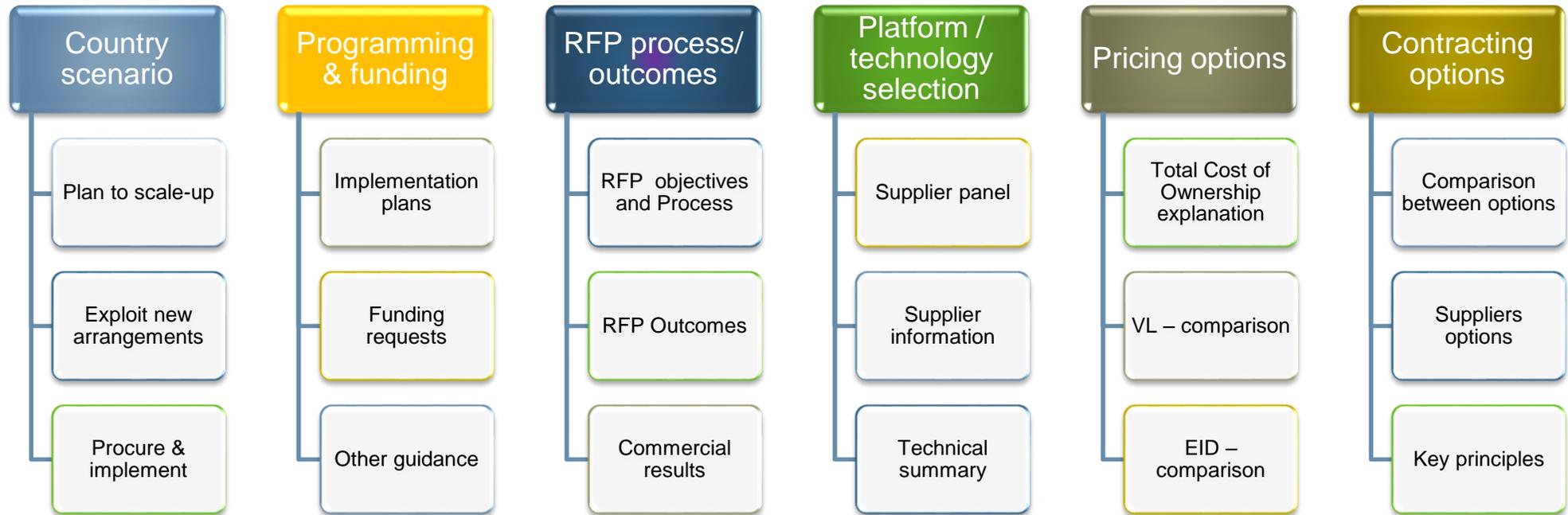


Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool



Navigation diagram – Home page

Version 18 January 2016



This tool is being continually updated and the latest version of this tool can be downloaded from <http://www.theglobalfund.org/en/procurement/viral-load-early-infant-diagnostics/>. 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 context and existing testing capacity
- Assess utilization rate of existing testing platforms in country
- Review technology options
- Integrate sample transport 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 and controls
- Understand options and opportunities for price breaks or committing volume
- Compare added value services
- Consider cost of switching technologies

Country scenario: Procurement and implementation of VL/EID

- Finalize product selection
- Consider Quality Assurance requirements
- Review pricing options
- Determine contracting option
- Consider total cost elements
- Strengthen 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

Contextual Information

HIV disease burden	National HIV/AIDS program: policies and strategies	Laboratory services and experiences with HIV testing and monitoring
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Viral Load guiding principles

Testing lab capacity	Testing Algorithm	Testing VL/EID Targets	Human resources	Technical requirements	Strategy for phased implementation /scale	Role of point of care (POC) VL/EID testing
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Selection, Procurement and Contracting

Selection	Contracting and pricing
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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/

Technology Selection Process

Testing strategy

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

Country Context

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

Technical

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

Commercial

- Costs: equipment reagents, consumables, add-ons, 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

What is included/ excluded

- Equipment – for purchase; or reagent rental
- Installation and training; initial warranty
- Extended warranties; maintenance; ongoing support and training
- Other items offered such as lab equipment; fridges, freezers
- Additional cost levied by distributors (travels, training...)

Type of acquisition

- Purchase vs lease
- Reagent rental with analyser placement
- Threshold pricing depending on output; consequences of not meeting the anticipated or contracted thresholds

Incoterms

- Trade terms outlining responsibilities of manufacturer and purchasers with regards to transport, international freight and insurance costs
- The price difference between different incoterms could be more than 10-20%

Currency

- Conversion to one currency for comparison purposes
- Contractual management of currency fluctuations

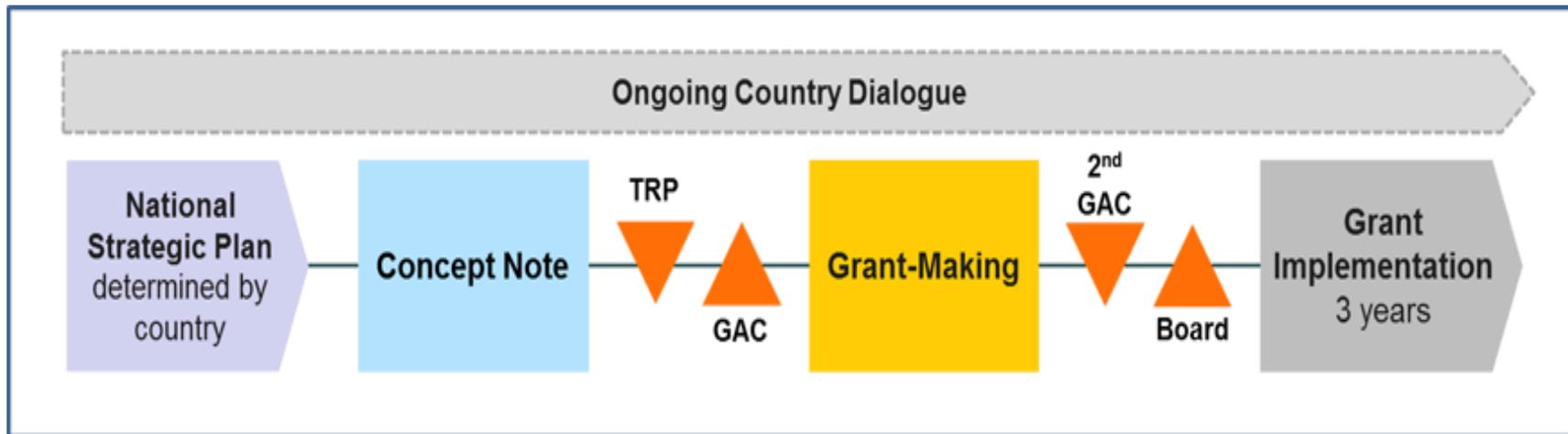
Price tiers / differentials

- Country income level
- Geographical location

Price per test/TCO

- Does it include the total price of all reagents, buffers, and controls needed; maintenance and service?
- Insurance for rental or placement models

VL/EID funding requests within grant life-cycle



Funding proposals

Key VL/EID
programmatic
components to
consider:

Current and up-coming revised testing algorithms for the ARV population (with or without priority segments of population)

Summary of testing targets for the 4 coming years

Mapping of existing testing capacities for EID/VL and CD4 testing

Draft phased VL implementation plan (pilot or broad)

List of the proposed equipment (with quantities and placement approach)

Comprehensive budget with various costing scenarios for implementation

Provision of ARVs for infants and second-line treatments

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, reagents and consumables

Staff training

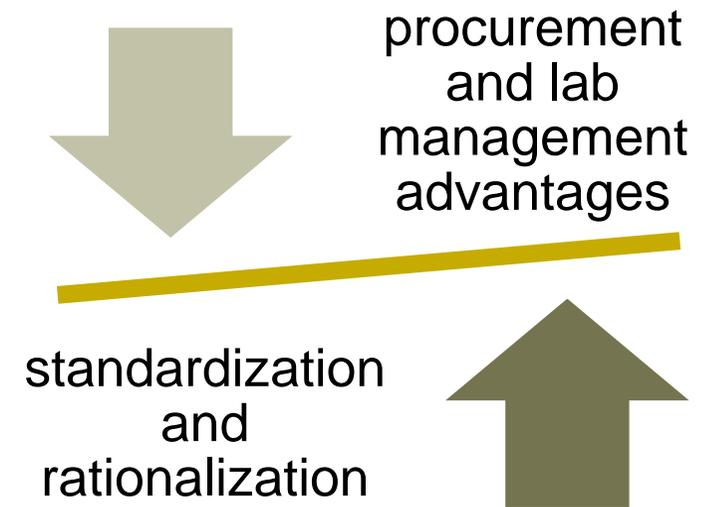
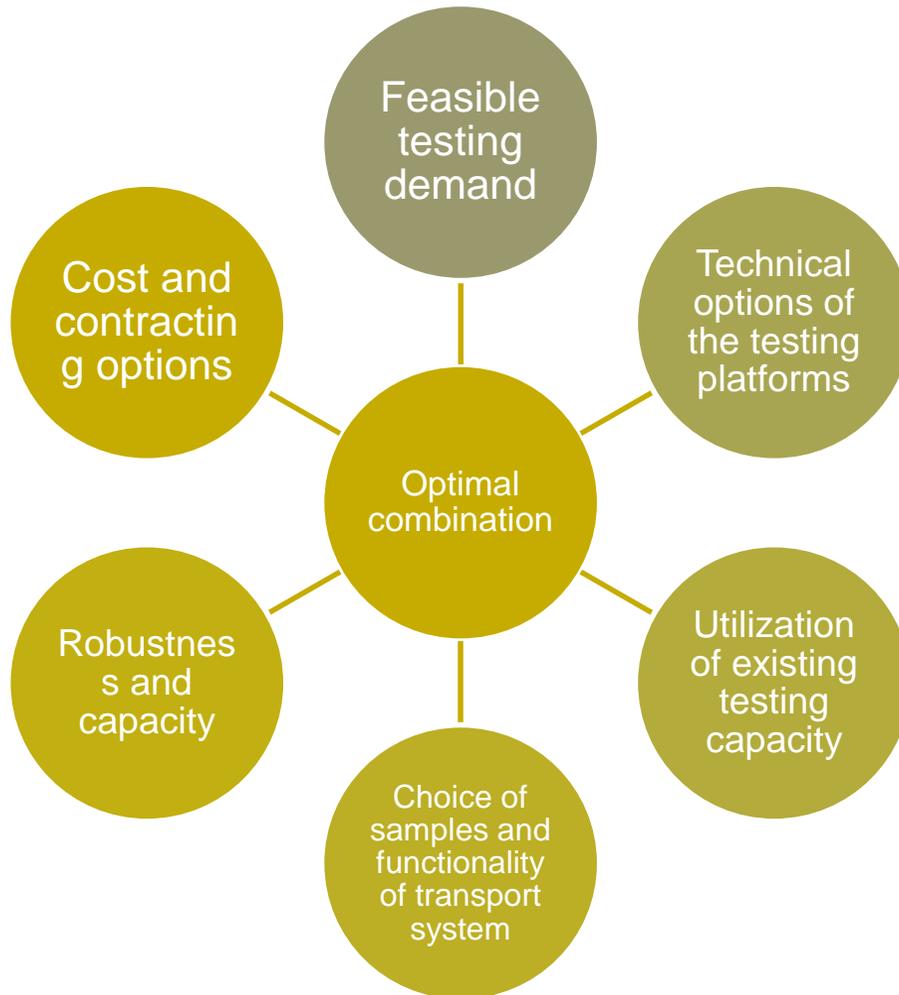
Transportation system for the samples or referral system for the patients to reach the lab or sample collection facilities

Results reporting system and Lab Information System

Routine maintenance of equipment

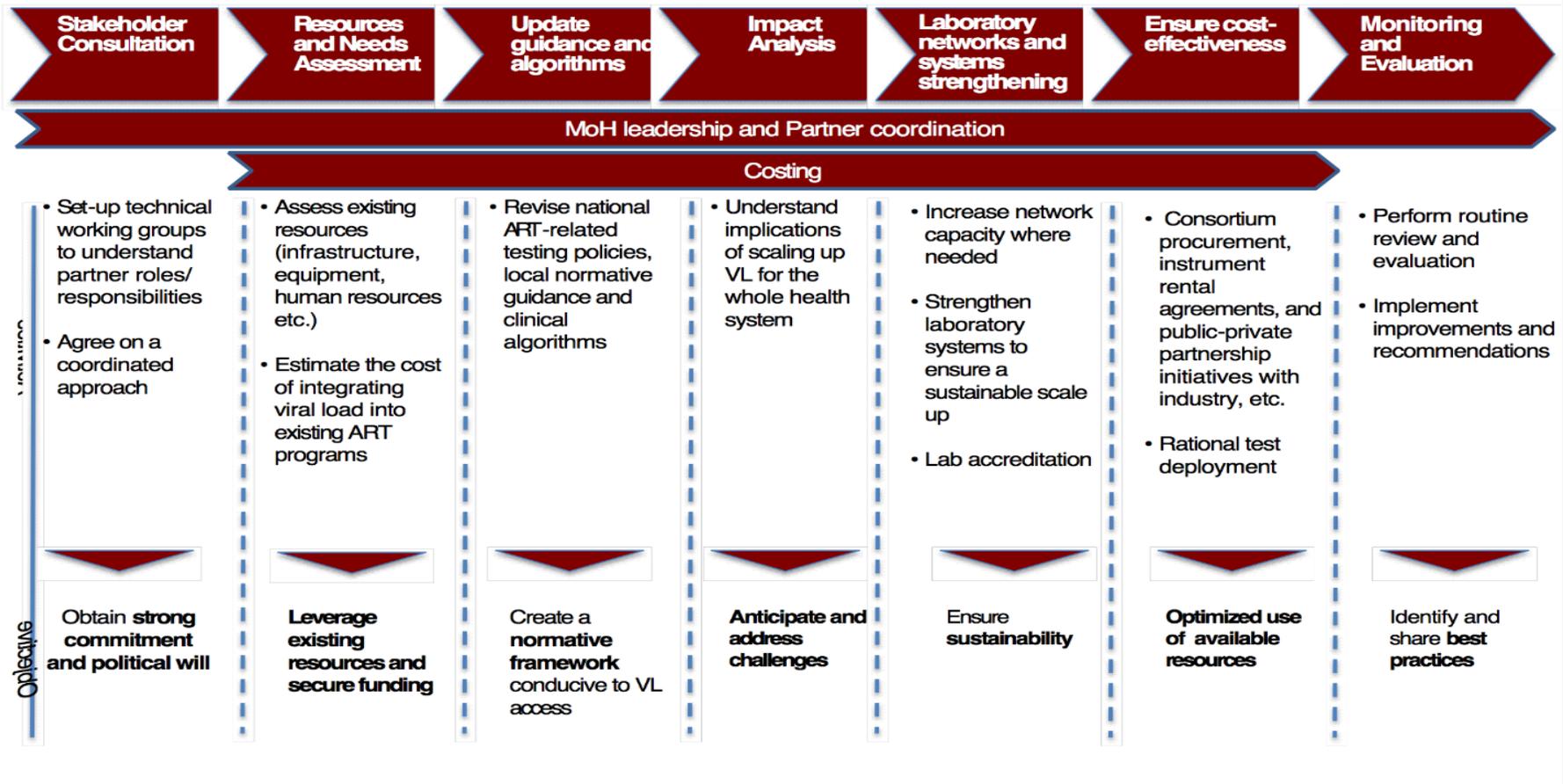
Supportive quality assurance systems

A comprehensive approach for selection, procurement and contracting



ASLM – VL implementation framework

ASLM recommends a framework for viral load implementation



MSF: Guidance and Tool Kit



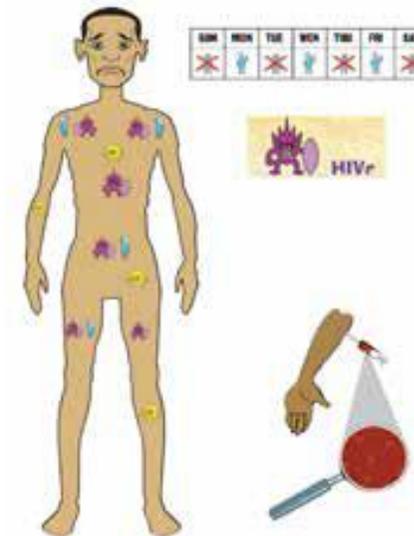
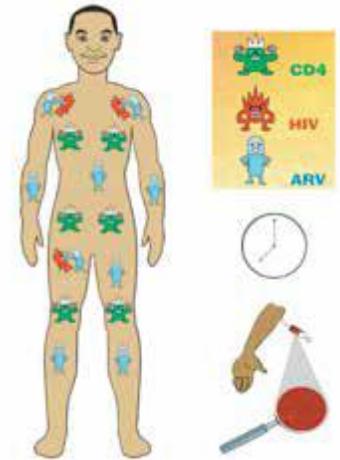
PUTTING HIV TREATMENT TO THE TEST

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

www.msfaccess.org



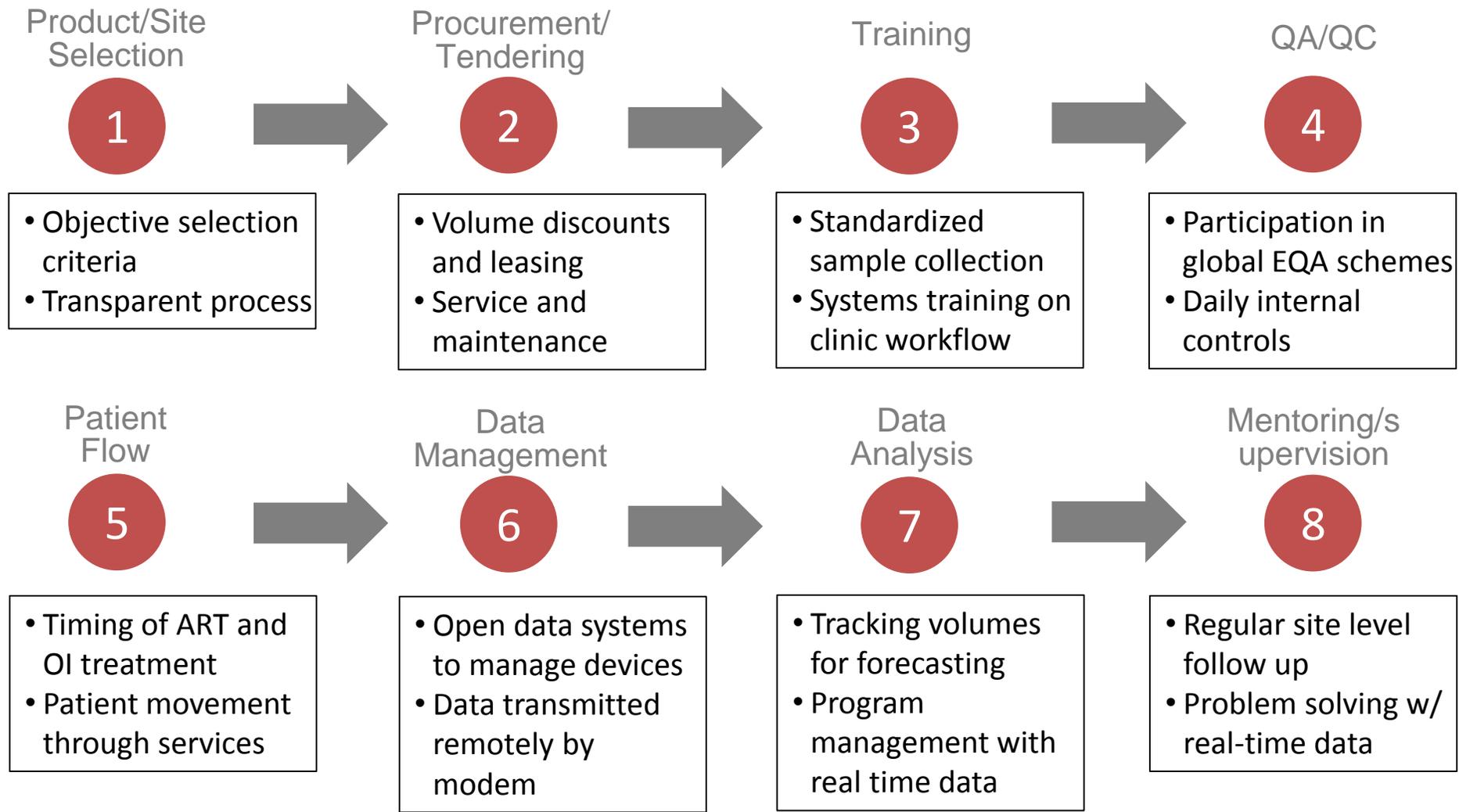
MÉDECINS SANS FRONTIÈRES VIRAL LOAD TOOLKIT AN IMPLEMENTER'S GUIDE TO INTRODUCING HIV VIRAL LOAD MONITORING



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

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

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



WHO Guidance

Phase 1: Planning

- Policies and leadership
- Harmonization
- Algorithm
- Mapping and forecasting
- Viral load testing network
- Assess capacity
- Costing
- Specimen and product selection
- Equipment procurement

Phase II: Scale-up

- Phase in
- Human resources
- Training and supervision
- Quality management system

Phase III: Sustainability

- Partner Harmonization
- M&E
- Data collection
- Operational research

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/
- WHO. Prequalification of Diagnostics programme public reports. 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

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 Note on Health Systems Strengthening for Global Fund Applicants: “Improving laboratory infrastructures and systems”. March 2014. <http://www.theglobalfund.org/en/fundingmodel/support/infonotes>
- Global Fund’s QA policy for Diagnostics: http://www.theglobalfund.org/documents/psm/PSM_QADiagnostics_Policy_en/

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

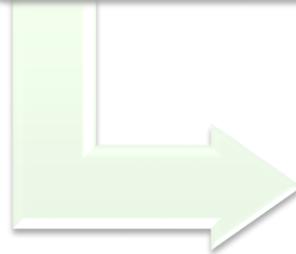
Navigation diagram



- Objectives
- Process
- Schedule



- Key outcomes
- Price variability



- Total Cost of Ownership - explanation
- Total Cost of Ownership - VL
- Total Cost of Ownership - EID
- Cost / volume relationships – VL
- Cost / volume relationships – EID
- Reagent rental
- Equipment illustration

Objectives of the Request for Proposal



1. To select a panel of manufacturers to enter into Framework Agreements to supply PRs both through all procurement channels of Global Fund recipients
2. To improve transparency of cost and contracting elements to enable better selection, acquisition and 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 majority of suppliers that is comparable with the equivalent “all in” bottom up price – no or small “premium”
- ✓ Identifies various value-added solutions available

Broader supplier base

- ✓ Includes 2 new offerings for lab-based systems
- ✓ Includes 2 new entrants for lower throughput/near-Point-of-Care offerings
- ✓ Establishes process for new entrants with a clear target for pricing and contracting

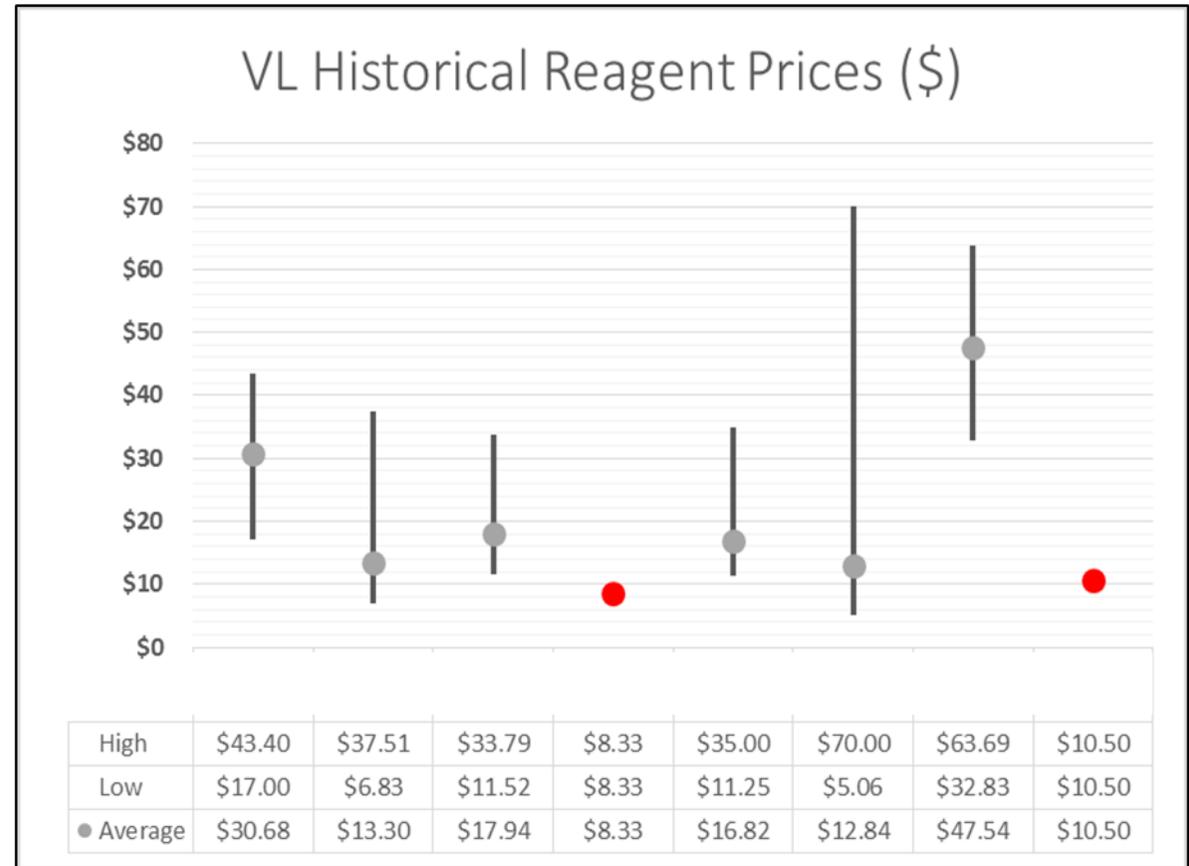
Global visibility

- ✓ 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 (June 2015)

	Eligibility and Testing products	
	Regulatory status	Tests
Abbott	WHO PQ	VL, EID
Alere	CE mark	EID
BioMérieux	WHO PQ	VL
Cepheid	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 (www.theglobalfund.org/en/procurement/quality/diagnostics/).

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

HOLOGIC



- Panther® system
- Test: Aptima HIV quant Dx
- www.hologic.com

ALERE



- Alere q
- Test: Alere q HIV-1/2 Detect assay
- www.alerehiv.com

QIAGEN



- QIASymphony SP, QIASymphony AS, Rotor-Gene Q MDx 5plex HRM
- Test: Artus™ HIV-1 QS-RGQ RT-PCR System
- www.qiagen.com

bioMérieux



- NucliSENS® EasyMAG®/EasyQ®
- NucliSENS® Mini MAG®/EasyQ®
- Test: NucliSENS EasyQ HIV-1 v2.0
- www.biomerieux-diagnostics.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

CEPHEID



- GeneXpert® system
- Test: Xpert HIV-1 viral load
- www.cepheid.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

Content not yet submitted by the company

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**

POWERED BY

NucliSENTRAL™

LIS

**WHO
Prequalified**

CE MARKED DBS protocol
for venous and
capillary blood



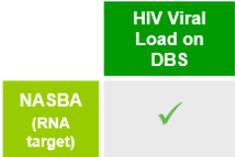
EasyQ HIV-1 v2.0
LoD (95% detection level), 1ml input volume

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)

Dried blood spot (2 spots = 0.1 ml)	802 VQA cps/ml
--	-------------------

- ✓ **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.

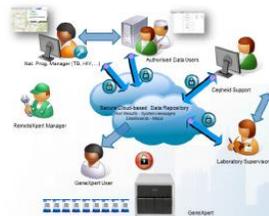
- Co-infection (TB, HCV)
- Women's Health, Healthcare-Associated Infection, Oncology, Critical Infectious Disease, & Virology



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

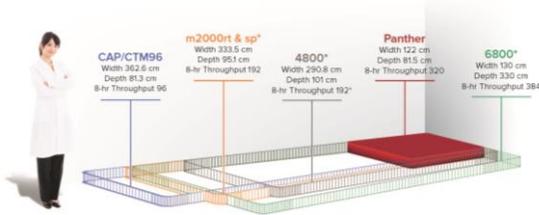
- Informative dashboards for M&E
- Epidemiological monitoring
- Remote servicing capacity



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



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 45-45x10⁶ 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 54-45x10⁶ cop/ml
- Sample type: plasma
- 24 or 96 rxn kits
- Manual extraction and assay set-up, for lower throughput

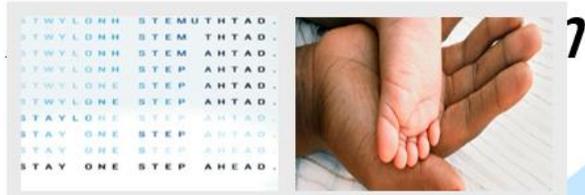
- ✓ Flexibility of batch size with no wastage
- ✓ Continuous sample loading*
- ✓ Primary tube capability*
- ✓ Integrated barcode reading*
- ✓ Minimal hands on time
- ✓ Predefined assay runs
- ✓ Automatic transfer to assay setup*
- ✓ Automated result interpretation
- ✓ Flexible hardware with a broad assay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

* Only available on QS-RGQ automated solution



Roche Molecular Diagnostics

Trusted experience with the HIV-1 Global



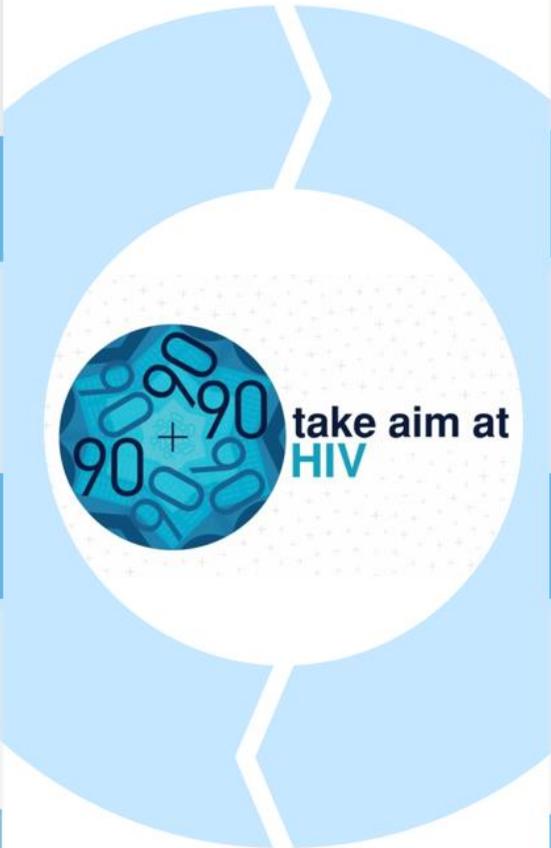
Dual Target technology for reliable and secure results



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

Guidance: Selection of Testing Platforms

Consider VL 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 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

Equipment: assess maintenance requirements

Review pricing offers for equipment, reagents and consumables.

Budget QA, lab infrastructure, training, sample transportation

Guidance: Review characteristics of VL/EID testing platforms

Ease of use
(automation,
technical skills)

Equipment capacity
(number of tests per
day), testing menu

Performance of the
products, 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 footprint,
ancillary equipment

Results reporting and
lab management
information system



Comparison of technical options for VL

	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 day)
Abbott	RNA	m2000sp	m2000rt	Plasma	High	Freezer	18 months	TB, HCV, HBV	Required on new lot or biannually	165 (on a 9h day)
bioMérieux automated	RNA	EasyMag	EasyQ	Plasma & Dry Blood Spot	High	Fridge	18 months	no	Not required	144
bioMérieux semi-automated		MiniMag	EasyQ	Plasma & Dry Blood Spot	Medium					48
Cepheid	RNA	GeneXpert XVI		Plasma	High	Room Temperature 2-28°C. Transport refrigerated	8 months	TB HCV	Not required	80
		GeneXpert IV								20
Hologic	RNA	Panther system		Plasma	High	Freezer	18 months	no	Required	320
Qiagen automated	RNA	QIA Symphony SP/QIA SymphonyAS	Rotor-Gene Q	Plasma	High	Freezer	17 months	HCV HBV	Not required	96
Qiagen semi-automated	RNA	manual	Rotor-Gene Q	Plasma	Medium					
Roche	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

	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 per day
Abbott	Total Nucleic Acids	m2000sp	m2000rt	Plasma & Dry Blood Spot	High	Freezer	18 months	Not Required	165 (on a 9h day)
Alere	DNA	Alere q		Whole Blood	High	Room Temperature 4-30°C	6 months	Not required	8
Cepheid	Total Nucleic Acids	GeneXpert XVI		Whole Blood & Dry blood spot	High	Room Temperature 2-28°C. Transport refrigerated	8 months	Not required	80
		GeneXpert IV							20
Roche	DNA	Cobas Ampliprep	Cobas Taqman	Plasma & Dry Blood Spot	High	Fridge	12 and 22 months	Not Required	144

Guidance: Regulatory status of VL/EID products

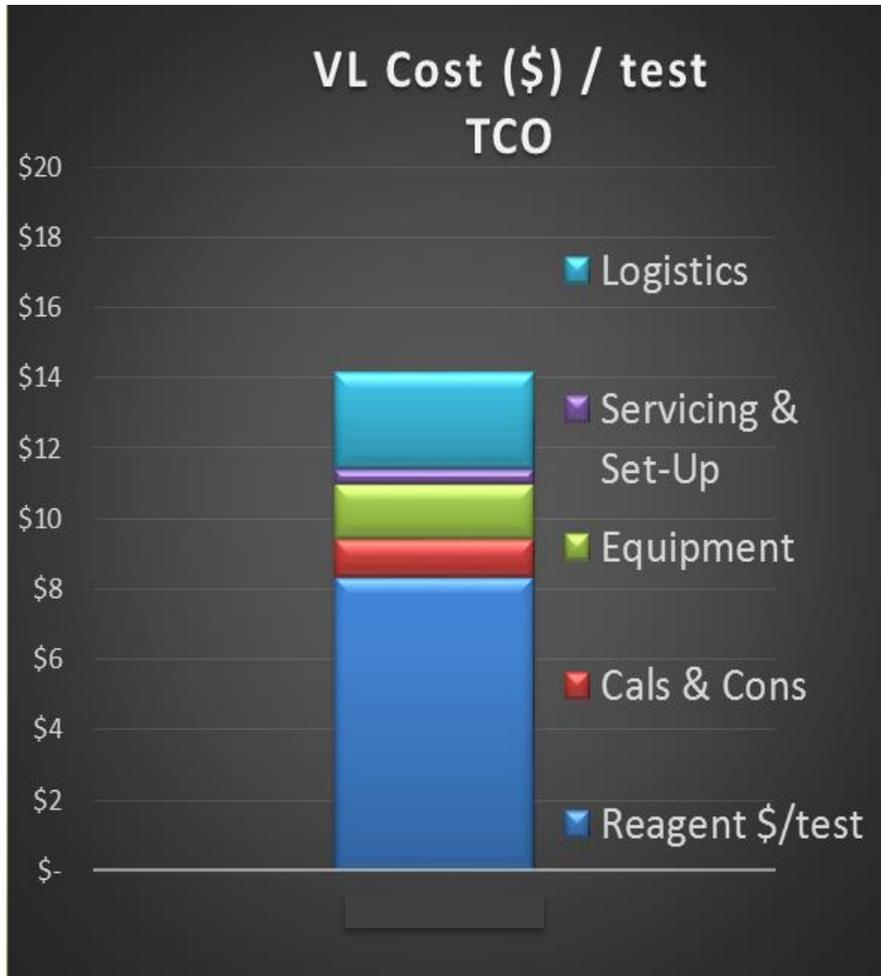
Global Fund list of HIV Diagnostic Products

http://www.theglobalfund.org/documents/psm/PSM_ProductsHIV-WHO_List_en/

WHO Pre-qualification for Diagnostic Products

http://www.who.int/entity/diagnostics_laboratory/evaluations/150508_prequalified_products_list.pdf?ua=1

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

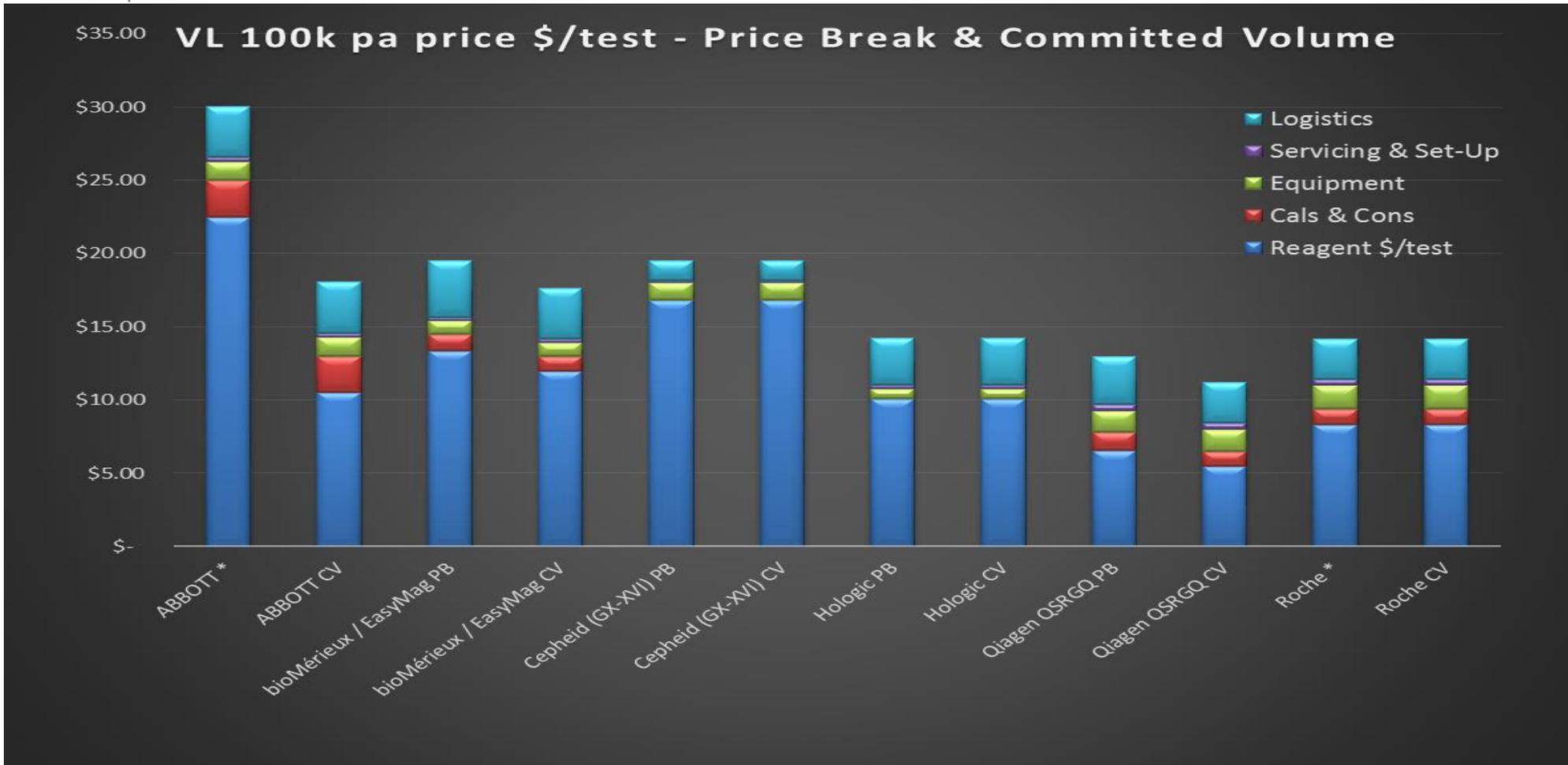
Controls / Calibrations / Consumables / test based on supplier guidance

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 100k pa Price Break and Committed Volumes

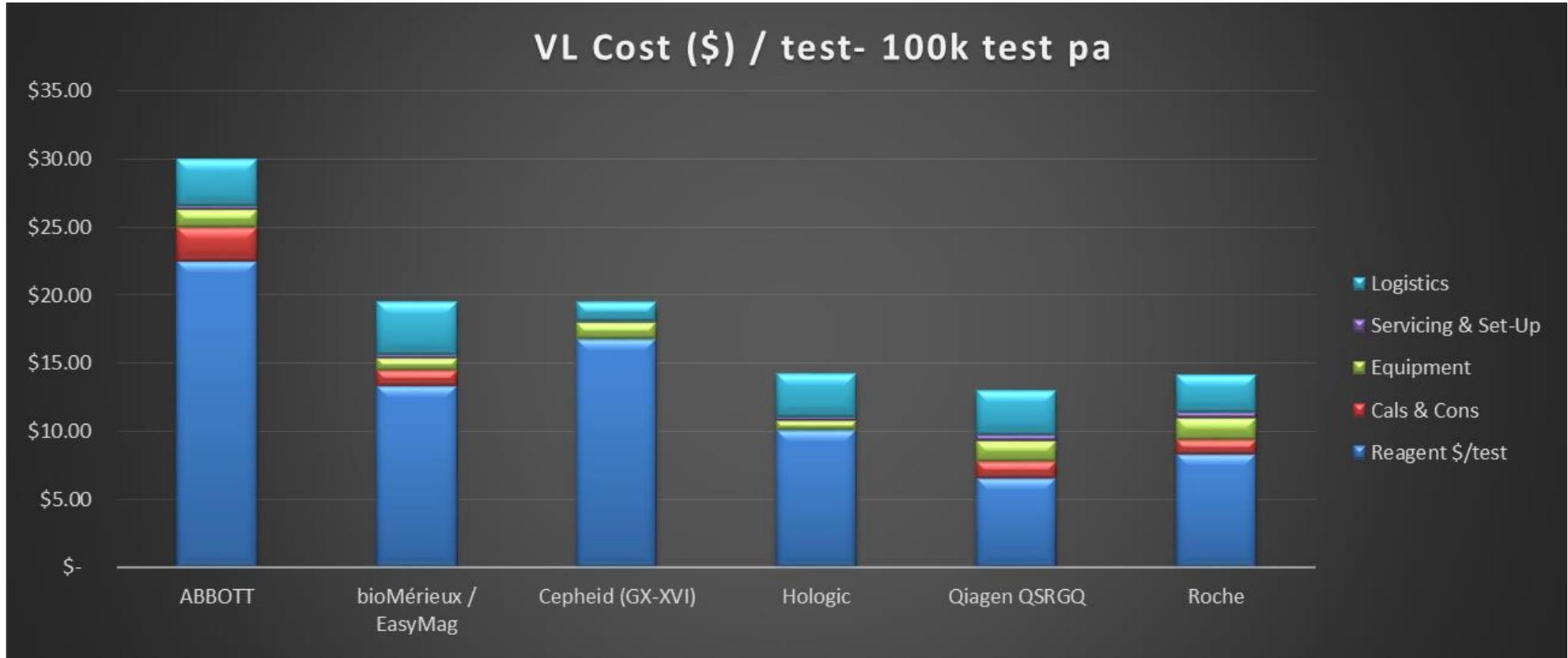
Graph provides indicative TCO price make-up for each supplier assuming 100k global tests undertaken per annum (i.e. 300k over three years). CV prices are either the same or less: for certain suppliers, hence where possible to commit to CV, then buyer will benefit from lower prices for all the order



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. * Where a supplier did not offer pricing for committed volumes and/or price breaks, these charts present that suppliers base price – see the later “What contracting options are available” page for details of the price offers made by each company.

Total Cost of Ownership – Viral Load at 100k pa price break

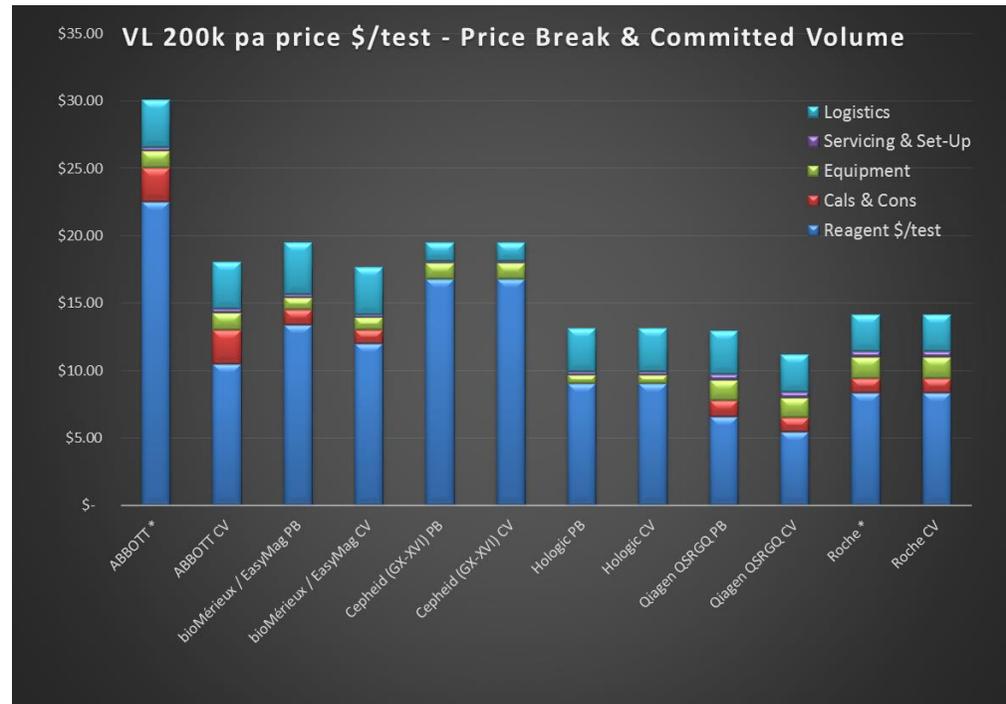
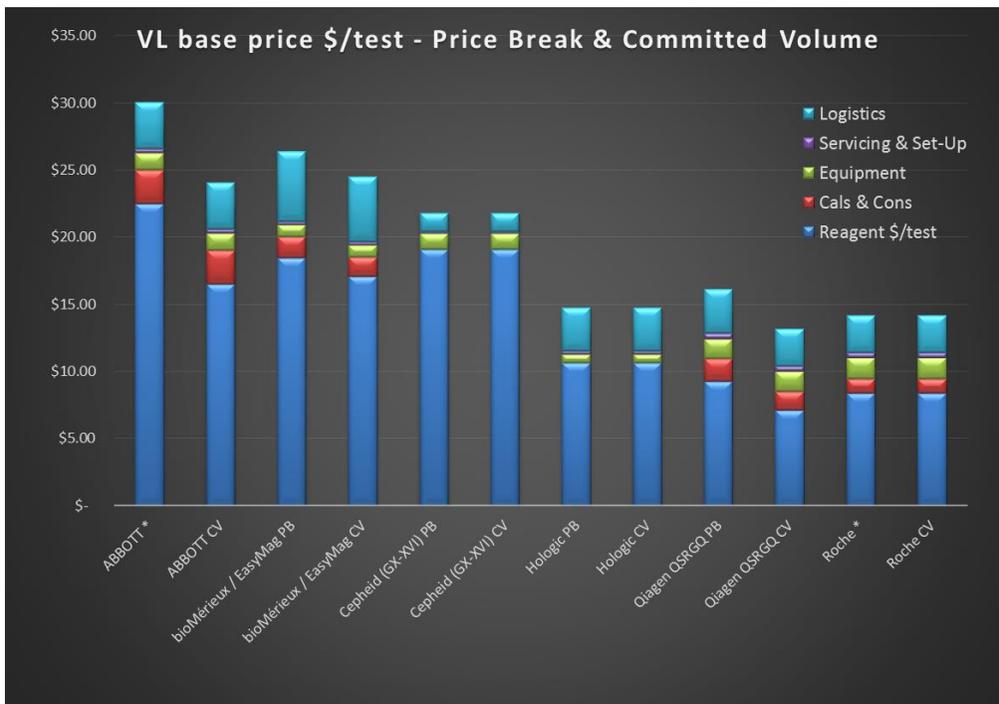
Graph provides indicative TCO price make-up for each supplier assuming 100k global tests undertaken per annum (i.e. 300k over three years)



1. 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

VL – comparison between price break and committed volumes

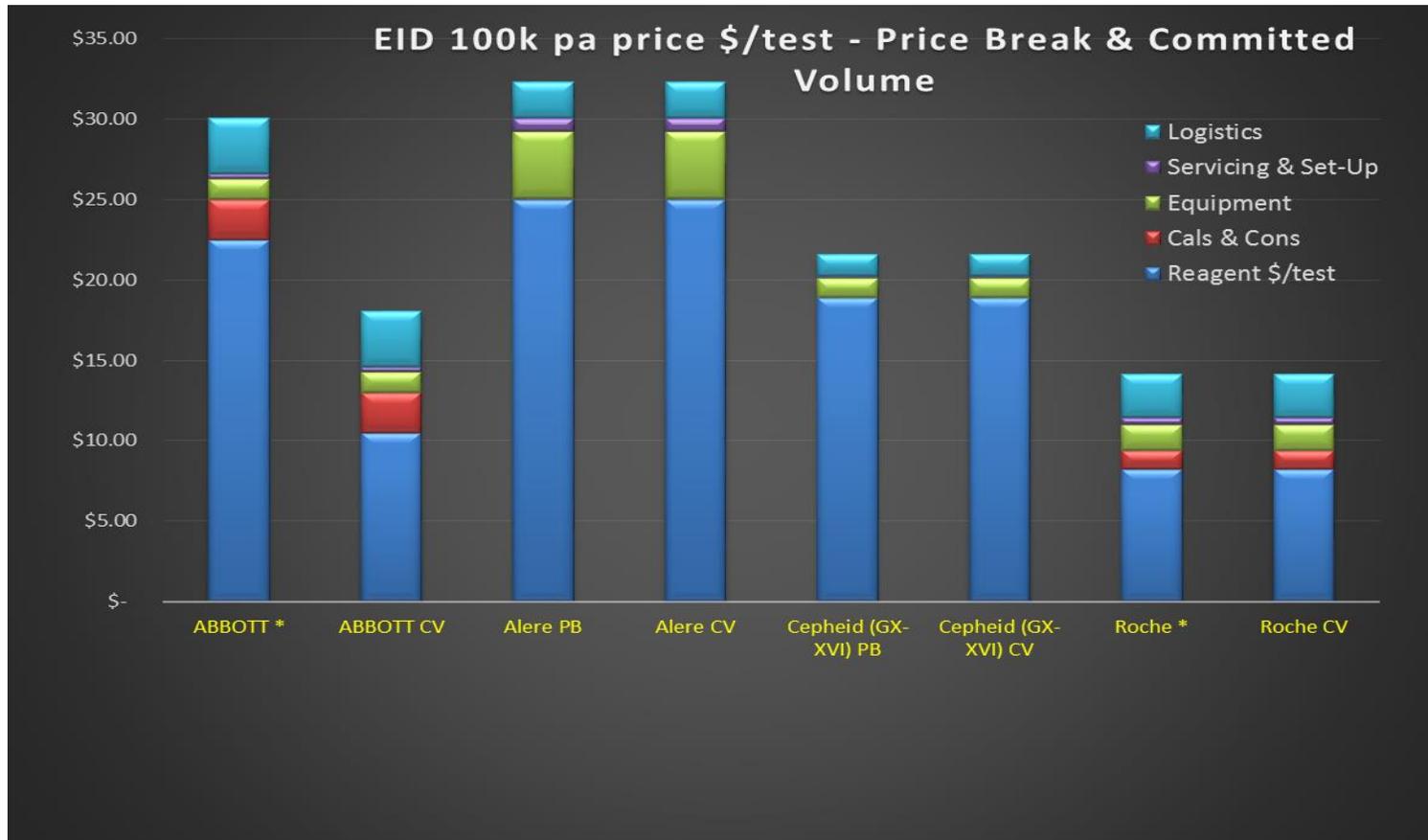
Graphs compare TCO for price break (PB) and committed volumes (CV) for each supplier at base case (entry price) and volumes of 200k tests pa. CV are same or lower with lowest prices achieved at higher committed volumes for some suppliers



*Where a supplier did not offer pricing for committed volumes and/or price breaks, these charts present that suppliers base price – see the later “What contracting options are available” page for details of the price offers made by each company.

EID TCO prices for Price Breaks and Committed Volumes (CV)

Graph provides indicative TCO price make-up for each supplier assuming 100k global tests undertaken per annum (i.e. 300k over three years). CV prices are either the same or less: for certain suppliers, hence where possible to commit to CV, then buyer will benefit from lower prices for all the order

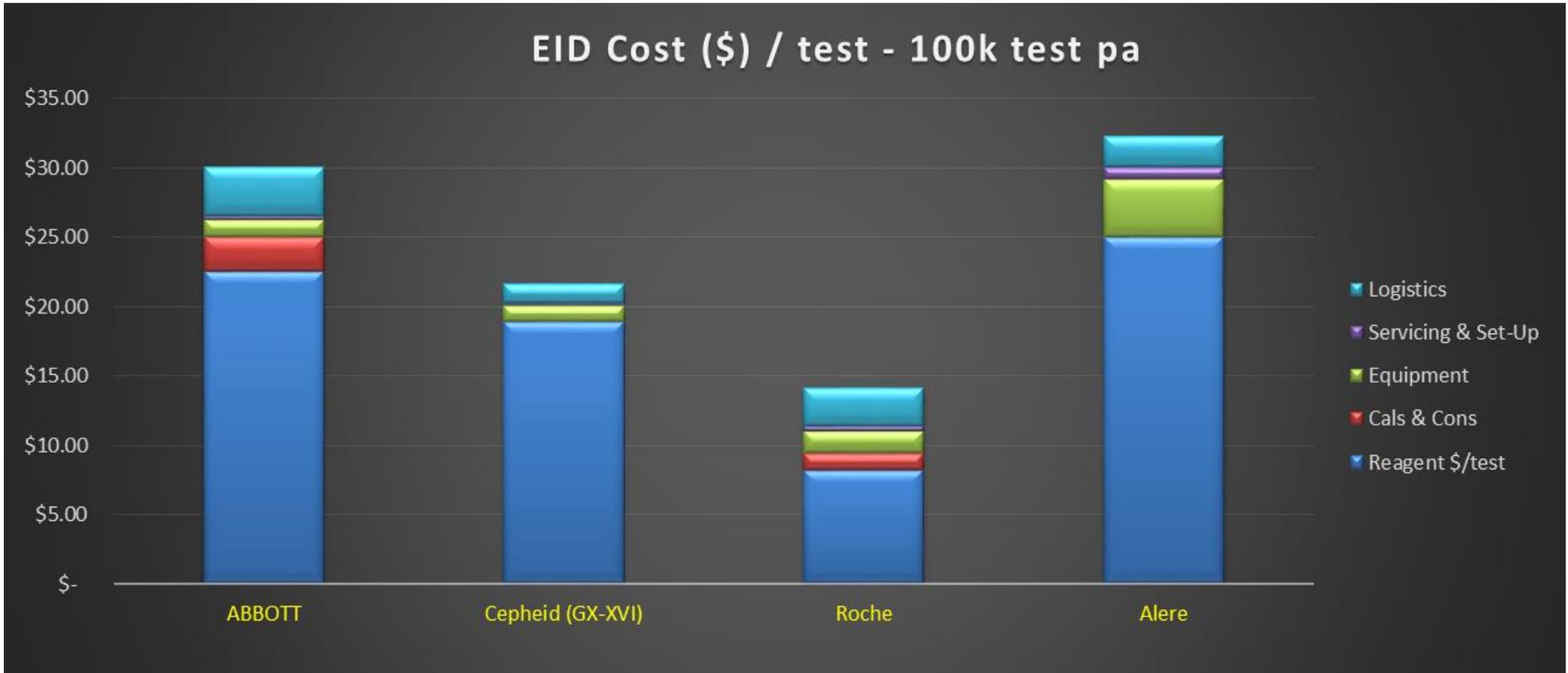


Indicative TCO as individual suppliers will have slightly different models; for example, logistics costs will vary between countries. Whilst the presented TCO numbers are illustrative, actual costs should not vary substantively from these numbers – and if a proposal submitted does so without proper justification,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

*Where a supplier did not offer pricing for committed volumes and/or price breaks, these charts present that suppliers base price – see the later “What contracting options are available” page for details of the price offers made by each company.

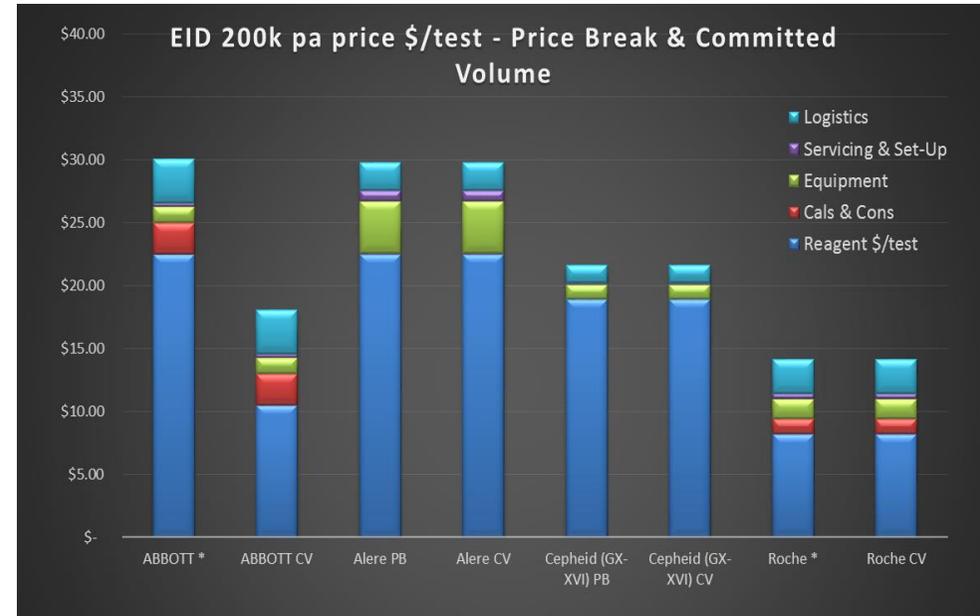
Total Cost of Ownership – EID at 100k pa price break

Graph provides indicative TCO price make-up for each supplier assuming 100k global tests undertaken per annum (i.e. 300k over three years)



EID: Price break and committed volumes

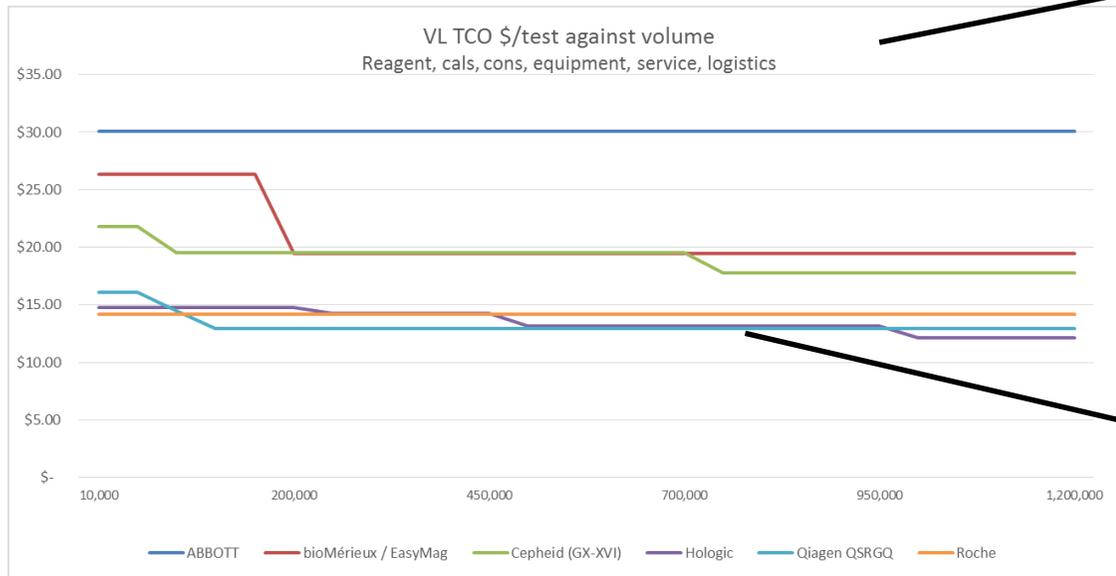
Graphs indicate the compare TCO for price break (PB) and committed volumes (CV) for each supplier at base case (entry price) and volumes of 200k tests pa.



Where a supplier did not offer pricing for committed volumes and/or price breaks, these charts present that suppliers base price – see the later “What contracting options are available” page for details of the price offers made by each company.

Interpreting the cost /test volume graphs

Variety of analysis graphs developed to aim understanding and decision making



Price per test (\$)

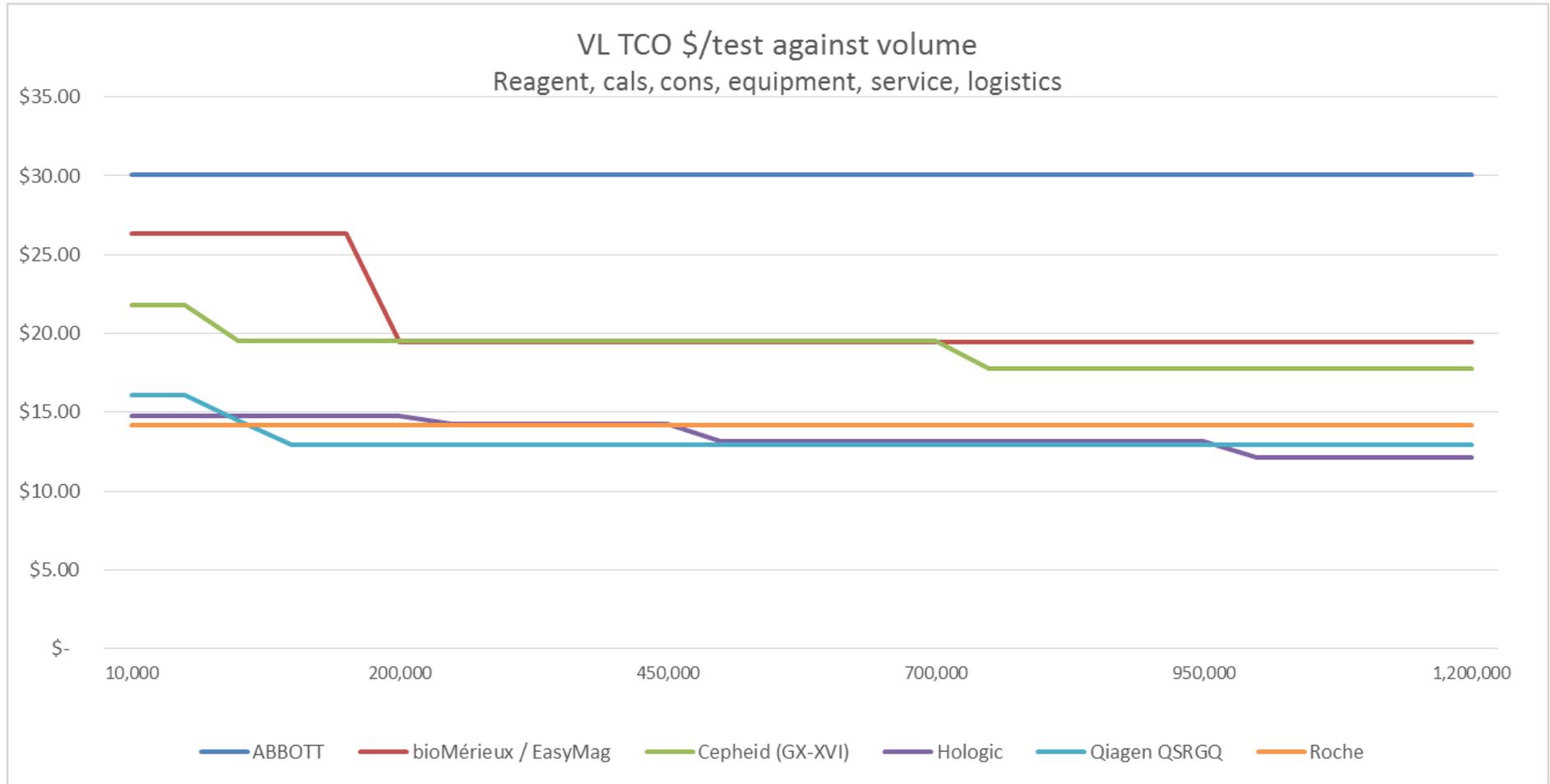
Commercial scenario – e.g. reagent price with price breaks

Individual supplier prices

Global cumulative tests (over 3 years) procured through framework contract (or equivalent comparison)

TCO VL cost/test - Supplier summary for increasing volume

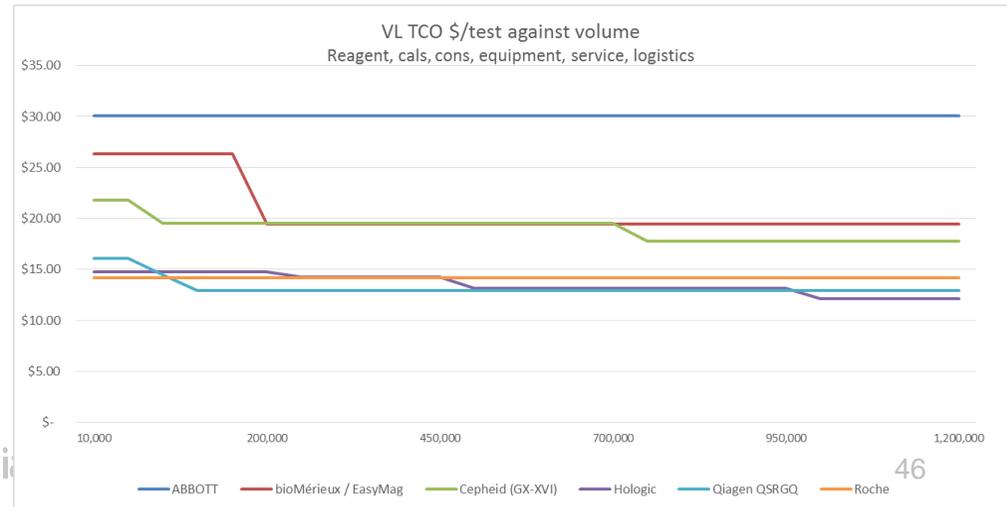
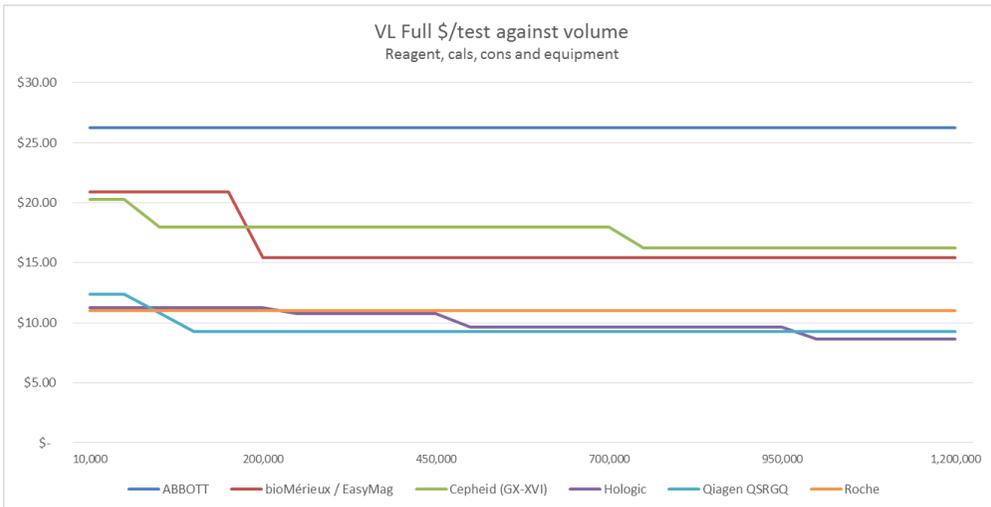
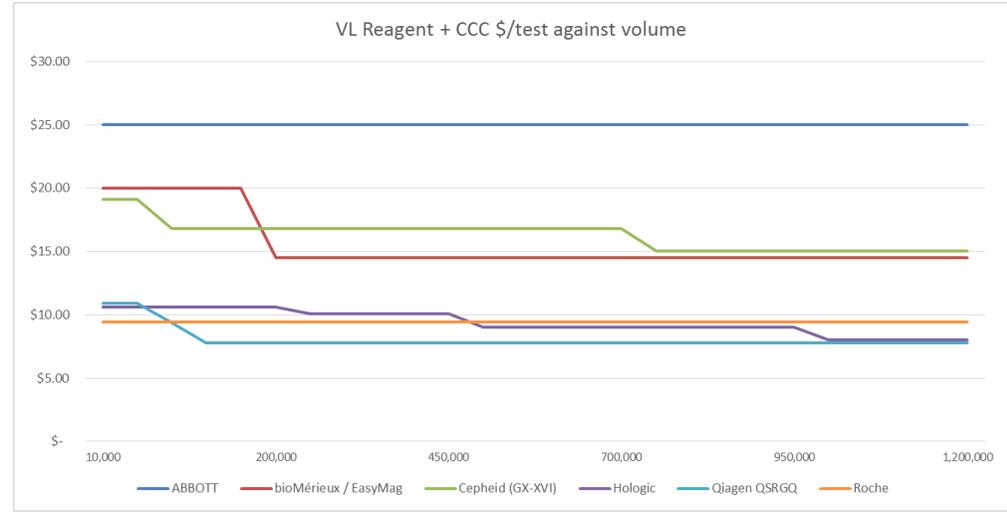
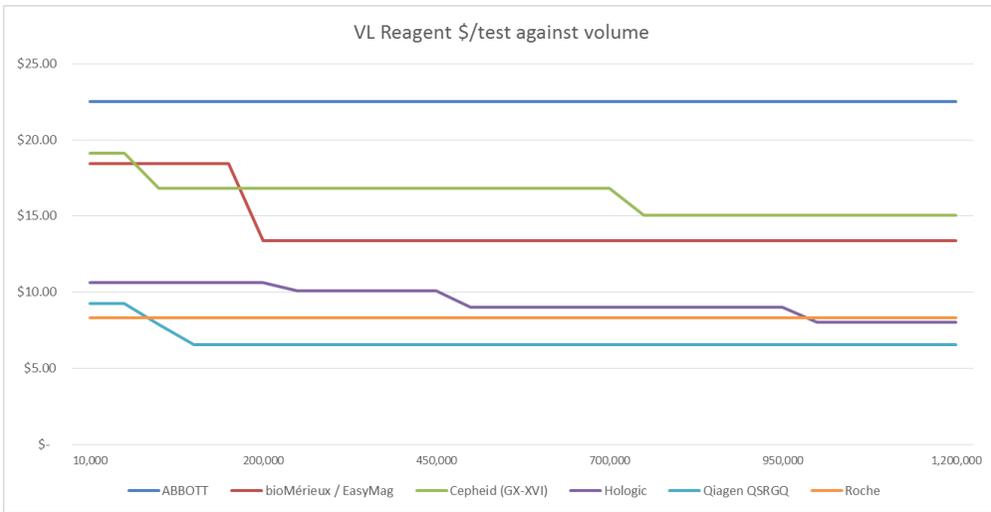
- Range of credible, cost-effective, competitive options now available



Full analysis – Viral Load price / test – volume price breaks

Graphs illustrate different cost/ volume relationships for different cost elements

(1) Reagent; (2) Reagent & calibrations & consumables; (3) with equipment; (4) Total Cost of Ownership

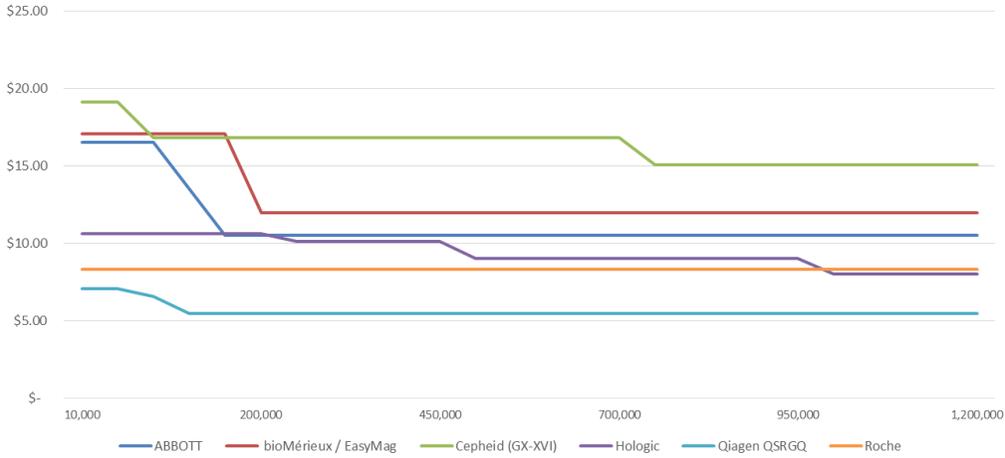


Full analysis – Viral Load price / test – committed volumes

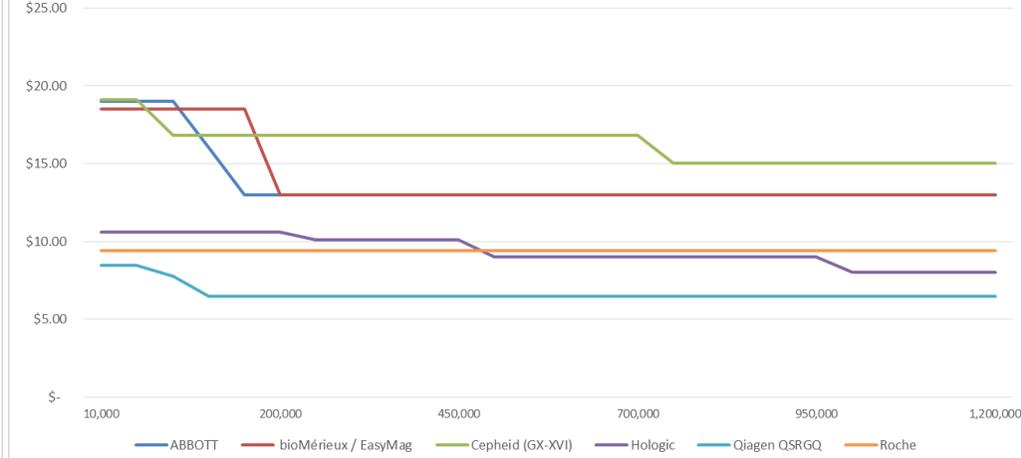
Graphs illustrate different cost/ volume relationships for different cost elements

(1) Reagent; (2) Reagent & calibrations & consumables; (3) with equipment; (4) Total Cost of Ownership

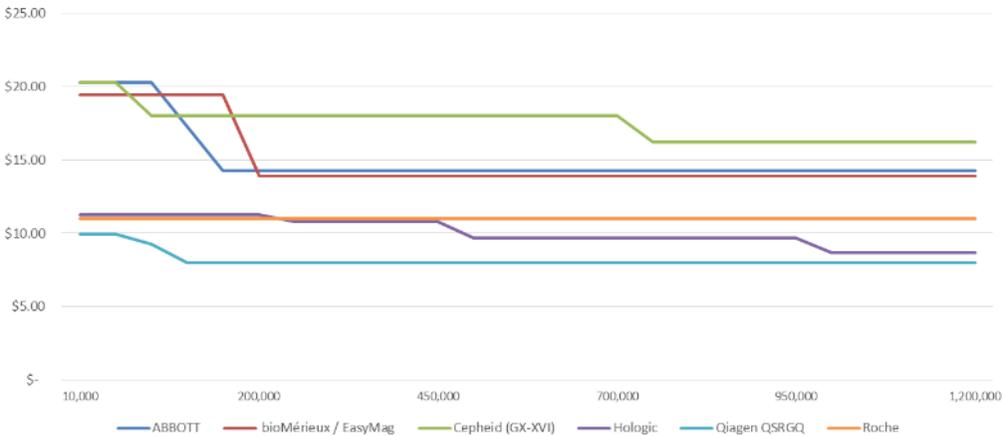
VL Reagent \$/test against volume



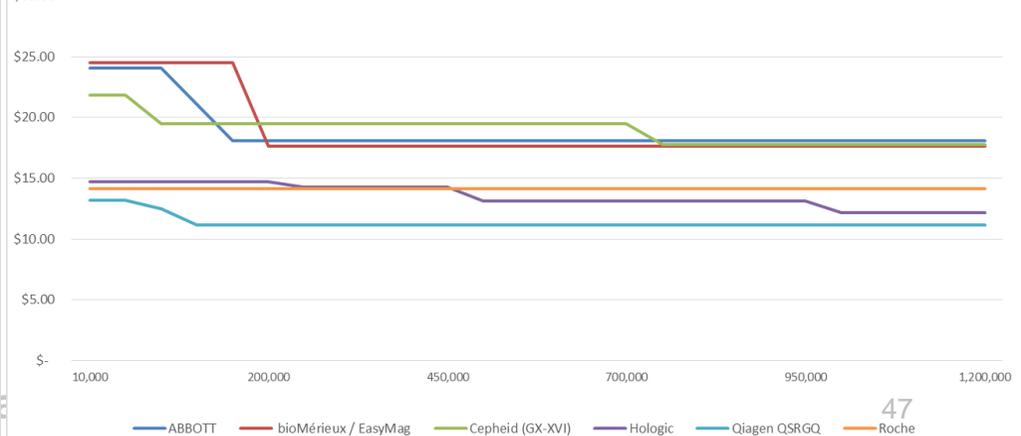
VL Reagent + CCC \$/test against volume



VL Full \$/test against volume
Reagent, cals, cons and equipment

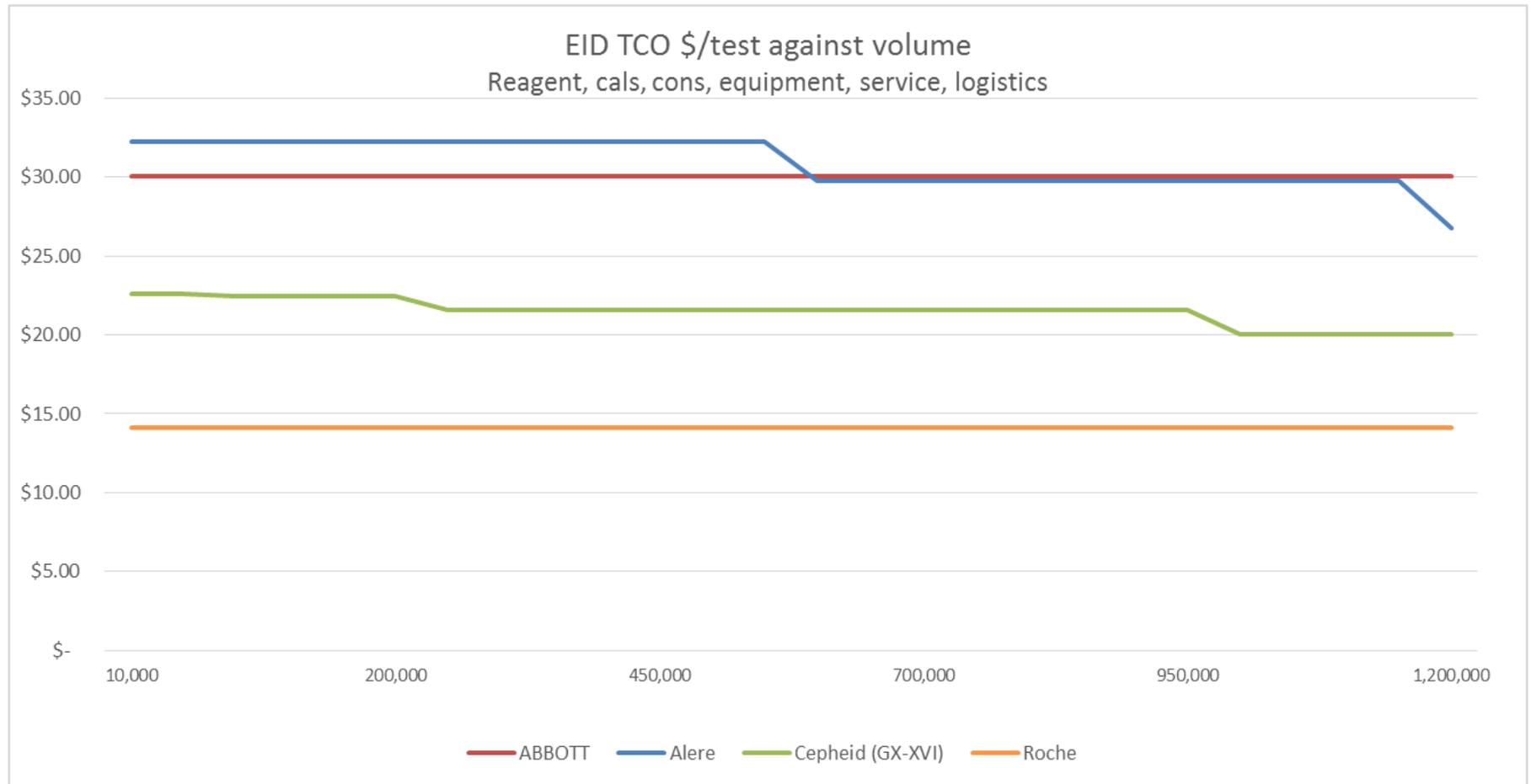


VL TCO \$/test against volume
Reagent, cals, cons, equipment, service, logistics



TCO EID \$/test - Supplier summary

Less competition, however increased cost transparency of incumbents, with new lower throughput/ Point of Care (POC) offerings available

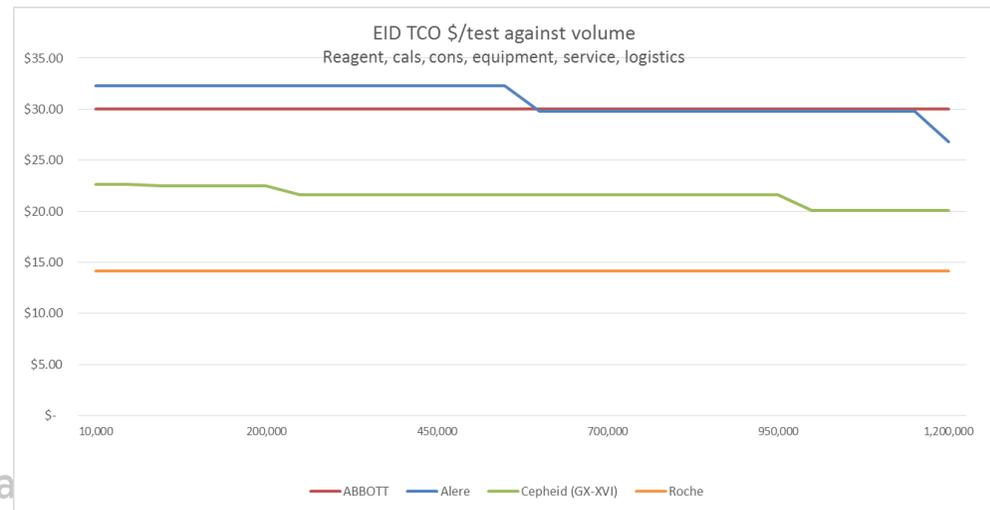
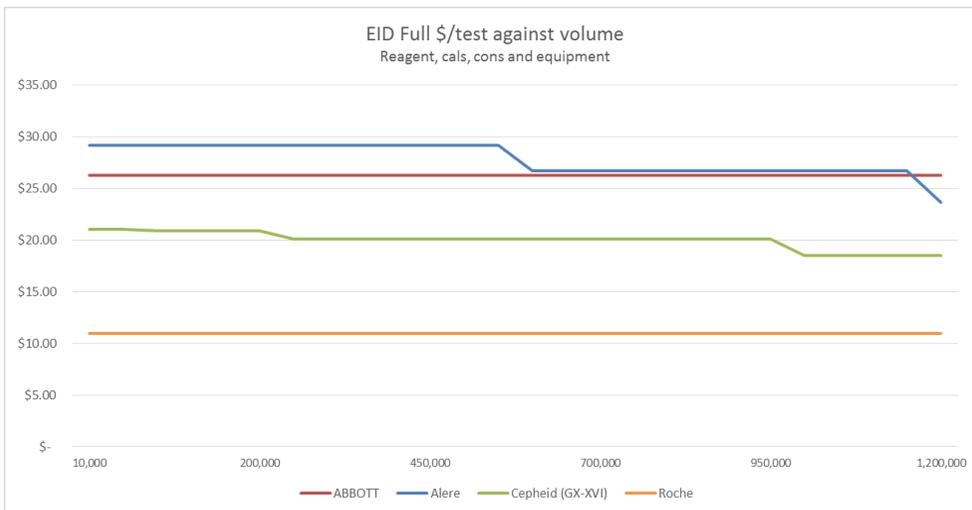
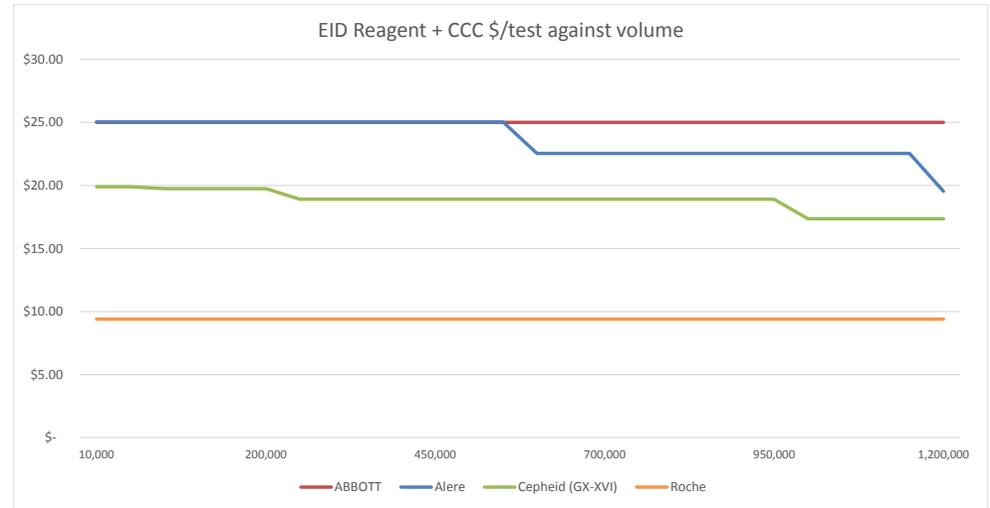
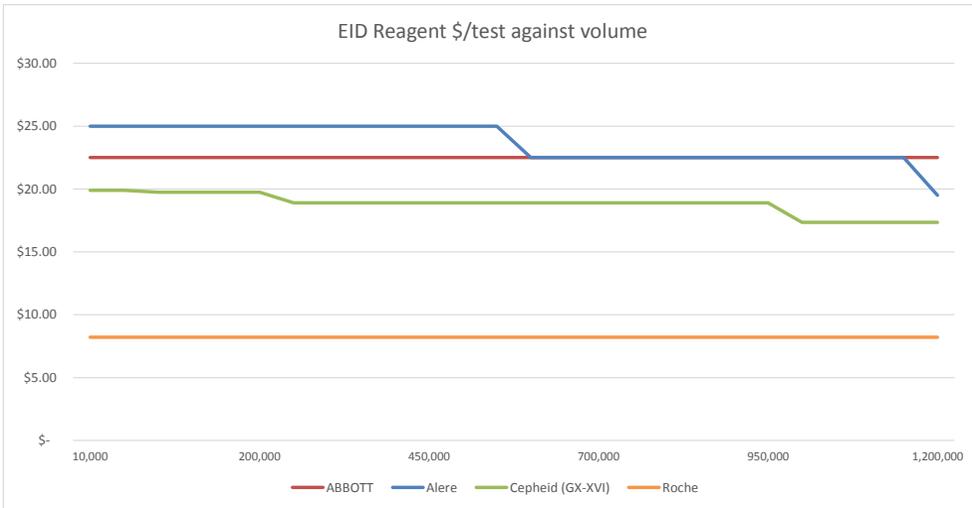




Full analysis – EID Load price / test – price breaks

Graphs illustrate different cost/ volume relationships for different cost elements

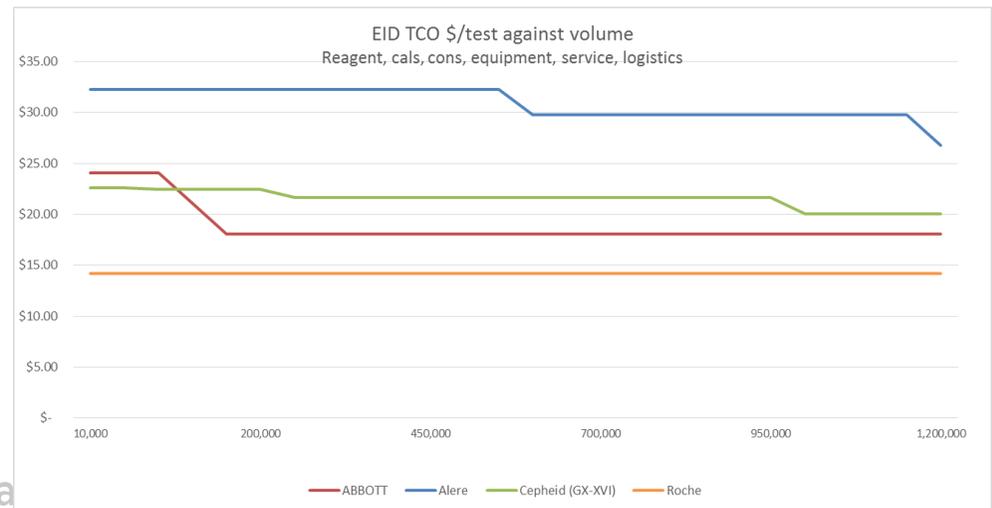
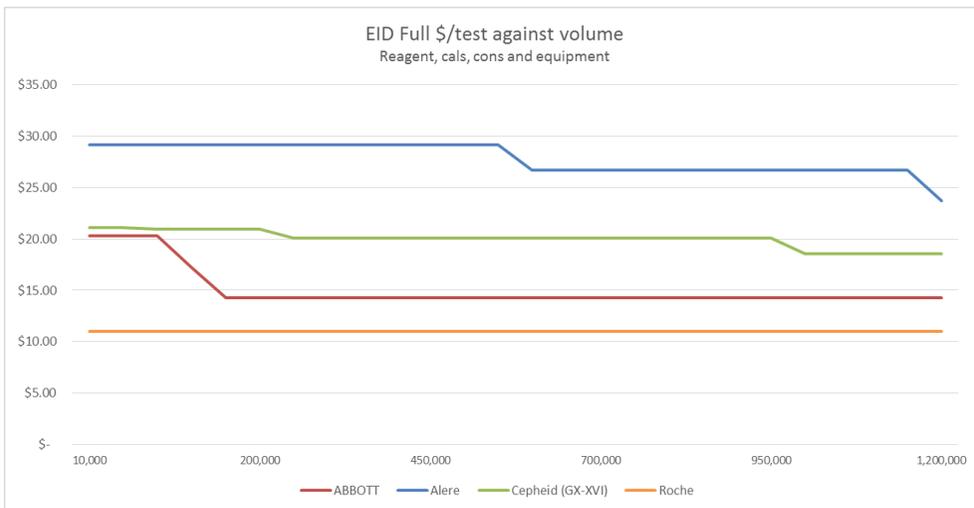
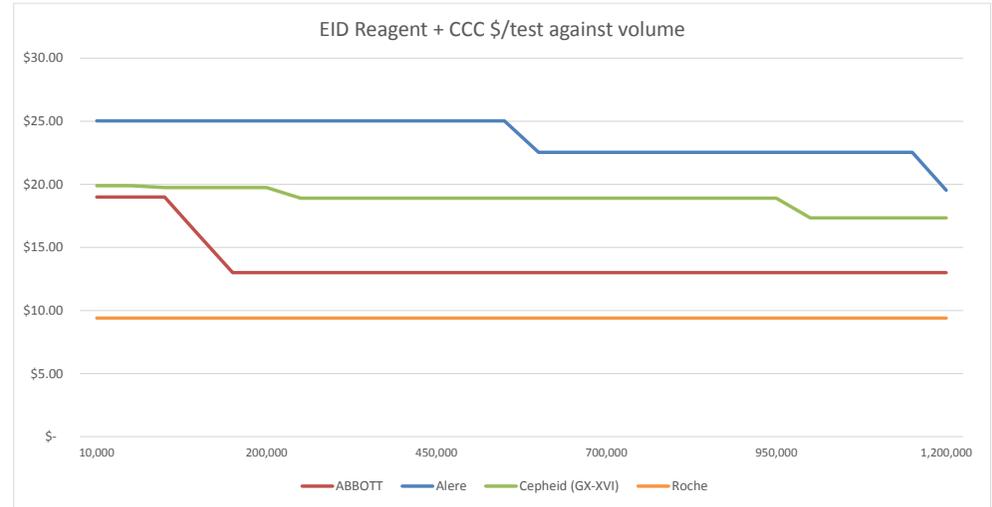
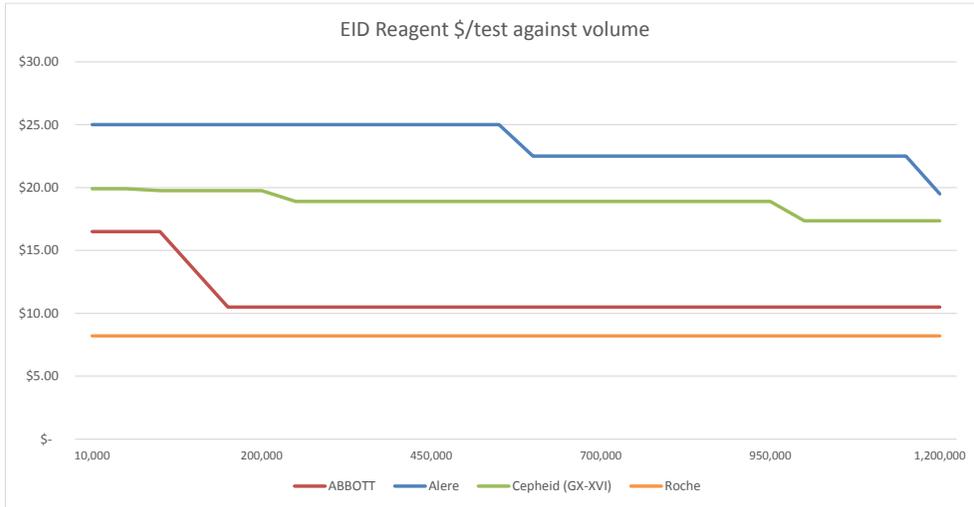
(1) Reagent; (2) Reagent & calibrations & consumables; (3) with equipment; (4) Total Cost of Ownership



Full analysis – EID price / test – committed volumes

Graphs illustrate different cost/ volume relationships for different cost elements

(1) Reagent; (2) Reagent & calibrations & consumables; (3) with equipment; (4) Total Cost of Ownership



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

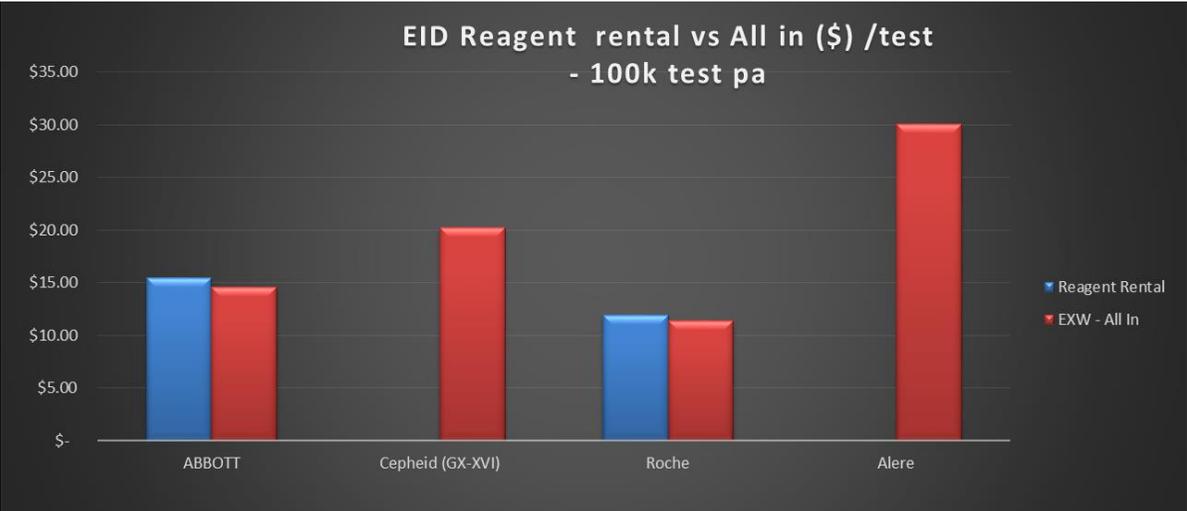
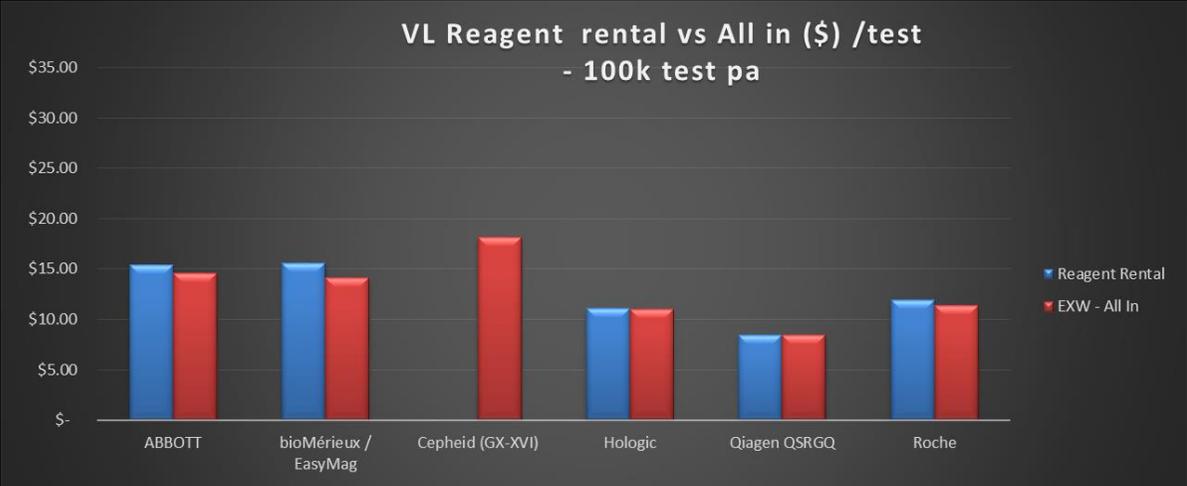
Reagent price includes cost of equipment and service

Requires volume commitment

Higher equipment up-time and use

“Reagent rental” now available from majority of suppliers

- Reagent rental is a single per 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)	bioMérieux Cepheid (8) Hologic Qiagen	Abbott (6) bioMérieux Cepheid (8) Hologic Qiagen	Roche (7)	bioMérieux Hologic Qiagen	Abbott (6) bioMérieux Hologic Qiagen	
EID offers	Roche (7)	Alere (9) Cepheid (8)	Abbott (6) Alere (9) Cepheid (8)	Roche (7)		Abbott (6)	

#	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	Basic price unless committed volumes at a country level agreed annually and for 3+ year contract. Annual increases
7	Roche	Global Access Program price for Viral Load (VL) and EID irrespective of volume or commitments available to defined set of low and middle income countries
8	Cepheid	Prices are based on volumes sold globally to all customers
9	Alere	Prices are based on annual volumes per procurement channel

What are Price Breaks and Committed Volume?

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/ machines?

YES :

- The prices and contracting terms should also apply to “legacy countries or machines” 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.