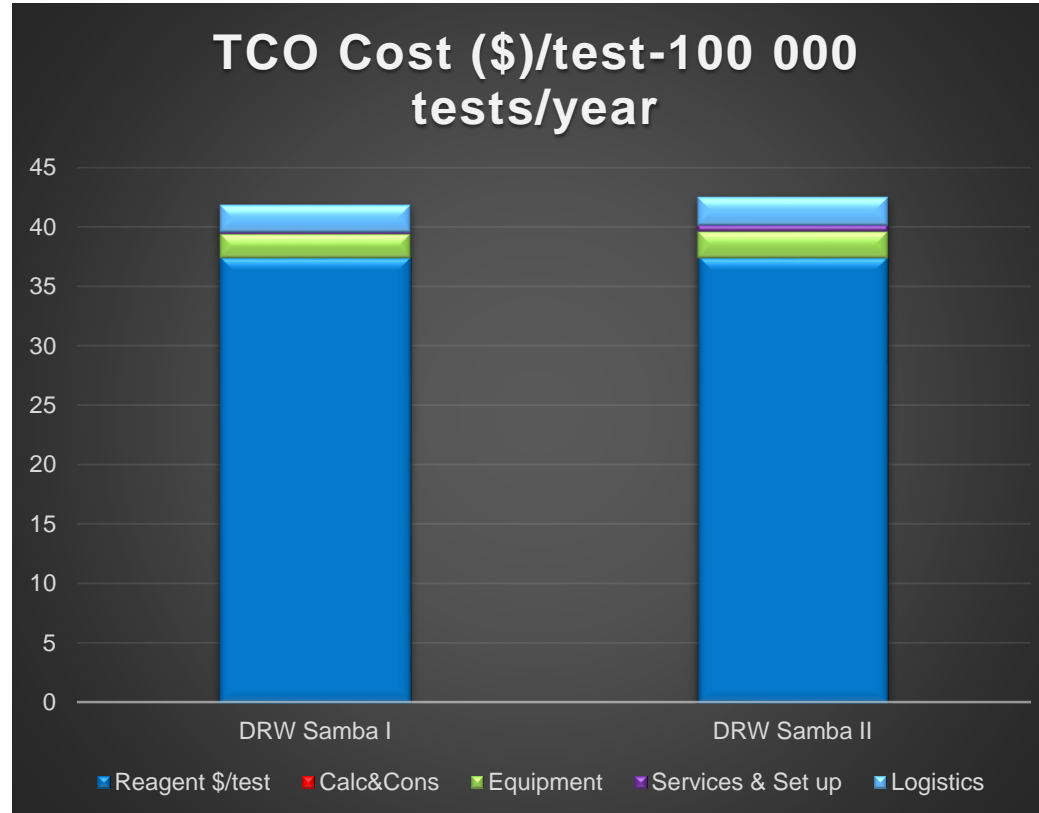


Indicative TCO as individual suppliers will have slightly different models; for example, logistics costs will vary between countries. Whilst the presented TCO numbers are illustrative, actual costs should not vary substantively from these numbers – and if a proposal submitted does so without proper justification, then an alternative supplier should be strongly considered

\*CEPHEID: the desktop configuration is presented in this slide

# TCO - **Viral Load** at 100 000 tests/ year (Price Break) – POC analyzers

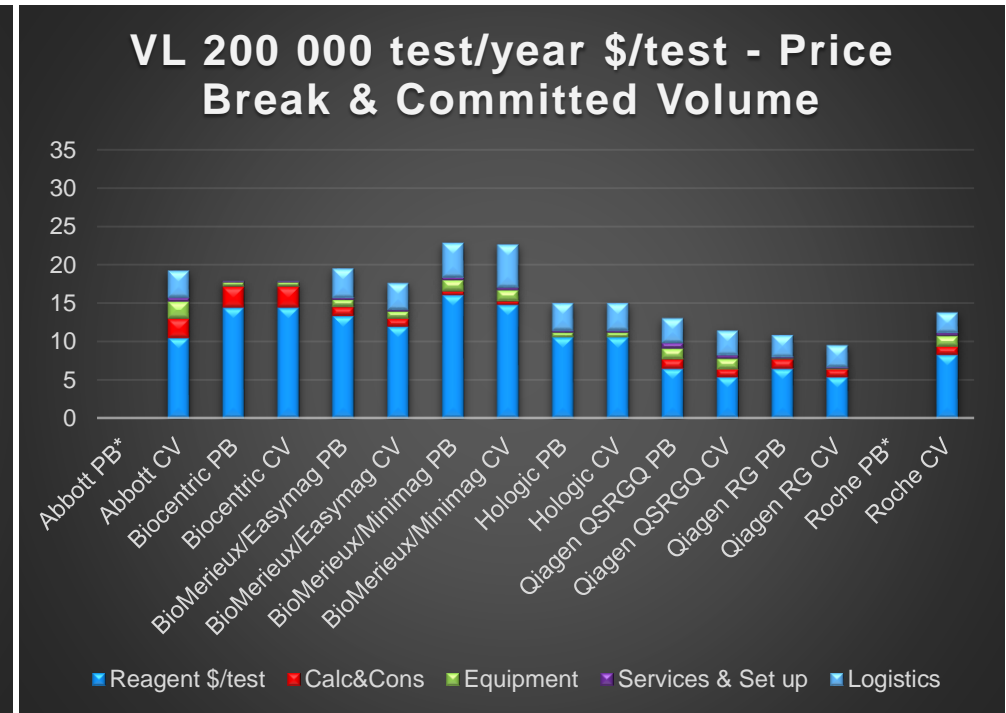
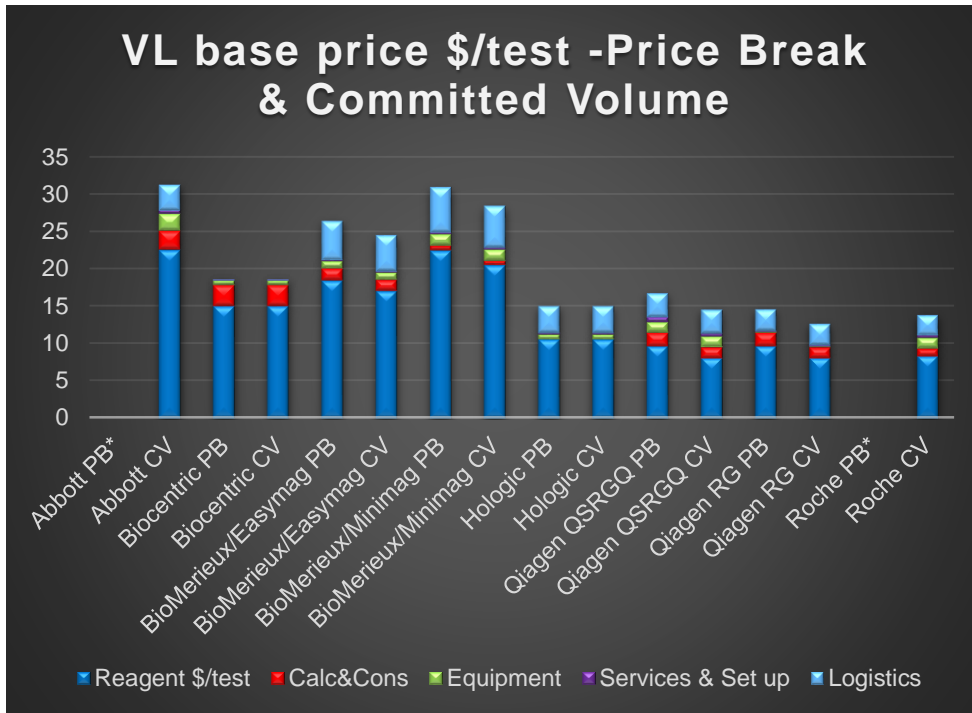
Graph provides indicative TCO price make-up for each supplier assuming 100 000 tests/year.



Indicative TCO as individual suppliers will have slightly different models; for example, logistics costs will vary between countries. Whilst the presented TCO numbers are illustrative, actual costs should not vary substantively from these numbers – and if a proposal submitted does so without proper justification, then an alternative supplier should be strongly considered

# TCO - **Viral Load**: comparison between price break and committed volume for lab-based analyzers

Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at baseline (entry price) and volume of 200 000 tests/year.

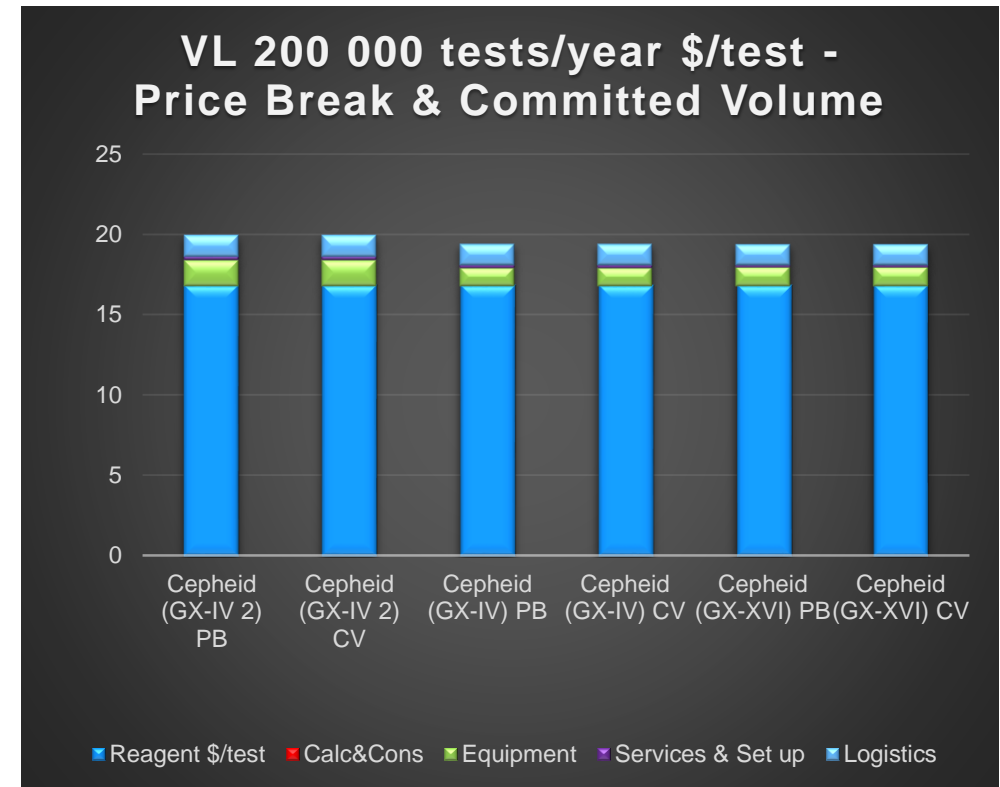
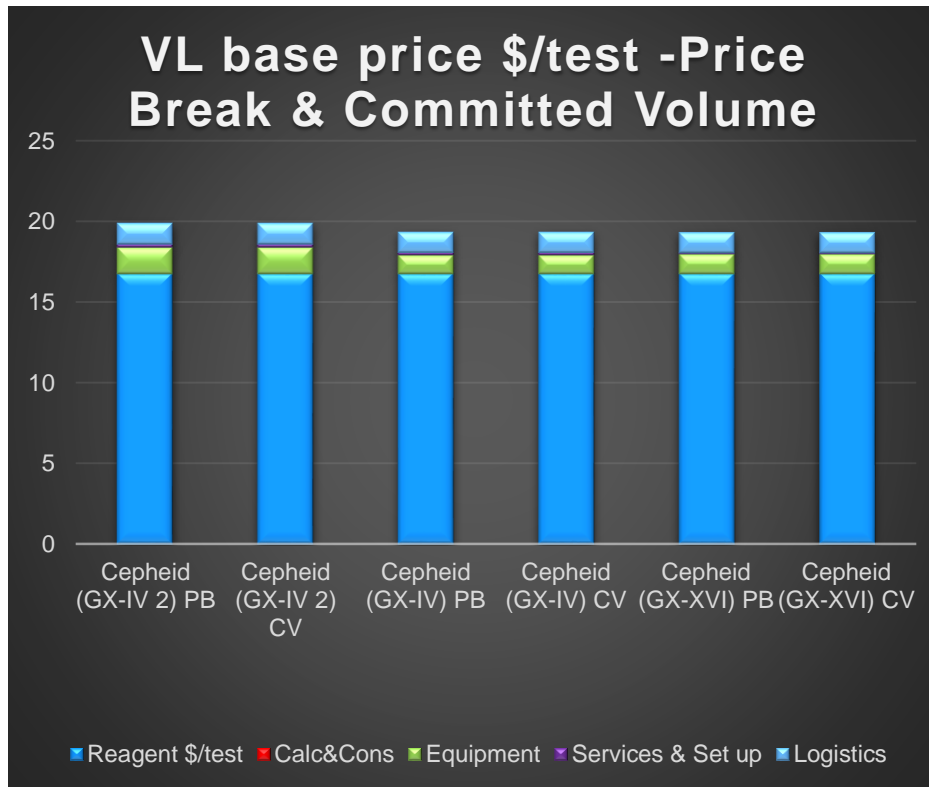


\*ABBOTT and ROCHE did not propose any offer for Price Break option



# TCO – **Viral Load**: comparison between price break and committed volume – POC equipment

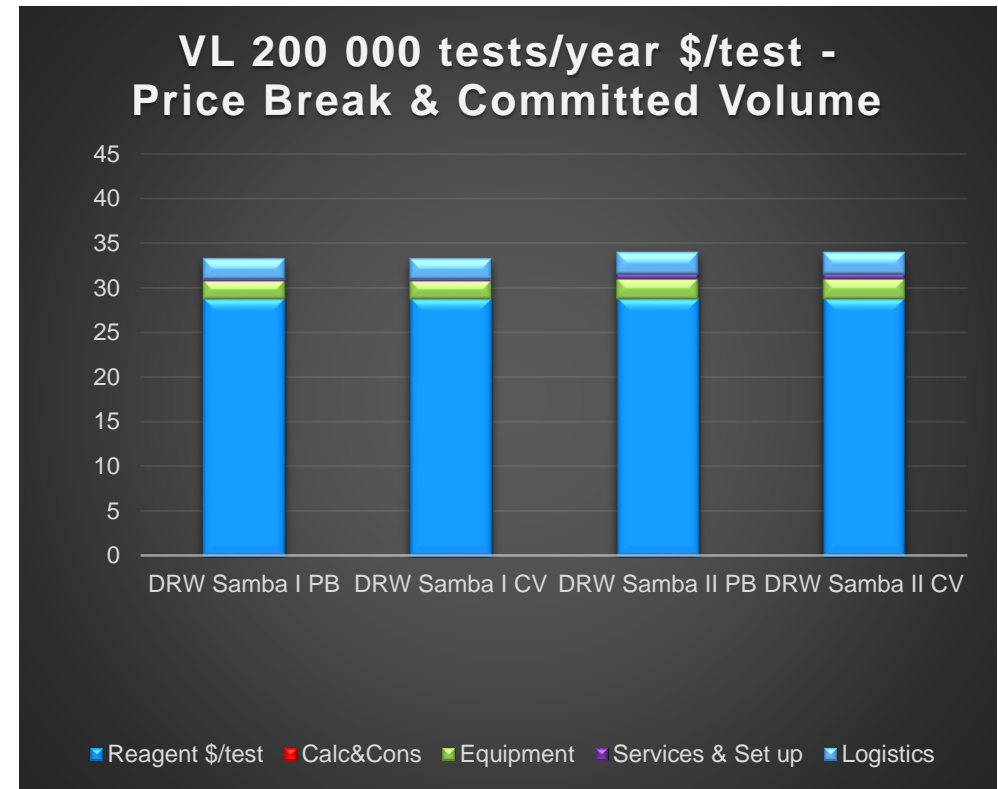
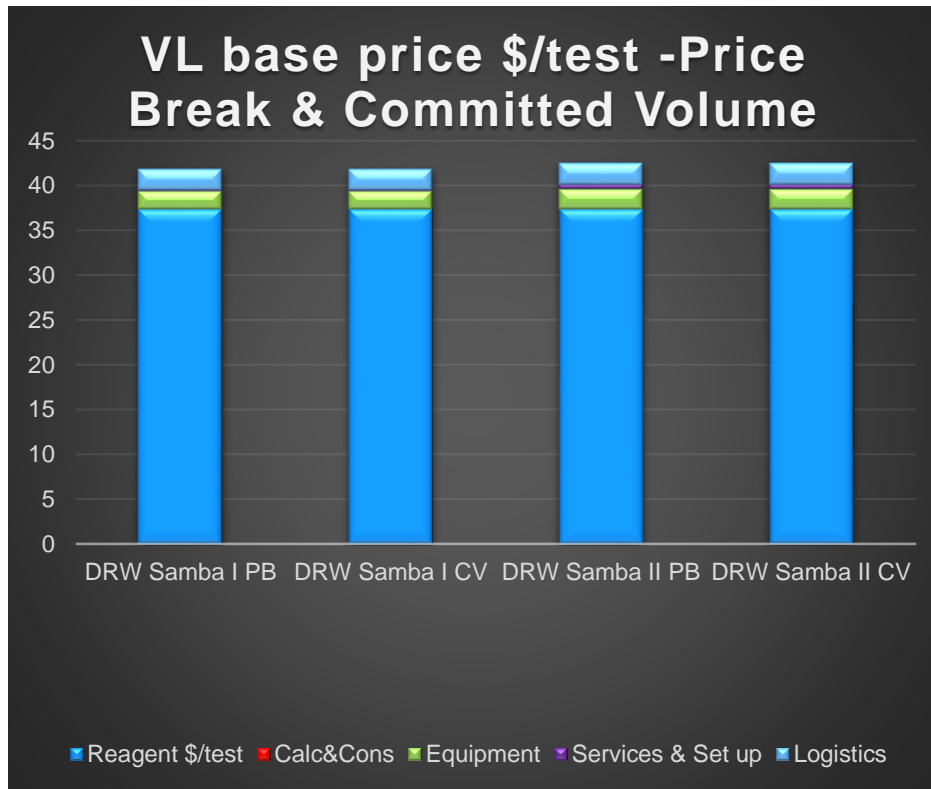
Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at base case (entry price) and volumes of 200 000 tests/year.



CEPHEID: the desktop configuration is presented in this slide

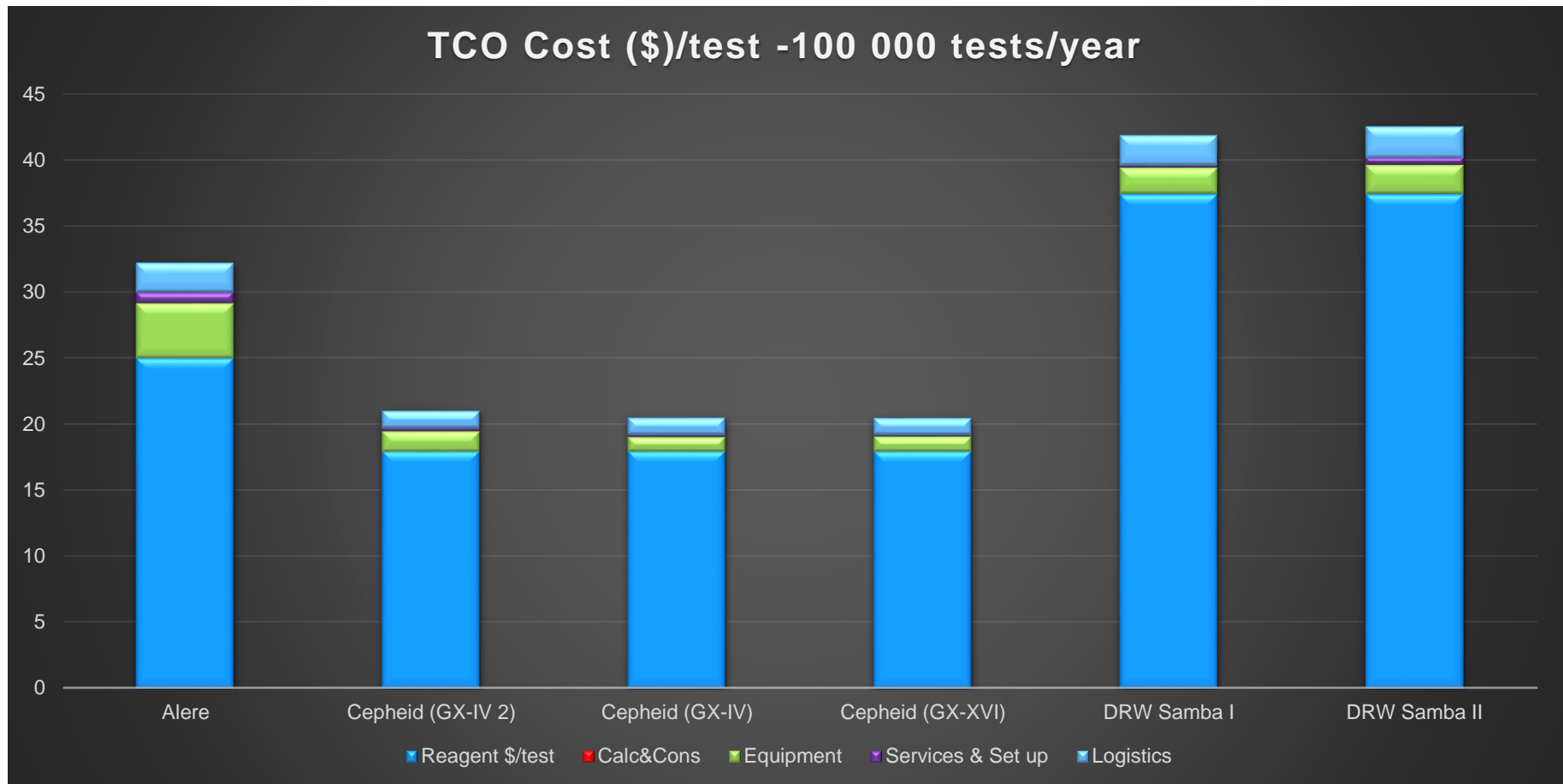
# TCO – **Viral Load**: comparison between price break and committed volume – POC equipment

Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at base case (entry price) and volumes of 200 000 tests/year.



# TCO – EID at 100 000 tests/year Price Break – POC analyzers

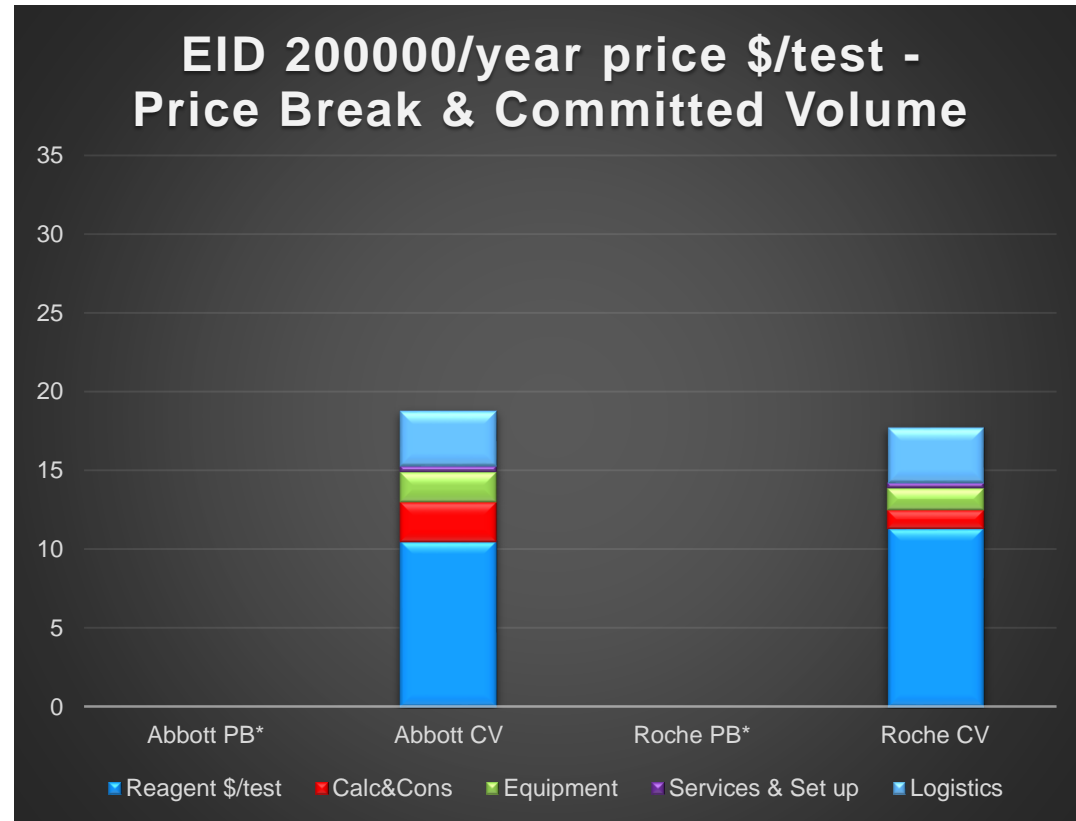
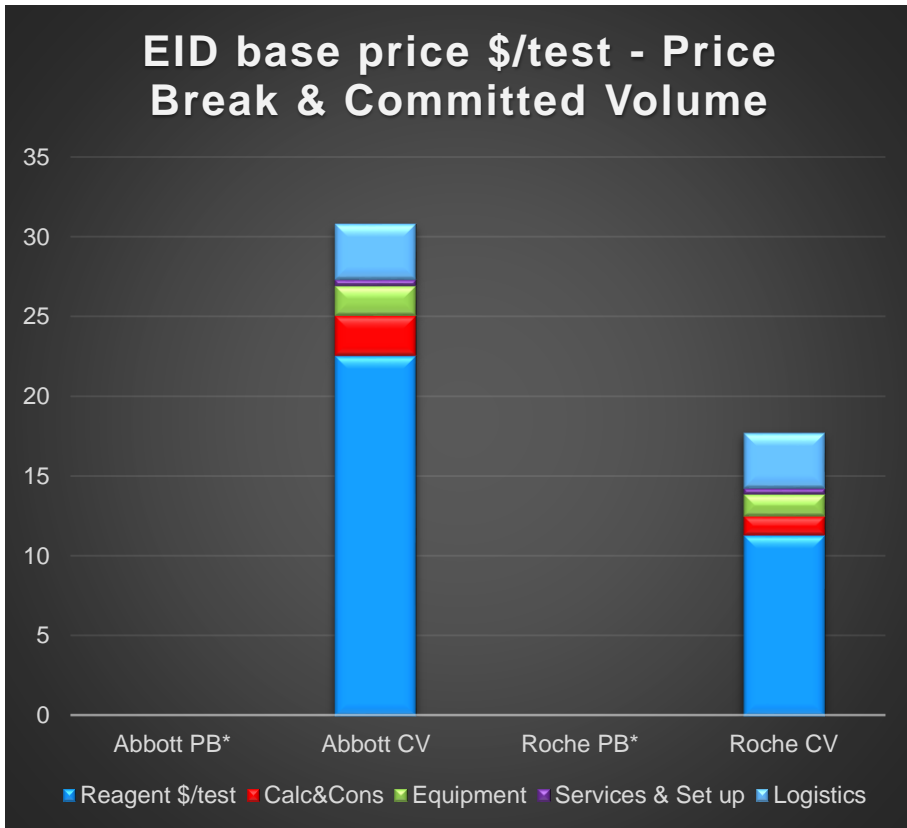
Graph provides indicative TCO price make-up for each supplier assuming 100 000 tests/year.



CEPHEID: the desktop configuration is presented in this slide

# TCO – EID: comparison between price break and committed volumes – Lab based analyzers

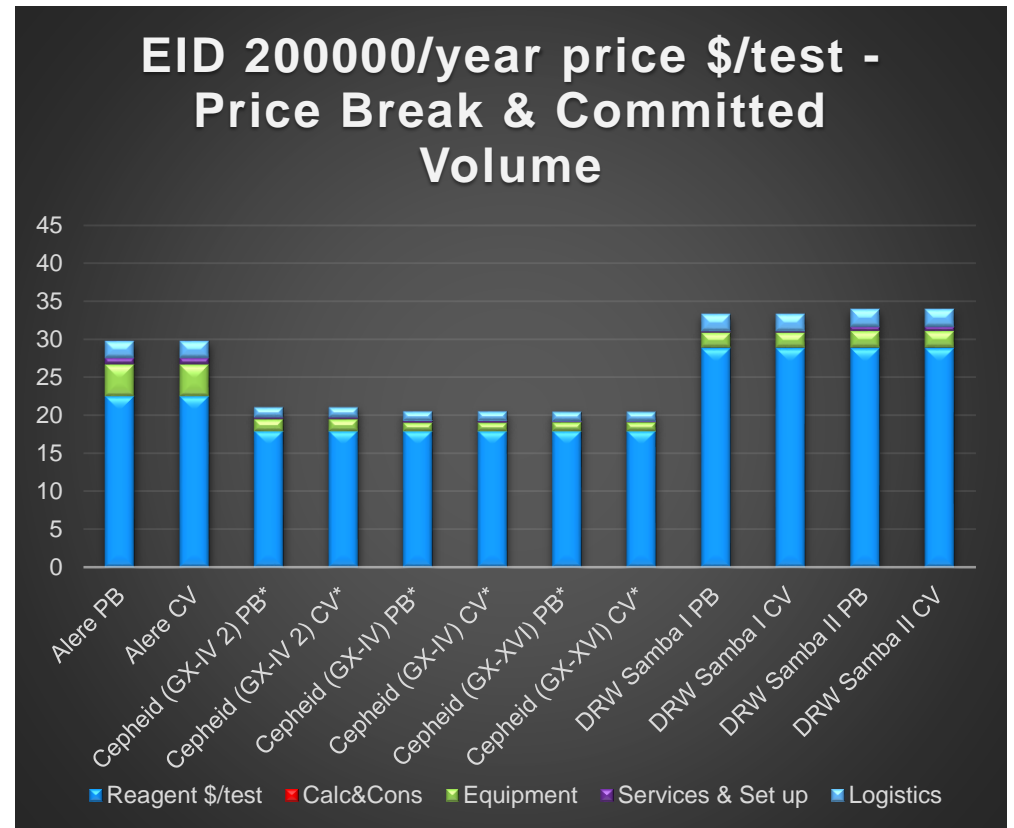
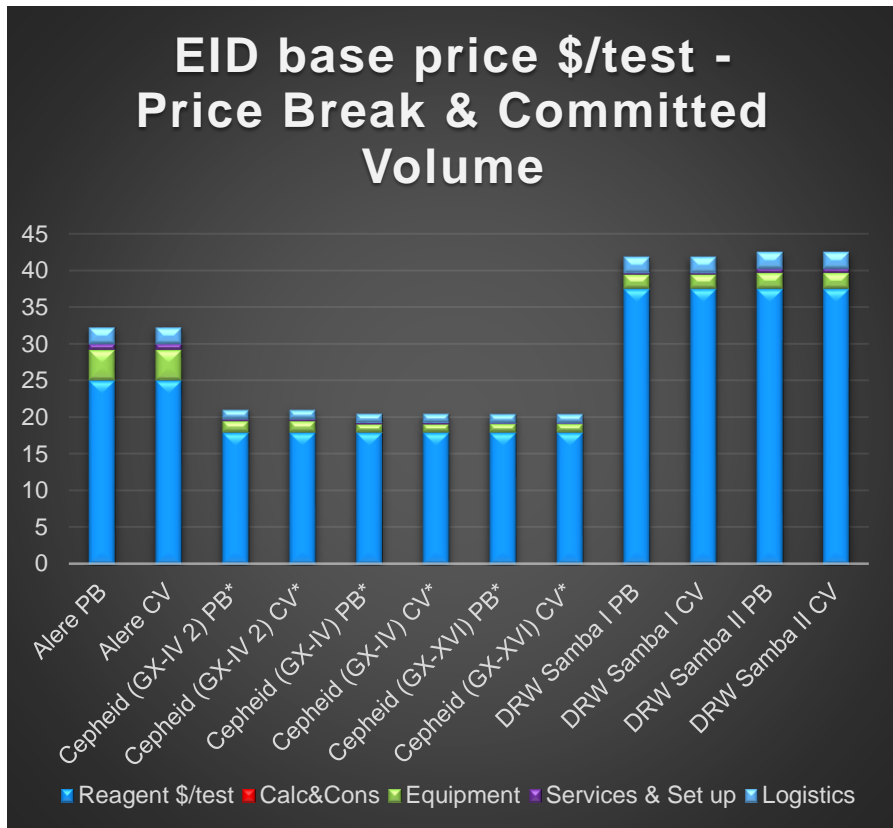
Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at baseline (entry price) and volume of 200 000 tests/year



\*ABBOTT and ROCHE did not propose any offer for Price Break option

# TCO – EID: comparison between price break and committed volumes – POC analyzers

Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at baseline (entry price) and volume of 200 000 tests/year.



# Contracting and pricing components

Contracting options:  
purchasing or reagent rental

Provisions for initial staff training, routine maintenance for existing and new equipment

Start-up package:  
installation, commissioning

Preventive maintenance and spares

In-country support

Competition - avoid country monopole

INCOTERMS, committed volumes and assistance provisions

Pricing scenarios and affordability

# Standard Purchase vs Reagent Rental

## STANDARD PURCHASE

Up-front purchase of equipment required

No volume commitment

Lower price if no servicing bought

Extended warranty is negotiated separately

## REAGENT RENTAL

Total price is higher but monthly cost is predictable

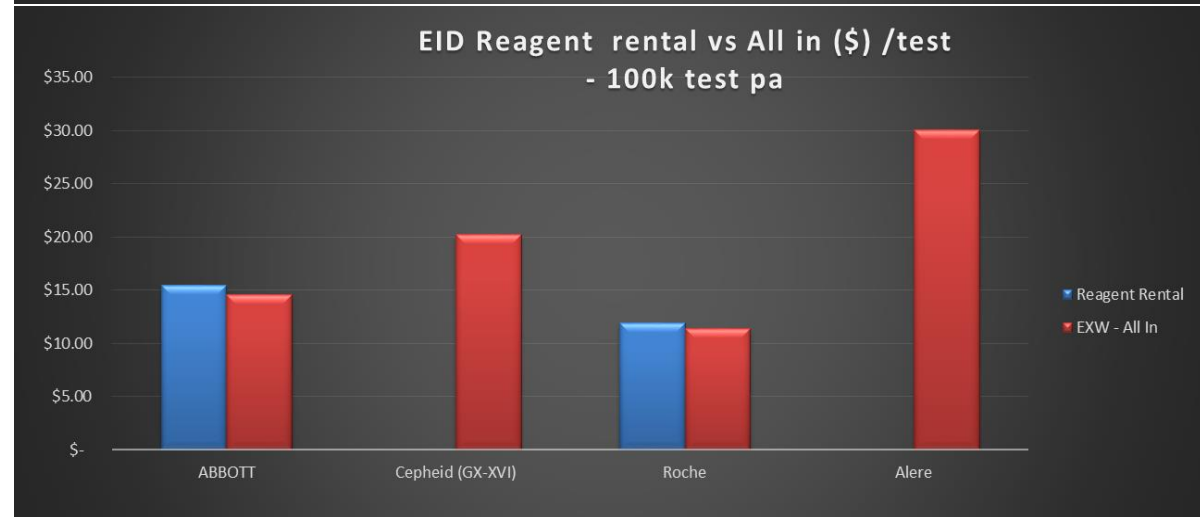
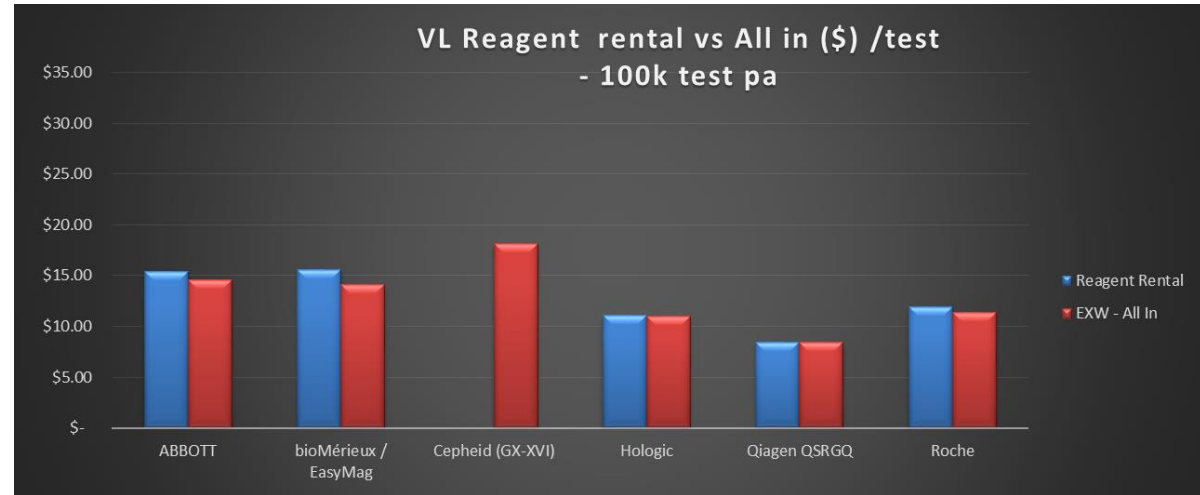
Reagent price includes cost of equipment and service

Requires volume commitment

Higher equipment up-time and use

# “Reagent rental” now available from majority of suppliers

- Reagent rental is a single test price that includes reagents, controls, equipment and servicing
- Contracting approach is the preferred mechanism to support high equipment availability and use
- Costing was previously “opaque”
- Graphs indicate reagent rental prices at different commitment levels
- The graphs show that reagent rental is comparable with the equivalent “all in” purchase option price (EXW) – indicating no “premium” for electing this option





# What **contracting options** are available?

Contracting options		STANDARD PURCHASE(1)			REAGENT RENTAL(2)		
Volume discount options	No volume discount (3)	Price breaks (4)	Committed volumes (5)	No volume discount	Price breaks	Committed volumes	
VL offers	Roche (7)	Biocentric bioMérieux Cepheid (8) DRW Hologic Qiagen	Abbott (6) Biocentric bioMérieux Cepheid (8) Hologic Qiagen Roche		Hologic Qiagen	Abbott (6) Biocentric bioMérieux Hologic Qiagen Roche	
EID offers	Roche (7)	Alere (9) Cepheid (8) DRW	Abbott (6) Alere (9) Cepheid (8) Roche			Abbott (6) Roche	

#	Term	Notes
1	Standard purchase:	Capital purchase of equipment. Separate purchasing of reagents, control, consumables, servicing
2	Reagent rental	Single price per test paid that includes reagents, controls, equipment and servicing, usually linked to planned volumes
3	No volume discount	Simple basic price with no volume discount available
4	Price break	Indicates if supplier has proposed price reductions once price break points achieved. In general price break point is the number of tests when the global total number of future tests (all reagent types) procured through the GF Framework Contract under any channel during the term of the agreement. Please also see supplier specific variations.
5	Committed volume:	Indicates if supplier has proposed committed volume price reductions if committed volume contracted based on volumes across 3 years of contracts (unless company-specific variation). All items procured within the committed volume will be at the same unit price. Please also see supplier specific variations.
6	Abbott	Prices are decreasing with commitment in time and/or volume
7	Roche	Global Access Program price for Viral Load (VL) and EID offered through 3 options: standard purchase, reagent rental and hybrid
8	Cepheid	Prices are based on volumes sold globally to all customers
9	Alere	Prices are based on annual volumes sold globally to all customers

# What are Price Breaks and Committed Volumes?

## Price Breaks

- Supplier has proposed a reduced unit price once a price break points (PBP) is achieved.
- From this point the reduced unit price will apply
- Applicable to all buyers under the contract
- PBP is total number of tests procured during the term of the agreement.
- There may be supplier specific variations.

## Committed Volumes

- Supplier has proposed a reduced unit price for all units committed in advance
- Committed volume can be contracted based on volumes across 3 years of contracts (unless company-specific variation).
- All items procured within the committed volume will be at the same unit price.
- There may be supplier specific variations.
- Committed Volumes offer maximum value for money

# Key principles underpinning the arrangements

1. The Global Fund will create and manage strategic relationships with key suppliers; where procurement for PRs is through the PPM, the Procurement Services Agent (PSA) may be responsible for transactional operations and physical logistics.
2. The Global Fund will hold manufacturers accountable for the performance of their agents and/or distributors. This will include ongoing performance measurement of delivery and quality. Performance in a country (cost, quality, time) will be a factor in future allocations and selection algorithms,
3. Longer term contracts that encourage maximal testing within country-specific algorithms and funding envelopes, and, where feasible and commercially advantageous, committed volumes for the appropriate period.
4. Closer collaboration to improve efficiency and maximize utilization of installed equipment
5. A focus on value as well as affordability considering both commercial and technical factors.
6. The Global Fund should be notified when arrangements are not reasonably respected.

# Do the prices apply to legacy countries/analyzers?

## YES :

- The prices and contracting terms should also apply to “legacy countries or analyzers” where machines are already in place, whether previously procured, leased or placed.
- The detailed transition arrangements will depend on any existing contracts in place between a supplier and PR.
- The Global Fund should be notified when arrangements are not reasonably respected.