PUTTING HIV AND HCV TO THE TEST

A PRODUCT GUIDE FOR POINT-OF-CARE CD4 AND LABORATORY-BASED AND POINT-OF-CARE VIROLOGICAL HIV AND HCV TESTS

2nd Edition – July 2015

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THE MSF ACCESS CAMPAIGN

In 1999, on the heels of Médecins Sans Frontières (MSF) being awarded the Nobel Peace Prize – and largely in response to the inequalities surrounding access to HIV/AIDS treatment between rich and poor countries – MSF launched the Campaign for Access to Essential Medicines. Its sole purpose has been to push for access to, and the development of, life-saving and lifeprolonging medicines, diagnostics and vaccines for patients in MSF programmes and beyond.

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ADDITIONAL MSF RESOURCES ON HIV AND HCV

HIV: UNDETECTABLE

The MSF Access Campaign has published a series of briefing documents to equip policymakers, people living with HIV/AIDS, and communities with information about the products, costs, and operational strategies needed to help scale-up viral load monitoring, which is an essential tool, along with adherence support, to help as many people on ARVs as possible to reach and maintain viral suppression. MSF's **HIV: Undetectable** reports provide detailed information on HIV viral load testing, including pricing information, in-country market assessments, and training and implementation tools.

Volume 1 – **Undetectable: How Viral Load Monitoring Can Improve HIV Treatment in Developing Countries**

Volume 2 – **Putting HIV Treatment to the Test: A Product Guide for Viral Load and Point-of-Care CD4 Diagnostic Tools**

Volume 3 – **How Low Can We Go? Pricing for HIV Viral Load Testing in Low- and Middle-Income Countries**

Volume 4 – **HIV Status? Undetectable: Four Essential Interventions to Improve HIV Treatment, Save Lives, and Reduce Transmission**

Volume 5 – **Getting to Undetectable: Usage of HIV Viral Load Monitoring in Five Countries**

Volume 6 – **Achieving Undetectable: What Questions Remain in Scaling-Up HIV Virologic Treatment Monitoring?**

Viral Load Toolkit – **An Implementer's Guide to Introducing HIV Viral Load Monitoring from MSF's Southern Africa Medical Unit**

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UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS

Over the past 15 years, the MSF Access Campaign has been monitoring the patent barriers, prices and availability of antitretroviral medicines through its Untangling the Web reports and pushing for the uptake of policies that promote access to affordable, quality-assured treatments.

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DIAGNOSIS AND TREATMENT OF HEPATITIS C: A TECHNICAL LANDSCAPE

Direct-acting hepatitis C antivirals are not only transforming the potential to treat and cure hepatitis C virus (HCV), but are also drastically simplifying and reducing the costs of HCV diagnosis and treatment monitoring, paving the way for scale up of HCV treatment programmes in low- and middle-income countries. This report provides an overview and a framework for action with regard to hepatitis C diagnosis and treatment in resource-poor settings.

msfaccess.org/diagnosis-treatment-hepatitis-C-technical-landscape

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ABOUT THIS REPORT

This report is a guide for policymakers, treatment providers and advocates interested in learning more about laboratory-based and point-of-care virological HIV and hepatitis C (HCV), and point-of-care CD4, diagnostic and monitoring tests.

Although global access to antiretroviral treatment (ART) has substantially increased, today only about one third of the 35 million people infected with HIV have access to ART. Only about half of those infected know their status, and there are still 1.5 million AIDS-related deaths a year.[32] Moreover, access to optimized standards of care, including routine viral load testing as recommended by World Health Organization (WHO), remains low. Of the three UNAIDS "90/90/90" goals—that by 2020, 90% of people will know their status, 90% of HIV positive people will receive sustainable ART and 90% of those on ART will be virally suppressed—two rely on access to diagnostic and monitoring tools. It is therefore imperative that affordable and adapted HIV diagnostic tests be made available in resource-limited settings.

Access to antiviral treatment for people infected with HCV in resource-limited settings is in its infancy. Until recently, the available treatment was interferon-based – a toxic, inadequately effective therapy that requires a plethora of frequent and expensive diagnostic and monitoring tests often not available in resource-limited settings. New all-oral therapy, if made affordable and accessible, is set to transform the ability to treat the more than 150-180 million people currently chronically infected with HCV, of which an estimated 350,000 die each year from HCV-related liver diseases. The 4-5 million people estimated to be co-infected with HIV and HCV are at risk of increased disease progression and have a higher mortality risk.[3] Thus, as with HIV, access to affordable and adapted HCV diagnostic tools suitable for resource-limited settings must be urgently scaled up.

This report includes technical specifications and pricing information for 20 diagnostic platforms, summarized below:

POINT-OF-CARE PLATFORMS INCLUDED IN THIS REPORT

SUPPLIER	CD4	HIV EID	HIV VL	HCV VL
Alere	Pima Analyser			
BD	FACSPresto			
Millipore	Muse Auto CD4/CD4% system			
Omega Diagnostics	Visitect CD4			
Sysmex Partec	CyFlow miniPOC			
Alere		q HIV 1/2 Detect		
Cepheid		Xpert HIV-1 qual	Xpert HIV-1 Viral Load	Xpert HCV Viral Load
Diagnostics for the Real World		SAMBA HIV-1 Qual Test SAMBA II HIV-1 Qual Whole Blood Test	SAMBA HIV-1 Semi Q Test SAMBA II HIV-1 Semi Q Plasma Test	
Molbio Diagnostics			Truelab/Truenat HIV	Truelab/Truenat HCV
Northwestern Global Health Foundation / Quidel		LYNX HIV p24 Antigen Test	Savanna Quantitative RealTime HIV-1 Assay	

LAB-BASED PLATFORMS INCLUDED IN THIS REPORT

SUPPLIER	HIV EID	HIV VL	HCV VL	HCV CORE ANTIGEN	HCV GENOTYPING
Abbott	RealTime HIV-1 Qualitative	RealTime HIV-1	RealTime HCV	ARCHITECT HCV Ag	RealTime HCV Genotype II
Biocentric	Generic HIV DNA Cell	Generic HIV Charge Virale	Generic HCV Charge Virale		
bioMérieux		NucliSENS EasyQ HIV-1			
Cavidi		ExaVir Load			
Hologic		Aptima HIV-1 Quant Dx Assay	Aptima HCV Quant Dx Assay		
Qiagen		artus HI Virus-1 RG RT-PCR artus HI Virus-1 QS-RGQ	artus HCV RG RT-PCR artus HCV QS-RGQ		
Roche Molecular Diagnostics	CAP/CTM HIV-1 Qualitative	CAP/CTM HIV-1	CAP/CTM HCV Qualitative and CAP/CTM HCV		
Sacace Biotechnologies		HIV Real-TM Quant Dx	HCV Real-TM Quant Dx		HCV Genotype Plus Real-TM
Siemens		VERSANT HIV-1 RNA Assay	VERSANT HCV RNA Assay		VERSANT HCV Genotype 2.0 Assay

MSF AND HIV DIAGNOSTIC AND MONITORING TOOLS

With 229,900 people living with HIV on treatment in MSF-supported HIV programmes in more than 20 countries, MSF is exploring the best strategies for rolling out HIV diagnostic and monitoring tools in order to optimise treatment outcomes.

MSF is an early adopter of viral load (VL), point-of-care (POC) and early infant diagnosis (EID) testing in resource-limited settings, and is currently field testing or evaluating these technologies in 18 countries. With support from UNITAID, MSF is implementing a three-year project to evaluate various VL and CD4 testing technologies in eight projects across seven countries. The project aims to establish the feasibility of routine VL testing in resource-limited settings, including assessing which existing and pipeline devices are suitable for specific resource-limited contexts, how they can have the greatest impact on treatment outcomes, and to what extent viral load testing can or should be decentralised, and how existing models of care can be adapted so as to allow for implementation of routine VL monitoring. MSF publishes its findings from on-going implementation research on the diagnostic tools selected for its programmes.

MSF believes it is medically important and operationally feasible to implement VL monitoring in developing countries, and that cost should not remain a barrier to implementation. Cost savings from optimised treatment management and adaptation of VL protocols to resource-limited settings can help mitigate higher costs. In addition, price transparency, negotiations through pooled procurement, using polyvalent platforms and increased competition among diagnostic manufacturers is expected to reduce test prices further in the coming years.

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THE IMPORTANCE OF EARLY HIV INFANT DIAGNOSIS

The implementation and scale-up of prevention of mother to child transmission (PMTCT) programmes has successfully abrogated infant HIV infections, however, many mothers are still unaware of their HIV status, or become infected during pregnancy or breast-feeding. UNAIDS estimates that 240,000 children became HIV infected in 2013.[32] Other reasons for infant HIV infection include late ART initiation in mothers, and mothers inadequately adhering to ART during pregnancy and breast-feeding.[13] As infant mortality peaks at 2-3 months of age in infected infants, early treatment is imperative to prevent illness and death[14,15], and may also reduce the latent HIV-1 reservoir[16], which has additional health benefits. It is also important that either systematic or opportunistic testing be performed outside of PMTCT depending on the context. A pre-published systematic review of paediatric HIV diagnosis outside of PMTCT settings, performed for the WHO 2015 guidelines, found a significant yield of new HIV diagnoses in paediatric inpatient settings and nutrition centres.[17]

Many of the products included in this guide for early infant diagnosis have a more general diagnostic use intended for more broadly detecting HIV, whether in adults or paediatric populations. As the demand for infant diagnostic tests is relatively small, these other uses greatly expand the marketability of these products in developing countries for the measurement of acute HIV infection and/or confirmation of serological positivity to improve diagnostic specificity.[18]

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SNAPSHOT OF IMPLEMENTATION OF HIV TESTING GUIDELINES

This is a brief summary of implementation of WHO guidelines for HIV testing in developing countries. For a detailed look at this information, please review the supplementary material published at: www.msf.org/HIV-HCV-diagnostic-product-guide-2015

EARLY INFANT DIAGNOSIS

Most EID national guidelines reflect the WHO 2013 guidelines for initial HIV testing between 4-6 weeks of age. A number of countries' guidelines provide for earlier testing: Columbia, Chile and Mexico recommend EID testing 48 hours after birth and Morocco at one week of age. South Africa is the only country thus far to recommend testing at birth (known as 'birth testing' or 'very early infant diagnosis').

CD4 AND VIRAL LOAD

The national guidelines of 47 out of 54 low- and middle-income countries recommend routine VL monitoring for people on ART, in line with WHO recommendations. However, in reality, viral load testing is only available in a handful of countries. One country, Ethiopia, still does not recommend routine viral load testing at all due to limited resources. Six countries recommend viral load testing only in the case of suspected treatment failure – this testing is mandatory in Morocco, Myanmar and South Sudan (if the test is available), and optional in Haiti, India and Zimbabwe. In countries where viral load testing does occur, the systems and clinical capacity to act promptly on the findings are rarely in place. Most countries are also still recommending routine immunological treatment monitoring, with only eight countries having dropped routine CD4 testing post-ART initiation (Cameroon, Kenya, Malawi, Namibia, South Africa, Swaziland, Thailand and Uganda).

RESULTS OF FIRST GLOBAL FUND TENDER ON EID AND VIRAL LOAD

The results of the first three-year tender issued by the Global Fund to Fight AIDS, TB, and Malaria ('Global Fund') for EID and viral load will be released by the end of June 2015.*

Based on information available in mid-June, at a 300,000 test volume price break, the total cost of ownership (TCO) for viral load ranges from US$13-23 per test, and for EID from US$18-$34. TCO includes reagents; controls, calibrators and consumables; equipment (divided over a three-year period and testing the maximum number of samples in an eight hour day for 250 days per year); servicing and set-up; and all logistics, including in-country.

Although the TCOs have not achieved lower pricing than already offered, many countries were paying much higher prices in the past when purchasing tests through the Global Fund – up to around US$40 per test, all inclusive[9] – therefore countries that had previously been excluded from more affordable pricing will benefit substantially.

Fortunately, reagent rental options are now available from the majority of suppliers, which was not previously the case, and there is no price premium for countries to select this option. Across standard instrument purchase and reagent rental options, manufacturers offered TCOs based either on no volume discounts, price breaks (i.e. a reduced unit price once price break points have been achieved) or committed volumes (i.e. reduced unit price for all units committed in advance). Price breaks were offered by Alere, bioMérieux, Cepheid, Hologic and Qiagen for standard purchase and by bioMérieux, Hologic and Qiagen for reagent rental. Committed volume pricing was offered by Abbott, Alere, bioMérieux, Cepheid, Hologic and Qiagen for standard purchase and Abbott, bioMérieux, Hologic and Qiagen for reagent rental. Only Roche offered pricing irrespective of volume for both standard purchase and reagent rental. Fortunately, the tender also applies to legacy countries and machines that are already in place.

The tender has already resulted in more transparency of pricing and competition between manufacturers, among other advantages. Future tenders should include the option for manufacturers of polyvalent platforms to submit bundled TCO discounts across disease testing platforms (for example, TB and HCV), and the criteria for the tender should be transparent.

* Further information may be accessed at: http://www.theglobalfund.org/en/procurement/viral-load-early-infant-diagnostics/

MSF AND HEPATITIS C

MSF recently began providing direct-acting antiviral treatment for HCV in Pakistan and intends to expand its programming, in part through a UNITAID grant and in collaboration with the Ministries of Health, to about seven countries, including Kenya, India, Iran, Mozambique, Myanmar and Uganda. The objective is to scale up improved treatment for HCV (see box below), which allows for simplified diagnostic and monitoring algorithms, and, for the first time, makes treating HCV in resource-limited settings feasible.

TRANSFORMING HCV CARE USING DIRECT ACTING ANTIVIRAL MEDICINES

Approximately 150-180 million people are chronically infected with HCV worldwide -- five times the number infected with HIV. HCV is often called the 'silent killer'[1,2], causing about 350,000 deaths each year. A new class of drugs called direct-acting antivirals (DAAs) has the potential to radically improve our ability to effectively treat HCV in low- and middle-income countries, provided that these drugs are made accessible and affordable in low-resource settings. DAAs can also facilitate greatly simplified diagnostic and monitoring requirements. Where DAAs are not yet available, patients are still being treated with the injectable drug pegylated interferon, which forms the basis of a toxic treatment regimen that has poor cure rates[3,4] and requires complicated diagnostic algorithms.

The testing algorithm to support DAA-based treatment programmes may be significantly reduced (see Tables 1 and 2). Additionally, it is possible that molecular RNA tests may be replaced by cheaper and more decentralisable core antigen tests for the measurement of the virus. If the core antigen test can be made cheaply enough, it would obviate the need for the currently used serological screening test, which can diagnose exposure to HCV but not active infection.

Using a single HCV antigen rapid test could collapse the serological screening plus virological confirmatory test into one, making diagnosing HCV much quicker and easier. Considering that the performance of most point-of-care serological screening tests is extremely poor in low-income settings[5,6], especially in HIV co-infection, eliminating the reliance on screening tests would be even more beneficial for appropriate HCV diagnosis. If sensitivity is sufficient, this affordable HCV antigen rapid test could also be used at SVR12 or 24 to prove cure.

Table 1: The current standard of HCV monitoring during HCV treatment with PEG-IFN-alpha

	PRE-TREATMENT	BASELINE	WEEK 4	WEEK 12	END OF TREATMENT (WEEK 24)	SVR12	SVR24
Antibody screening	x						
Virological confirmation	x						
Liver staging		x					
IL-28B		x					
Genotype		x					
Viral load		x	x	x	x	x	x
Complete blood count with differential		x	x	x			x
Thyroid stimulating hormone		x	x	x			
Clinical chemistry and haematology		x	x	x			x
Alpha-fetoprotein		x					
Lipids panel		x					

Table 2: The proposed standard of diagnostic monitoring with an ideal, all oral, pan-genotypic regimen

	PRE-TREATMENT	BASELINE	WEEK 4	END OF TREATMENT (WEEK 12)	SVR12/24
Core antigen (qualitative)	x				x
Alanine transaminase		x	x	x	
Creatinine		x	x	x	
Haemaglobin		x	x	x	

Source: EASL Clinical Practice Guidelines: 2013 revised version. Clinical practice guidelines to optimize the management of HCV infection.

WHY WE URGENTLY NEED AN ACCURATE AND AFFORDABLE POINT-OF-CARE SCREENING TEST FOR HCV

At present, the HCV diagnostic and monitoring package is complex. For example, after HCV screening using a serological test, multiple virological tests are needed to confirm active HCV infection and monitor treatment effectiveness. In addition, a genotype test is required to determine treatment duration, the extent of liver fibrosis must be measured, and toxicity must be monitored. This package costs in the region of USD$500-600 per patient. Crucial to a global roll out, therefore, is the development of reliable, practical, and affordable POC rapid HCV antibody screening and virological diagnostic and monitoring tools to allow for simplification and decentralisation of care[3]. With the new DAAs, healthcare providers might only need a serological screening test, two virological tests, and monthly ALT, creatinine and haemoglobin testing – toxicity monitoring tests that are all readily available and inexpensive in contexts where HIV treatment already takes place.

As HCV care and treatment programs using DAAs are scaled up, attention must be focused on an improved POC rapid diagnostic test (RDT). Key requirements for a POC RDT for use in resource-limited settings are a test that is accurate (close to 100% sensitivity and high negative predictive value, and equally accurate in HCV/HIV co-infection); simple (with minimal training requirements and no cold chain); reliable (WHO-prequalified, CE marked or FDA approved); and cheap, at <$2 per test. The most promising serological POC RDT, in MSF's view, remains the OraQuick test (OraSure, USA), but at typically well over $10 per test it remains unaffordable. Additionally, as explained in the previous box (page 5), an HCV antigen test would be more specific and allow the serological screening and virological confirmation tests to be collapsed into one single diagnostic test. However, while a CE-marked laboratory-based core antigen assay exists that is fully automated and sensitive (Abott ARCHITECT HCV Ag), affordable POC versions of this test do not yet exist.

The WHO is responsible for pre-qualification of RDTs and virological tests that are needed to maintain the momentum towards improved diagnostics. To date only two HCV tests have been prequalified: the Bioelisa HCV 4.0 (Biokit S.A., Spain; CE-marked version 3000-1115 and 3000-1116), and the Murex anti-HCV 4.0 (DiaSorin South Africa (Pty) Ltd., South Africa; rest of world version 7F51-01 and 7F51-02), both laboratory-based serological tests.

Although access to HCV virological testing, liver fibrosis assessment, and genotyping is still far too limited, the introduction of effective, pan-genotypic, interferon-free treatment regimens may obviate the need for fibrosis, genotyping and more complex toxicology measurements. Therefore, the most urgent need today is for an accurate and affordable POC RDT that is also suitable for screening HIV positive individuals.

THE PRODUCT GUIDE FINDINGS – IN BRIEF

This report compiles information that manufacturers were willing to share on commercially available products, with the exception of a few pipeline products that were only included if pricing and other information could be made available.

POINT-OF-CARE CD4 TESTS	COST PER TEST IN USD[1]
Alere Pima Analyser *Well-established and fairly widely implemented in resource-limited settings; cartridge-based*	**$6 – 12**
BD FACSPresto *Market launched and quality assured, fully decentralisable, batching is possible; measures CD4 count, CD4 % and Hb; cartridge-based*	**<$10**
Millipore Muse Auto CD4/CD4% system *Not yet commercially available; measures both CD4 count and CD4 %; flow cytometry-based*	**~$5**
Omega Visitect CD4 *Disposable, instrument-free, semi-quantitative, lateral flow test (reader is optional); currently at 350 cells/µL but intend to offer 500 cells/µL in the future*	**$5.20**
Sysmex Partec CyFlow miniPOC *Is higher throughput than the other POC CD4 tests; measures CD4 count, CD4 % and total lymphocyte count; flow cytometry-based*	**$3.15**
POINT-OF-CARE HIV AND HCV VIROLOGICAL TESTS	
Alere q HIV 1/2 Detect (EID) *Market launched and quality assured, fully decentralisable; cartridge-based*	**$15 - 25**
Cepheid Xpert HIV-1 qual (EID), Xpert HIV-1 Viral Load and Xpert HCV Viral Load *Market launched and quality assured; GeneXpert is modular and near POC; but not fully decentralisable, cartridge-based*	**<$20**
Diagnostics for the Real World SAMBA HIV-1 Qual Test, SAMBA II HIV-1 Qual Whole Blood Test, SAMBA HIV-1 Semi Q Test and SAMBA II HIV-1 Semi Q Plasma Test *Semi-quantitative test for viral load at the 1,000 copies/mL virological failure threshold, SAMBA II is more decentralisable than SAMBA, is fully automated and has random access but has a lower throughput, SAMBA operates by batch testing and requires additional pipetting steps compared to SAMBA II; cartridge-based*	**$17 - 28**
Molbio Diagnostics Truenat HIV and Truenat HCV (viral load) *Not yet market launched; may be launched in India first; cartridge-based*	**$15**
NWGHF LYNX HIV p24 Antigen Test *Not yet market launched; non-molecular test, simple, affordable and fully decentralisable; cartridge-based*	**$6.50 - 15**
NWGHF/Quidel Savanna Quantitative RealTime HIV-1 Assay *Not yet market launched; 50µL plasma (capillary whole blood separated by plasma separator) and 200µL plasma options; cartridge-based*	**$11**
LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS	
Abbott ARCHITECT HCV Ag *The only fully automated, highly sensitive, commercially available, quality approved, HCV core antigen test; chemiluminiscent microparticle immunoassay*	**$25 - 50**
Abbott RealTime HIV-1 Qualitative (EID), RealTime HIV-1 (viral load) and RealTime HCV (viral load) and RealTime HCV Genotype II *Fully polyvalent single m2000 platform for HIV EID and viral load, as well as HCV viral load and genotyping; different throughput options (m24sp and m2000sp); RNA specific for HIV viral load*	**HIV: $13 – 30** **HCV: $13 – 35**
Biocentric Generic HIV DNA Cell (EID), Generic HIV Charge Virale and Generic HCV Charge Virale *Open platform for HIV and HCV; platform has a small footprint; allows for low instrument and test prices without the need for high volumes to bring costs down*	**EID: $13** **HIV: $15** **HCV: $23**
bioMérieux NucliSENS EasyQ HIV-1 *Only platform that has received regulatory approval to use DBS as a sample type for HIV viral load*	**$23**
Cavidi ExaVir Load *Non-molecular platform and therefore not affected by amplicon contamination; not as dependent on precision pipetting; not automated and very hands-on; medium throughput; can only be used with plasma*	**$12 - 25**

Continued overleaf

LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS (continued)	COST PER TEST IN USD[1]
Hologic Aptima HIV-1 Quant Dx Assay and Aptima HCV Quant Dx Assay *New automated platform for HIV and HCV; awaiting market launch of HCV test*	**HIV: $10 - 25**
Qiagen artus HI Virus-1 RG RT-PCR, artus HI Virus-1 QS-RGQ, artus HCV RG RT-PCR and artus HCV QS-RGQ (viral load) *Different options available for HIV and HCV viral load testing; platform not widely used in low-resource settings*	**$16 - 45**
Roche CAP/CTM HIV-1 Qualitative (EID), CAP/CTM HIV-1 (viral load), CAP/CTM HCV Qualitative and CAP/CTM HCV (viral load) *Different throughput options (Taqman 48 and Taqman 96); current extraction method extracts DNA and RNA but HIV viral load is currently being optimised on DBS using the "Free Virus Elution" protocol, which is RNA-specific*	**EID: $12.50** **HIV: $9.40** **HCV: dependent on country income level and volume commitments**
Sacace HIV Real-TM Quant Dx, HCV Real-TM Quant Dx and HCV Genotype Plus Real-TM *Open platform for HIV and HCV; platform has a small footprint; allows for low instrument and test prices without the need for high volumes to bring costs down*	**>$20**
Siemens VERSANT HIV-1 RNA Assay, VERSANT HCV RNA Assay (viral load) and VERSANT HCV Genotype 2.0 Assay *Widely used for HCV viral load and genotyping, but not widey found in low-resource settings; expensive*	**HIV: $54 – 72** **HCV: $72 – 100** **GT: $132 – 350**

(1) Incoterms for prices are EXW or FCA

CD4 POINT-OF-CARE TESTS

The currently available POC CD4 tests surveyed are priced quite competitively, within the $3–6 range per test, with the BD FACSPresto being priced higher at around $10 but delivering three different results (CD4 count, CD4 percentage and haemaglobin). The Alere Pima Analyser, which is well-established and fairly widely implemented, currently costs around $6 per test. The Millipore Muse is likely to cost $5 per test, and will deliver both a CD4 count and percentage result, but is not yet available. Similarly, the Sysmex Partec CyFlow miniPOC measures both CD4 count and percentage and is the most affordable option at $3.15 per test. It also offers higher throughput than the other tests and may thus be useful at district level. The Omega Diagnostics Visitect CD4 test is a semi-quantitative, disposable, instrument-free test coming on to the market this year, and will cost around $5 a test.

Both the BD FACSPresto and Millipore Muse are able to measure CD4 percentage (for the treatment eligibility testing and monitoring of children under five years of age). However, as the new 2013 WHO guidelines recommend ART initiation regardless of CD4 and CD4% for all HIV-positive children under five years of age, and as viral load testing becomes increasingly available as the preferred treatment monitoring tool, the need for CD4 percentage to monitor treatment efficacy following immune reconstitution in children will decline.

Market availability of a number of additional POC tests for CD4, as described in the HIV/AIDS Diagnostic Technology Landscape published by UNITAID[7], some without power requirements, will increase competition and is expected to drive prices down, and allow for further decentralisation.

Critically, two CD4 POC products have not come to market due to disinvestment based on the phasing out of the use of routine CD4 testing for treatment monitoring, and the move towards ART initiation regardless of CD4 count.[8] The need for POC CD4 testing may continue for a while depending on the rate of scale-up of routine viral load testing in countries and the progression of the WHO guidelines to recommend test and treat. Regardless, CD4 (and CD4% for children < 5 years) will continue to be an important test to gauge the risk of morbidity due to immunosuppression, both pre-ART for the "late presenters" and potentially as a triggered test during treatment failure, and therefore some market demand will continue indefinitely.[9]

HIV AND HCV VIROLOGICAL TESTS

Only commercially available laboratory-based products were included. Although many in-house assays have been developed that are often cheaper and better regionally optimised for locally circulating strains, they are not covered in this report.

There are three dedicated early infant HIV diagnostic tests, all similarly priced at around $13 per test, from Abbott, Biocentric and Roche. Importantly, the Abbott and Roche tests measure total nucleic acid, which may serve to maximise sensitivity (especially important for birth testing and testing after treatment exposure) rather than measuring DNA alone.

Many more tests exist for HIV viral load, including from Abbott, Biocentric, bioMérieux, Cavidi (the only non-molecular test), Hologic, Qiagen, Roche, Sacace and Siemens. Prices were reasonably competitive, with all companies except Siemens offering per test costs below about $25. The lowest price is offered by Roche at $9.40 and the highest by Siemens at $54-72. Only bioMérieux has a regulatory-approved product for using dried blood spot (DBS) as a sample type for viral load testing, although Abbott and Roche, among others, are working on DBS solutions that will hopefully be approved for use in 2016.[10]

A cost modelling study has revealed that both the test price and the cost of second-line ART are important determinants of cost-effectiveness of new POC VL technologies, as is the threshold used to define virological failure. Critically better evidence on the effect of adherence support to prevent treatment failure and transmission is needed to improve modelling outcome estimates for these important factors.[11] Additional cost modelling studies that include the now-lower prices for HIV viral load and second line treatment are expected imminently.

As countries start to implement and scale-up HCV testing programmes, it will be useful to be able to use existing molecular platforms for HCV testing. Abbott, Biocentric, Qiagen, Roche, Sacace and Siemens all have test kits for HCV RNA that may be run on the same platform as for HIV testing, and Abbott and Sacace both offer real time PCR-based HCV genotyping kits all on the same platform. The Siemens HCV genotyping kit is a line probe assay and therefore requires separate instrumentation. HCV pricing is currently higher than that for HIV, ranging from $13 to $100 per RNA test, and from $13 to $350 per genotype test. As market demand increases volumes and competition in developing countries, pricing should hopefully drop to similar levels as for HIV. Considering the similar technologies employed, there is no reason for cost of goods to differ between HIV and HCV, and countries and donors should also negotiate bundled pricing where multiple tests are purchased from the same supplier for use on the same instrument, and strive to opt for reagent rental contracts rather than purchasing instruments upfront. If instruments are purchased then comprehensive service and maintenance contracts should be negotiated for the length of instrument use.

Those countries that have a low HIV prevalence and may not therefore have invested in molecular technologies may prefer core antigen testing for HCV instead. Work on pipeline products for point-of-care testing for HCV has begun, however, in the meantime the most sensitive and the only fully automated instrument for core antigen testing is the Abbott ARCHITECT HCV Ag, at $25-30 per test. Considering that the ARCHITECT platform has a wide screening menu, it may be interesting for countries as a general, high-volume, high-throughput, laboratory-based tool for screening multiple analytes.

None of the POC or near-POC HIV or HCV virological tests are commercially available yet, with the exception of the Alere EID and the Cepheid EID and HIV and HCV viral load tests. Dedicated EID tests are offered by Alere, Cepheid, Diagnostics for the Real World and NWGHF (who offer the only non-molecular test). Pricing ranges from $10-28, with the exception of the NWGHF p24 EID test, for less than $15, that is less complicated and likely cheaper to produce. Near-POC HCV tests that run on the same platform as for HIV are offered by Cepheid and Molbio at less than $20 per test, and may be a better option for low throughput needs compared to the laboratory-based platforms. POC test prices are likely to remain higher than laboratory-based tests, at least consumable-wise, due to the extremely integrated, complex, robust, temperature-stable cartridges being more expensive to produce.[12] Similarly to CD4, the imminent availability of these products will ensure further competition, and therefore price reductions, and will facilitate decentralised testing. Further technical information on pipeline tests may be found in the HIV/AIDS Diagnostic Technology Landscape published by UNITAID.[7]


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THE CHALLENGES OF SAMPLE TRANSPORT IN RESOURCE LIMITED SETTINGS

The gold standard for laboratory testing is fresh whole blood for CD4 and infant diagnostic testing, and plasma (or sometimes serum) for virological testing (whether antigen- or nucleic acid-based). Plasma processing requires centrifugation, and both whole blood and plasma require either prompt transport to the laboratory or refrigeration for longer preservation. This is difficult to impossible in decentralised, low-resource settings, where sample transport from the "the last mile" is particularly challenging.[19] As a solution for nucleic acid measurement, DBS are often used to mitigate sample transport challenges. A DBS is prepared by spotting blood from venous puncture or via fingerprick where phlebotomy services are unavailable[20], on to filter paper that is then preserved through a process of desiccation. In this way the sample can be stored at room temperature for weeks. This has been demonstrated to work both for HIV and HCV nucleic acid testing.[8,21] Some other good sample stability solutions exist, such as the PrimeStore tube (Longhorn Vaccines and Diagnostics LLC, Bethesda, USA), but may not be as affordable as DBS or other blood stabilising tubes.

There have been some restrictions with using DBS as a sample type: 1) Companies do not typically apply for regulatory approval of their platform using alternative or more feasible sample types, and thus countries who must currently use DBS as the only method of providing patient access to molecular testing must risk using DBS "off-label", based only on their own laboratory validation; 2) Viral load testing is typically performed on up to 1mL of plasma, but one spot of blood contains only 50-70µL of whole blood, somewhat decreasing the sensitivity of the assay. In addition, HIV pro-viral DNA can compromise the specificity of the result. Both of these issues are only problematic at lower viral load thresholds, particularly around the 1,000 copies/mL failure threshold recommended in the WHO 2013 guidelines.[22] The good news is that some manufacturers are working on solving the DBS challenge and improving the correlation with plasma, and are in the process of applying for regulatory approval; therefore it is likely that this sample type will continue to be a necessary and important part of viral load scale-up.[8,10]

One of the reasons that countries have had to adopt the use of DBS as a sample solution is that the current recommendations for the storage and transport of whole blood and plasma are incredibly restrictive, and companies have not performed additional stability studies to inform recommendations that could go beyond current norms. This despite the fact that there is clear evidence that both time and temperature requirements may be extended.[23] Increased flexibility would greatly expand the geographical scope beyond the molecular laboratory from where it would still be feasible to transport blood tubes, thus limiting the need for DBS to more remote areas not easily accessible or without phlebotomy services. Some countries have performed their own validation studies to extend transport recommendations, but are again running the risk of using the product "off-label".

Donors and end-users must continue to put pressure on manufacturers to consider more practical sample solutions, and to apply for regulatory approval for additional sample types, as well as extended storage and transport recommendations. This will greatly improve the practicality and feasibility of sample transport in low-resource and decentralised settings.

QUALITY ASSURANCE

This report is a pricing guide and, apart from indicating whether the product has received regulatory approval, does not include detailed information about the quality of the products listed. However, quality is an important factor in procurement decisions. This section provides a brief overview of the key entities that provide quality assessments of diagnostic tools.

1. WHO PREQUALIFICATION

The WHO List of Prequalified Diagnostic Products, commonly known as WHO Prequalification, was initiated by WHO and developed in collaboration with other UN organisations, principally for procurement by UN agencies. The project evaluates diagnostic and monitoring test manufacturers according to WHO-recommended standards of quality and compliance with Good Manufacturing Practices[24].

The WHO Prequalification Programme is a benchmark for the identification of quality diagnostics for HIV, malaria and hepatitis B and C, and includes both a laboratory evaluation (to assess the operational and performance characteristics) and site inspection (to assess manufacturing quality). However, the programme is still is its infancy relative to medicines prequalification and, as such, many products have yet to be prequalified.

A key success factor is that financial support to national programmes is dependent on purchasing medicines and diagnostics that meet clear quality assurance criteria. The WHO Prequalification Programme has played an important role in providing guidance to purchasers on the quality of diagnostics, thereby creating a positive market dynamic where manufacturers strive to reach WHO standards in order to comply with procurement policies.

WHO recognises the evaluation of products by regulatory authorities that apply stringent standards for quality similar to those recommended by WHO, such as the US Food and Drug Administration (US FDA), and the European Economic Area conformity mark (CE mark). However, in order to comply with the standards set by WHO, which may be more suited to resource-limited areas, further information may be required from manufacturers.

It is important that manufacturers approach WHO for guidance before submitting a dossier.

2. US FOOD AND DRUG ADMINISTRATION

The US FDA is a public organisation offering strict regulatory approval for medical devices, including in vitro diagnostics[25]. Approval based on a pre-market notification (510K) may be issued for products only needing to demonstrate substantial equivalence to an already-approved product, whereas, for Class III (the highest-risk category) medical devices, a more stringent pre-market approval is required.

3. EUROPEAN CONFORMITY

European standards for medical devices are based on the European Council Directive 93/42/EEC for CE marking[26]. Under this directive, private notified bodies in each country are responsible for the CE marking of medical devices, with stringency based on a Class system – Class A (the highest-risk category) requiring the most stringency. Products submitted under low-risk categories (such as tests for tropical diseases, tuberculosis and CD4) only require a self-declaration for certification, and are therefore not well scrutinised. This is due to the fact that disease-risk classifications may not always coincide between Europe and low-resource settings, and illustrates the point that low- and middle-income countries require their own strict regulatory authorities to mitigate the problems of relying on regulation of products by richer countries.

4. INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

The International Medical Device Regulators Forum (IMDRF) was founded in February 2011, replacing the Global Harmonisation Task Force. It is composed of a voluntary group of medical device regulators from countries around the world with the aim of accelerating harmonisation and convergence.[27]

5. ISO CERTIFICATION

ISO International Standards are a benchmark for safety, reliability and quality. The ISO13485:2003 standard, used to assess the manufacturing quality of medical devices, may be used to assess the quality of the management system for production.[28] It is usually one of the requirements to gain approval from a strict regulatory authority (unless the SRA has its own parallel system).

6. DONOR PROCUREMENT POLICIES

The Global Fund to Fight AIDS, Tuberculosis and Malaria and UNITAID have a quality assurance policy for the procurement of diagnostic products that is effective from March 2011.[29] It refers to the WHO "List of HIV diagnostics eligible for procurement by WHO in 2012". As this list is currently limited to serological and antigen-based tests, countries may procure other products as long as a regulatory authority member belonging to the IMDRF authorises them for use.

In addition, the Expert Review Panel for Diagnostics (ERPD) was established in 2014 to provide guidance on the purchase of products that are still in the process of obtaining regulatory approval but are urgently required for patient benefit in countries. The ERPD is intended as a time-limited stop-gap measure to facilitate market entry of new products into countries without unnecessary delay, and is modelled on the successful Expert Review Panel for Medicines.[30] Based on a risk-benefit analysis, ERPD classifies products into four categories: products falling into Risk Categories 1 and 2 may be considered for time-limited procurement; products falling into Risk Category 3 may be considered for time-limited procurement only if there is no other option and the benefit of diagnosing and/or making treatment decisions is higher than the risk of using the product; and products falling into Risk Category 4 may not be procured under any circumstances. Both HIV and HCV tests are considered by the ERPD and there have been three invitations for product applications so far.

7. POST-MARKET SURVEILLANCE

It is important to note that authorisation by a strict regulatory body is only a starting point. It is critical that continuous post-market surveillance on the performance and quality of the product, as used as intended and on the population of interest, be captured so that any problems may be reported to the relevant authorities and promptly addressed.

METHODOLOGY

This report includes technical and price information for all known commercially available, or soon to be available, point-of-care CD4, and POC and laboratory-based HIV and HCV virological, tests.

Data was collected between January and May 2015. All companies known to be developing and producing included technologies were contacted and asked to fill in a standard questionnaire on product and pricing information. Some companies did not respond, while other products were not yet ready for inclusion in this report, as they are still too early in the development pipeline.

Some important preliminary remarks on the data presented in this report:

- This report provides information on the prices of products. It does not include costs linked to equipment shipping, standing laboratory, staff, sample transport, external quality control, maintenance or other overhead expenses.
- The manufacturers provided the prices listed in this publication. These are indicative prices only, therefore the actual costs paid for these items may be higher or lower, depending on specific contexts.
- Companies use different trade terms (known as incoterms).* These trade terms outline the responsibilities of the manufacturer and purchaser with regards to transport, international freight and insurance costs. In order to provide comparable pricing, companies were asked to provide pricing information using FCA (free carrier pricing).
- In general, the price per test calculation consists of the total price of reagents, buffers, and controls needed per test result. It does not factor in the price of instrumentation, consumables required but not supplied by the manufacturer, infrastructure or labour.

*For more information on incoterms, please refer to the Glossary.


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HOW TO READ THE PRODUCT TABLES

1. GENERAL INFORMATION

HIV diagnostic companies were asked to provide information on their products' technical specifications; pricing information; volume-based and tiered pricing; maintenance, training and warranty information; and contact information. The majority of information requested was provided and all information that was received is included in this report. Only company-provided information was included. The narrative provides a brief comparison of the products.

All prices are quoted in United States Dollars (US$). When currency was converted from Euro (€) to (US$) a currency exchange rate of €1 to $1.1 was used, as per currency exchange on 21 May 2015.

Performance information was requested but, in most cases, was supplied by the companies derived from the product insert only and end-users should therefore perform a more comprehensive investigation of performance. In particular, independent and peer-reviewed literature will be important to gauge the true performance in real world settings.

2. TECHNICAL SPECIFICATIONS

Technological set-up refers to the type of assay (either laboratory or POC, which can also be near-POC), instrument compatibility with other brands, and the extent to which processes are automated or manual.

The mean time between failures refers to the elapsed time between inherent failures of a system during operations.

Polyvalency refers to the platform's capability to be used for multiple disease assays, or measurement of other analytes.

3. PRICING INFORMATION

When applicable, pricing for diagnostics assays were divided into categories: whether consumables, instruments, or required materials are or are not provided by the company. When applicable, sample extraction and preparation items were separated from items required for amplification and detection. If manual or automated options are available, both were included.

The sample throughput capacity, and therefore the number or size of the instruments required, will vary depending on the laboratory and context. Therefore, the number of samples per run and run times for instruments are provided, when available. Prices are displayed according to the incoterm provided by the company.

The price per test is the sum cost of reagents and controls per test result. When manual or automated options exist, these costs per tests are differentiated. When companies provided cost per test result in a different manner, the components of these test results are specified. FCA prices were requested.

4. VOLUME-BASED AND TIERED PRICING

Companies were asked to provide details on their volume-based and/or tiered pricing schemes, although this was rarely provided. Some companies requested that interested parties contact them directly for more information on possible volume-based or tiered pricing. Some companies have preferential pricing for high disease burden and/or developing or low-income countries (such as Cepheid and Roche).

5. MAINTENANCE, TRAINING AND WARRANTY INFORMATION

The details and pricing information provided by manufacturers has been incorporated into the maintenance, training, and warranty tables. Unfortunately, most manufacturers do not offer reagent rental plans (RAP). It is unclear why, but is likely due to unreliable volume forecasts from end-users or too few volumes to make a RAP contract affordable to the supplier.

6. CONTACT INFORMATION

Contact information is given to enable interested parties to contact the companies directly for more detailed pricing and other information, and to place orders.

* For more information on incoterms, please refer to the Glossary.

POINT-OF-CARE CD4
ALERE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ALERE		Product	PIMA ANALYSER	
ASSAY		**INSTRUMENT**		**KIT**	
Intended use (as per regulatory approval)	CD4 testing	**Size of device**	23 cm x 13 cm x 16 cm	**Kit components**	Only the instrument and the CD4 cartridge are required. Optional accessories are available (see pricing table).
Principle of the assay	Fixed volume cytometry	**Weight of device**	2.54 kg	**Kit sizes**	25 & 100
Type of result	Quantitative	**Robustness**	Very robust & portable	**Internal control(s)**	Yes
Dynamic range	3 - 2,168 cells/µL	**Environmental requirements**	Temperature: 10 - 40°C Humidity: 10 - 95% Altitude: 0 - 2,000m	**Compatible with EQA and which?**	Yes, QUASI, UK NEQAS, AFRIQAS, LYMPHOSURE, STRECK, etc.
Output	CD4 count in cells/µL	**Power requirements**	100 - 240 V at 47 - 63 Hz	**Mean time between failures**	Not provided
T-cell specific?	Yes	**Time to battery charge**	Recommendation overnight	**Transport and storage**	Room temperature
Polyvalency	In development	**Battery duration (hours)**	8 hours (when battery is new)	**Fridge at -80°C required?**	No
PERFORMANCE		**Alternative charging options**	Solar & car charger	**Shelf life (of each item in the kit)**	12 months
Accuracy (source)	See package insert (V&V studies)	**Ease of use**	Keypad on the device & optional USB printer	**Performance protocol (steps)**	Collect sample in the cartridge and run the test
Bias - CD4 counts, adults (source)	-10 cells (21 - 3) / µL (V&V studies)	**Display languages**	English & simplified Chinese	**Non-proprietary components required outside of the kit**	No, fingerstick kit and printer paper are optional
Bias - CD4 counts & %, children (source)	-10 cells (21 - 3) / µL (V&V studies)	**Built-in memory storage capacity**	1,000 tests	**Regulatory approval**	CE-IVD, WHO PQ
Within run precision, counts & % (source)	11.6% (7 - 16.6%) (V&V studies)	**Connectivity options**	Yes, USB cellular modem with datapoint connectivity solution	**In-country approvals**	Most countries in the developed world; contact local representative
SAMPLE		**Interpretation of result**	No	**USAGE**	
Sample preparation	None	**Instrument lifespan**	Alere guarantee 10 years	**Technical skill required**	No
Sample type	WB capillary & venous WB from EDTA Vacutainer	**Other non-proprietary equipment required**	No	**Applicable settings**	Point-of-care & small labs
Sample volume	25µL	**Regulatory approval**	CE-IVD, WHO PQ	**Laboratory set-up**	No
Sample stability	48 hours in an EDTA Vacutainer			**Waste disposal requirements**	Standard biohazard waste disposal
Time to result	18 - 20 minutes				
Capacity	1 test at a time				
Batching?	No				
Throughput per end-user per hour and/or 8hr day	24 tests				

Continued overleaf

Point-of-Care CD4 – Alere continued

02 | PRICING

Prices quoted to MSF for 2015. Please consider pricing indicative only.

Instrument		Reference number	FCA ($)
Pima Analyser	1 Pima Analyser device	260300003	$5,500
	1 power transformer		
	1 EU power cable		
	1 Pima Analyser User Guide		
	1 Pima bead standard (260400011)		
Pima Instrument & Accessory Pack	1 Pima Analyser	260300004	$6,050
	1 Power transformer		
	1 EU cable		
	1 Pima Analyser User Guide		
	1 Pima Bead standard (260400011)		
	1 Pima Bag (260400001)		
	1 Pima Printer (260400007)		
	1 Connectivity Pack (260400015)		

Cartridge/reagents		Reference number	FCA ($)
Pima CD4 100X cartridge kit	100 Pima CD4 foil sealed test cartridges with 1 product insert	260100100	$595
Pima CD4 2 5X cartridge kit	25 Pima CD4 foil sealed test cartridges with 1 product insert	260100025	
Fingerprick Sample Collection Kit for 100 Pima CD4 tests	4 units of safety lancets (x28)	260400199	$80
	4 units of gauze swabs (x25)		
	1 unit of alcoholic swabs (x100)		
	4 units of plasters (x26)		
	1 safety-lancet user guide		
Pima Printer Paper I	10 rolls thermal paper, non-adhesive	260400009	$32
Pima Printer Paper 2	10 rolls thermal paper, adhesive	260400010	$180
Pima Bead Std	1 normal cartridge	260400011	$50
	1 low cartridge		
	1 Pima bead standard user guide		

Instrument Accessories		Reference number	FCA ($)
Pima Instrument Bag	1 Pima Analyser bag	260400001	$180
Pima Printer	1 Pima Printer	260400007	$350
	1 Pima Printer User Guide		
	1 Roll thermal paper 1, coated, non-adhesive		
Pima Connectivity Pack 1	1 Pima Connectivity Pack	260400015	$550
	1 User Manual		
Alere Solar Solution	1 Solar Panel	260400040	$1,750
	1 Power Pack (260400015)		
	1 User Manual		
Alere Power Pack	1 Power Pack	260400017	$1,150
	1 User Manual		

Non-proprietary equipment and consumables	Reference number	FCA ($)
None		

Cost per device	$6,000 – $12,000	Cost per test result	$6 – $12

03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Maintenance (including instrument swap)	The instrument does not require any preventative maintenance.
Length(s) of warranty and additional costs for extended warranty/care plan	Alere offer a 2 year warranty. Customers can negotiate an extended warranty and several options are available.

05 | CONTACT INFO

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70650, Israel

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Email: rosanne.tzuk@alere.com

POINT-OF-CARE CD4
BD

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	BD INTERNATIONAL, BECTON, DICKINSON AND COMPANY	Product	BD FACSPRESTO
ASSAY		**PERFORMANCE**	
Intended use (as per regulatory approval)	Automated system for in vitro diagnostic use in performing the direct enumeration of CD4 absolute count, CD4 percentage of lymphocytes, and haemoglobin concentration.	**Intra-assay precision, counts & % (source)**	CD4 absolute count CV: - 2.59% for 927 cells/µL - 5.78% for 155 cells/µL %CD4 CV - 1.53% for 44% CD4 and SD of 0.73 for 13% CD4 Hb CV - 1.09% for 13 g/dL - 2.26% for 7 g/dL (Clinical trial data)
Principle of the assay	3-color Imaging cytometry with fluorescent labeled antibodies to count CD4 and %CD4 in whole blood. Imaging for absorbance for total haemoglobin.	**Intra-assay precision, counts & % (source)**	CD4 absolute count CV - 3.30% for 962 cells/µL - 6.79% for 112 cells/µL %CD4 CV - 1.74% for 44% CD4 and SD of 0.75 for 13% CD4 - Hb CV - 1.14% for 17 g/dL - 1.52% for 13 g/dL - 2.42% for 7 g/dL (Clinical trial data)
Type of result	(1) Absolute CD4 count (CD4 lymphocytes/µL) (2) %CD4 (CD4 percent of total lymphocytes) (3) Hb (g/dL)	**SAMPLE**	
Linear range	Validated range: (1) CD4 absolute counting: 50 - 4,000 cells/µL (2) %CD4: 5 - 60% (3) Hb concentration: 2 - 20g/dL	**Sample preparation (steps)**	None
Output	(1) Absolute CD4 count (CD4 lymphocytes/µL) (2) %CD4 (CD4 percent of total lymphocytes) (3) Hb (g/dL)	**Sample type**	Capillary and venous whole blood.
T-cell specific?	Yes: The assay identifies CD4 positive lymphocytes within a population of total lymphocytes (including T, B, and NK cells) identifed by CD3 and/or CD45RA. CD14 expressing cells (monocytes) are excluded.	**Sample volume**	<30µL
Polyvalency	No (current product is already a multiplexed assay for CD4 absolute count, %CD4, and Hb in a single cartridge).	**Sample stability**	2 hours (sample loaded in cartridge); 24 hours (venous EDTA blood not loaded in cartridge)
PERFORMANCE		**Time to result**	22 minutes for first sample; thereafter 4 minutes per sample for batched samples.
Accuracy (source)	For the CD4 or %CD4 assay using venous or capillary whole blood: correlation with gold standard FACSCalibur shows R^2 ≥0.96 and deming slope ranging from 0.97 to 1.03; For Hb from venous samples, correlation with gold standard Sysmex shows R^2 ≥0.96 and deming slope of 0.94. (Clinical trial data from Kenya)	**Capacity**	10 samples/hour
		Batching?	Yes, 10+ samples.
		Throughput per end-user per hour and/or 8hr day	80 samples per operator per day.
Bias - CD4 counts, adults (source)	%Bias compared to gold standard FACSCalibur: - CD4 count: venous -0.28%, capillary 7.1% - %CD4: venous 3.6%, capillary 0.7% for capillary %Bias for Hb compared to gold standard Sysmex - Venous -3.04%, capillary -1.14% (Clinical trial data from Kenya)		
Bias - CD4 counts & %, children (source)	Separate analysis for children was not conducted.		

Continued overleaf

Point-of-Care CD4 – BD continued

INSTRUMENT		KIT	
Size of device	W 25.9 x H 28.5 x D 25.1 cm	**Kit components**	BD FACSPresto Cartridge Kit: - Cartridges for 100 tests - Finger Stick Sample collection kit (100) - 100 BD Lancets - 100 alcohol swabs - 100 cotton gauzes - 100 band-aids - 100 transfer pipettes
Weight of device	7 kg	**Kit sizes**	100 tests
Robustness	Robust: designed for resource limited settings (no maintenance required, no internal cleaning required, only outside cleaning as needed).	**Internal control(s)**	Yes, embedded in cartridge
Environmental requirements	Operating temperature: 10 - 40°C Humidity: 10 - 95%	**Compatible with EQA and which?**	UKNEQAS (Also compatible with BD Multicheck Controls)
Power requirements	Built in battery. 100 - 240V, 50 - 60Hz.	**Mean time between failures**	<5% failure in 12,000 test cycles
Time to battery charge	Overnight charge (8 hours).	**Transport and storage (include temperature)**	Shipping temperature: 45 - 60°C; shipping humidity: 10 - 95% (5 days) Storage temperature: 4 - 31°C; storage humidity: 10 - 95%
Battery duration (hours)	6 Hours when fully charged.	**Fridge at -80°C required?**	No
Alternative charging options	Solar Charger kit and external back-up battery.	**Shelf life (of each item in the kit)**	12 months
Ease of use	- Large color touchscreen display. - Home screen with intuitive menu for incubation timer, sample run, results, QC and help. - On-board 10 timers to manage incubation for up to 10 samples at the same time. - Running sample menu allows for patient ID input, operator selection and running the sample inside instrument by opening the cartridge inlet door. - Result will be displayed and printed automatically. - All errors and malfunction of system will be displayed. - Status of battery charging will be actively displayed on the screen all the time. - In QC mode, on demand instrument QC can be run. - In QC mode, process controls and EQA samples can be run. - Results menu will allow data filtration for printing and export via USB port. - Help menu offers on-board video for entire workflow from sample collection to result exporting.	**Performance protocol (steps)**	(1) Collect sample, (2) incubate, (3) run test and read result.
		Non-proprietary components required outside of the kit	None
		Regulatory approval	CE-Marked (IVD 98/79/EC) and WHO Prequalified
		In-country approvals	Yes, in most countries, where CE Mark is accepted.
		USAGE	
		Technical skill required	Medium to low skill lab technician or health care worker.
		Applicable settings	Resource-limited settings, health center, PMTCT center, HIV clinic.
		Laboratory set-up	No installation required.
		Waste disposal requirements	Dispose cartridge in biohazard waste disposal container.
Display languages	N/A (pictograms and numbers are displayed).		
Built-in memory storage capacity	Data for 12,000 patient results.		
Connectivity options	Direct connectivity option currently not available. USB can be used to export data.		
Interpretation of result	No		
Instrument lifespan	5 years		
Other non-proprietary equipment required	None (on-board mini printer is part of the instrument).		
Regulatory approval	CE-Marked (IVD 98/79/EC) and WHO Prequalified		

02 | PRICING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
BD FACSPresto	Near Patient CD4 Counter	651000	<$10,000	BD FACSPresto Cartridge Kit	Cartridges for 100 tests, finger stick sample collection kit, 100 BD lancets, 100 alcohol swabs, 100 cotton gauzes, 100 band-aids, 100 transfer pipettes.	655495	~$1,000
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
BD FACSPresto Solar charger kit	1x Solar panel 1x Solar generator 1x Power supply 1 x Instructions for Use in English, French, Spanish	658212	<$1,500				
BD FACSPresto Car battery charger adaptor	1x 12 VDC power adaptor with car cigarette lighter plug 1 x Instructions for Use in English, French, Spanish	658860	<$400				
BD FACSPresto Power Generator (rechargeable power battery)	1x 8mm Power supply 1 x Instructions for Use in English, French, Spanish	658885	<$600				
BD FACSPresto printer paper	1x 10 rolls: sufficient for printing 1,200 test results	655038	<$50				
Cost per device			**~$10,000**	**Cost per test result**			**<$10**

Intellectual property		
Patent number / application number / PCT number	Title	Legal Status
US7738094 PCT/US2008/050241	Method, system, and compositions for cell counting and analysis	Granted
US8248597 PCT/US2008/052041	Method, system, and compositions for cell counting and analysis	Granted
US14/537,769 PCT/US2014/064873	Microimager Analysis System Comprising Optics, and QC for Analysis of Microcartridge Data	Pending
US13/590,114 PCT/US2008/052041	Method, System, and Compositions for Cell Counting and Analysis	Pending
US14/533,949 PCT/US2014/064159	Porous Solid Frit Comprising Reagent for Passive Mixing	Pending
US14/152,954 PCT/US2014/011163	Means for enabling capillary flow within a sealed microfluidic device	Pending

03 | TIERED AND VOLUME-BASED PRICING | No Information Provided

Continued overleaf

Point-of-Care CD4 – BD continued

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental	Reagent rental programme available. Please inquire.
Installation	No installation required.
Training	In-country 2-day Good Start Program (GSP) training will be provided. Training can be conducted in English or French. On site training can be arranged if requested and will be conducted by the local team. Training tools will be available and provided. Proficiency testing will be conducted after training. Training materials will be provided including SOP's and Quick Reference Guides. Web links to training materials may be available in some regions.
Maintenance	No maintenance required. All inclusive warranty for 3 years, including instrument swap.
Length(s) of warranty and additional costs for extended warranty / care plan	3 Years all inclusive. Warranty extension available for additional 2 years for a fixed price.
Warranty components	- All inclusive in warranty. - No preventive maintenance required. - Instrument performs self-check each time it is turned on. - No calibration required (factory calibrated). - Internal self calibration performed as needed. - Warranty includes replacement of units. - No internal cleaning required. - No on site repair needed. - Instrument will be swapped by local depot center. - Local dedicated POC coordinator will manage logistics and any issues related to instrument performance. - All parts are fully tested and reliable for the warranty period.
Turnkey option	No (no installation required).
in-country / regional technical support availability	- In-country technical support team and depot center available for repair and swap. - In addition, in-country POC coordinator available to coordinate and support all BD FACSPresto activities, including logistics, order placement and swaps.

05 | CONTACT INFO

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POINT-OF-CARE CD4
MILLIPORE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	EMD MILLIPORE (MERCK MILLIPORE)	Product	MUSE AUTO CD4/CD4% SYSTEM
ASSAY		**INSTRUMENT**	**KIT**
Intended use (as per regulatory approval)	Enumeration of CD4 absolute count and CD4 percentage of lymphocytes.	**Size of device**	H 22 x W 20 x D 28 cm
Principle of the assay	Flow Cytometry, green laser, forward scatter, two color fluorescence.	**Weight of device**	4kg
Type of result	Quantitative	**Robustness**	TBD after testing in Cameroon.
Linear range	TBD	**Environmental requirements**	Temperature: 16 - 35 °C
Output	CD4 count and percentage	**Power requirements**	100 - 200 VAC, 50/60 Hz, 80 W, 15 VDC, 5A
T-cell specific?	Yes	**Time to battery charge**	TBD
Polyvalency	Not at this time	**Battery duration (hours)**	TBD
PERFORMANCE		**Alternative charging options**	External battery in development.
Accuracy (source)	Clinical study in process.	**Ease of use**	5 USB ports available. Data station on board. Touch screen. Histograms and Scatterplots displayed. No printer included, printer must be Microsoft 7 compatible.
Bias - CD4 counts, adults (source)			
Bias - CD4 counts & %, children (source)			
Intra-assay precision, counts & % (source)		**Display languages**	English
Inter-assay precision, counts & % (source)		**Built-in memory storage capacity**	Unlimited, Dell computer.
SAMPLE		**Connectivity options**	5 USB ports for accessories or for interface.
Sample preparation	Two steps, no wash, 30 minutes.		
Sample type	Venous blood.	**Interpretation of result**	Auto acquisition; automated and manual gating.
Sample volume	10µL	**Instrument lifespan**	10 years
Sample stability	48 hours	**Other non-proprietary equipment required**	Pipettes, vortex.
Time to result	4 minutes	**Regulatory approval**	Not applied for yet as clinical study is still in process.
Capacity	15 tests per hour		
Batching?	Yes		
Throughput per end-user per hour and/or 8hr day	15 Samples per hour / 120 per day, not including sample prep time		

KIT	
Kit components	Reagent cocktail, cell lyses.
Kit sizes	100, 500 and 1000 test kits.
Internal control(s)	Not provided.
Compatible with EQA and which?	TBD
Mean time between failures	TBD
Transport and storage	2 - 8 °C
Fridge at -80°C required?	No
Shelf life (of each item in the kit)	12 months
Performance protocol (steps)	Two steps, no wash protocol.
Non-proprietary components required outside of the kit	None
Regulatory approval	Not applied for yet as clinical study is still in process.
In-country approvals	Not applied for yet as clinical study is still in process.
USAGE	
Technical skill required	HS Diploma.
Applicable settings	Small hospital or clinic laboratory.
Laboratory set-up	Hospital lab, clinic lab, ambulatory care lab.
Waste disposal requirements	Liquid waste is bleached.

Continued overleaf

Point-of-Care CD4 – Millipore continued

02 | PRICING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
Muse Auto CD4/ CD4% system	Not yet available for sale; pending regulatory release.	0500-3115	$17,783 (€16,000)	Not yet available for sale; pending regulatory release.			
				Muse Auto CD4/CD4% reagent kit	100 test kit	MCA100101	$445 (€400)
				Muse Auto CD4/CD4% reagent kit	500 test kit	MCA500101	$2,223 (€2,000)
				Muse Auto CD4/CD4% reagent kit	1,000 test kit	MCA1XK101	$4,445 (€4,000)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
UPS	Product in development			These products are in development: Pipettes Pipette tips (disposable, bio-degradable) Sample tubes (disposable, biodegradable)			
Alternate Battery Pack	Release data: Q1 2016						
Cost per device			**~$18,000**	**Cost per test result**			**~$5**

03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Not provided.
Installation	Not provided.
Training	(1) Training is on site and takes 1-2 days. (2) An operator's manual, package insert, material data safety sheet and product brochure will be available in English, French and Portuguese. (3) Proficiency testing will be available through a third party. (4) A training website for the product is in development.
Maintenance (including instrument swap)	Distributors will handle servicing the instruments.
Length(s) of warranty and additional costs for extended warranty / care plan	One year warranty.
Warranty components	All parts and service.
Turnkey option	Not provided.
in-country / regional technical support availability	Through distributor and at Merck regional offices.

05 | CONTACT INFO

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POINT-OF-CARE CD4 OMEGA DIAGNOSTICS

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	OMEGA DIAGNOSTICS	Product	VISITECT CD4
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Estimation of CD4+ T-cell count to be used as an aid to initiation in the treatment of HIV infection.	**Sample preparation (steps)**	None
Principle of the assay	Rapid immunochromatographic assay for the estimation of full-length CD4 protein associated with CD4+ T-cells in human whole blood. A capture monoclonal antibody (MAb) specific for the cytoplasmic domain of CD4 is applied as a line on a nitrocellulose membrane. A second MAb directed against CD4 and labeled with biotin is dried onto a blood collection pad. Whole blood is added directly to the VISITECT CD4 test where it mixes with the biotin-labeled MAb. Red blood cells and monocytes are retained in the blood collection pad and, following the addition of running buffer, other white blood cells (including CD4+ T-cells) migrate to a reaction area where cell lysis occurs, resulting in the release of full-length CD4 for capture and detection on the test strip. Colloidal gold-labeled anti-biotin antibody detects the complexes of full-length CD4 and biotin-labeled antibody at the test line. A reference control line is included to allow estimation of CD4 levels by comparison to a set cut-point (e.g. the signal level generated by samples containing 350 cells/µL).	**Sample type**	Capillary and venous (EDTA) whole blood
		Sample volume	30µL
		Sample stability	Less than 24 hour old blood sample
		Time to result	40 minutes
		Capacity	N/A
		Batching?	Possible
		Throughput per end-user per hour and/or 8hr day	Up to 120 samples/day
		INSTRUMENT (OPTIONAL AX-2X STRIP READER)	
		Size of device	W 123 x H 113 x D 109 mm
		Weight of device	600g
		Robustness	Robust
Type of result	Semi-quantitative	**Environmental requirements**	5 - 45°C
Linear range	To be determined.	**Power requirements**	12V DC / 100-240 V, 50 Hz AC/DC supplied plug pack
Output	Visual or optional instrument estimation of line intensity for sample under test compared to a reference line, the intensity of which is designed to match that of a particular CD4 cells/µL, for example, 350 CD4+ T cells/µL.	**Time to battery charge**	N/A
		Battery duration (hours)	N/A
T-cell specific?	Yes	**Alternative charging options**	12 V DC Battery Pack, 12 V DC Rechargeable Solar Battery Pack
Polyvalency	No	**Ease of use**	3.4 LCD colour touch screen (pictogram & keypad). USB printer is optional.
PERFORMANCE		**Display languages**	English, French, Portugese, Spanish, Italian, German
Accuracy (source)	Not provided	**Built-in memory storage capacity**	1,000 Patient Records
		Connectivity options	Multiple data export options
Bias - CD4 counts, adults (source)	N/A	**Interpretation of result**	Above or below cut-off reference (e.g. 350 cells/µL)
Bias - CD4 counts & %, children (source)	N/A	**Instrument lifespan**	5 years (reader)
Intra-assay precision, counts & % (source)	N/A (single use test)	**Other non-proprietary equipment required**	None
Inter-assay precision, counts & % (source)	To be determined	**Regulatory approval**	Not available for reader.

Continued overleaf

Point-of-Care CD4 – Omega Diagnostics continued

KIT		USAGE	
Kit components	CD4 strip test, running buffer, lancets, swabs, micro-pipette, desiccant, instructions for use.	**Technical skill required**	Trained health professional or health care worker.
Kit sizes	25 & 100 test packs	**Applicable settings**	Primary Health Care level zero and above.
Internal control(s)	A procedural control is built in to the test.	**Laboratory set-up**	None required
Compatible with EQA and which?	No	**Waste disposal requirements**	Disposal by incineration of infectious disease materials; simple trash for other materials.
Mean time between failures	N/A		
Transport and storage	Indicative transport and storage under ambient temperatures to be confirmed by ongoing long term stabilty data.		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	To be determined by on going long term stability trial data.		
Performance protocol (steps)	(1) Collect capillary blood sample; (2) Fill tube with blood; (3) Squeeze sample on to strip test; (4) Add buffers and incubate; (5) Read result.		
Non-proprietary components required outside of the kit	None		
Regulatory approval	In progress: - PQDx 0235-077-00 - VISITECT CD4 Plus 350 25T Cat # OD296 and 100T Cat # OD396 (with blood collection accessories) - PQDx 0237-077-00 - VISITECT CD4 Plus 500 25T Cat # OD256 (with blood collection accessories)		
In-country approvals	In progress		

02 | PRICING

POC Test Kits		**Reference number**	**FCA ($)**
Visitect CD4 Plus 350	25 Test Kit	OD296	$130
Visitect CD4 Plus 350	100 Test Kit	OD396	$520
Optional Reader		**Reference number**	**FCA ($)**
Visitect AX-2X Reader	1 Unit	OD 286	$3,500
Cost per device	**$3,500**	**Cost per test result**	**$5.2**

Intellectual property		
Patent Numbers		Legal Status
Primary Patent Information	PCT/AU2007/001449 Title: 'A method of diagnosis and kit therefore.'	Granted
National Phase Information of the Primary Patent	Australia AU2007302626	Granted
	Canada CA2664698	Pending
	European Patent Office EPO7815265.9	Pending
	USA US8409818	Granted
	South Africa ZA2009/02151	Granted
	African Regional IP Office AP2703	Granted
	Organisation Africaine de la Propriété Intellectuelle 14479	Granted
	China CN101558309.B	Granted

03 | TIERED AND VOLUME-BASED PRICING

No tiered pricing is in place for the test consumables. Volume based pricing is offered on the reader with a single unit at US$3,500; 10+ readers at US$3,000 each and 100+ readers at US$2,500 each.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	N/A	
Installation	For optional reader: 1/2 day.	Included
Training	2-day on-site 'train the trainer' course and local workshops for POC device to include: PowerPoint / Training Manuals / Bench Materials / Wall Posters / Training Video (YouTube)	Included, but local costs such as transportation and living expenses to be handled by the recipient.
Maintenance	Optional instrument is maintenance-free. Swap out if required during 12-month warranty period.	
Length(s) of warranty and additional costs for extended warranty / care plan	N/A	
Warranty components	N/A	
Turnkey option	N/A	
In-country / regional technical support availability	Yes. Initially from Cape Town.	

05 | CONTACT INFO

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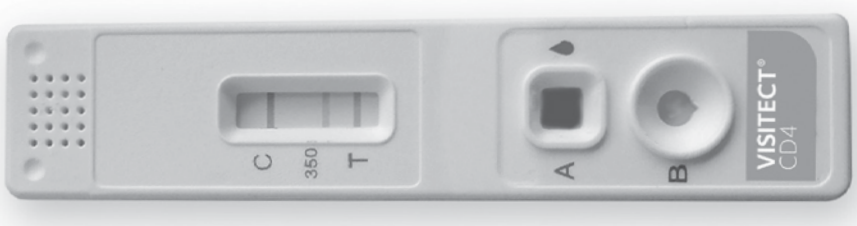

POINT-OF-CARE CD4
SYSMEX PARTEC

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	SYSMEX PARTEC GmbH	Product	CYFLOW MINIPOC
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Determination of CD4 absolute and CD4%.	**Sample preparation (steps)**	(1) 20µl EDTA blood has to be transferred into the ready-to-use CD4/CD45 dry mAb reagent tube and shaken by hand for approximately 3 seconds, then stored in the dark for 15 minutes (during this incubation time, in parallel other blood samples can be processed in batches). (2) The ready-to-use prefilled buffer solution "Buffer 1" has to be added (no pipetting required). (3) Prior to analysis, the ready-to-use prefilled buffer solution "Buffer 2" has to be added (no pipetting required). The sample must be transferred into the plastic disposable syringe (no pipetting required), which will be placed at the sample port of the device, and analysis can be started. (4) The result of the measurement will be automatically displayed and stored on the hard disk drive of the instrument as well as printed by the built-in thermo transfer printer.
Principle of the assay	Single platform flow cytometry based on TVAC.		
Type of result	Quantitative, absolute count and percentage.		
Linear range	5 - 5,000 cells/µL		
Output	CD4 absolute (CD4+ T-lymphocytes/µL), CD4% (CD4+ T-lymphocytes among all lymphocytes).		
T-cell specific?	Yes, fluorochrome conjugated CD4/CD45 mAb.	**Sample type**	Venous EDTA whole blood.
Polyvalency	No	**Sample volume**	20µL
PERFORMANCE		**Sample stability**	48 hours at 2 - 8°C
Accuracy (source)	Against Cytomic FC500: - Correlation coefficient = 0.98 for CD4 count and 0.97 for CD4% Against CyFlow Counter: - Correlation coefficient = 0.99 for CD4 count and 0.99 for CD4% (PLOS ONE DOI:10.1371/journal.pone.0116848 January 26, 2015) Sensitivity: - Normal room temperature = 95% at the different ART-initiation thresholds (200, 350 and 500 CD4 cells/µL) - Room temperature of 30 - 35°C =≥94% (PLOS ONE DOI:10.1371/journal.pone.0116663 February 17, 2015)	**Time to result**	3 Minutes for counting analysing and saving (sample attached to the instrument) plus 15 minutes incubation time outside the instrument.
		Capacity	20 Tests per hour, one sample run on the instrument at a time.
		Batching?	Batching samples for incubation is possible.
		Throughput per end-user per hour and/or 8hr day	Approx. 20 tests per hour = 160 tests per day.
		INSTRUMENT	
		Size of device	W 270 x D 188 x H 240 mm
		Weight of device	6.2kg
		Robustness	Robust, no laser alignment after transport necessary.
Bias - CD4 counts, adults (source)	Against FACSCalibur - Absolute mean bias = -12.6 cells/µL for CD4 count and -0.1% for CD4% - Relative mean bias = -2.3% for absolute for CD4 count Against FACSCount CD4 - Absolute mean bias = -31.2 cells//µL for CD4 count and 1.3% for CD4% - Relative mean biases = -4.7% for CD4 count Against FACSCount CD4 at room temperature of 30 - 35°C - Absolute mean bias = 7.6 cells/µL for CD4 count and 0.4% for CD4% - Relative mean bias = 2.8% for CD4 count (PLOS ONE DOI:10.1371/journal.pone.0116663 February 17, 2015)	**Environmental requirements**	Temperature: 15 - 30°C (operative) Humidity: 20 - 85% relative (non-condensing)
		Power requirements	100/230 VAC power supply - 50/60 Hz. Battery Pack available
		Time to battery charge	3 hours
		Battery duration (hours)	4-5 hours
		Alternative charging options	- Set to connect with car battery is standard equipment - Battery Pack available - Solar Panel for Battery Pack also available
		Ease of use	- Built-in computer - "5.7" TFT colour touchscreen - Automated analysis - Automated data saving - Built-in thermal printer
Bias - CD4 counts & %, children (source)	Mean absolute bias = <1% (PLOS ONE DOI:10.1371/journal.pone.0116663 February 17, 2015)	**Display languages**	English, French, Spanish and German.
		Built-in memory storage capacity	Data storage of approximately 20,000 data sets.
Intra-assay precision, counts & % (source)	<±5% deviation (PLOS ONE DOI:10.1371/journal.pone.0116848 January 26, 2015) CD4 >200 cells/µl: ≤10% CD4 <200 cells/µl: ≤15% (Internal study)	**Connectivity options**	USB
		Interpretation of result	- CD4 in cells/µL - CD4% - Lymphocytes in cells/µL
		Instrument lifespan	8 Years is expected.
Inter-assay precision, counts & % (source)	CD4>200 cells/µL: ≤10% CD4>200 cells/µL: ≤15% (internal study)	**Other non-proprietary equipment required**	No
		Regulatory approval	- CE (TÜV) IVD (Directive 98/79/EG) - Not eligible as POC for GF ERPD - Submission of product dossier for WHO PQ is on-going

KIT		USAGE	
Kit components	Partec miniPOC CD4% count kit – dry, includes: - 20 Sample tubes with pre-filled dry CD4/CD45 mAb reagents - 20 Test tubes pre-filled with Buffer 1 - 20 Test tubes pre-filled with Buffer 2 - 2 Sheath Fluid containers - 2 bottles of Sheath Fluid (each 250mL) - 20 Pipette tips (2 - 200µL) - 5 Sample tubes with pre-filled Count Check Beads green – dry - 5 Test tubes pre-filled with Rehydration Solution for Count Check Beads green – dry - 2 Tubes with Cleaning Solution (each 5mL) - 1 Tube with Decontamination Solution (5mL) - 1 Roll Thermo Printer Paper - 40 Syringes - Quality Check Protocol	**Technical skill required**	Technical skill required for laboratory staff: nurse or lab technician.
		Applicable settings	Technology can be used at all levels of the health system, including central, regional, district and mobile labs, and some primary sites.
Kit sizes	20 tests/kit	**Laboratory set-up**	Clean desk or table.
Internal control(s)	Supports internal QC (Partec Count Check Beads as non-biological controls).	**Waste disposal requirements**	According to the local regulations.
Compatible with EQA and which?	Yes, with CD4 EQA programmes.		
Mean time between failures	Proprietary.		
Transport and storage (include temperature)	Recommended transport temperature: 2 - 35°C, do not freeze Recommended storage temperature: 2 - 8°C, do not freeze		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	Minimum 6 months.		
Performance protocol (steps)	(1) Sample staining, (2) Incubation (15 min), (3) Adding buffers, (4) Sample run, (5) Data analysis and results (automated).		
Non-proprietary components required outside of the kit	None.		
Regulatory approval	- CE (TÜV) IVD (Directive 98/79/EG) - Not eligible as POC for GF ERPD - Submission of product dossier for WHO PQ is on-going		
In-country approvals	In-country registration available through local distributors/affiliates.		

02 | PRICING

Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
CyFlow miniPOC Set	Consisting of: - CY-S-3033 CyFlow miniPOC device - 04-6-3500 Lab Coat - 1 x Starterkit consisting of: - 05-8409-d Partec miniPOC CD4% count kit, dry (20 tests) - 04-6-1023 Eppendorf Pipette fix 20µL - 04-6-2040 Vacuette Blood collection System (100 pcs.) - 04-2000-03 Sample Tubes Rack for CyFlow miniPOC - 04-4012 Hypochlorite Solution (250mL)	CY-S-3033_S	$10,767.75 (including user training of $1,433.25)*	Partec miniPOC CD4% count kit - dry	20 tests	05-8409-d	$63.00*
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Transportation Bag	For instrument	CY-S-3091	$339.15*	None			
Battery Pack	For instrument	CY-S-3096	$367.50*				
Solar Panel for Battery Pack	For instrument	CY-S-3099	$294.00*				
Cost per device			**~$11,000**	**Cost per test result**			**$3.15***

*Additional Clause:
- Exchange Rate: EUR 1,00 = USD 1.05
- If the exchange rate fluctuates by 10%, Sysmex Partec reserves the right to adjust the prices

Continued overleaf

Point-of-Care CD4 – Sysmex Partec continued

03 | TIERED AND VOLUME-BASED PRICING

Available on request.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$) (FCA)
Leasing or reagent rental (RAP)	Reagent rental options can be inquired in a partnership approach with the local distributor.	Upon request.
Installation	The CyFlow miniPOC Instructions for Use (IFU) provides all the information for set-up, instrument operation and maintenance.	N/A
Training	Common training procedure: (1) Six hours (1 day) on site training will be offered by a Sysmex Partec trained local distributor. Also, centralised training programmes and training seminars are available on demand. (2) English, French and local languages for training are available on request. (3) On site training is provided. (4) Training tools available include a PowerPoint presentation, Instructions for Use and Product Insert Sheet. (5) Trained persons are considered proficient.	Training is included in the price of CY-S-3033_S CyFlow miniPOC Set at a value of $1,433.25.
Maintenance (including instrument swap)	Service/maintenance: the usual response time for service/maintenance is two working days under normal conditions. Depending on very specific factors, longer response times may be possible. For any support, service or maintenance inquiry, the responsible local service provider should be contacted.	Besides regular warranty coverage, preventive maintenance and service contracts can be requested at the local service provider (Sysmex affiliates/ distributors).
Length(s) of warranty and additional costs for extended warranty / care plan	Common Warranty: 12 months (preventive maintenance and service contracts optionally available on request).	Upon request.
Warranty components	Common Warranty: 12 months on all parts except filters, mirrors, other quartz or glass parts, disposables, as long as not otherwise stated.	Not provided.
Turnkey option	Available on request.	Upon request.
In-country / regional technical support availability	Available through Sysmex trained in-country distributors (first level support - available in nearly all countries), and through Sysmex regional affiliates (second level support - Sysmex Training Centres for South-East Africa as well as Central-West Africa and one Support Hub for East Africa).	Upon request.

05 | CONTACT INFO

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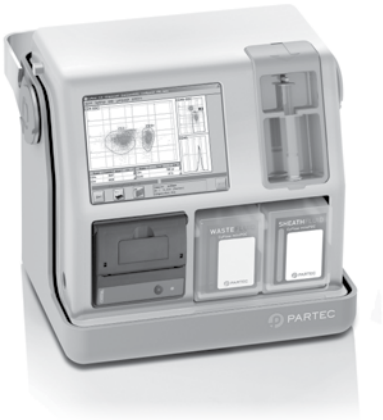

POINT-OF-CARE HIV EID
ALERE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ALERE	Product	ALERE Q HIV 1/2 DETECT
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	EID and acute stage adult diagnosis.	**Sample preparation**	None
		Sample type	Whole blood (capillary or venous EDTA) & plasma EDTA.
Principle of the assay	Multi-plexed real time PCR.	**Sample volume**	25µL
Target	Proprietary	**Sample stability**	Venous whole blood, collected into EDTA tubes, can be stored at: - Ambient temperature (18 - 28°C) for ≤24 hours after draw. - Otherwise aliquoted and frozen at -80°C immediately after draw (there is no need to generate plasma before freezing). - Frozen samples should be thawed at ambient temperature and, once thawed, tested immediately (invert the thawed sample tubes 10-15 times before pipetting).
Genotypes and/ or subtypes	HIV-1 (M/N), HIV-1 (O) & HIV-2	**Nucleic acid extraction method**	Automated (in cartridge)
Type of result	Qualitative	**Time to result**	52 minutes
Linear range	N/A	**Capacity**	1 test at a time
Output	Detected or not detected.	**Batching?**	No
DNA or RNA specific?	RNA	**Throughput per end-user per hour and/or 8hr day**	8/day
Polyvalency	In development	**INSTRUMENT**	
PERFORMANCE		**Size of device**	20 x 21 x 30 cm
Sensitivity - analytical and clinical (source)	Venous blood: 98.98% Capillary blood: 98.65% Plasma: 99.57% (V&V Studies Pack insert)	**Weight of device**	7.8 kg
		Robustness	Very robust.
Specificity - analytical and clinical (source)	100% (V&V Studies Pack Insert)	**Environmental requirements**	Temperature: 10 - 40°C Humidity: 0 - 85% Altitude: 0 - 2,000 m NN
Bias (source)	N/A	**Power requirements**	100 - 240 V at 50 - 60 Hz
Intra-assay precision (source)	N/A	**Time to battery charge**	Recommended: overnight
Inter-assay precision (source)	To evaluate precision, 6 HIV negative whole blood samples from cohort G were spiked with virus preparations of HIV-1 group M subtype B (strain IIIB) at a concentration of 8,000 copies/mL. For all 348 tests on spiked venous whole blood samples performed on 8 different Alere q analysers over the course of 6 days, HIV-1 M/N was 100% successfully detected. There were no false positive results for HIV-1 O and HIV-2. The results are considered to be representative for all analytes of the Alere q HIV-1/2 Detect test (HIV-1 group M/N, HIV-1 group O and HIV-2).	**Battery duration (hours)**	8 hours
		Alternative charging options	External battery.
		Ease of use	Touch screen, optional USB printer.
		Display languages	English, French, German.
		Built-in memory storage capacity	1,000 tests
		Connectivity options	USB cellular modem with datapoint connectivity.
		Interpretation of result	Printed as detected or not detected.
		Instrument lifespan	Alere guarantee 10 years.
		Other non-proprietary equipment required	No
		Regulatory approval	GF ERPD & CE-IVD

Continued overleaf

Point-of-Care HIV EID – Alere continued

KIT		USAGE	
Kit components	50 foiled cartridges	**Technical skill required**	No
Kit sizes	50 tests	**Applicable settings**	Point-of-care and small laboratories.
Internal control(s)	Yes	**Laboratory set-up**	None required.
Compatible with EQA and which?	Compatible WHO panel	**Waste disposal requirements**	Standard biohazard waste disposal.
Mean time between failures	Proprietary		
Transport and storage	4 - 30°C		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	6 months (currently)		
Performance protocol (steps)	None		
Non-proprietary components required outside of the kit	No		
Regulatory approval	GF ERPD & CE-IVD		
In-country approvals	Speak to local representative.		

02 | PRICING

Depends on volume tier & deployment conditions.

Prices quoted to MSF for 2015. Alere aim to provide same pricing to all global humanitarian and development stakeholders howver please consider pricing as indicative only.

Instrument		**Reference number**	**EXW ($)**	**Cartridge/reagents**		**Reference number**	**EXW ($)**
Alere q Analyser Complete	Includes Instrument, Power Drum, Modem, Printer	270300002	$25,000	Alere q HIV 1/2 Detect	50 Tests	270110050	$747.50 - 1,250 (depending on tier)
Instrument Accessories		**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**EXW ($)**
None				Optional Extras:			
				Finger Stick Sample Collection Kit	100 Tests	260400199	$100
				Neonatal Sample Collection Kit	100 Tests	270400200	$120
				Pima Printer Paper 1 (same for Alere q)	10 rolls	260400009	$32
				Pima Printer Paper 2 (same for Alere q)	10 rolls	260400010	$180
				Plastic Capillaries Plane	1,000	270400005	$180
				Plastic Capillaries ETDA-K2	1,000	270400006	$180
Cost per device			**$25,000**	**Cost per test result**			**≥$14.95 - 25**

03 | TIERED AND VOLUME-BASED PRICING

Instrument	Assay cartridge/kit	
The complete instrument costs $25,000 Ex Works. If customers procure 25 or more instruments on a single PO that is shipped to a single country then Alere will offer an additional 2-year warranty (valued at $5,000) FOC.	**Volume tier per tests per year**	**Ex Works ($) per test (50 Tests per Kit)**
	0 - 199,999	$25
	200,000 - 399,999	$22.50
	400,000 - 599,999	$19.95
	600,000 - 799,999	$17.95
	≥800,000	$14.95
	Only individual organisation orders will count towards the tiers and consumption will be reviewed quarterly.	

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	No RRP offered at this stage.	
Installation	None required.	
Training	- Training will be provided in country on a regional/national basis. - Half a day is required.	Training is included in the purchase price.
Maintenance	None required but warranty includes instrument swap.	
Length(s) of warranty and additional costs for extended warranty / care plan	12 months, afterwhich a Care Plan can be procured.	$2,500 per year
Warranty components	Labour, parts and a swap instrument.	
Turnkey option	None required.	
In-country / regional technical support availability	- Alere offer a tiered system. - Certain repairs can be done in country while others would be done regionally at Alere's hubs. - Customers will receive a swap device while their device is in for repair.	

05 | CONTACT INFO

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POINT-OF-CARE HIV EID, HIV VL, HCV VL
CEPHEID

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Cepheid**		
Product	**XPERT HIV-1 QUAL**	**XPERT HIV-1 VIRAL LOAD**	**XPERT HCV VIRAL LOAD**
ASSAY			
Intended use (as per regulatory approval)	In vitro diagnostic test designed to detect HIV-1 total nucleic acids from individuals suspected of HIV-1 infection. Intended to aid in the diagnosis of HIV-1 infection in conjunction with clinical presentation and other laboratory markers.	In vitro diagnostic test designed for the rapid quantitation of HIV-1 from HIV-1 infected individuals. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. Not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.	In vitro diagnostic test designed for the rapid quantitation of HCV RNA from HCV infected individuals. Intended for use as an aid in the management of HCV-infected patients undergoing antiviral therapy. The test measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and nonsustained virological response to HCV therapy. The results should be used in conjunction with clinical presentation and other laboratory markers and findings. Not intended to be used as a donor screening test for HCV or as a diagnostic test to confirm the presence of HCV infection.
Principle of the assay	GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real time reverse transcription PCR (RT-PCR). The systems consist of an instrument, personal computer, and preloaded software for performing tests and viewing the results. The systems require the use of single-use disposable GeneXpert cartridges that hold the RT-PCR reagents and host the RT-PCR processes. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the system, see the GeneXpert Dx System Operator Manual or the GeneXpert Infinity System Operator Manual. The assays include reagents for the detection of nucleic acids in specimens as well as an internal control to ensure adequate processing of the target and to monitor the presence of inhibitor(s) in the RT and PCR reactions. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. A sample adequacy control ensures sufficient sample has been added for accurate viral load measurement.		
Target	3′-end of 5′ LTR		5′ UTR
Genotypes and/ or subtypes	HIV-1, Group M Subtypes A-H, AB, AE, AG, J, K, Group N, Group O.		Genotypes 1-6
Type of result	Qualitative	Quantitative	Quantitative
Linear range	N/A	40 – 10,000,000 HIV-1 copies/mL	10 – 100,000,000 HCV IU/ml
Output	HIV infected / HIV uninfected	copies/mL	IU/mL
DNA or RNA specific?	TNA	TNA (RNA from plasma)	RNA
Polyvalency	MRSA/Staph aureas, C. difficile, vanA, norovirus, MTB/RIF, Flu/RSV, EV, CT/NG, GBS, FII & FV, and a number of others (see full menu).		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	Not provided.		

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
PERFORMANCE (CONTINUED)			
Specificity - analytical and clinical (source)	**Analytical specificity:** - Evaluated by adding cultured organisms at 5 x 10^3 particles or cp/mL into HIV-1 negative EDTA whole blood and into HIV-1 positive EDTA whole blood at 900 cp/mL HIV-1 reference material (subtype B). Organisms were tested using the whole blood procedure. - Tested organisms are listed: Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, hepatitis C virus, herpes simplex virus 1, herpes simplex virus 2, human herpesvirus 6, HIV-2, human T-cell lymphotropic virus type 1, human T-cell lymphotropic virus type 2, influenza A, Staphylococcus aureus. None of the organisms tested showed cross reactivity or interference with the HIV-1 detection. **Clinical specificity:** - Whole blood collected in EDTA was collected from 1,017 blood donors at two sites in the United States (Washington and Minnesota). The specimens were determined to be HIV-1 negative by standard blood bank FDA-licensed antibody and nucleic acid methods. - Of the 1,017 specimens, 503 were prepared as DBS and 514 were tested as whole blood. One DBS and two WB specimens were indeterminate on both initial and retest, and therefore excluded from the specificity calculation. - The specificity was 100% (1014/1014), 95% CI: 99.6-100.0.	**Analytical specificity:** - Evaluated by adding cultured organism at 5 x 10^4 particles or cp/mL input concentration into HIV-1 negative EDTA plasma and in plasma that contained 1,000 cp/mL HIV-1 reference material (HIV-1 subtype B). - Tested organisms are listed: HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, human herpes virus 8, Varicella zoster virus, BK Human polyoma virus, Banzi virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, Staphylococcus pidermis, Staphylococcus aureus. None of the organisms tested showed cross reactivity and all HIV-1 positive replicates resulted in a titer within ± 0.5 log of the HIV-1 positive control. **Clinical specificity:** - Evaluated using 109 EDTA plasma specimens from HIV-1 negative blood donors. - None of the 109 specimens tested were detected equating to 100% specificity (95% CI = 96.7–100.0).	**Analytical specificity:** - Evaluated by adding potentially cross-reacting organisms at 1 x 10^5 CFU/mL, copy/mL or TCID 50/mL input concentration into HCV negative EDTA plasma and in plasma that contained ~25 IU/mL HCV reference material (clinical specimen genotype 1). None of the tested organisms showed cross reactivity and all positive replicates resulted in concentrations of HCV RNA within ± 0.5 log from a HCV positive control. - In addition to the species listed here, HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, human herpes virus 8, Varicella zoster virus, BK Human polyoma virus, Banzi virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, Staphylococcus epidermis, Staphylococcus aureus, Dengue virus and vaccinia virus were analysed in silico since material representing the viruses could not be obtained for testing. No practical significant sequence similarity was found between the analyzed viruses and the primers and probes of the assay.
Bias (source)	Not provided.		
Intra-assay precision (source)	Not provided.	Total precision: - 1.6 log10 cp/mL: SD 0.25, CV 62.5% - 3 log10 cp/mL: SD 0.09, CV 20.5% - 5 log10 cp/mL: SD 0.08, CV 17.8% - 7 log10 cp/mL: SD 0.10, CV 22.6%	Total precision: - 1.0 log10 cp/mL: SD 0.21, CV 51.7% - 2.7 log10 cp/mL: SD 0.09, CV 22.1% - 5.4 log10 cp/mL: SD 0.11, CV 25.8% - 8.2 log10 cp/mL: SD 0.13, CV 30.5%
Inter-assay precision (source)	VQA Reference Standard: - WB: 88 - 96% ≥200 copies/mL - DBS: 100% ≥800 copies/mL WHO Reference Standard: - WB: 100% ≥420 copies/mL - DBS: 96 - 100% ≥1,000 copies/mL		
SAMPLE			
Sample preparation (steps)	None (whole blood or DBS). Processing DBS requires a 15 min incubation at 56°C in a thermometer rotating at 500rpm. The eluate is then transferred into the cartridge. WB does not require any preparation.	Prepare plasma.	Prepare plasma or serum.
Sample type	Whole Blood or DBS	EDTA, EDTA-PPT plasma, ACD plasma	EDTA, EDTA-PPT plasma or serum
Sample volume	100µL WB or 1 DBS (50-70µL)	1mL plasma	1mL serum or plasma
Sample stability	• EDTA-anticoagulated whole blood may be stored at - 31–35°C for ≤8 hours - 15–30°C for ≤24 hours - 2–8°C for ≤72 hours • DBS cards may be stored at - ≤31–35°C for ≤8 weeks - 2-25°C or -15 °C or colder for up to 12 weeks	• Whole blood may be held at - 15–30°C for ≤8 hours - 2–8°C for ≤72 hours • After centrifugation, plasma may be held at - 2–8°C for ≤6 days - 15–30°C for ≤24 hours • Plasma specimens are stable frozen (≤ -18°C and ≤ -70°C) for 6 weeks. • Plasma specimens are stable for ≤3 freeze/thaw cycles.	• Whole blood may be held at - 15–35°C for ≤6 hours - 2–8°C for up to 72 hours • After centrifugation, plasma and serum may be held at - 2–8°C for ≤3 days - 15–35°C for ≤24 hours • Plasma and serum specimens are stable frozen (-70 to -18°C) for 6 weeks. • Plasma and serum specimens are stable for ≤3 freeze/thaw cycles.
Nucleic acid extraction method	Automated		
Time to result	90 minutes		105 minutes
Capacity	**Time (hours) 8 10 12 24** 1 module 6 7 8 16 2 modules 12 14 16 32 4 modules 24 28 32 64 16 modules 96 112 128 256		
Batching?	No		
Throughput per end-user per hour and/or 8hr day	**8hr throughput/m²:** 1 module 190 2 modules 250 4 modules 289 16 modules 494		

Continued overleaf ⋰

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
INSTRUMENT			
Size of device	1 module W 10.60 x H 30.48 x D 29.72 cm 2 modules W 16.13 x H 30.48 x D 29.72 cm 4 modules W 27.94 x H 30.48 x D 29.72 cm 16 modules W 57.79 x H 65.53 x D 33.66 cm		
Weight of device	1 module: 8.16 kg 4 modules: 12 kg 16 modules: 57 kg		
Robustness	Systems are robust with minimal maintenance/cleaning. In routine use at many TB centres globally.		
Environmental requirements	15 - 30°C		
Power requirements	220-240V, 50-60 Hz - 110V version also available		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	Solar panel installations have been demonstrated as well as inverters linked to arrays of lead/acid batteries.		
Ease of use	No internal printer. USB printer can be added to print all of the parameters mentioned.		
Display languages	Choice of English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin selected at installation.		
Built-in memory storage capacity	None, other than laptop, or desktop computer.		
Connectivity options	Ethernet, Wifi and USB ports. Communications protocols for HL7 and ASTM standards are included in the GeneXpert software. Remote Xpert software available for download.		
Interpretation of result	The instrument will display Positive, Negative, Invalid, Error or 'No Result' if the process is interrupted by the user.	The instrument will display: - HIV detected XX copies/mL - HIV detected <40 copies/mL - HIV Detected >1x10^7 copies/mL - HIV not detected - Invalid, Error or 'No Result', if the process is interrupted by the user	The instrument will display: - HCV detected XX IU/mL - HCV detected <10 IU/mL - HCV detected >1x10^8 IU/mL - HCV not detected - Invalid, Error or 'No Result', if the process is interrupted by the user
Instrument lifespan	7 Years (except for the computer, which may require updating before this time).		
Other non-proprietary equipment required	Printer, as needed.		
Regulatory approval	FDA Approved	FDA Approved	FDA Approved
KIT			
Kit components	Each kit contains: - 10 Xpert HIV-1 Qual Assay Cartridges with Integrated Reaction Tubes - Xpert HIV-1 Qual Sample Reagent Set (Sample Reagent) 10, containing 1.0mL Lysis Reagent (Guanidinium Thiocyanate) per vial - 10 Disposable (1mL) Transfer Pipettes - 10 Disposable 100µL Transfer Micropipettes - CD with ADF, PI	Each kit contains: - 10 Xpert HIV-1 VL Assay Cartridges with Integrated Reaction Tubes; - 10 Disposable (1mL) Transfer Pipettes - CD with ADF, PI	Each kit contains: - 10 Xpert HCV VL Assay Cartridges with Integrated Reaction Tubes - 10 Disposable (1mL) Transfer Pipettes - CD with ADF, PI
Kit sizes	10 tests per kit		
Internal control(s)	Each test includes a - Sample Volume Adequacy (SVA) - Sample Processing Control (SPC) - Probe Check Control (PCC)	Each test includes a - Sample Volume Adequacy (SVA) - Internal Quantitative Standard High and Low (IQS-H and IQS-L, also acts a specimen processing control [SPC]) - Probe Check Control (PCC)	
Compatible with EQA and which?	Yes, any.		
Mean time between failures	Not provided.		
Transport and storage	2 - 8°C shipping initially until sufficient stability data supports transport at 2 - 28°C, storage at 2 - 8°C.		
Fridge at -80°C required?	No	No, unless for long term storage of plasma.	
Shelf life (of each item in the kit)	At launch: 8 months, but working towards 9-12 months. Typically, Xpert cartridges are stable for between 12 - 24 months from manufacture depending on the amount of historical stability data available.		

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
KIT (CONTINUED)			
Performance protocol (steps)	WB: (1) Transfer 750µL of the sample reagent into the sample chamber of the cartridge using transfer pipette provided; (2) Mix EDTA blood by inverting vial; (3) Transfer 100µLof blood into the sample chamber using micropipette provided; (4) start test within 30 minutes. DBS: (1) Excise one DBS for each specimen; (2) Place one DBS in sample reagent vial (fully submerged); (3) Place in ThermoMixer and incubate for 15 minutes at 56°C and rotate at 500 rpm; (4) Transfer all liquid into sample chamber of cartridge using 1mL transfer pipette provided.	(1) Prepare the specimen; (2) Prepare the cartridge by transferring 1mL of plasma into the sample chamber using the transfer pipette provided; (3) Load cartridge onto GeneXpert and run.	
Non-proprietary components required outside of the kit	If using DBS: • DBS Collection Kit (Filter paper cards, e.g., Whatman 903, Munktell or equivalent, lancets and swabs). • Eppendorf ThermoMixer C (Eppendorf order number 5382 000.015). • Eppendorf SmartBlock (Eppendorf order number 5309 000.007).	Blood collection tube, centrifuge.	
Regulatory approval	CE-IVD marked	CE-IVD marked	CE-IVD marked
In-country approvals	Pending		
USAGE			
Technical skill required	Basic		
Applicable settings	All		
Laboratory set-up	Minimal		
Waste disposal requirements	As per local authority.		

02 | PRICING

All prices are based on prepayment.

EARLY INFANT DIAGNOSIS, HIV VIRAL LOAD & HCV VIRAL LOAD

Instrument		Reference number	EXW ($)	Cartridge/reagents		Reference number	EXW ($)
GeneXpert Desktop Instruments	*Modules*			Xpert HIV-1 Qual	10 test per kit	GXHIV-QA-CE-10	$199
GeneXpert II	2	GXII-2-D	$11,530	Xpert HIV-1 VL	10 tests per kit	GXHIV-VL-CE-10	$191
GeneXpert IV	2	GXIV-2-D	$11,780	Xpert HCV VL	10 tests per kit	GXHCV-VL-CE-10	$192
GeneXpert IV	4	GXIV-4-D	$17,000	Xpert HIV-1 Qual At launch: $19.90 >50,000 tests: $19.75 >250,000 tests: $18.90 >1 million tests: $17.35 Xpert HIV-1 VL At launch: $19.10 >50,000 tests: $16.80 >750,000 tests: $15.05 >1.5 million tests: $14.20 Xpert HCV VL At launch: $19.20 >50,000 tests: $17.10 >750,000 tests: $15.55 >1.5 million tests: $15.05			
GeneXpert XVI	4	GXXVI-4-D	$30,680				
GeneXpert XVI	8	GXXVI-8-D	$44,120				
GeneXpert XVI	12	GXXVI-12-D	$57,560				
GeneXpert XVI	16	GXXVI-16-D	$71,000				
GeneXpert Laptop Instruments	*Modules*						
GeneXpert II	2	GXII-2-D	$12,030				
GeneXpert IV	2	GXIV-2-D	$12,280				
GeneXpert IV	4	GXIV-4-D	$17,500				
GeneXpert XVI	4	GXXVI-4-D	$31,180				
GeneXpert XVI	8	GXXVI-8-D	$44,620				
GeneXpert XVI	12	GXXVI-12-D	$58,060				
GeneXpert XVI	16	GXXVI-16-D	$71,500				

Instrument Accessories	Reference number	EXW ($)	Non-proprietary equipment and consumables	Reference number	EXW ($)
For DBS (EID): • Eppendorf ThermoMixer C • Eppendorf SmartBlock	Eppendorf order number 5382 000.015 Eppendorf order number 5309 000.007		For DBS(EID): Collection kit (filter paper cards, lancets, swabs)		
Centrifuge					
Cost per device	**GXIV-4-D**	**$17,000**	**Cost per test result**		**$19.10 - 19.90**

Continued overleaf

03 | TIERED AND VOLUME-BASED PRICING | Pending finalisation.

04 | MAINTENANCE, WARRANTY & TRAINING

	EARLY INFANT DIAGNOSIS, HIV VIRAL LOAD & HCV VIRAL LOAD	
	Description	**Cost (US$)**
Leasing or reagent rental (RAP)	Not for High Burden Developing Country Programme.	
Installation	1-2 hrs for GX-1 to -16 modules 3-5 days for Infinity 80	
Training	1. 2-3 hours of training required 2. Languages available: English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin 3. On site training is available 4. Training tools are available 5. Weblink to training materials is available	N/A
Maintenance (including instrument swap)	Robust system, minimal maintenance required. Daily wiping down of the instrument is recommended.	N/A
Length(s) of warranty and additional costs for extended warranty / care plan	2 years with purchase. Extended warranty available as single year extensions or 3 year extensions.	Example: 3 Year Warranty Extension purchased with system - GXIV-2 $4,500 - GXIV-4 $6,840 - GXXVI-16 $18,504
Warranty components	Parts and labour	
Turnkey option	No information provided.	
In-country / regional technical support availability	Will be available direct from Cepheid, present directly in 15 countries, or through our network of service providers. 24 hour tech support hotline available globally.	

05 | CONTACT INFO

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POINT-OF-CARE HIV EID & HIV VL DIAGNOSTICS FOR THE REAL WORLD

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	
Company	**Diagnostics for the Real World, Ltd**	
Product	**SAMBA HIV-1 QUAL TEST**	**SAMBA II HIV-1 QUAL WHOLE BLOOD TEST**
ASSAY		
Intended use (as per regulatory approval)	Qualitative detection of HIV-1 as an aid in the diagnosis of HIV-1 infection in paediatric samples for early infant diagnosis.	
Principle of the assay	Performing the test is divided into two steps: sample preparation and sample testing (amplification/detection). The first step is the extraction of the target RNA/DNA using an automated sample preparation procedure in the SAMBAprep instrument. The procedure lyses the virus and releases the nucleic acid, which is then captured onto a silica membrane in a column. The column with the bound nucleic acid is then washed, followed by elution of the nucleic acid into the Output Tube. The Output Tube is then transferred into the SAMBAamp instrument for the amplification and detection steps. The SAMBAamp cartridge and Reagent Tube are placed into the SAMBAamp instrument. Detection buffer is added to the color-labeled anti-hapten sphere in the SAMBAamp cartridge. The sample is transferred from the Output Tube to the Reagent Tube, heated, and then transferred to the hermetically sealed SAMBAamp cartridge previously placed in the SAMBAamp instrument. The SAMBAamp cartridge contains all the reagents required to amplify HIV-1 nucleic acids in the SAMBAamp instrument. At the end of the amplification cycle, the Detection Buffer is added to the sample by depressing the plunger on the SAMBAamp cartridge and the amplified sample is then wicked up on the Test Strip by capillary action within the SAMBAamp cartridge, giving a visual readout of the result.	The test is a fully automated assay run on the SAMBA II instrument system consisting of the SAMBA II Assay Module, and a control unit, the SAMBA II Display Module or the SAMBA II Phone Module. Nucleic acid extraction, amplification of the nucleic acid target and the detection of the amplification products are performed in the SAMBA II Assay Module. The extraction phase of the assay involves lysis to release the nucleic acid into solution, which is then captured by a silica membrane column. The bound nucleic acid is washed and eluted from the membrane and the HIV target sequence is amplified in the sealed SAMBA II QB II Cartridge 1. After amplification, a coloured-labeled anti-hapten detection solution is mixed with the amplification product and the mixture is wicked in a Test Strip. The test result (i.e. bluish to purple lines on the Control Line and/or Test Line) is captured by a built-in camera, which is recorded and can be read on the Display Module or the Phone Module. Results are stored and may be printed from the Display Module. The SAMBA II Phone Module does not have the print function but results can be recorded manually following routine laboratory procedures.
Target	Proviral DNA and RNA	
Genotypes and/ or subtypes	Group M (A, B, C, D, CRF01_AE, F, G), Group N, Group O and a variety of recombinants including: CRF02_AG, CRF06_cpx, CRF11_cpx, CRF13_cpx, A/AE, D/A and D/F. (Assessed using the 1st WHO International HIV-1 RNA Genotype Panel, Rush University Genotype panels and subtyped clinical samples consisting of samples representing various subtypes and or groups.)	
Type of result	Qualitative, Yes or No result.	
Linear range	N/A. Limit of detection: 400 copies/mL of HIV-1 RNA.	
Output	Yes or No result.	
DNA or RNA specific?	Proviral DNA and RNA.	
Polyvalency	Only HIV test portfolio.	Development stage: SAMBA II CT/NG Duplex test, SAMBA II Flu A/B Duplex test. Evaluation stage: Leukodepleted SAMBA II Whole Blood Viral Load Test.
PERFORMANCE		
Sensitivity - analytical and clinical (source)	Clinical sensitivity: 95.7 - 100%. (From three independent clinical evaluations in Kenya, Uganda and Zimbabwe.)	TBD
Specificity - analytical and clinical (source)	Clinical specificity: 99.2 - 100%. (From three independent clinical evaluations in Kenya, Uganda and Zimbabwe.)	TBD
Bias (source)	N/A	TBD
Intra-assay precision (source)	N/A	TBD
Inter-assay precision (source)	N/A	TBD
SAMPLE		
Sample preparation (steps)	Whole blood using a capillary based blood collection system.	
Sample type	Whole blood (capillary or venous).	
Sample volume	150µL sample input, assay requires 100µL	
Sample stability	4 - 30°C for up to 8 hours	
Nucleic acid extraction method	Semi-automated system with three manual interventions at the sample transfer step from SAMBAprep extraction system to the SAMBAamp amplification detection system.	Automated (sample in - result out system).

Continued overleaf

Product	SAMBA HIV-1 QUAL TEST	SAMBA II HIV-1 QUAL WHOLE BLOOD TEST
SAMPLE		
Time to result	~ 2 hours	
Capacity	4 samples per run (simultaneously)	1 sample per run
Batching?	Yes	Random access modular system: - Each display module can control up to 8 assay modules. - The phone module can control up to two assay modules for low throughput settings.
Throughput per end-user per hour and/or 8hr day	1 SAMBAprep + 1 SAMBAamp = 16 - 20 tests/day 1 SAMBAprep + 2 SAMBAamp = 28 - 32 tests/day 1 SAMBAprep + 3 SAMBAamp = 42 - 48 tests/day	4 runs/day/assay module (Number of assay modules can be increased to increase throughput).
INSTRUMENT		
Size of device	SAMBAprep: 68 x 65 x 51 cm SAMBAamp: 41 x 32 x 11 cm	Display module: 22 x 22 x 19 mm Assay module: 22 x 40 x 36 cm
Weight of device	SAMBAprep: 53 kg SAMBAamp: 3.8 kg	Display module: 2.1 kg Assay module: 9.9 kg
Robustness	Suitable for resource-limited settings.	
Environmental requirements	Temperature: 15 - 35ºC Relative humidity: 20 – 95%	Temperature: 10 - 40 ºC Relative humidity: ≤80% up to 31ºC, decreasing linearly to 50% RH at 40ºC
Power requirements	100 - 250 V, 50 - 60 Hz	
Time to battery charge	N/A	
Battery duration (hours)	N/A	
Alternative charging options	None	Can be charged via solar panel or car battery.
Ease of use	SAMBAprep: 4.3 inch back-lit LCD touch panel showing operational status, step by step instructions and any system errors. SAMBAamp: Two line alpha-numeric back-lit display screen which reports status, operator instructions and any errors, such as temperature.	1. The display module has a seven inch back-lit touch panel with alphanumeric display. 2. The results can be sorted by patient name, patient ID, date of test, assay type etc. 3. The display module reports system errors. 4. The assay module has a LED strip which indicates instrument status (white = machine available, green = in use and red = system error). 5. In-built printer in display module. 6. In-built camera for automated results recording.
Display languages	English	
Built-in memory storage capacity	None	100,000 test results can be stored by the display module.
Connectivity options	None	Display module includes a built-in ethernet port and USB port.
Interpretation of result	Visual results on a test-strip.	Automated camera read out with visual verification step.
Instrument lifespan	Expected: 3 years; ideal: 5 years.	TBD
Other non-proprietary equipment required	None	None
Regulatory approval	CE-marked. Pre-submission stage for WHO PQ.	CE-marked. Pre-submission stage for WHO PQ.
KIT		
Kit components	**SAMBA HIV-1 Qual Test Extraction kit (4001-24):** QB Cartridge 1 (4001A), QB Cartridge 2 (4001B), QB Cartridge 3 (4001C), Output Tube (4001D). **SAMBA HIV-1 Qual Test Amplification kit (4000-24):** SAMBAmp Cartridge (4000A), Reagent Tube (4000B), SAMBA Detection buffer (4000C).	QB II Cartridge 1 (4500A), QB II Cartridge 2 (4500B), QB II Cartridge 3 (4500C), QB II Cartridge 4 (4500D).
Kit sizes	24 tests/kit	12 tests/kit
Internal control(s)	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
Compatible with EQA and which?	CDC Proficiency testing panel, Rush University EQA panel, others to be determined.	
Mean time between failures	Proprietary	TBD
Transport and storage	2 - 37°C for long term storage -10 - 55°C shipping stability (for 1 month) No cold chain transport required	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	12 months	12 months (based on component stability study data, kit stability in progress).

Product	SAMBA HIV-1 QUAL TEST	SAMBA II HIV-1 QUAL WHOLE BLOOD TEST
KIT		
Performance protocol (steps)	(1) Sample collection (2) Insert sample and cartridges into SAMBAprep machine (3) Push start button (4) Upon completion of run, place tube containing extracted sample into SAMBAamp (5) Load SAMBAamp cartridge (6) Transfer extracted sample into reagent tube (7) Push start button (8) When beep sounds transfer sample to the SAMBAamp cartridge (9) Amplification cartridge at completion of ampfication step (beep will sound), rotate cartridge manually, plunge detection buffer (10) Read test results visually at end of detection	(1) Scan test kit on the display module (2) Scan patient tracking card on the display module (3) Load cartridges and sample on the machine (4) Press start (5) Verify and print results
Non-proprietary components required outside of the kit	Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab.	
Regulatory approval	ERPD Category 3, pre-submission stage for WHO PQ	CE-IVD for test kits planned for submission.
In-country approvals	Kenya, Uganda and Zimbabwe. Evaluation currently on-going in Nigeria and Malawi.	Kenya and Uganda (approved). Pending equivalency testing with SAMBA I, refer to other SAMBA I countries.
USAGE		
Technical skill required	Trained laboratory technician or laboratory assistant.	No laboratory skills required. Task shifting studies performed on SAMBA II system in Uganda and Zimbabwe have demonstrated that all levels of healthcare workers are able to run the assay proficiently and, upon completion of the training protocol, provide training to fellow workers. Healthcare levels participating in the study ranged from laboratory technologists, laboratory assistants, nurses, midwives, microscopists, nursing assistants and counsellors.
Applicable settings	Hospitals, clinics and large healthcare centres with electricity.	All levels of hospitals and healthcare setting with electricity or provision for solar power.
Laboratory set-up	None except for electricity.	None except for electricity or provision for solar power.
Waste disposal requirements	Sample tube to be disposed of in infectious waste. All other cartridges can be disposed of in laboratory waste.	

	HIV VIRAL LOAD	
Company	**Diagnostics for the Real World, Ltd**	
Product	**SAMBA HIV-1 SEMI Q TEST**	**SAMBA II HIV-1 SEMI Q PLASMA TEST**
ASSAY		
Intended use (as per regulatory approval)	In vitro nucleic acid-based amplification assay for the semi-quantitative detection of HIV-1. Intended for use as an aid in the monitoring of HIV-1 viral load in patients on antiretroviral therapy. Not intended to be used as a screening test nor as a diagnostic test for HIV-1.	
Principle of the assay	Performing the test is divided into two steps: sample preparation and sample testing (amplification/detection). The first step is the extraction of the target RNA using an automated sample preparation procedure in the SAMBAprep instrument. The procedure lyses the virus and releases the nucleic acid, which is then captured onto a silica membrane in a column. The column with the bound nucleic acid is then washed, followed by elution of the nucleic acid into the Output Tube. The Output Tube is then transferred into the SAMBAamp instrument for the amplification and detection steps. The SAMBAamp cartridge and Reagent Tube are placed into the SAMBAamp instrument. Detection buffer is added to the color-labeled anti-hapten sphere in the SAMBAamp cartridge. The sample is transferred from the Output Tube to the Reagent Tube, heated, and then transferred to the hermetically sealed SAMBAamp cartridge previously placed in the SAMBAamp instrument. The SAMBAamp cartridge contains all the reagents required to amplify HIV-1 nucleic acids in the SAMBAamp instrument. At the end of the amplification cycle, the Detection Buffer is added to the sample by depressing the plunger on the SAMBAamp cartridge and the amplified sample is then wicked up on the Test Strip by capillary action within the SAMBAamp cartridge, giving a visual readout of the result.	The test is a fully automated assay run on the SAMBA II instrument system consisting of the SAMBA II Assay Module, and a control unit – the SAMBA II Display Module or the SAMBA II Phone Module. Nucleic acid extraction, amplification of the nucleic acid target and the detection of the amplification products are performed in the SAMBA II Assay Module. The extraction phase of the assay involves the lysis to release nucleic acid into solution, which is then captured by a silica membrane column. The bound nucleic acid is washed and eluted from the membrane and the HIV target sequence is amplified in the sealed SAMBA II SQ Cartridge 1. After amplification, a coloured-labeled anti-hapten detection solution is mixed with the amplification product and the mixture is wicked in a Test Strip. The test result (i.e. bluish to purple lines on the Control Line and/or Test Line) is captured by a built-in camera, which is recorded and can be read on the Display Module or the Phone Module. Results are stored and may be printed from the Display Module. The SAMBA II Phone Module does not have the print function but results can be recorded manually following routine laboratory procedures.

Continued overleaf ⋰

Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI Q PLASMA TEST
ASSAY		
Target	HIV-1 RNA	
Genotypes and/ or subtypes	Group M (A, B, C, D, CRF01_AE, F, G), Group N, Group O and a variety of recombinants including: CRF02_AG, CRF06_cpx, CRF11_cpx, CRF13_cpx, A/AE, D/A and D/F. (Assessed using the 1st WHO International HIV-1 RNA Genotype Panel, Rush University Genotype panels and subtyped clinical samples consisting of samples representing various subtypes and or groups.)	
Type of result	Semi-Quantitative (>/< 1,000 ± 0.3 log copies/mL).	
Linear range	N/A. Cut-off at 1,000 copies/mL (± 0.3 log assay variation).	
Output	Viral load >/< 1,000 ± 0.3 log copies/mL.	
DNA or RNA specific?	RNA	
Polyvalency	Only HIV test portfolio.	Development stage: SAMBA II CT/NG Duplex test, SAMBA II Flu A/B Duplex test.
PERFORMANCE		
Sensitivity - analytical and clinical (source)	Overall concordance: 98%, 94.8%, 95.9%, 96.4% (In independent clinical evaluations performed in Malawi, Uganda, Kenya and Zimbabwe, respectively.)	TBD
Specificity - analytical and clinical (source)	Invalid rate of 0.52% (Data from 6 MSF sites where the test has been used for the monitoring of 19,003 patients on ART.)	TBD
Bias (source)	N/A	TBD
Intra-assay precision (source)	N/A	TBD
Inter-assay precision (source)	N/A	TBD
SAMPLE		
Sample preparation (steps)	As per vendor instructions (laboratory and vendor specific).	
Sample type	Plasma	
Sample volume	300µL sample input, assay requires 200µL	
Sample stability	15 - 30°C for up to 12 hours or 2 - 8°C for up to 5 days	
Nucleic acid extraction method	Semi-automated system with three manual interventions at the sample transfer step from SAMBAprep extraction system to the SAMBAamp amplification detection system.	Automated (sample in - result out system).
Time to result	~ 90 mins	
Capacity	4 samples per run (simultaneously)	1 sample per run
Batching?	Yes	Random access modular system: - Each display module can control up to 8 assay modules. - The phone module can control up to two assay modules for low throughput settings.
Throughput per end-user per hour and/or 8hr day	1 SAMBAprep + 1 SAMBAamp = 24 - 28 tests/day 1 SAMBAprep + 2 SAMBAamp = 32 - 36 tests/day 1 SAMBAprep + 3 SAMBAamp = 48 - 54 tests/day	5 runs/day/assay module (Number of assay modules can be increased to increase throughput).
INSTRUMENT		
Size of device	SAMBAprep: 68 x 65 x 51 cm SAMBAamp: 41 x 32 x 11 cm	Display module: 22 x 22 x 19 mm Assay module: 22 x 40 x 36 cm
Weight of device	SAMBAprep: 53 kg SAMBAamp: 3.8 kg	Display module: 2.1 kg Assay module: 9.9 kg
Robustness	Suitable for resource-limited settings.	
Environmental requirements	Temperature: 15 - 35ºC Relative humidity: 20 – 95%	Temperature: 10 - 40 ºC Relative humidity: ≤80% up to 31ºC, decreasing linearly to 50% RH at 40ºC
Power requirements	100 - 250 V, 50 - 60 Hz	
Time to battery charge	N/A	
Battery duration (hours)	N/A	
Alternative charging options	None	Can be charged via solar panel or car battery.
Ease of use	SAMBAprep: 4.3 inch back-lit LCD touch panel showing operational status, step by step instructions and any system errors. SAMBAamp: Two line alpha-numeric back-lit display screen which reports status, operator instructions and any errors, such as temperature.	1. The display module has a seven inch back-lit touch panel with alphanumeric display. 2. The results can be sorted by patient name, patient ID, date of test, assay type etc. 3. The display module reports system errors. 4. The assay module has a LED strip which indicates instrument status (white = machine available, green = in use and red = system error). 5. In-built printer in display module. 6. In-built camera for automated results recording.

Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI Q PLASMA TEST
INSTRUMENT		
Display languages	English	
Built-in memory storage capacity	None	100,000 test results can be stored by the display module.
Connectivity options	None	Display module includes a built-in ethernet port and USB port.
Interpretation of result	Visual results on a test-strip.	Automated camera read out with visual verification step.
Instrument lifespan	Expected: 3 years; ideal: 5 years.	TBD
Other non-proprietary equipment required	Centrifuge to process plasma.	
Regulatory approval	CE-marked. Pre-submission stage for WHO PQ.	CE-marked. Pre-submission stage for WHO PQ.
KIT		
Kit components	SAMBAamp Cartridge (4000A), Reagent Sphere (4000B), SAMBA Detection Buffer (4000C), Semi-Q Cartridge 1 (4000E), Semi-Q Cartridge 2 (4000F), Semi-Q Cartridge 3 (4000G), Output Tube (4000H).	SQ Cartridge 1 (4400A), SQ Cartridge 2 (4400B), SQ Cartridge 3 (4400C), SQ Cartridge 4 (4400D).
Kit sizes	12 tests/kit	
Internal control(s)	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
Compatible with EQA and which?	CDC Proficiency testing panel, Rush University EQA panel, others to be determined.	
Mean time between failures	Proprietary	TBD
Transport and storage	2 - 37°C for long term storage -10 - 55°C shipping stability (for 1 month) No cold chain transport required	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	12 months	12 months (based on component stability study data, kit stability in progress).
Performance protocol (steps)	(1) Sample collection (2) Insert sample and cartridges into SAMBAprep machine (3) Push start button (4) Upon completion of run, place tube containing extracted sample into SAMBAamp (5) Load SAMBAamp cartridge (6) Transfer extracted sample into reagent tube (7) Push start button (8) When beep sounds transfer sample to the SAMBAamp cartridge (9) Amplification cartridge at completion of ampfication step (beep will sound), rotate cartridge manually, plunge detection buffer (10) Read test results visually at end of detection	(1) Scan test kit on the display module (2) Scan patient tracking card on the display module (3) Load cartridges and sample on the machine (4) Press start (5) Verify and print results
Non-proprietary components required outside of the kit	Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab.	Sample collection sytem for venipuncture used on-site.
Regulatory approval	ERPD Category 3. Dossier submitted to WHO PQ.	CE-IVD for test kits planned for submission. Pre-submission stage to WHO PQ.
In-country approvals	Kenya, Malawi, Uganda and Zimbabwe. Evaluation currently on-going in Nigeria.	Uganda (approved). Pending equivalency testing with SAMBA I, refer to other SAMBA I countries.
USAGE		
Technical skill required	Skilled laboratory technician or laboratory assistant.	No laboratory skills required. Task shifting studies performed on SAMBA II system in Uganda and Zimbabwe have demonstrated that all levels of healthcare workers are able to run the assay proficiently and, upon completion of the training protocol, provide training to fellow workers. Healthcare levels participating in the study ranged from laboratory technologists, laboratory assistants, nurses, midwives, microscopists, nursing assistants and counsellors.
Applicable settings	Hospitals, clinics and large healthcare centres with electricity.	All levels of hospitals and healthcare setting with electricity or provision for solar power.
Laboratory set-up	None except for electricity.	None except for electricity or provision for solar power.
Waste disposal requirements	Sample tube to be disposed of in infectious waste. All other cartridges can be disposed of in laboratory waste.	

Continued overleaf ⋰

02 | PRICING

SAMBA HIV-1 EARLY INFANT DIAGNOSIS AND VIRAL LOAD						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
SAMBAprep	Sample preparation			**SAMBA HIV-1 Qual Test**		
SAMBAamp	Sample amplification and detection			*SAMBA HIV-1 Qual Test Extraction kit*	List No. 4001-24	
				- QB Cartridge 1	List No. 4001A	
				- QB Cartridge 2	List No. 4001B	
				- QB Cartridge 3	List No. 4001C	
				- Output Tube	List No. 4001D	
				SAMBA HIV-1 Qual Test Amplification kit	List No. 4000-24	
				- SAMBAmp Cartridge	List No. 4000A	
				- Reagent Tube	List No. 4000B	
				- SAMBA Detection buffer	List No. 4000C	
				SAMBA HIV-1 Semi Q Test		
				- SAMBAamp Cartridge	4000A	
				- Reagent Sphere	4000B	
				- SAMBA Detection Buffer	4000C	
				- Semi-Q Cartridge 1	4000E	
				- Semi-Q Cartridge 2	4000F	
				- Semi-Q Cartridge 3	4000G	
				- Output Tube	4000H	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
None				Centrifuge if plasma is used		
				Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab		
				Or sample collection system for venipuncture		
Cost per device			**$37,000***	**Cost per test result**		**$17- 23****

SAMBA II HIV-1 EARLY INFANT DIAGNOSIS AND VIRAL LOAD						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
SAMBA II Assay Module				**SAMBA II HIV-1 Qual Whole Blood Test**		
SAMBA II Display Module				- QB II Cartridge	4500A	
or SAMBA II Phone Module				- QB II Cartridge 2	4500B	
				- QB II Cartridge 3	4500C	
				- QB II Cartridge 4	4500D	
				SAMBA II HIV-1 Semi Q Plasma Test		
				- SQ Cartridge 1	4400A	
				- SQ Cartridge 2	4400B	
				- SQ Cartridge 3	4400C	
				- SQ Cartridge 4	4400D	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
None				Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab		
				Or sample collection sytem for venipuncture		
Cost per device			**$25,000 - 30,000***	**Cost per test result**		**$20-28****

***At cumulative volume >200 instruments.**
**** At cumulative volume >500,000 tests.**

03 | TIERED AND VOLUME-BASED PRICING | No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	TBD	
Installation	Provided	Included in the price
Training	Training takes 4-6 hours	Can be provided free of charge at the time of installation
Maintenance	No routine maintanance required	
Length(s) of warranty and additional costs for extended warranty / care plan	1 year under warranty covered by DRW, year 2 and 3 under extended warranty	
Warranty components	Available upon request	
Turnkey option	N/A	
in-country / regional technical support availability	Available upon request	

05 | CONTACT INFO

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SAMBA

SAMBA II

POINT-OF-CARE HIV VL & HCV VL
MOLBIO DIAGNOSTICS

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Molbio Diagnostics Pvt. Ltd.**	
Product	**TRUELAB/TRUENAT HIV**	**TRUELAB/TRUENAT HCV**
ASSAY		
Intended use (as per regulatory approval)	Early infant diagnosis / viral load estimation / HIV treatment monitoring	Viral load estimation / HCV treatment monitoring
Principle of the assay	Real-time reverse transcription PCR	
Target	pol gene	5' UTR
Genotypes and/or subtypes	HIV-1	All genotypes and subtypes
Type of result	Quantitative	
Linear range	Not provided	
Output	IU/mL	
DNA or RNA specific?	DNA and RNA	RNA
Polyvalency	Existing: malaria pf, M. tuberculosis, MTB-RIF, Dengue, Chikungunya, H1N1, HBV. Pipeline: salmonella, HIV viral load, HCV viral load, HPV (cervical cancer), chlamydia, gonorrhea, trichomonas.	
PERFORMANCE		
Sensitivity - analytical and clinical (source)	TBD	
Specificity - analytical and clinical (source)	>99%	
Bias (source)	TBD	
Intra-assay precision (source)	TBD	
Inter-assay precision (source)	TBD	
SAMPLE		
Sample preparation	A few pipetting steps involved.	
Sample type	Whole Blood for EID. Plasma for viral load.	Whole blood or plasma.
Sample volume	100µL	
Sample stability	Not provided	
Nucleic acid extraction method	Semi-automated. An automated version will be available soon.	
Time to result	1 hour	
Capacity	1 sample per run. A 4 sample per run version will be available soon.	
Batching?	No	
Throughput per end-user per hour and/or 8hr day	12 samples / 8hr day (45 samples/8hr day with 4 sample version).	

Product	TRUENAT HIV	TRUENAT HCV
INSTRUMENT		
Size of device	Sample prep device: 210 x 155 x 109 mm MicroPCR device: 210 x 140 x 109 mm	
Weight of device	Sample prep device: 1.6 kg MicroPCR device: 0.9 kg	
Robustness	Rugged, for field use.	
Environmental requirements	Temperature: ≤40°C Relative humidity: ≤80%	
Power requirements	Rechargeable Lithium Ion Battery Pack. Input to AC/DC adaptor: Single Phase 100 – 240V; 50/60Hz; 1500 mA	
Time to battery charge	4 hours	
Battery duration (hours)	8 hours	
Alternative charging options	None	
Ease of use	Very user friendly. All data entry though touch screen. Result available on touch screen, can be printed with Bluetooth printer provided.	
Display languages	English	
Built-in memory storage capacity	5,000 tests	
Connectivity options	Wi-Fi / GPRS / Bluetooth	
Interpretation of result	None	
Instrument lifespan	Minimum 5 years	
Other non-proprietary equipment required	None	
Regulatory approval	No, product not yet market launched.	
KIT		
Kit components	Proprietary buffers for sample preparation, disease specific microPCR chips, fixed volume pipettes and filter barrier tips.	
Kit sizes	Packaged for 5 and 20 tests	
Internal control(s)	Full process internal control	
Compatible with EQA and which?	Not provided	
Mean time between failures	Not provided	
Transport and storage	Kit is stable at ≤40°C for 1 month and ≤30°C for one year.	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	1 year at room temperature	
Performance protocol	Sample is processed using semi-automated device through repeated pipetting steps and extracted nucleic acids are used to perform fully automated PCR on a chip	
Non-proprietary components required outside of the kit	None	
Regulatory approval	No, product not yet market launched.	
In-country approvals	No, product not yet market launched.	
USAGE		
Technical skill required	Minimally skilled operator.	
Applicable settings	All settings including in the field.	
Laboratory set-up	Any laboratory.	
Waste disposal requirements	Waste to be decontaminated with bleach and disposed as per local regulations and guidelines for medical waste.	

Continued overleaf

Point-of-Care HIV VL & HCV VL – Molbio Diagnostics continued

02 | PRICING

HIV VIRAL LOAD AND HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Truelab Real Time micro PCR Workstation	Truelab Real Time micro PCR Analyser	603010001	$9,000	Truenat HIV	Chip-based Real Time PCR test for HIV	N/A (not yet available)	$14
	Trueprep Mag Sample prep Kit			Truenat HCV	Chip-based Real Time PCR test for HCV		$14
	Truelab Real Time micro PCR Printer			Trueprep Mag Blood kit	Sample prep kit		$1
	Truepet micropipettes						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				Centrifuge if plasma is used			
				Blood collection kit for capillary blood sample			
				Or sample collection sytem for venipuncture			
Cost per device			**$9,000**	**Cost per test result**			**$15**

03 | TIERED AND VOLUME-BASED PRICING

HIV VIRAL LOAD AND HCV VIRAL LOAD

Instrument		**Test kit**	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
10	$80,000	1,000	$14,000

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Not provided.
Installation	No information provided.
Training	No information provided.
Maintenance	Yes
Length(s) of warranty and additional costs for extended warranty / care plan	One year
Warranty components	No information provided.
Turnkey option	Not provided.
in-country / regional technical support availability	Will be provided.

05 | CONTACT INFO

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POINT-OF-CARE HIV EID & HIV VL
NORTHWESTERN GLOBAL HEALTH FOUNDATION / QUIDEL

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD 200µl	HIV VIRAL LOAD 50µl
Company	**Northwestern Global Health Foundation**	**Quidel / Northwestern Global Health Foundation**	
Product	**LYNX HIV P24 ANTIGEN TEST**	**SAVANNA QUANTITATIVE REALTIME HIV-1 ASSAY**	
ASSAY			
Intended use (as per regulatory approval)	Birth to 18 months but no evalutions have taken place in infants less than 4 weeks (these studies are planned).	Aid in assessing viral response to antiretroviral treatment as measured by changes in HIV-1 RNA levels to (i) identify virological failure; (ii) enable clinicians to provide adherence counseling or (iii) switch failing patients to new drug regimens.	
Principle of the assay	Qualitative p24 antigen based immunochromatographic assay.	An in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of HIV-1.	
Target	p24 antigen	HIV-1	
Genotypes and/ or subtypes	HIV-1 (expected to be all subtypes, but still in the process of verifiying).	HIV-1 (all subtypes)	
Type of result	Qualitative	Quantitative	
Linear range	N/A	200 - 1,000,000 copies/mL	1,000 - 1,000,000 copies/mL
Output	Control line and/or test line	Copies/mL of HIV-1 in plasma	
DNA or RNA specific?	Neither, p24 antigen.	RNA	
Polyvalency	None.	TB and Rif resistance tests under development.	
PERFORMANCE			
Sensitivity - analytical and clinical (source)	TBD pending external/independent evaluations.		
Specificity - analytical and clinical (source)			
Bias (source)			
Intra-assay precision (source)			
Inter-assay precision (source)			
SAMPLE			
Sample preparation (steps)	(1) Heel prick (capillary/gravity-based collection device) (2) Dispense blood to LYNX plasma separator; wait 10 minutes (3) Plunge Plasma Collection Pad into the Reaction Tube (4) Separate the Reaction Tube from the LYNX plasma separator	(1) Prepare plasma (2) Dispense 200µL of plasma directly into the cartridge	(1) Collect 165µL whole blood (via finger stick) using plasma separator provided in the kit (2) Place the plasma separator into Minifuge for 2-3 minutes (3) Remove plasma separator from device and attach to assay cartridge
Sample type	Capillary whole blood.	Plasma	
Sample volume	80µL	200µL	165µL of whole blood collected in plasma separator yielding 50µl of plasma.
Sample stability	TBD		
Nucleic acid extraction method	N/A	Fully automated.	
Time to result	51 minutes	60 minutes	
Capacity	Instrument will accommodate 1 test at a time.	The instrument is random access and will accommodate 2 tests.	
Batching?	No	Random access	
Throughput per end-user per hour and/or 8hr day	11-12 tests per 8 hr day.	14 tests per Instrument per 8 hr day.	

Continued overleaf

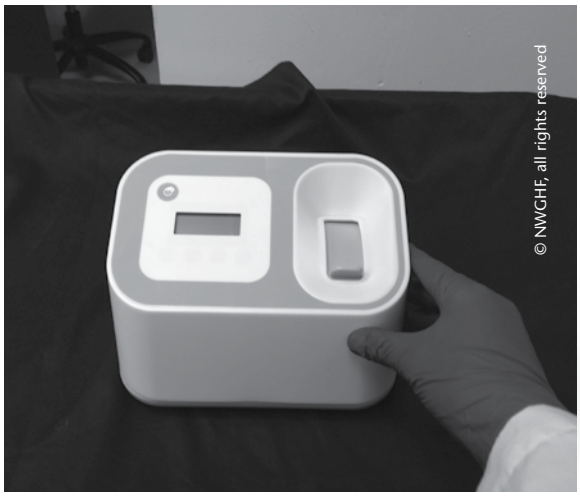
Product	LYNX HIV P24 ANTIGEN TEST	SAVANNA QUANTITATIVE REALTIME HIV-1 ASSAY	
INSTRUMENT			
Size of device	20.2 x 15.6 x 13.4 cm	W 24 x H 59 x D 62 cm	
Weight of device	1.7 kg	TBD	
Robustness	Completely enclosed for operation in dusty environments. Comply with EN 60529.		
Environmental requirements	15 - 35°C	15°C - 40°C	
Power requirements	Powered by AC mains or 12V DC with internal rechargeable Li-ion battery.	Powered by AC or DC mains with external battery backup.	
Time to battery charge	<1 hour	TBD	
Battery duration (hours)	The platform has a built-in rechargeable battery that lasts up to 8 hours.	Standard: External battery shall complete the cartridges in the instrument. Optional: Expanded external battery capacity.	
Alternative charging options	No	TBD	
Ease of use	LYNX has a small screen with a timer which counts down from 11 to 0 (heating step) and from 30 to 0 (strip development step).	Fully functional and integrated touch screen with no external computer required.	
Display languages	N/A (none displayed)	1. English; 2. French; 3. Spanish; 4. Portuguese	
Built-in memory storage capacity	None	Yes	
Connectivity options	Optional reader with connectivity.	Internal modem or wired data connection. Data can be sent via cellular, data cable or USB.	
Interpretation of result	Visually read or interpreted with optional reader.	Standard: Quantitative results based upon copies/mL of plasma or CTs or International Units. Optional: Qualitative copies/mL of plasma based upon a user-defined cutoff.	
Instrument lifespan	TBD		
Other non-proprietary equipment required	No	Centrifuge	No
Regulatory approval	Expect to get: - ISO 13485 in 2015 - CDC approval and GF ERPD by 2016 - WHO PQ approval by 2017	- Quidel has ISO 13485 Certification - Expect to get WHO PQ approval by 2017	
KIT			
Kit components	TBD	Cartridge	Lancet, plasma separator, cartridge.
Kit sizes	10	Multiple	
Internal control(s)	Yes, control line on strip test.	Internal controls will verify proper conditions and assay performance for amplification.	
Compatible with EQA and which?	TBD	Cartridge is combatible with Virology Quality Assurance (VQA) and UK National External Quality Assessment Service (NEQAS).	
Mean time between failures	TBD	Target: 10,000 tests per module.	
Transport and storage	No cold chain or humidity control is required for shipping and transport.		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	Target: 12-18 months at temperatures up to 30 - 40°C and humidity up to 70 - 90%.		
Performance protocol (steps)	(1) Add LYNX buffer into reaction tube and place the reaction tube in the LYNX platform (2) The LYNX will heat the sample (11 minutes) (3) Insert the LYNX test strip (30 minutes) (4) Read the result	(1) Scan assay cartridge on Savanna (2) Scan or enter patient/sample data on Savanna (3) Load cartridge on Savanna (4) Read results on Savanna	
Non-proprietary components required outside of the kit	Phlebotomy consumables (gloves, lancet, alcohol swab, gauze pad).	Phlebotomy consumables (gloves, lancet if finger/needle plus EDTA Vacutainer, alcohol swab, gauze pad).	
Regulatory approval	Expect to get: - ISO 13485 in 2015 - CDC approval and GF ERPD by 2016 - WHO PQ approval by 2017	- Quidel has ISO 13485 Certification - Expect to get WHO PQ approval by 2017	
In-country approvals	None		
USAGE			
Technical skill required	All staff levels, but feasibility studies are still being done to assess this.		
Applicable settings	For use in sites that perform dried blood spot (DBS) collection or local laboratories.	ART clinics, clinics, hospitals.	
Laboratory set-up	No laboratory required.	Centrifuge required to separate whole blood into plasma.	No laboratory required.
Waste disposal requirements	Standard biohazardous waste disposal.		

02 | PRICING

EARLY INFANT DIAGNOSIS							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
LYNX HIV p24 Antigen Test Processor			$1,000 - 2,000	LYNX HIV p24 Antigen Test	10 tests per kit		$65 - 150
				Blood collection tube (12)			
				LYNX plasma separator (10)			
				LYNX buffer (10)			
				LYNX test strip (10)			
				Package Insert (1)			
				Gloves (20)			
				Lancet (10)			
				Alcohol swab (10)			
				Gauze (10)			
Instrument Accessories	**Reference number**		**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Battery and AC adapter			Included	None			
Cellular modem			$200				
Cost per device			**$1,000 - 2,000**	**Cost per test result**			**$6.50 - 15**

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Savanna Quantitative RealTime HIV-1 assay Device			~$12,000	HIV Viral Load			~$11
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Centrifuge if plasma is used				Phlebotomy consumables (gloves, lancet if fingerprick / needle plus EDTA Vacutainer, alcohol swab, gauze pad).			
Minifuge if capillary blood is used							
Cost per device			**~$10,000**	**Cost per test result**			**~$11**

LYNX



Savanna

Continued overleaf

03 | TIERED AND VOLUME-BASED PRICING

EARLY INFANT DIAGNOSIS (LYNX)

Instrument		Test kit	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
100	$900	25,000	$15
250	$800	50,000	$10
1,000	$700	100,000	$9
		500,000	$6.50

HIV VIRAL LOAD (SAVANNA)

Tiered pricing based on volume TBD.

04 | MAINTENANCE, WARRANTY & TRAINING

	EARLY INFANT DIAGNOSIS		HIV VIRAL LOAD
	Description	**Cost (US$)**	**Description**
Leasing or reagent rental (RAP)	Leasing, capital purchase and reagent rental options anticipated.		Leasing, capital purchase and reagent rental options anticipated.
Installation	None required.	N/A	None required.
Training	- NWGHF recommends the train-the-trainer model whereby several 'super-users' are selected by the customer to perform further training in the field. - Training materials will be provided by NWGHF for these purposes.	$1,000 per training	TBD
Maintenance	None required. Instrument swap during warranty rather than performing on-site service and maintenance.	N/A	TBD
Length(s) of warranty and additional costs for extended warranty / care plan	1-2 years; with instrument swap if processor breaks down within the year.		1-2 years
Warranty components	Local distributor for instrument swap.		Local distributor for instrument swap.
Turnkey option	Total installation package (containing necessary instruments, training, installation and maintenance, as appropriate) is anticipated to be offered.		Total installation package (containing necessary instruments, training, installation and maintenance, as appropriate) is anticipated to be offered.
In-country / regional technical support availability	Via local distributors.		Via local distributors.

05 | CONTACT INFO

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LAB-BASED HCV CORE ANTIGEN
ABBOTT (ARCHITECT)

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ABBOTT	Product	ARCHITECT HCV AG
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Quantitative determination of HCV core antigen.	**Sample preparation (steps)**	(1) Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. (2) To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at 3000 x g for 10 minutes before testing if: • they contain fibrin, red blood cells, or other particulate matter, • they require repeat testing, or • they were frozen and thawed. (3) Transfer clarified specimen to a sample cup or secondary tube for testing. (4) Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
Principle of the assay	Two-step immunoassay using Chemiluminescent Microparticle Immunoassay (CMIA) technology (with flexible assay protocols, referred to as Chemiflex)		
Type of result	Quantitative		
Linear range	0.00 - 20,000.00		
Output	Result concentration units: fmol/L A 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method is used to generate a calibration curve Interpretation of Results: • Specimens with concentration values <3.00 fmol/L are considered nonreactive for HCV Ag • Specimens with concentration values ≥3.00 fmol/L are considered reactive for HCV Ag • Specimens with concentration values ≥3.00 fmol/L to <10.00 fmol/L should be retested in duplicate	**Sample type**	Human serum (including serum collected in serum separator tubes), human plasma (collected in Sodium EDTA, Potassium EDTA, Lithium Heparin, Sodium Heparin, Sodium Citrate, or CPD).
Polyvalency	ARCHITECT anti-HCV among others: https://www.abbottdiagnostics.com/en-us/products/ARCHITECT-i2000SR.html#test-menu	**Sample volume**	The minimum sample volume for a single test is 158µL Each Additional Test requires 108µL
PERFORMANCE		**Sample stability**	Specimens may be stored on or off the clot, red blood cells, or separator gel for up to 5 days, refrigerated at 2-8°C. • If testing will be delayed more than 5 days, remove serum or plasma from the clot, red blood cells, or separator gel and store frozen at -20°C or colder. • Avoid more than two freeze/thaw cycles. • Specimens may be shipped at 2-8°C (wet ice), or -20°C or colder (dry ice).
Sensitivity (source)	≤3.00 fmol/L [A total of 452 serum and plasma specimens known to be positive for HCV RNA including genotypes 1a, 1b, 2a, 2b, 3a, 3k, 4a, 5a, 6a, and 6i, were tested. Of the 452 specimens, 97.8% (442/452) were reactive. Seroconversion: sensitivity was evaluated utilizing 10 commercially available panels of sequential specimens from patients who seroconverted for the detection of anti-HCV antibodies. In each panel, a positive result was obtained prior to detection of anti-HCV antibody, resulting in an average reduction between the times of infection and detection of 35.8 days. (package insert)]	**Time to result**	Time to the 1st result: 36 minutes
		Capacity	100 tests/hour
		Batching	Yes
		Throughput	100 tests/hour
Specificity (source)	≥99.5% [In a study where specimens from a blood donor population, hospitalized patients and specimens containing potentially interfering substances were tested. This study includes the specimens from individuals with medical conditions unrelated to HCV infection. A total of 5027 serum and plasma specimens from blood donors were evaluated. (package insert)]	**INSTRUMENT**	
		Size of device	i1000SR: 125.1 H x 149.9 W x 76.2cm D i2000SR: 121.9 H x 154.9 W x 124.5cm D
		Weight of device	i1000SR: 288kg i2000SR: 490.3kg
		Environmental requirements	Water requirements: Type II or better, to dilute buffer concentrate
Intra-assay precision (source)	<10% total CV (package insert)	**Power requirements**	i1000: AC 110-240V ±10%, 47-63 Hz i2000: AC 180-264V, 47-63 Hz
		Regulatory approval	CE Marked, available in 150+ countries

Continued overleaf

Lab-based HCV Core Antigen – Abbott (Architect) continued

Company	ABBOTT	Product	ARCHITECT HCV AG
KIT		**KIT**	
Kit components	Reagents: 6L47 (Microparticles, Conjugate, Assay specific diluent, Pre-treatment reagent 1 and 2, Specimen diluent) Controls: 6L47-10, -11 Calibrators: 6L47-01, -02 Assay CD-ROM: 8K30	**Non-proprietary components required outside of the kit**	Materials required but not provided outside the 6L47 HCV Ag Reagent kit: • ARCHITECT i System • ARCHITECT i System e-Assay CD-ROM (found on www.abbottdiagnostics.com) • 6L47-02 ARCHITECT HCV Ag Calibrators • 6L47-11 ARCHITECT HCV Ag Controls • ARCHITECT i Pre-trigger solutions, trigger solutions, Wash buffer, Reaction vessels, sample cups, septum, replacement cups • Pipettes or pipette tips (optional)
Kit sizes	100 tests		
Internal control(s)	3 Bottles (8 mL each) of ARCHITECT HCV Ag Controls (Negative, Positive 1 and 2)	**Regulatory approval**	CE Marked
Transport and storage	The ARCHITECT HCV Ag Reagent Kit is shipped on dry ice and must be stored at 2-8°C in an upright position after receipt. • When stored and handled as directed, reagents are stable until the expiration date. • The ARCHITECT HCV Ag Reagent Kit may be stored on board the ARCHITECT i System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5. • Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position.	**In-country approvals**	Available in all countries that accept a CE-mark and in countries that require registration (approx. 60 countries, excluding the USA and China)
		USAGE	
		Technical skill required	Medium to highly trained lab personel
		Applicable settings	From low- to highly-resourced settings
		Laboratory set-up	Two dedicated areas are recommended: Sample Preparation Area and Instruments Run Area
Refridgeration at -80°C required?	No		
Shelf life (of each item in the kit)	Shelf life upon manufacture: 12 months	**Waste disposal requirements**	According to the regulations of each country
Performance protocol (steps)	2		

02 | PRICING

Instrument		Reference number	FCA ($)
Abbott ARCHITECT i2000SR	Immunoassay Analyser	03M74-02	
Abbott ARCHITECT i2000SR	Stand Alone Base RSH Kit (60 carriers, 8 RSH trays), Two-toned color	02J47-12	

Cartridge/reagents		Reference number	FCA ($)
ARCHITECT HCV Ag Reagent Kit	100 tests/kit	6L47	
ARCHITECT HCV Ag Calibrators	Calibrators A-F (6 x 4mL)	6L47-02	
ARCHITECT HCV Ag Controls	Negative (1 x 8mL) Control 1 (1 x 8mL) Control 2 (1 x 8mL)	6L47-11	

Instrument Accessories		Reference number	FCA ($)
ARCHITECT i Pre-Trigger Solution	4 x 975 mL	06E23-65	
ARCHITECT i Trigger Solution	4 x 975 mL	06C55-60	
ARCHITECT i Wash Buffer	4 x 975 mL	06C54-58	
ARCHITECT i Wash Buffer (for use with ARCHITECT iARM (Automated Reconstitution Module))	1 x 9.75 L	06C54-88	
ARCHITECT i Reaction Vessels	2000/box 4000/box	07C15-01 07C15-02	
ARCHITECT i Sample Cups	1000/box	07C14-01	
ARCHITECT i Septum	200/box	04D18	
ARCHITECT i Replacement Caps	100/box	04D19-01	

Non-proprietary equipment and consumables		Reference number	FCA ($)
Pipettes			
Pipette tips			

Cost per instrument	Not provided	Cost per test result	$25 - $50
		Cost per person (test result plus instrumentation and other materials)	$200

03 | TIERED AND VOLUME-BASED PRICING

Volume based pricing is determined at a local level. Please contact the local Abbott Representative for additional details.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Installation	Provided: installation performed by Abbott service engineer or distributor service engineer certified by Abbott following internal SOP. Prior to installation the Abbott field service representative ensures the site is prepared. The location must meet environmental specifications and electrical requirements before the system can be installed.
Training	Comprehensive Integration: • Validation Expertise, • Certified Training. Training can be done on customer sites or in ADD Commercial Trainings centres. If you have any questions regarding your ARCHITECT System, please contact the local representative or find country-specific contact information on www.abbottdiagnostics.com.
Maintenance (including instrument swap)	Proper maintenance of the ARCHITECT System is important. These suggestions, which are especially useful for integrated and multi-module systems, are provided to help determine efficient strategies for performing maintenance procedures and reducing downtime. When scheduling and performing maintenance procedures: • Schedule maintenance procedures during times of slower workflow. • Verify adequate supplies are on board the system, or available to load, prior to initiating a maintenance procedure. • Perform procedures within the weekly, monthly, and quarterly maintenance categories on different shifts or days. To avoid having these procedures scheduled for the same day, perform some of them early to stagger the schedule.
Length(s) of warranty and additional costs for extended warranty / care plan	Generally a warranty is provided, depending on the country and contract details
Turnkey option	No
in-country / regional technical support availability	Yes, please contact the local representative or find country-specific contact information on www.abbottdiagnostics.com. Remote Diagnostics: AbbottLink system

05 | CONTACT INFO

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LAB-BASED HIV EID, HIV VL, HCV VL, HCV GT
ABBOTT (REALTIME)

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPING
Company	**Abbott**			
Product	**ABBOTT REALTIME HIV-1 QUALITATIVE**	**ABBOTT REALTIME HIV-1**	**ABBOTT REALTIME HCV**	**ABBOTT REALTIME HCV GENOTYPE II**
ASSAY				
Intended use	Qualitative detection of HIV-1 nucleic acids. Intended to be used as an aid in the diagnosis of HIV-1 infection in pediatric and adult subjects. Not intended to be used as a donor screening test for HIV-1.	Quantitation of HIV-1. Intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels. This assay is not intended to be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.	Quantitation of HCV RNA. Intended for use as an aid in the management of HCV-infected patients undergoing antiviral therapy. This assay is not intended to be used for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection.	Intended for determining the genotype(s) of HCV. Not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection in donated blood, plasma, serum or tissue.
Principle of the assay	Real time PCR for the in vitro amplification of HIV-1 nucleic acids.	Real time RT-PCR for the in vitro quantitation of HIV-1.	Real time PCR for the in vitro quantitation of HCV.	Real time PCR for the genotyping of HCV.
Target	HIV-1 RNA polymerase	HIV-1 RNA polymerase	5' UTR of HCV genome	5' UTR for GT 1-6, NS5b for subtypes 1a, 1b
Genotypes and/ or subtypes	Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G and H), Group O and Group N.	Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H), Group O, and Group N. In addition publications are available regarding the detection of other subtypes and group P (Plantier J.C. et al., published online at http://www.nature.com/naturemedicine).	Genotypes 1-6	Genotypes 1, 1a, 1b, and 2 - 6
Type of result	Qualitative	Quantitative	Quantitative	Qualitative
Linear range	N/A	40-10,000,000 copies/mL	12 IU/mL (1.08 log IU/mL) to 100 million IU/mL (8.0 log IU/mL)	N/A
Output	"HIV-1 Detected" or "Not Detected".	Results can be reported in copies/mL, log [copies/mL], IU/mL or log [IU/mL]	Results can be reported in IU/mL or log IU/mL	Qualitative result
DNA or RNA specific?	TNA extraction	RNA selective extraction	RNA	RNA
Polyvalency	HIV-1 viral load, HCV, HCV GT, HBV, HPV, CT/NG, CMV, MTB detection; MTB RIF/INH Resistance			
PERFORMANCE				
Sensitivity - analytical and clinical (source)	LOD: 110 copies/mL in plasma and 2,500 copies/mL in whole blood using the DBS procedure (package insert)	LOD: 40 copies/mL for 1.0mL sample volume 40 copies/mL for 0.6mL sample volume 75 copies/mL for 0.5mL sample volume 150 copies/mL for 0.2mL sample volume (package insert)	LOD: 12 IU/mL for 0.5mL sample volume 30 IU/mL for 0.2mL sample volume (package insert)	LOD: 500 IU/mL (package insert)

Product	ABBOTT REALTIME HIV-1 QUALITATIVE	ABBOTT REALTIME HIV-1	ABBOTT REALTIME HCV	ABBOTT REALTIME HCV GENOTYPE II
Specificity - analytical and clinical (source)	HIV-1 was not detected for 550/550 seronegative samples in both specimen types, resulting in 100% specificity (95% CI 99.33 – 100.00%) for both the plasma and DBS assay procedures in a representative study (package insert).	HIV-1 RNA was not detected for 187/187, resulting in 100% specificity (95% CI 98.05 - 100.00) in a representative study (package insert).	Specificity was evaluated by analyzing 760 unique HCV negative specimens; 380 plasma specimens and 380 serum specimens. HCV RNA was detected in two of the specimens tested. Observed specificity was therefore 99.74% (758/760) (95% CI 99.05 to 99.97%).	100% specificity (95% CI)
Bias (source)	N/A	Quantification of the 1st WHO reference panel for HIV-1 genotypes demonstrated bias of <0.5 log copies/mL for (A,B,C,D,AE,F,G,AG-GH,N) (Shutten et al 2007).	The bias observed for each dilution of the 2nd WHO IS ranged from -0.17 to 0.03 log IU/mL (package insert).	N/A
Intra-assay precision (source)	N/A	<0.25 log copies/mL when viral load >LOD (package insert)	<0.25 log IU/mL when viral load >LOD (package insert)	N/A
Inter-assay precision (source)	N/A	<0.25 log copies/mL when viral load >LOD (package insert)	<0.25 log IU/mL when viral load >LOD (package insert)	N/A
SAMPLE				
Sample preparation	Steps include vortexing (internal control, calibrators if applicable, controls and specimens), pipetting, centrifuge, etc. Once all required consumables, reagents and samples are placed in the m2000sp or m24sp, each process is walk away (extraction and mastermix addition).			
Sample type	Plasma, DBS	Plasma, DBS (RUO) HIV VL on DBS in development for CE Mark in 2016.	Serum, plasma	
Sample volume	Plasma: 0.2mL DBS: 2 spots of 50µL whole blood each	Plasma: 0.2 mL, 0.5 mL, 0.6 mL, 1.0 mL DBS: open mode (RUO), 1 spot (70µL whole blood)	0.5 mL, 0.2 mL	0.5 mL
Sample stability	Freshly drawn specimens (whole blood) may be held at 15-30°C for ≤6 hours or at 2-8°C for ≤24 hours, prior to preparing plasma specimens through centrifugation or preparing DBS specimens. Plasma: Plasma specimens may be stored at 15-30°C for ≤24 hours or at 2-8°C for ≤5 days. If longer storage is required, plasma specimens may be stored at -10 to -30°C for ≤30 days, or at -70°C or lower. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2-8°C for ≤6 hours. DBS: Freshly drawn specimens (whole blood) may be held at 15-30°C for ≤6 hours or at 2-8°C for ≤24 hours. DBS on cards may be stored at 15-30°C for ≤12 weeks. Alternatively, cards may be stored at 2-8°C or -10°C or colder for ≤12 weeks.	Freshly drawn whole blood may be held at 15-30°C for ≤6 hours or at 2-8°C for ≤24 hours, prior to preparing plasma specimens through centrifugation. Plasma specimens may be stored at 15-30°C for ≤24 hours or at 2-8°C for ≤5 days. If longer storage is required, plasma specimens must be kept at -70°C or lower. If frozen, thaw plasma specimens at 15-30°C or at 2-8°C. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2-8°C for ≤6 hours.	Freshly drawn whole blood can be held at 2–30°C for up to 6 hours. After centrifugation, serum or plasma can be stored at 15–30°C for ≤24 hours, at 2–8°C for ≤3 days, at -25 to -15°C for ≤60 days, and at -70°C for ≤60 days.	Freshly drawn whole blood can be held at 2–30°C for up to 6 hours. After centrifugation, serum or plasma can be stored at 15–30°C for ≤24 hours, at 2–8°C for ≤3 days, at -25 to -15°C for ≤60 days.
Nucleic acid extraction method	Manual and automated extraction.			
Time to result	5.4 - 7.7 hours	5.4 - 7.6 hours		5.25 hours
Capacity	1 - 96 samples/run including 2 controls	1 - 96 samples/run including 3 controls		24 samples/run including 2 controls
Batching?	Yes	Yes, flexible sample input with mPLUS available		Yes
Throughput per end-user per hour and/or 8hr day	96 samples per 8h day 192 samples per 12h day			48 samples per 8.5hr day

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

Product	ABBOTT REALTIME HIV-1 QUALITATIVE	ABBOTT REALTIME HIV-1	ABBOTT REALTIME HCV	ABBOTT REALTIME HCV GENOTYPE II
INSTRUMENT				
Size of device m2000sp	179 L x 187 H x 124.4 cm D			
Size of device m24sp	88.1 L x 75.9 H x 69.6 cm D (not available for HIV-1 Qualitative)			
Size of device m2000rt	34 L x 49 H x 45 cm D			
Weight of device m2000sp	326.8 kg instrument and cabinet			
Weight of device m24sp	84kg (not available for HIV-1 Qualitative)			
Weight of device m2000rt	34.1kg			
Robustness	Calls Per Year (CPY) metric, which is ~1.7 CPY for the m2000sp; 0.5 CPY for the m2000rt; and 0.8 CPY for the m24sp.			
Environmental requirements	**Sample Prep:** Operation Temperature: 15-30°C Operation Humidity: 30-80% relative (non-condensing) at ≤30°C Pollution Degree: 2 Operating Altitude: Max 3,000 m Heat: 4,100 BTU/1200 Wh External Light: <8,000 lux (direct sunlight can interfere with the PosID) **Real Time PCR:** Operation Temperature: 15-30°C Maximum change of less than 15°C per 24 hours Operation Humidity: 30-80% relative (non-condensing) Pollution Degree: 2 and only be installed in an environment that has non-conductive pollutants Operating Altitude: Max 3,000 m Heat: 4,100 BTU/1,200 Wh; meets Class B emission limits			
Power requirements	100-240 V			
Time to battery charge	GE UPS (Uninterruptable Power Supply) specified; depends on how long it will take to be charged when attached to the system.			
Battery duration (hours)	GE (General Electric) unit to last at least 20 minutes			
Alternative charging options	No, lab mains power only			
Ease of use	High ease of use: data station, keypad, mouse, printer, and bar code scanner.			
Display languages	m2000: English, French, Spanish, Italian, German, Portuguese, Russian, and Chinese m24: French, Italian, German, Spanish, and Portuguese (not for HIV-1 Qualitative)			
Built-in memory storage capacity	2 MB			
Connectivity options	Yes, connectivity via Laboratory Information Systems available and interface to mobile system in development; AbbottLink available.			
Interpretation of result	"HIV-1 Detected" or "Not Detected"	Viral load provided without interpretation		Qualitative result
Instrument lifespan	At least 10 years; through preventive maintenance and total call procedures they can be kept in operation indefinitely.			
Other non-proprietary equipment required	Centrifuge, vortex mixer. In addition, for manual extraction, dry heating blocks.			
Regulatory approval	CE-marked, WHO-prequalification with assay	CE-marked, FDA approved, WHO-prequalification with assay; DBS is RUO	CE-marked, FDA approved	
KIT				
Kit components	DNA Extraction kit: DBS Buffer, Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer Amplification kit: amplification reagent pack and internal control Control kit: 12 vials negative control, 12 vials positive control	RNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer Amplification kit: amplification reagent pack and internal control Control kit: 8 vials negative control, 8 vials high positive control, 8 vials low positive control Calibrator kit: 12 vials cal A and 12 vials cal B		RNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer Amplification kit: amplification reagent pack and internal control Control kit: 4 vials negative control, 4 vials positive control
Kit sizes	Extraction: 96 tests (4 x 24 tests/pack) Amplification: 96 tests (4 x 24 tests/pack)			Extraction: 96 tests (4 x 24 tests/pack) Amplification: 24 tests (1 x 24 tests/pack)
Internal control(s)	Yes; processed through sample extraction until detection with each sample.			
Compatible with EQA and which?	Amenable to EQA			
Mean time between failures	384.2 days / 0.95 Calls Per Year			
Transport and storage	Amplification reagents and controls transported on dry ice and stored at -10°C or colder; Sample preparation reagents stored at 15-30°C			Amplification reagents and controls transported on dry ice and stored at -25°C to -15°C; sample preparation reagents stored at 15-30°C
Fridge at -80°C required?	No			
Shelf life (of each item in the kit)	Shelf life upon manufacture: 18 months			

Product	ABBOTT REALTIME HIV-1 QUALITATIVE	ABBOTT REALTIME HIV-1	ABBOTT REALTIME HCV	ABBOTT REALTIME HCV GENOTYPE II
KIT				
Performance protocol	3 steps: 1. Extraction of the nucleic acid 2. Mastermix preparation and addition: preparation of the mastermix by combining the individual amplification reagent components and addition of the prepared mastermix to aliquots of the extracted nucleic acid samples in order to set up PCR plate 3. Amplification and Detection: Simultaneous amplification and detection of the target sequences (e.g. HIV-1 and internal control) on a cycle by cycle.			
Non-proprietary components required outside of the kit	Yes, see package insert for details (e.g. pipette tips)			
Regulatory approval	CE-marked, WHO prequalified	CE-marked, FDA approved, WHO pre-qualified	CE-marked, FDA approved	
In-country approvals	Available in countries which accept CE mark and, in addition, registered/ CE-certified in 8 low- and middle-income countries that require registration.	Australia, Canada, Japan, Thailand; available in countries that accept FDA and CE mark and in addition registered/ CE certified in 14 low- and middle-income countries that require registration.	Australia, Canada, Japan, Thailand, available in countries that accept FDA and CE-mark and in addition registered/ CE-certified in 11 low- and middle-income countries that require registration.	
USAGE				
Technical skill required	Medium-highly trained. Precision pipetting required at low volumes.			
Applicable settings	From low- to highly-resourced settings			
Laboratory set-up	Two dedicated areas are recommended: Sample Preparation Area and Amplification Area			
Waste disposal requirements	According to the regulations of each country.			

02 | PRICING

Please note that pricing is country-specific, and depends on factors such as length of contract, equipment requirements, volume per year, local support requirements, taxes, as well as 3rd party handling fees and logistics.

EARLY INFANT DIAGNOSIS

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$162,000	*m*Sample Preparation Systems DNA (4x24 Preps) (RealTi*m*e HIV-1 qualitative)	Sample preparation, extraction reagent	06K12-024	
*m*2000*rt*	Amplification and detection	09K15-001	$45,000	Abbott RealTi*m*e HIV-1 Qualitative Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	04N66-090	
				Abbott RealTi*m*e HIV-1 Qualitative Control Kit CE	1 kit (2 levels with 12 replicates per level)	04N66-080	
				Abbott RealTi*m*e HIV-1 Qualitative Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	04N66-066	
				*m*Sample Preparation System RNA Bulk Lysis Buffer (for DBS procedure)	3 x 70 ml	02N77-001	

Instrument Accessories		Reference number	FCA ($)	Non-proprietary equipment and consumables	Reference number	FCA ($)
Abbott RealTi*m*e HIV-1 Qualitative *m*2000 Combined Application CD-ROM	Application CD ROM	04N66-001 or higher		None		
Manual sample preparation startup kit	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-001				
Preparation rack		02N28-002				
Disposable Tips (DiTis): 1mL (2304 Tips)		04J71-010				
Disposable Tips (DiTis): 200µL (2304 Tips)		04J71-017				
5mL Reaction Vessles (2000 Vessles)		04J71-020				
200 mL Reagent Vessles (90 Vessels)		04J71-060				
96 Deep Well Plates (32 Plates)		04J71-030				
96-Well Optical Reaction Plates (20 Plates)		04J71-070				
Optical Adhesive Covers (100 Covers)		04J71-075				
Master Mix Tubes/Caps (150 Tubes/Caps)		04J71-080				
Splash Free Support Base (5 each)		09K31-001				
13mm Sample Racks		04J72-082				
mSystems Wrench (1 each)		01N71-001				
Optical Calibration Kit (1 each)		04J71-093				
Cost per device			**$207,000**	**Cost per test result**		**$13 - 30**

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

HIV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
*m*24*sp* (not available in US)	Sample Extraction, up to 24 samples	03N06-001	$80,000	*m*Sample Preparation Systems RNA (4x24 Preps) (viral load)	Sample preparation, extraction reagent	04J70-024	
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$162,000	Abbott RealTi*m*e HIV-1 Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	02G31-90	
*m*2000*rt*	Amplification and detection	09K15-001	$45,000	Abbott RealTi*m*e HIV-1 Control Kit CE	1 kit (3 levels with 8 replicates per level)	02G31-080	
				Abbott RealTi*m*e HIV-1 Calibrator Kit CE	1 kit (2 levels with 12 replicates per level)	02G31-070	
				Abbott RealTi*m*e HIV-1 Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	02G31-066	
				Abbott RealTi*m*e HIV-1 Amplification Reagent Kit FDA	1 kit (96 tests; 4 x 24 tests/pack)	06L18-090	
				Abbott RealTi*m*e HIV-1 Control Kit FDA	1 kit (3 levels with 8 replicates per level)	06L18-080	
				Abbott RealTi*m*e HIV-1 Calibrator Kit FDA	1 kit (2 levels with 12 replicates per level)	06L18-070	
				*m*Sample Preparation System DBS Buffer (for DBS)* *please note: DBS available as open mode, CE mark expected in 2016	4 x 46 mL	08N80-001	

Instrument Accessories		Reference number	FCA ($)	Non-proprietary equipment and consumables	Reference number	FCA ($)
RealTi*m*e HIV-1 Application CD-ROM CE	Application CD ROM	01L68		None		
RealTi*m*e HIV-1 Application CD-ROM US FDA IVD	Application CD ROM	06L83				
Manual sample preparation startup kit*	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-01				
Preparation rack		02N28-002				
Disposable Tips (DiTis): 1mL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-010				
Disposable Tips (DiTis): 200µL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-017				
5mL Reaction Vessles (2000 Vessles)	needed for *m*2000*sp* and *m*24*sp*	04J71-020				
200 mL Reagent Vessles (90 Vessels)	needed for *m*2000*sp* and *m*24*sp*	04J71-060				
96 Deep Well Plates (32 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-030				
96-Well Optical Reaction Plates (20 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-070				
Optical Adhesive Covers (100 Covers)	needed for *m*2000*sp* and *m*24*sp*	04J71-075				
Master Mix Tubes/Caps (150 Tubes/Caps)	needed for *m*2000*sp* and *m*24*sp*	04J71-080				
Splash Free Support Base (5 each)	needed for *m*2000*sp* and *m*24*sp*	09K31-001				
13mm Sample Racks	needed for *m*2000*sp* and *m*24*sp*	04J72-082				
mSystems Wrench (1 each)	needed for *m*2000*sp* and *m*24*sp*	01N71-001				
Optical Calibration Kit (1 each)	needed for *m*2000*sp* and *m*24*sp*	04J71-093				
1.4 mL Internal Control Vial	needed for *m*24*sp*	03N19-001				
1.4 mL Internal Control Vial Cap	needed for *m*24*sp*	03N20-001				

* please note: Abbott RealTime HIV-1 Amplification Reagent Kit FDA does not include manual extraction

Cost per device			$207,000	Cost per test result	$13 - 30

HCV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
*m*24*sp*	Sample Extraction, up to 24 samples	03N06-001	$80,000	Abbott RealTi*m*e HCV Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	04J86-090	
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$162,000	Abbott RealTi*m*e HCV Control Kit CE	1 kit (3 levels with 8 replicates per level)	04J86-080	
*m*2000*rt*	Amplification and detection	09K15-001	$45,000	Abbott RealTi*m*e HCV Calibrator Kit CE	1 kit (2 levels with 12 replicates per level)	04J86-070	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Abbott RealTime HCV Application CD-ROM	Application CD ROM	01L69		None			
Manual sample preparation startup kit	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-01					
Preparation rack		02N28-002					
Disposable Tips (DiTis): 1mL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-010					
Disposable Tips (DiTis): 200µL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-017					
5mL Reaction Vessles (2000 Vessles)	needed for *m*2000*sp* and *m*24*sp*	04J71-020					
200 mL Reagent Vessles (90 Vessels)	needed for *m*2000*sp* and *m*24*sp*	04J71-060					
96 Deep Well Plates (32 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-030					
96-Well Optical Reaction Plates (20 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-070					
Optical Adhesive Covers (100 Covers)	needed for *m*2000*sp* and *m*24*sp*	04J71-075					
Master Mix Tubes/Caps (150 Tubes/Caps)	needed for *m*2000*sp* and *m*24*sp*	04J71-080					
Splash Free Support Base (5 each)	needed for *m*2000*sp* and *m*24*sp*	09K31-001					
13mm Sample Racks	needed for *m*2000*sp* and *m*24*sp*	04J72-082					
mSystems Wrench (1 each)	needed for *m*2000*sp* and *m*24*sp*	01N71-001					
Optical Calibration Kit (1 each)	needed for *m*2000*sp* and *m*24*sp*	04J71-093					
1.4 mL Internal Control Vial	needed for *m*24*sp*	03N19-001					
1.4 mL Internal Control Vial Cap	needed for *m*24*sp*	03N20-001					
Cost per device			**$207,000**	**Cost per test result**			**$13 - 35**

HCV GENOTYPING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$162,000	Abbott RealTi*m*e HCV Genotype II Amplification Reagent Kit CE	24 tests	08K24-90	
*m*2000*rt*	Amplification and detection	09K15-001	$45,000	Abbott RealTi*m*e HCV Control Kit CE	4 positive, 4 negative	08K24-80	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Abbott RealTi*m*e HCV Genotype II *m*2000-System-Combined Application CD-rom	Application CD ROM	08L36		None			
Manual sample preparation startup kit	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-001					
Preparation rack		02N28-002					
Disposable Tips (DiTis): 1mL (2304 Tips)		04J71-010					
Disposable Tips (DiTis): 200µL (2304 Tips)		04J71-017					
5mL Reaction Vessles (2000 Vessles)		04J71-020					
200 mL Reagent Vessles (90 Vessels)		04J71-060					
96 Deep Well Plates (32 Plates)		04J71-030					
96-Well Optical Reaction Plates (20 Plates)		04J71-070					
Optical Adhesive Covers (100 Covers)		04J71-075					
Master Mix Tubes/Caps (150 Tubes/Caps)		04J71-080					
Splash Free Support Base (5 each)		09K31-001					
13mm Sample Racks		04J72-082					
mSystems Wrench (1 each)		01N71-001					
Optical Calibration Kit (1 each)		04J71-093					
Cost per device			**$207,000**	**Cost per test result**			**Not provided**

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

03 | TIERED AND VOLUME-BASED PRICING | No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Abbott has options for reagent rental (RAP) agreements. The RAP agreements require certain terms and conditions to be met, including but not limited to: contract term, volume, and amount of instrumentation. Specific criteria and considerations can vary and are negotiated on a case by case basis.
Installation	Provided: installation performed by Abbott service engineer or third party engineer certified by Abbott following internal SOP.
Training	Provided: • Training done at customer site for up to 6 people. • Averages [m2000sp: training 3 days duration; m2000rt: 2 days; m2000sp and m2000rt: 4 days together] and is dependent on the number of assays. • After installation, training will be provided onsite (customer's site) for up to 6 technicians per session and in a maximum of 2 training sessions per laboratory. • The second training session can be done as a refresher (considered as on-going training) / Training materials and operator manual may be found on-line. • Done by Molecular Application Specialists (Abbott Molecular or third party certified by Abbott) as soon as the instrument installation is validated by the service engineer. • Languages: English, French, Portuguese, Spanish. • Done in real conditions / using true samples / using samples and material from the laboratory. • Content of training: - m2000 System Overview, Hardware Overview. - Good Laboratory Practices, Set-up RealTime extraction for all assays, RNA/DNA Extraction reagents. - Review of RealTime results. - Perform maintenance, decontamination procedure, troubleshooting, lamp replacement, optical calibration, and contamination check. • End user lab technician is certified by Abbott. Additional training on top of the 2 sessions will be on demand and charged.
Maintenance	• During the warranty period: repair is assured. • Following year 1 of the service contract, maintenance includes - Preventive maintenance - Repair visits - Phone support by molecular expert (Abbott Molecular engineer or third party engineer certified by Abbott) • Preventive maintenance = 1 PM/year - Software is upgraded as required - Phone support is available from 9am-5pm (depending on the country) • Repair maintenance is availble 5 days/week from 9am-5pm - Spare parts are included - Can be purchased upfront or paid monthly/annually
Length(s) of warranty and additional costs for extended warranty / care plan	Warranty = 12 months
Warranty components	Installation, repair, spare parts, labour, initial training, phone support.
Turnkey option	Available on request.
in-country / regional technical support availability	Depends on country. Service assumed by Abbott Molecular service engineer or distributor service people certified by Abbott.

05 | CONTACT INFO

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LAB-BASED HIV EID, HIV VL, HCV VL
BIOCENTRIC

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Biocentric**		
Product	**GENERIC HIV DNA CELL**	**GENERIC HIV CHARGE VIRALE**	**GENERIC HCV CHARGE VIRALE**
ASSAY			
Intended use (as per regulatory approval)	Qualitative or quantitative detection of HIV-1 DNA.	Quantitative determination of HIV viral load in HIV infected patients.	Quantitative determination of HCV viral load in HCV infected patients.
Principle of the assay	Real time PCR assay with fluorescence detection.	Real time RT-qPCR with fluorescence detection.	
Target	HIV-1 LTR (Long Terminal Repeat).		Not disclosed.
Genotypes and/or subtypes	HIV-1: Group M, B and non B subtypes, including CRF.		Genotypes 1 to 6.
Type of result	Qualitative and quantitative.	Quantitative	
Linear range	300 - 300,000 copies/mL = 6 - 6,000 copies DNA/ PCR test.	Standard: 165 - 5,000,000 copies/mL Sensitive: 50 - 5,000,000 copies/mL	50 - 10,000,000 copies/mL
Output	Detection of HIV-1 DNA or quantitation of HIV-1 DNA copies/10^6 cells.	RNA viral load in copies/mL or IU/mL.	
DNA or RNA specific?	DNA	RNA	
Polyvalency	HIV-2 viral load, M. tuberculosis and drug resistance, HBV viral load.		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	Input whole blood volume of 200µL: 40 copies/10^6 cells (= 6 DNA copies per PCR test).	Input plasma volume of 250µL: 416 copies/mL [CI 95%: 388 - 450 copies/mL] Input plasma volume of 1mL: 132 copies/ mL [CI 95%: 119 - 149 copies/mL]	TBD
Specificity - analytical and clinical (source)	100%	100%	
Bias (source)	N/A	δ= -0.12 to 0.22 copies/mL (from: clinical comparative studies)	
Intra-assay precision (source)	Samples tested in duplicate (n = 172): Spearman, r = 0.940; p<0.0001	<2%	
Inter-assay precision (source)	<5%	<6%	
SAMPLE			
Sample preparation (steps)	Prepare DBS.	Prepare plasma.	
Sample type	Venous or capillary whole blood or PBMCs or DBS (RUO).	Plasma (EDTA or citrated) or DBS (RUO).	Plasma (EDTA or citrated).
Sample volume	Whole blood and PBMCs: 200µL DBS: 2 spots of ≈ 50µL WB each	Plasma: 250 or 1,000µL DBS: 2 spots of ≈ 50µL WB each	Plasma: 250 or 1,000µL
Sample stability	Whole blood: ≤6 hours at 15 - 30°C DBS: 1-2 weeks at 15 - 30°C; ≥2 weeks at 2 - 8°C	Plasma: ≤24 hours at 15 - 30°C; 5 days at 2 - 8°C; ≤1 year at -20°C DBS: 1-2 weeks at 15 - 30°C, ≥2 weeks at 2 - 8°C	Plasma: ≤24 hours at 15 - 30°C; 5 days at 2 - 8°C; ≤1 year at -20°C
Nucleic acid extraction method	Manual methods: - QIAamp DNA blood Mini kit (Qiagen REF 51106) - Nucleospin blood, Macherey (Nagel REF 740951-10 or 50 or 200) Automated (NorDiag Arrow system, DiaSorin Ireland) or GenoExtract (Hain Life Science, Germany)		
Time to result	4 hours	3.5 hours, including RNA isolation	
Capacity	180 - 360 patient samples per kit.		
Batching?	Yes		
Throughput per end-user per hour and/or 8hr day	One working day ≈ 40 samples	One working day: - one Arrow extractor = 40 samples - two Arrow extractors = 82 samples	

Continued overleaf

Product	GENERIC HIV DNA CELL	GENERIC HIV CHARGE VIRALE	GENERIC HCV CHARGE VIRALE
INSTRUMENT			
Size of device	40 x 45 x 46 cm		
Weight of device	30 kg		
Robustness	Not provided.		
Environmental requirements	Not provided.		
Power requirements	220 V		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	External battery and UPS.		
Ease of use	Data station, printer option.		
Display languages	English and French.		
Built-in memory storage capacity	100 GB		
Connectivity options	Ethernet to LIMS.		
Interpretation of result	Qualitative or viral load.	Viral load	
Instrument lifespan	10 years		
Other non-proprietary equipment required	For automated nucleic acid extraction.		
Regulatory approval	CE-Marked		
KIT			
Kit components	Primers, probes, enzyme mix, set of standards.	Primers, probes, enzyme mix, set of standards, internal control, positive and negative controls.	
Kit sizes	220 or 440 tests		
Internal control(s)	Yes		
Compatible with EQA and which?	CDC Proficiency Testing Programme.		TBD
Mean time between failures	Not provided.		
Transport and storage	Transport on dry ice ; storage at -20°C.		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	(1) Preparation of sample and automatic extraction of nucleic acids. (2) Preparation of Master Mix and dispensing of nucleic acid eluates in PCR microplate, followed by PCR amplification. (3) Interpretation of results.		
Non-proprietary components required outside of the kit	None		
Regulatory approval	CE-Mark and WHO PQ are pending.		
In-country approvals	Not provided.		
USAGE			
Technical skill required	Medium to highly trained in molecular biology; precision pipetting required.		
Applicable settings	Low- to medium-resourced settings.		
Laboratory set-up	1 Room with benches and electric plugs.		
Waste disposal requirements	Waste disposal for biological hazards.		

02 | PRICING

EARLY INFANT DIAGNOSIS							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$20,000	Generic HIV DNA Cell	220 tests	TR002-250	$1,540
	LED				440 tests	TR002-500	$2,900
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract	12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Blood 500 cartridge	96 tests	12.17.02	$620
	Ready-to-use cartridge			or Arrow Blood DNA 500			
	Disposable pumps						
	The package includes two instruments at US$11,000 each						
Cost per device			**$42,000**	**Cost per test result**			**$13.05**

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$20,000	Generic HIV Charge Virale	220 tests	TR001-250	$2,000
	LED				440 tests	TR001-440	$3,500
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract	12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Viral Cartridge	96 tests	12.08.02	$620
	Ready-to-use cartridge			or Arrow Blood Viral NA			
	Disposable pumps			Proteinase K 1mL	100 mg/mL	405002100	$45
	The package includes two instruments at US$11,000 each						
Cost per device			**$42,000**	**Cost per test result**			**$14.9**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$20,000	Generic HCV Charge Virale	220 tests	TR005-250	$3,600
	LED				440 tests	TR005-440	$6,900
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract	12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Viral Cartridge	96 tests	12.08.02	$620
	Ready-to-use cartridge			or Arrow Blood Viral NA			
	Disposable pumps			Proteinase K 1mL	100 mg/mL	405002100	$45
	The package includes two instruments at US$11,000 each						
Cost per device			**$42,000**	**Cost per test result**			**$22.60**

*For two instruments (i.e. $11,000 each).

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Biocentric continued

03 | TIERED AND VOLUME-BASED PRICING

No tiered or volume-based pricing provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost ($)
Leasing or reagent rental (RAP)	3 year contract leasing for 1 thermocycler and one 12-sample automated extraction instrument.	Approx. $1,300/month
Installation	On request.	
Training	(1) Training takes 5 days (2) Available in English, French and German (3) On site training provided (4) Training material available as videos, manuals and slides (5) Possibility to adhere to ANRS proficiency program after training (6) Online training material available	Free of charge
Maintenance	Full on-site servicing (preventive and curative) as well as instrument swap, if necessary.	$5,500/year
Length(s) of warranty and additional costs for extended warranty / care plan	- 12 months warranty. - Extended warranty included in maintenance program.	Not provided.
Warranty components	On Thermocycler and Automated Extraction instrument.	Not provided.
Turnkey option	Includes: - 1 Realtime thermocycler - 3 automated extraction instruments - 1 microplate centrifuge - 2 mechanical pipette sets - 2 electronic pipettes - 1 PCR cabinet - 1 plate sealer	$60,000
In-country / regional technical support availability	Technical support centralized from France / Regional offices in South Africa and Kenya.	On request.

05 | CONTACT INFO

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LAB-BASED HIV VIRAL LOAD
BIOMÉRIEUX

01 | TECHNICAL AND PERFORMANCE INFORMATION

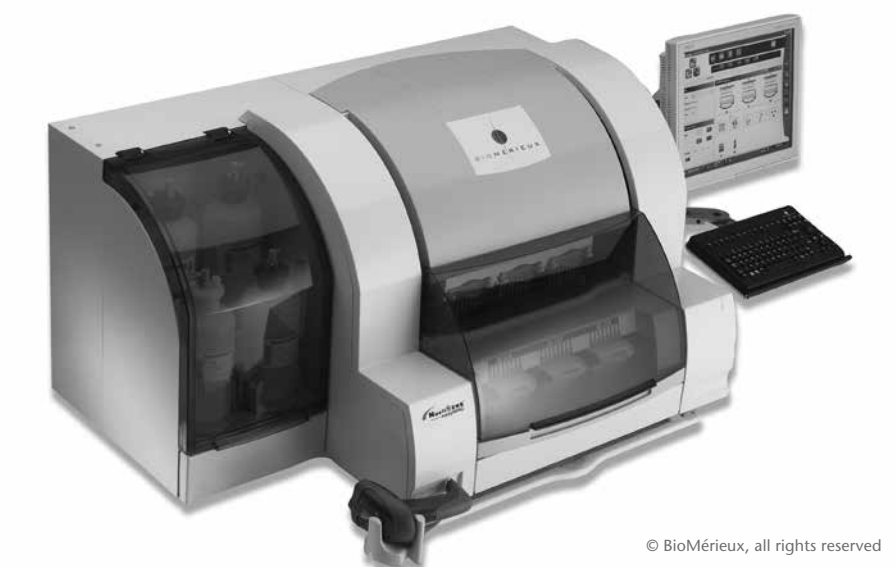
Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
ASSAY		**PERFORMANCE**	
Intended use	Detection of isolated HIV-1 RNA. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of anti-retroviral therapy by measuring changes in plasma/DBS HIV-1 RNA levels during the course of anti-retroviral treatment. Must not be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.	**Bias (source)**	Not provided.
Principle of the assay	Real time NASBA isothermal signal amplification using molecular beacons for detection.	**Intra-assay precision (source)**	Plasma: Viral quality assurance input: <79 copies/mL = 0.38 - 0.44 10Log 79 - 794 copies/mL = 0.20 - 0.23 10Log >794 copies/mL = 0.10 - 0.11 10Log DBS: Viral quality assurance input: <710 copies/mL = 0.46 10Log 710 - 7100 copies/mL = 0.30 10Log >7100 copies/mL = 0.15 10Log (bioMérieux)
Target	HIV-1 RNA gag	**Inter-assay precision (source)**	Plasma: Viral quality assurance input: <79 copies/mL = 0.00 - 0.16 10Log 79 - 794 copies/mL = 0.02 - 0.10 10Log >794 copies/mL = 0.03 - 0.05 10Log DBS: Viral quality assurance input: <710 copies/mL = 0.00 10Log 710 - 7100 copies/mL = 0.03 10Log >7100 copies/mL = 0.05 10Log (bioMérieux)
Genotypes and/ or subtypes	A, B, C, D, F, G, H, J, CRF01_AE and CRF02_AG. In addition, various circulating recombinant forms and additional subtypes were tested on the following NIBSC samples: ARP1050 (CRF01_AE), ARP1066 and ARP1037 (CRF02_AG, consisting of subtype A and G), ARP1038 (CRF11-cpx, consisting of subtype A, G, J and CRF01_AE), ARP1034 (CRF14_BG, consisting of subtype B and G) and ARP176 (GH-AA, consisting of GH recombinant and A subtype), ARP1036 (subtype K) ARP1017.1 and ARP1017.2 (subtype J), ARP1043 (subtype H) and ARP190 (HIV-1 group N).	**Accuracy (source)**	Plasma: <0.25 10Log DBS: <0.30 10Log (bioMérieux)
Type of result	Quantitative	**SAMPLE**	
Linear range	25 - 10,000,000 copies/mL	**Sample preparation (steps)**	Blood collection and plasma preparation: - Blood should be collected in sterile tubes by normal venipuncture techniques using EDTA as an anticoagulant and should be handled with the proper precautions. - After centrifugation (e.g. 10 minutes at 1,500 x g), the obtained plasma specimen should be used as sample input. - No special specimen preparation or fasting of the patient is necessary. - No adverse effects were observed using EDTA as the anticoagulant. - Any deviations from the described procedures should be validated by users in their own laboratory setting. DBS Collection: - Collect whole blood in a tube with EDTA-anticoagulant and, on the same day, spot 50 µL of blood on Whatman 903 Specimen Collection Paper (e.g. Proteinsaver 903 Card) using a calibrated device (e.g. pipette). - Note: Fill each printed circle with a SINGLE application of blood. Prevent spotting outside the circles. - Note: Avoid touching or smearing the blood spots. - Two spots are needed for the nucleic acid extraction procedure. - If blood spots cannot be prepared immediately after blood draw, the blood tubes should be stored in a refrigerator for up to 24 hours until spotting. - Dry the filter paper for at least 3 hours (and for a maximum of overnight) at room temperature (15 to 30 °C).
Output	Time-to-result: 2.5 - 3 hours		
DNA or RNA specific?	RNA		
Polyvalency	HPV; ARGENE molecular menu: immunocompromised, meningitis, respiratory diseases RT-PCR kits.		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	Linear quantitative range: - Testing diluted samples from 9 to 79,000,000 copies/mL, derived from HIV-1 RNA reference material with two lots of NucliSENS EasyQ HIV-1 v2.0 reagents, demonstrated a direct proportional relationship between the dilution factor and the number of HIV-1 RNA copiess reported. - The performance of the assay using EDTA plasma was found to give a linear response over a range of 25 to 79,000,000 copies/mL, for a 1 mL input of EDTA plasma, over a range of 50 to 15,000,000 copies/mL for a 0.5 mL input of EDTA plasma; over a range of 292 to 71,000,000 copies/mL for 0.1 mL input of EDTA plasma; and over a range of 500 to 21,000,000 copies/mL for DBS. (bioMérieux)		
Specificity - analytical and clinical (source)	Observed specificity: N = 261 (1mL EDTA plasma) = 100% [95% CI (98.6 - 100)] N = 129 (0.1mL EDTA plama) = 100% [95% CI (97.2 - 100)] N = 100 DBS from randomly selected healthy blood donors = 100% [95% CI (96.4 - 100)] - All non-reactive for HIV-1 & HIV-2 antibodies (bioMérieux)	**Sample type**	EDTA plasma or dried blood spot (venous EDTA or capillary (without anticoagulant) whole blood spotted on card).

Continued overleaf

Lab-based HIV Viral Load – Biomérieux continued

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
SAMPLE		**INSTRUMENT**	
Sample volume	Plasma: 0.1 / 0.5 / 1 mL DBS: 2 spots of 50µL each	**Power requirements**	MiniMAG: 100-240 VAC, 47-63 Hz EasyMAG: 100-240 VAC, 50/60 Hz; power rating 400 W EasyQ: 100-120 VAC, 50/60 Hz, nominal (operating range 90-136 V) or 200-240 VAC, 50/60 Hz, nominal (operating range 180-256 V)
Sample stability	Venous blood: EDTA blood can be stored for 24 hours at 2 - 8°C. Plasma: EDTA plasma specimens can be stored at 2 - 8°C for ≤7 days, 1 month at -20°C or 1 year at -70°C. EDTA plasma specimens can be stored in NucliSENS Lysis Buffer for a maximum of: - 14 days at 2 - 8°C - 24 hours at ambient temperature (2 to 30°C) DBS: Venous EDTA DBS can be stored with dessicant sachets in an air-impermeable bag at room temperature (15-30°C) for a maximum of 9 months. Packed venous DBS can alternatively be stored for a maximum of: - At 2-8°C for ≤3 weeks - At 37°C for ≤9 weeks (in case of high humidity then ≤3 weeks) - At -20°C (frozen) for ≤3 months Capillary DBS can be stored with desiccant sachets in an air-impermeable bag at room temperature (15-30°C) for a period of 7 weeks.	**Time to battery charge**	N/A
		Battery duration (hours)	N/A
		Alternative charging options	N/A
		Ease of use	MiniMAG equipped with keypad. EasyMAG equipped with PC and touch screen. EasyQ equipped with PC and standard screen. Data from EasyQ HIV-1 stored on computer. Mini Strip Centrifuge (EasyQ) and printer (EasyMAG and EasyQ) available as additional options.
		Display languages	English, German, Italian, Spanish, French.
		Built-in memory storage capacity	Storage on the computer (capacity of 250 GB).
Nucleic acid extraction method	Semi-automated	**Connectivity options**	Can be linked with LIS using NucliSENtral, which is an integrated software that can be used to link NucliSENS easyMAG and NucliSENS EasyQ with a Laboratory Information System.
Time to result	Less than 3 hours, from sample to result (sample acquisition, extraction, amplification, detection).	**Interpretation of result**	Quantitative results in copies/mL. TND = Target not detected. Please refer to product package insert for detailed information of interpretation of results (section 8.2 of the package insert: "Reviewing results").
Capacity	Can be configurated to run 8 - 1,000 tests/day but only 8 - 140 tests/day if only one instrument is used.		
Batching?	Yes. Maximum run size: NucliSENS EasyMAG = 24 samples NucliSENS miniMAG = 12 samples NucliSENS EasyQ Analyser = 48 samples	**Instrument lifespan**	Approximately 8 years depending on usage conditions, usage frequency, and systems environment.
Throughput per end-user per hour and/or 8hr day	Around 140 samples can be tested per 8-hour shift if 1 EasyMAG and 1 EasyQ are used.	**Other non-proprietary equipment required**	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".
		Regulatory approval	CE-IVD
INSTRUMENT		**KIT**	
Size of device	MiniMAG: W 43.8 x D 11.4 x H 15.3 cm EasyMAG: W 100 x D 65 x H 53 cm EasyQ: W 42 x D 42 x H 22 cm	**Kit components**	NucliSENS EasyQ HIV-1 v2.0 (48 tests) ref. 285033 contains: - 1 x CD-ROM - 6 x 6 mg calibrator - 6 x 1.5 mL calibrator diluent - 6 x 6 mg enzymes - 6 x 0.5 mL enzyme diluent - 6 x 15 mg primers - 6 x 1.4 mL primer diluent
Weight of device	MiniMAG: ±3.6 kg EasyMAG: ±125 kg EasyQ: ±20.5 kg		
Robustness	Yes, refer to mean-time between failures: EasyMAG = 384 days; EasyQ = 5 years.	**Kit sizes**	48 tests
Environmental requirements	MiniMAG: - Temperature: 4 – 45°C Easy Mag: - Temperature: 15 - 30ºC - Relative humidity: ≤80%, non-condensing at 30ºC DB - Altitude: 0 - 2,500 meters above sea level EasyQ: - Temperature: 10 - 40ºC - Relative humidity: ≤90% - Tested according to IEC 68-2-1 test Ab (cold); IEC 68-2-2 test Bb (dry heat); and IEC 68-2-3 test Ca (damp heat)	**Internal control(s)**	Yes
		Compatible with EQA and which?	HIV-1 RNA positive and negative controls are commercially available and can be obtained from several suppliers, e.g. Seracare/BBI, Acrometrix. For the positive control, bioMérieux recommends to use a viral concentration of approximately 5,000 copies/mL. Please refer to product package insert for detailed information.
		Mean time between failures	EasyMAG: 384 days; EasyQ: 5 years

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
KIT		**USAGE**	
Transport and storage	Amplification reagents: 2-8°C Extraction reagents (buffers 1, 2 and lysis buffer): 2-30°C Buffer 3 and magnetic silica: 2-8°C	**Technical skill required**	Medium-highly trained, precision pipetting required at low volumes.
Fridge at -80°C required?	Not required unless EDTA plasma samples are stored for more than 1 month, in this case samples should be placed at -70°C and remain stable for a maximum of 1 year.	**Applicable settings**	Technology can be used at regional / central level or national reference (or comparable) laboratories. Access to decentralized settings via DBS.
Shelf life	>210 days: buffers 1, 2, 3; magnetic silica; lysis buffer; disposables >150 days: amplification reagents >120 days: extraction reagents	**Laboratory set-up**	Specialized; 2-3 dedicated areas required.
Performance protocol (steps)	Please refer to product package insert sent in appendix, for detailed information on protocol and each step, depending on the sample which is used for testing.	**Waste disposal requirements**	Containers for solid waste, container for liquid waste, waste plastic bags.
Non-proprietary components required outside of the kit	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".		
Regulatory approval	WHO PQ, CE-IVD (plasma and EDTA + capillary DBS)		
In-country approvals	Please refer to bioMérieux for country-specific registration information.		



Continued overleaf

02 | PRICING

Prices are given as indication only and should be confirmed at quotation stage on a case by case basis.

Instrument		Reference number	EXW ($)	Cartridge/reagents/consumables		Reference number	EXW ($)
NucliSENS miniMAG	1-12 extractions/run	4700015	$20,000.00	NucliSENS lysis buffer 2mL	48 tests	200292	
				NucliSENS Magnetic Extraction Reagents	48 tests	200293	
NucliSENS EasyMAG	1-24 extractions/run	4700014	$80,000.00				
Keyboard AZ		*280154*		NucliSENS easyMAG extraction Buffer 1	4 x 1 litre	280130	
Keyboard QW		*280155*		NucliSENS easyMAG extraction Buffer 2	4 x 1 litre	280131	
EasyMAG Biohit Adapter - US		*280147*		NucliSENS easyMAG extraction Buffer 3	4 x 1 litre	280132	
EasyMAG Biohit Adapter - AU		*280148*		NucliSENS easyMAG magnetic silica	384 extractions	280133	
EasyMAG Biohit Adapter - EU		*280149*		NucliSENS easyMAG extraction Lysis Buffer	4 x 1 litre	280134	
EasyMAG Biohit Adapter - JP		*280150*		Disposables	48 x 8 tests	280135	
EasyMAG Biohit Adapter - UK		*280151*		NucliSENS lysis buffer 2 ml	48 tests	200292	
NucliSENS EasyQ	48 samples/run	4700016	$45,000.00	NucliSENS Easy Q HIV-1 V2.0	48 tests	285033	
Strip centrifuge	220V	285056	$1,500.00				
UPS converters UPS APC 1,500 VA EU		413647	$1,450.00				
Printer Lexmark E360DN 230V		93621	$400.00				
bioMérieux DBS Puncher		411022	$2,500.00				

Instrument Accessories	Reference number	EXW ($)	Non-proprietary and proprietary equipment and consumables needed but not provided		Reference number	EXW ($)
			For miniMAG			
			Microtubes 1,5 ml	(500 tubes and 500 caps)	200294	
			Centrifuge (1,500 x g) for Lysis buffer tube 15 mL			
			Thermo shaker for 1.5 ml microtubes (Eppendorf)		5350000.013	
			Highly recommended: vacuum pump with intermediate recipient for eluant (IBS Integra biosciences)		158320	
			Vortex			
			ELISA microplates			
			Rack for 15 mL tubes			
			Rack for 1.5 mL tubes			
			Pipette 10 - 100 µL			
			Pipette 20 - 200 µL			
			Pipette 100 - 1,000 µL			
			Non-filtered tips for vacuum			
			Filtered tips 10 - 100 µL			
			Filtered tips 20 - 200 µL			
			Filtered tips 100 - 1,000 µL			
			Detergent		1075552500	
			For EasyMAG			
			Filter tips for multichannel bioHIT	10 x 96 tips	280146	
			EasyMAG disposables	48 x 8 tests	280135	
			Strip Plates Greiner	100 x 96 wells	278303	
			For EasyQ			
			EasyQ 8-Tube Caps		285051	
			EasyQ 8-Tube Strips		285048	
			For DBS			
			Whatman 903 paper e.g. Protein saver		10531018	
			Plastic zip lock bags (for storage)		10548232	
			Dessicant packs without indicator for storage		10548234	
			Humidity indicator			
			Roller mixer		SRT6	

Cost per device				Cost per test result	±$23.40*

*EXW price not including cost of non-propietary equipment and consumables.

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	None provided.
Installation	Installation of the instrument, as per bioMérieux recommendations and procedures, consists of: - Unpacking the instrument - Bench positioning - Configuration of the instrument - Verification of the instrument - Validation of the functioning of the instrument
Training	Training of a maximum of 2 people in the laboratory during a maximum of 3 days. Travelling expenses are included. If more people are to be added to the training, an invoice will be issued based on a quotation. The people must have the required knowledge to use the instrument. Training on the system is on-site and consists of: - Principles of the technique - Use of the system - Interpretation of the results Manuals are available in: English, French, German, Italian, Spanish, Danish, Norwegian, Swedish, Portuguese, Russian, Romanian, Estonian and Czech. Software languages are available in: English, German, Italian, Spanish and French. Training materials consist of: - Worksheet materials explaining the steps to follow depending on the protocols used (simple front & quick user guide). These worksheets are available on the CD-ROM sent with the kit. - How-to-use video available for the use of DBS. Webinars can be organized on a case by case basis.
Maintenance	Maintenance performed during the warranty period as per bioMérieux recommendations and procedures consists of: - 2 preventive maintenances for Nuclisens EasyMag - 1 preventive maintenance for Nuclisens EasyQ - Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions Preventive and corrective maintenance is provided by the bioMérieux legal representative in the country of destination following bioMérieux procedures and recommandations. Any warranty extension is studied on a case by case basis.
Length(s) of warranty and additional costs for extended warranty / care plan	A warranty period of 15 months is included in the price of the instrument, and is valid as of shipping date from the bioMérieux International Delivery Centre (Saint Vulbas, France). bioMérieux offers the possibility to extend the warranty. The conformance of the reagents to the specifications indicated in the package insert is guaranteed until their expiry date. Warranty services are provided by the bioMérieux legal representative in the country of destination following bioMérieux procedures and recommendations. Extended warranty includes: - 2 preventive maintenances for the Nuclisens EasyMag and 1 for the Nuclisens EasyQ - Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions. Any warrranty extension will be studied on a case by case basis and a quotation will be issued.
Warranty components	Included: - Instrument, parts and labour, within the frame of our ongoing Export Sales General Conditions. - Travelling expenses. Excluded: Disposables and replacement items with a normal life expectancy of less than 1 year (such as, but not limited to, batteries, lamps and tubing).
Turnkey option	Yes, to be discussed on a case by case basis.
In-country / regional technical support availability	bioMérieux has subsidiaries in 42 countries in the world and an extensive network of distributors to reach a presence in more than 160 countries worldwide. In Africa, the distribution and support relies on our network of distributors, supported by our subsidiary in South Africa and our offices in Ivory Coast, Egypt and Algeria. First level support is provided by bioMérieux local team and distributors. Second and third level support can be provided by our Global Customer Service, R&D, technical and supply teams.

05 | CONTACT INFO

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LAB-BASED HIV VIRAL LOAD
CAVIDI

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	**CAVIDI**		**Product**	**EXAVIR LOAD V3**	
ASSAY		**INSTRUMENT**		**KIT**	
Intended use (as per regulatory approval)	For determination of the activity of the enzyme reverse transcriptase (RT), as a marker of retroviral replication.	**Size of device**	Footprint on bench: <0.6 sqm	**Kit components**	Reagents + consumables
Principle of the assay	Determination of RT activity	**Weight of device**	12 kg	**Kit sizes**	32 samples / kit
Target	Reverse Transcriptase (RT)	**Robustness**	Very robust	**Internal control(s)**	HIV-I rRT Standard
Genotypes and/or subtypes	HIV-1 and HIV-2 and all subtypes	**Environmental requirements**	Laboratory	**Compatible with EQA and which?**	Yes, eg. NRL Australia and HUQAS Kenya
Type of result	Quantitative	**Power requirements**	AC power	**Mean time between failures**	No equipment failures recorded to date
Linear range	200 - 600,000 copies/mL				
Output	fg RT/mL and RNA copy equivalents/mL	**Time to battery charge**	N/A	**Transport and storage**	-14 to -25°C
DNA or RNA specific?	N/A				
Polyvalency	No	**Battery duration (hours)**	N/A	**Fridge at -80°C required?**	No
PERFORMANCE					
Sensitivity - analytical and clinical (source)	200 copies/mL	**Alternative charging options**	N/A	**Shelf life (of each item in the kit)**	2 years at customer
Specificity - analytical and clinical (source)	>99.5%	**Ease of use**	N/A	**Performance protocol (steps)**	Detailed in IfU, 21 steps over 2 days
Bias (source)	Not provided	**Display languages**	N/A	**Non-proprietary components required outside of the kit**	Pipette tips
Intra-assay precision (source)	4-8% CV				
Inter-assay precision (source)	2-3% CV	**Built-in memory storage capacity**	N/A	**Regulatory approval**	CE-IVD marked
SAMPLE					
Sample preparation (steps)	Prepare plasma from whole blood.			**In-country approvals**	Botswana, Zambia, Zimbabwe, Kenya, Uganda, Lesotho, India, Philippines and more.
Sample type	EDTA + Citrate plasma	**Connectivity options**	N/A		
Sample volume	1 mL			**USAGE**	
Sample stability	≤6 months at -20°C, >6 months at -80°C	**Interpretation of result**	N/A	**Technical skill required**	Lab Technician
Nucleic acid extraction method	N/A			**Applicable settings**	Near-POC / district hospital level
Time to result	48 hrs	**Instrument lifespan**	N/A	**Laboratory set-up**	Simple, not specialized, single work area, freezing required.
Capacity	32 samples per run	**Other non-proprietary equipment required**	ELISA plate reader, incubator, end-over-end mixing table, vortex, computer	**Waste disposal requirements**	Follow local SOPs for hazardous waste handling.
Batching?	Yes				
Throughput per end-user per hour and/or 8hr day	30-60 tests over 2 days	**Regulatory approval**	N/A		

02 | PRICING

Instrument		Reference number	EXW ($)	Cartridge/reagents		Reference number	EXW ($)
ExaVir Load Start-up equipment	230 V	59311	$4,500	ExaVir Load v3	Reagents & consumables to run 30 tests + 2 controls	55011	$360 - 750
ExaVir Load Start-up equipment	110 V	59310	$4,500				
Instrument Accessories		**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**EXW ($)**
None				ELISA plate reader			
				Incubator			
				End-over-end mixing table			
				Vortex			
				Computer			
Cost per device			**$4,500**	**Cost per test result**			**$12-25**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost ($)
Leasing or reagent rental (RAP)	Purchase, leasing and reagent rental options can be offered.	Offered and negotiated upon request.
Installation	Wherever Cavidi has representation, installation is free of charge. If a new market, costs can be negotiated.	None
Training	• 4-5 days of training is needed • English and Portuguese available • On-site training available • Training tools are available as a training package/tools for before, under and after training. • End-users are considered proficient after training • Comprehensive training material is available for trainers and users.	Free of charge in countries where Cavidi has represenation. If a new market, costs can be negotiated.
Maintenance (including instrument swap)	The ExaVir Load equipment only requires disinfection and wash. Maintenance of the microplate reader, while not part of our equipment supply, may be offered by the Cavidi local representative.	Cost varies depending on the make of reader and country and will be provided upon request.
Length(s) of warranty and additional costs for extended warranty / care plan	The ExaVir equipment is guaranteed (unlimited warranty) as long as the site is active.	None
Warranty components	Warranty covers all components of the ExaVir equipment.	N/A
Turnkey option	Can be offered upon request.	N/A
In-country / regional technical support availability	Yes	N/A

05 | CONTACT INFO

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LAB-BASED HIV VL & HCV VL
HOLOGIC

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Hologic**	
Product	**APTIMA HIV-1 QUANT DX ASSAY**	**APTIMA HCV QUANT DX ASSAY**
	ASSAY	
Intended use	Detection and quantitation of HIV-1 RNA. It is intended for use as an aid in the diagnosis of HIV-1 infection, including acute or primary infection, as a confirmation of HIV-1 infection, and as an aid in clinical management of patients infected with HIV-1. May be used as a supplemental test for specimens that have repeat reactive results with approved HIV immunoassays. If the specimen is reactive, HIV-1 infection is confirmed. May also be used in conjunction with clinical presentation and other laboratory markers for disease prognosis in HIV-1 infected individuals. When used as an aid in the diagnosis of HIV-1 infection, performance for qualitative results is established with both plasma and serum specimens. May be used as an aid in monitoring the effect of antiretroviral treatment by measuring changes in the concentration of HIV-1 RNA in plasma. When used as an aid in monitoring the effect of antiretroviral therapy, performance for quantitative results is established with plasma specimens only (serum specimens may not be used for quantitative results). Not intended for use in screening blood or plasma donors.	Detection and quantitation of HCV RNA. Indicated for use as an aid in the diagnosis of active HCV infection in the following populations: - Individuals with antibody evidence of HCV infection with evidence of liver disease - individuals suspected of being actively infected with HCV following antibody evidence - individuals at risk of HCV infection with antibodies to HCV Detection of HCV RNA indicates that the virus is replicating and, therefore, is evidence of active infection. Indicated for use as an aid in the management of HCV infected patients undergoing HCV antiviral drug therapy. The assay measures HCV RNA levels at baseline, during treatment, and after treatment as well as determining sustained virological response (SVR). Assay performance characteristics will be established for individuals infected with HCV genotypes 1 through 6 treated with sofosbuvir-based regimens using drugs approved by the United States Food and Drug Administration (FDA), prescribed in accordance with FDA-approved labeling and/or the current American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV treatment guidelines. No information is available on the assay's performance when other therapies are used. The results must be interpreted within the context of all relevant clinical and laboratory findings. Not intended for use as a screening test for the presence of HCV in blood or blood products.
Principle of the assay	Real-Time TMA	
Target	HIV-1 Pol and LTR	HCV 5' UTR
Genotypes and/ or subtypes	HIV-1 group M (A, B, C, D, F, G, H, CRF01_AE, CRF02_AG), group N, and group O	Genotypes 1-6
Type of result	Qualitative and quantitative	
Linear range	LOD = 13.1 copies Linear Range for Quantitation = 30 - 10e6 copies/mL	Performance characteristics have not yet been established.
Output	Qualitative output: Reactive or Non-reactive Quantitative output: viral load in copies/mL	Qualitative output: Reactive or Non-reactive Quantitative output: viral load in IU/mL
DNA or RNA specific?	RNA	
Polyvalency	Available: Chlamydia diagnosis, Gonorrhoea diagnosis, Chlamydia/Gonorrhoea combined diagnosis, Trichomonas vaginalis diagnosis, and HPV diagnosis and genotyping. In development: HBV viral load, Mycoplasma genitalium, HSV 1/2, Bacterial Vaginosis, Candida, Influenza A, B, RSV, Parainfluenza 1,2,3,4, Adenovirus, Human Metapneumovirus, and Rhinovirus.	
	PERFORMANCE	
Sensitivity - analytical and clinical (source)	13.1 copies/mL (95% detected in 500mL plasma) (package insert)	Performance characteristics have not yet been established.
Specificity - analytical and clinical (source)	100% (CI 99.4 - 100% in 500mL plasma) (package insert)	
Bias (source)	<0.05 log copies/mL (package insert)	
Intra-assay precision (source)	Within 0.05 log SD and <1.93% CV (package insert)	
Inter-assay precision (source)	Within 0.09 log SD and <3.75% CV (package insert)	

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
SAMPLE		
Sample preparation	Plasma and serum: after centrifugation, uncap primary blood tube and load onto system.	
Sample type	Plasma and serum. Hologic has developed a protocol for DBS that will be used to evaluate performance of the assay with this sample type. Hologic is investigating whether it will pursue regulatory certification for DBS.	
Sample volume	≥1.2mL in primary tubes, 700mL in specimen aliquot tubes, and 240mL with a 1:3 dilution in specimen aliquot tubes.	
Sample stability	Whole blood is stable for 24hrs at 2-30°C prior to centrifugation. Plasma is stable for 3 days in the primary tube or 5 days in secondary tubes at 2-8°C or 90 days in secondary tubes at -20°C or -70°C. Serum is stable for 5 days in primary or secondary tubes at 2-8°C or 7 days or in secondary tubes at -20°C.	Target: Whole blood is stable for 6hrs at 2-30°C prior to centrifugation. Plasma is stable for 24hrs in primary or secondary tubes at 2-25°C; 5 days in primary or secondary tubes at 2-8°C; or 60 days in secondary tubes at -20°C. Serum is stable for 24hrs in primary or secondary tubes at 2-30°C; 5 days in primary or secondary tubes at 2-8°C; or 60 days in secondary tubes at -20°C. Note: Performance characteristics have not yet been established.
Nucleic acid extraction method	Automated (platform is completely automated from sample to result).	
Time to result	Time to first 5 results is 2hr and 41 minutes, with additional 5 results every 5 minutes.	
Capacity	The Panther holds 8 sample racks of 15 samples per rack, thus on-board capacity is 120 specimens. Additional samples can be loaded every 15 minutes.	
Batching?	The Panther is NOT a batch system - users can continuously load samples at any time (random access). Controls are only needed every 24 hours or every 100 test kit.	
Throughput per end-user per hour and/or 8hr day	2 hours and 41 minutes to deliver the first 5 results, with an additional 5 results every 5 minutes. 324 samples/8 hours. At max capacity: 60 results/hr.	
INSTRUMENT		
Size of device	W x D x H: 122.0 x 81.5 x 175.0 cm. UPS (W x D x H): 21.4 x 41.0 x 32.5 cm.	
Weight of device	345kg. UPS (optional): 34.5kg.	
Robustness	• Direct tube sampling capability of primary tube and no processing of sample prior to loading onto the instrument. • Random Access Capability using on board sample barcode readers with samples and assay requests performed in a random manner, allowing samples to be loaded and tested as they are received throughout the day. • A reagent identification system (barcode or other) to automatically link reagent lot and expiration date information to the sample report. • Positive Sample Identification with ability to load samples and let the system run by itself automatically. • Reagent dispense verification and liquid level sensing capability to verify proper dispense of sample and reagents into reaction tube. • The ability to automatically decontaminate and remove amplification reaction tubes from the assay processing area without operator intervention in a closed system. • Ability to perform maintenance steps automatically at times scheduled by operator.	
Environmental requirements	Environment: indoor use only. Can be placed in general purpose lab and independent molecular lab not required Sunlight: No direct sunlight - sunlight may mislead optical sensors and affect performance Dust: No excessive dust Altitude: ≤2,000m above sea level Temperature: Ambient Operating 15–30°C; Storage 5–45°C; Transport -20–70°C Relative Humidity: Operating 20-85% non-condensing; Storage 10-90% non-condensing; Transport 10-90% non-condensing Pollution Degree: 2 Installation Class: 2	
Power requirements	Voltage: 100-240 + 10% VAC Frequency: 50-60Hz, single phase Current Input: Minimum of 15 amp circuit (dedicated); 20 amp circuit (dedicated if used with optional UPS) Current Draw: Average 700W; Peak 1400W; 100 VAC circuit draws 13 amps, 240 VAC circuit draws 5.4 amps Fuse: Thermal circuit breaker	
Time to battery charge	N/A	
Battery duration	N/A	
Alternative charging options	N/A	
Ease of use	The Panther has a touchscreen monitor connected to the system and a printer is included.	
Display languages	English	
Built-in memory storage capacity	250 GB	
Connectivity options	Panther hosts bi-directional LIS connectivity.	

Continued overleaf

Lab-based HIV VL & HCV VL – Hologic continued

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
INSTRUMENT		
Interpretation of result	Reported Aptima HIV-1 Quant Dx Results / Quantitative Interpretation / Qualitative Intepretation. Not Detected / HIV-1 RNA not detected / Non-reactive for HIV-1 RNA. <30 detected / HIV-1 RNA is detected but at a level below the Lower Limit of Quantitation (LLOQ) / Reactive for HIV-1 RNA. 30 - 10,000,000 / HIV-1 RNA concentration is within the linear range of 30 - 10,000,000 copies/mL / Reactive for HIV-1 RNA. >10,000,000 / HIV-1 RNA concentration is above the Upper Limit of Quantitation (ULOQ) / Reactive for HIV-1 RNA.	N/A
Instrument lifespan	7-10 years	
Other non-proprietary equipment required	No other third party equipment is required.	
Regulatory approval	N/A	
KIT		
Kit components	Assay Kit: Assay Box: TCR (liquid format), Enzyme, Amplification, and Promoter reagents (lyophilized with individual reconstitution solutions) Control Kit: Negative, Low Positive, and High Positive Calibrator Kit: Calibrator tube	
Kit sizes	100 tests	
Internal control(s)	Internal control is formulated into the TCR and run in every sample.	
Compatible with EQA and which?	Acrometrix, QCMD, WHO standard	
Mean time between failures	Average = 1,200 hours globally. This reflects new vs experinced uses as well as high vs. low volume labs. By company definition, this includes instrument repairs as well as user inquiries not requiring a repair.	
Transport and storage	Assay Box: stored at 2-8°C, shipped at controlled ambient temperature. Calibrator and Control Box: stored and shipped at -15°C to -35°C.	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	Maximum shelf life = 18 months post manufacturing.	Product currently under development. Performance characteristics have not been established.
Performance protocol	1. Centrifuge blood tube to separate plasma or serum 2. Prepare reagents, load onto Panther rack, and load on Panther 3. Load samples onto Panther rack, uncap tubes, and load on Panther 4. If samples do not have barcodes, manually enter sample ID into system 5. Close Panther door and Panther will start assay processing and report results when complete	
Non-proprietary components required outside of the kit	All consumables, both proprietary and non-proprietary, and assay fluids needed to perform testing on the Panther system are included and automatically calculated when ordering the Aptima Assay. The list of consumables that are included is provided below: - Multi-tube units (MTUs) – reaction vessel used on Panther - Waste Bags for Panther - Panther Waste Bin Cover - Assay Fluids needed to run Panther - Tecan tips used on Panther These are provided free of charge and how many of each that will be needed per instrument is calculated based on the number of tests ordered.	
Regulatory approval	CE-IVD certified (Nov 2014). Submitted for WHO Prequalificaiton, US FDA PMA and China FDA.	Will be submitted for the following: CE/IVD (expected in 2015), US FDA, and China FDA.
In-country approvals	Several planned.	
USAGE		
Technical skill required	Minimal skill level, no pipetting needed.	
Applicable settings	Can be run in general laboratory with minimal infrastructure requirements.	
Laboratory set-up	General purpose laboratory.	
Waste disposal requirements	Bleach automatically added by Panther system to each specimen after run. Waste disposal handled according to country regulations.	

02 | PRICING

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Panther System	1 integrated automated platform with on-board computer. Printer included.	303095	$150,000 - 175,000	Aptima HIV-1 Quant Dx Assay Kit	Assay kit 100 tests (includes 1 assay box, 1 Calibrator kit, and 1 Control kit). Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included (and calculated based on number of kits ordered).	PRD-03000	$10-25
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				None			
Cost per device			**$150,000 - 175,000**	**Cost per test result**			**$10-25**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Panther System	1 integrated automated platform with on-board computer. Printer included.	303095	$150,000 - 175,000	Aptima HCV Quant Dx Assay Kit	Assay kit 100 tests (includes 1 assay box, 1 Calibrator kit, and 1 Control kit). Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included (and calculated based on number of kits ordered).		price available upon commercialization
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				None			
Cost per device			**$150,000 - 175,000**	**Cost per test result**			**Price available upon commercialization**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

Continued overleaf

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Instrument purchase or reagent rental are available based on contractual volume commitments.
Installation	Included in instrument purchase or reagent rental, estimated at less than 3 days.
Training	Training for 2 individuals is included in instrument purchase or reagent rental, estimated at 5 days, and includes proficiency prior to the start of clinical testing.
Maintenance	Year 1: full warranty Year 2 and beyond: service contract available for purchased instruments or included in reagent rental
Length(s) of warranty and additional costs for extended warranty / care plan	12 month warranty included in instrument purchase. Annual service contract offered after warranty period. Instrument service and support included in reagent rental.
Warranty components	Warranty includes: - labour - travel expenses - replacement parts - preventative maintenance - access to technical support - factory authorized updates or modifications - up to two Pro360 and/or LIS configuration changes
Turnkey option	N/A
in-country / regional technical support availability	In-country/regional service and support will be offered locally by contractors or distributors.

05 | CONTACT INFO

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LAB-BASED HIV EID, HIV VL, HCV VL
QIAGEN

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD		HCV VIRAL LOAD	
Company	**Qiagen**			
Product	**ARTUS HI VIRUS-1 RG RT-PCR**	**ARTUS HI VIRUS-1 QS-RGQ**	**ARTUS HCV RG RT-PCR**	**ARTUS HCV QS-RGQ**
ASSAY				
Intended use	Quantitation of HIV-1 RNA. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment, as measured by changes in EDTA plasma HIV-1 RNA levels. Not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection.		Quantitation of HCV RNA. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiviral treatment as measured by changes in EDTA plasma HCV RNA levels. Not intended to be used as a screening test for HCV or as a diagnostic test to confirm the presence of HCV infection.	
Principle of the assay	Real time PCR			
Target	HIV-1 RNA LTR		HCV RNA, 240 nt region of the 5' UTR	
Genotypes and/ or subtypes	HIV-1: Group M (A-H)		HCV genotypes 1–6	
Type of result	Quantitative			
Linear range	60 - 50,000,000 copies/mL	45 - 45,000,000 (LOD 34 copies/mL)	65 - 1,000,000 IU/mL	35 - 17,700,000 IU/mL
Output	Viral load			
DNA or RNA specific?	No			
Polyvalency	HBV, CMV, EBV, BKV, VZV, HSV, CT, M. tuberculosis	HBV, CMV, EBV, BKV, VZV, HSV, C.Diff., VanR, CT/NG, GBS.	HBV, CMV, EBV, BKV, VZV, HSV, CT, M. tuberculosis	HBV, CMV, EBV, BKV, VZV, HSV, C.Diff., VanR, CT/NG, GBS.
PERFORMANCE				
Sensitivity - analytical and clinical (source)	4.5 IU/µL (analytical)	34.4 copies/mL (analytical)	33.6 IU/mL (analytical)	21.6 IU/mL (analytical)
Specificity - analytical and clinical (source)	Not provided			
Bias (source)	Not provided			
Intra-assay precision (source)	Not provided			
Inter-assay precision (source)	Not provided			
SAMPLE				
Sample preparation (steps)	Not provided			
Sample type	Plasma			
Sample volume	500µL	1,000µL	500µL	1,000µL
Sample stability	Not provided			
Nucleic acid extraction method	Manual (QIAamp DSP Virus Kit)	Automated	Manual (QIAamp DSP Virus Kit)	Automated
Time to result	5–6 hours			
Capacity	≤96 samples			
Batching?	Yes, flexible batch size.			
Throughput per end-user per hour and/or 8hr day	≤67 samples/run			

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Qiagen continued

Product	ARTUS HI VIRUS-1 RG RT-PCR	ARTUS HI VIRUS-1 QS-RGQ	ARTUS HCV RG RT-PCR	ARTUS HCV QS-RGQ
INSTRUMENT				
Size of device	W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	QIAsymphony SP/AS – QIAsymphony SP: 128 x 103 x 73cm QIAsymphony AS: 59 x 103 x 73cm QIAsymphony SP/AS (integrated operation): 185 x 103 x 73cm Rotor-Gene Q: W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	QIAsymphony SP/AS – QIAsymphony SP: 128 x 103 x 73cm QIAsymphony AS: 59 x 103 x 73cm QIAsymphony SP/AS (integrated operation): 185 x 103 x 73cm Rotor-Gene Q: W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm
Weight of device	12.5kg, standard configuration	QIAsymphony SP: 175kg QIAsymphony AS: 90kg QIAsymphony SP/AS (integrated operation): 265kg Rotor-Gene Q: 12.5kg (standard configuration)	12.5kg, standard configuration	QIAsymphony SP: 175kg QIAsymphony AS: 90kg QIAsymphony SP/AS (integrated operation): 265kg Rotor-Gene Q: 12.5kg (standard configuration)
Robustness	Not provided			
Environmental requirements	For indoor use only			
Power requirements	100–240 V AC, 50–60 Hz, <520 VA (peak) Power consumption <60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5a 250 V fuse	QIAsymphony SP/AS: 100–240 V AC, 50–60 Hz, 1,400 VA, mains supply voltage are not to exceed 10% of nominal supply voltages Rotor-Gene Q: 100–240 V AC, 50–60 Hz, 520 VA (peak) Power consumption 8 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5A 250 V fuse	100–240 V AC, 50–60 Hz, <520 VA (peak) Power consumption <60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5a 250 V fuse	QIAsymphony SP/AS: 100–240 V AC, 50–60 Hz, 1,400 VA, mains supply voltage are not to exceed 10% of nominal supply voltages Rotor-Gene Q: 100–240 V AC, 50–60 Hz, 520 VA (peak) Power consumption 8 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5A 250 V fuse
Time to battery charge	N/A			
Battery duration (hours)	N/A			
Alternative charging options	None			
Ease of use	None	Touch screen	None	Touch screen
Display languages	English			
Built-in memory storage capacity	None			
Connectivity options	Q!Alink software (for automated data transfer between QIAsymphony RGQ and LIMS).			
Interpretation of result	None			
Instrument lifespan	Not provided			
Other non-proprietary equipment required	Vortex mixer, Benchtop centrifuge			
Regulatory approval	CE-IVD	CE-IVD	CE-IVD	CE-IVD

Product	ARTUS HI VIRUS-1 RG RT-PCR	ARTUS HI VIRUS-1 QS-RGQ	ARTUS HCV RG RT-PCR	ARTUS HCV QS-RGQ
KIT				
Kit components	2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)			
Kit sizes	24 or 96 reactions	24 or 72 reactions	24 or 96 reactions	24 or 72 reactions
Internal control(s)	Yes			
Compatible with EQA and which?	Yes, QCMD			
Mean time between failures	Not provided			
Transport and storage	Store the kit at -20°C, with some variation by reagent, transport on dry ice.			
Fridge at -80°C required?	No			
Shelf life (of each item in the kit)	All reagents are stable until the expiration date stated on the label			
Performance protocol (steps)	Not provided			
Non-proprietary components required outside of the kit	None			
Regulatory approval	CE-IVD	CE-IVD	CE-IVD	CE-IVD
In-country approvals	Not provided			
USAGE				
Technical skill required	Medium to highly trained, precision pipetting required at low volumes.			
Applicable settings	Mid- to highly-resourced settings	Highly-resourced settings	Mid- to highly-resourced settings	Highly-resourced settings
Laboratory set-up	3 dedicated areas are required	2 dedicated areas are required	3 dedicated areas are required	2 dedicated areas are required
Waste disposal requirements	Not provided			

02 | PRICING

HIV & HCV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
QIAsymphony RGQ	QIAsymphony SP, QIAsymphony AS, Rotor-Gene Q 5plex HRM; includes required accessories and consumables, installation, and training; includes 1-year warranty on parts and labour	9001850	Enquire	QIAamp DSP Virus Kit	For 50 preps: QIAamp MinElute Columns, buffers, reagents, tubes, column extenders, VacConnectors. For use with the artus RG kit variants	60704 4513363 artus HI Virus-1 QS-RGQ Kit (24) CE 4513366 artus HI Virus-1 QS-RGQ Kit (72) CE 4518363 artus HCV QS-RGQ Kit (24) CE 4518366 artus HCV QS-RGQ Kit (72) CE	
Rotor-Gene Q 5plex HRM system	Real-time PCR cycler and High Resolution Melt Analyser with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labour, installation and training	9001650	Enquire	QIAsymphony DSP Virus/ Pathogen Midi Kit	For 96 preps (1,000µL each): includes 2 reagent cartridges and enzyme racks and accessories; for use with the QIAsymphony RGQ system	937055 4513263 artus HI Virus-1 RG RT-PCR Kit (24) CE 4513265 artus HI Virus-1 RG RT-PCR Kit (96) CE 4518263 artus HCV RG RT-PCR Kit (24) CE 4518265 artus HCV RG RT-PCR Kit (96) CE	

Instrument Accessories	Reference number	FCA ($)	Non-proprietary equipment and consumables	Reference number	FCA ($)
None			Vortex mixer		
			Benchtop centrifuge		
Cost per device		**Not provided**	**Cost per test result**		**$16 - 45**

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Qiagen continued

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	QSRGQ		ROTORGENE Q	
	Description	**Cost ($)**	**Description**	**Cost ($)**
Leasing or reagent rental (RAP)	Possible	N/A	Possible	N/A
Installation	• Installation of the system hardware and software • Introductory training • Help customer to get started quickly	$7,000 - 9,000	• Installation of the system hardware and software • Introductory training • Help customer to get started quickly	$2,000 - 3,000
Training	• 2-5 days required • English + local languages, if available • On site training possible • Training tools available • Certified user after training completed	~$1,500 - 3,000 per day	• 1-2 days required • English + local languages, if available • On site training possible • Training tools available • Certified user after training completed	~$1,500 - 3,000 per day
Maintenance (including instrument swap)	• Inspection of all components of the equipment • Bring the instrument to its optimal performance • Ensure instrument is performing according to specification	$5,000 - 7,000	• Inspection of all components of the equipment • Bring the instrument to its optimal performance • Ensure instrument is performing according to specification	$1,500 - 1,900
Length(s) of warranty and additional costs for extended warranty / care plan	1 year manufacturer warranty on parts, labour, and travel	10% instrument LP for extended warranty, 48hr response time, 1 on-site preventative maintenance	1 year manufacturer warranty on parts, labour, and shipping	10% instrument LP for extended warranty, 48hr response time via loaner instrument, 1 on-site inspection service
Warranty components	Parts, labour, travel	N/A	Parts, labour, shipping	N/A
Turnkey option	N/A			
in-country / regional technical support availability	Yes	N/A	Yes	N/A

05 | CONTACT INFO

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LAB-BASED HIV EID, HIV VL, HCV VL
ROCHE MOLECULAR DIAGNOSTICS

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV QUAL	HCV VIRAL LOAD
Company	**Roche Molecular Diagnostics**			
Product	**COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 QUALITATIVE TEST, V2.0**	**COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 TEST, V2.0**	**COBAS AMPLIPREP/ COBAS TAQMAN HCV QUALITATIVE TEST, V2.0**	**COBAS AMPLIPREP/ COBAS TAQMAN HCV TEST, V2.0**
ASSAY				
Intended use (as per regulatory approval)	In vitro diagnostic, total nucleic acid amplification test for the qualitative detection of HIV-1 DNA and RNA (or total nucleic acid, TNA). It is a diagnostic test, indicated for individuals who are suspected to be actively infected with HIV-1. Detection of HIV-1 TNA is indicative of active HIV infection. Infants born to mothers infected with HIV-1 may have maternal antibodies to HIV-1, and the presence of HIV-1 nucleic acid in the infant indicates active HIV-1 infection. In adults, the test may be used as an aid in the diagnosis of HIV-1 infection.	In vitro nucleic acid amplification test for the quantitation of HIV-1 RNA. Intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 group M and HIV-1 group O infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of treatment.	Qualitative in vitro nucleic acid amplification test for the detection of HCV RNA genotypes 1 to 6. Indicated for patients who have clinical and/or biochemical evidence of liver disease and antibody evidence of HCV infection, and who are suspected to be actively infected with HCV. Can be used to confirm antibody positive specimens. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.	In vitro nucleic acid amplification test for the quantitation of HCV RNA genotypes 1 to 6. Intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy, and to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels.
Principle of the assay	Real Time PCR.			
Target	GAG and LTR (dual target) and HIV-2.	GAG and LTR (dual target).	HCV	HCV
Genotypes and/ or subtypes	HIV-1 groups M, N, and O, and major recombinant forms, HIV-2 groups A and B.	HIV-1 groups M, N, O, and major recombinant forms.	Genotypes 1 to 6.	
Type of result	Qualitative	Quantitative	Qualitative	Quantitative
Linear range	N/A	20 - 1,000,000 copies/mL (33 - 16,700,000 IU/mL)	N/A	15 - 100,000,000 IU/mL
Output	Qualitative result	Quantitative viral load result	Qualitative result	Quantitative viral load result
DNA or RNA specific?	DNA and RNA (TNA)	RNA		
Polyvalency	CMV Viral Load, B*5701, Chlamydia trachomatis (COBAS TaqMan 48 Analyser), Mycobacterium tuberculosis (COBAS TaqMan 48 Analyser), HBV.			
PERFORMANCE				
Sensitivity - analytical and clinical (source)	100% (Instructions For Use)	100% (Instructions For Use)	100% (Instructions For Use)	100% (Instructions For Use)
Specificity - analytical and clinical (source)	EDTA plasma: 99.8% DBS: 99.9% (Instructions For Use)	EDTA plasma: 99.3% (Instructions For Use)	Plasma or serum: 99.8% (Instructions For Use)	Plasma or serum: 100% (Instructions For Use)
Bias (source)	Not provided.			
Intra-assay precision (source)	Not provided.			
Inter-assay precision (source)	Not provided.			

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Roche Molecular Diagnostics continued

Product	COBAS AMPLIPREP/COBAS TAQMAN HIV-1 QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV TEST, V2.0
SAMPLE				
Sample preparation (steps)	(1) Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated. (2) For DBS samples, a pre-analytical step is required before transfering to the Input S-tube.	Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated.		
Sample type	Plasma or dried blood spots (DBS)	Plasma	Plasma or serum	
Sample volume	Plasma: 1mL (850mL gets processed) DBS: 1 spot (60–70µL)	1mL (850mL gets processed)	1mL (650mL gets processed)	1mL (650mL gets processed)
Sample stability	Plasma specimens may be stored at room temperature (25-30°C) for ≤1 day, at 2-8°C for ≤5 days or frozen at -20°C to -80°C for ≤6 weeks. DBS may be stored in individual re-sealable bags, with a desiccant sachet, at ambient temperature for ≤3 months.	Plasma specimens may be stored at room temperature (25-30°C) for ≤1 day, at 2-8°C for ≤6 days or frozen at -20°C to -80°C for ≤6 weeks.	Plasma or serum specimens may be stored at 2-8°C for ≤3 days or frozen at -20°C to -80°C for ≤6 weeks.	Plasma or serum specimens may be stored at 4°C for ≤3 days or frozen at -20°C to -80°C for ≤6 weeks.
Nucleic acid extraction method	Automated (docked and undocked options).			
Time to result	5-8 hours			
Capacity	24 tests per batch (22 samples + 2 controls)	24 tests per batch (21 samples + 3 controls)	24 tests per batch (22 samples + 2 controls)	24 tests per batch (21 samples + 3 controls)
Batching?	Yes. System can perform additional batches with its interleaved capability.			
Throughput per end-user per hour and/or 8hr day	COBAS AmpliPrep: 144 tests/8 hours COBAS Taqman 48 Analyser: 22 samples/run; 20–100 tests/day COBAS Taqman Analyser: 88 samples/run; 100–250 tests/day 1 COBAS AmpliPrep Instrument can be connected to up to 3 COBAS TaqMan Analysers			
INSTRUMENT				
Size of device	W 165 x D 74.5 x H 93.5 cm			
Weight of device	310 kg			
Robustness	Not provided.			
Environmental requirements	Ambient room temperature (15 - 32 °C).			
Power requirements	Line voltage: 100-125 and 200-240 VAC (-15%, +10%) Line frequency: 50 or 60 Hz (±2 Hz) Power consumption: Max. 1,200 VA; Installation category II (EN/IEC 61010-1)			
Time to battery charge	N/A			
Battery duration (hours)	N/A			
Alternative charging options	None			
Ease of use	Data Station			
Display languages	English			
Built-in memory storage capacity	Not provided.			
Connectivity options	Yes			
Interpretation of result	Automatic interpretation of data.			
Instrument lifespan	Depends on number of samples run.			
Other non-proprietary equipment required	Vortex mixer (and Thermomixer for DBS).	Vortex mixer		
Regulatory approval	WHO-PQ, CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD, among others.	WHO-PQ, CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD, among others.	CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD, among others.	CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD, among others.

Product	COBAS AMPLIPREP/COBAS TAQMAN HIV-1 QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV TEST, V2.0
KIT				
Kit components	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, v2.0 COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	COBAS AmpliPrep/COBAS TaqMan HCV Qualitative Test, v2.0 COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	COBAS AmpliPrep/COBAS TaqMan HCV 72 Tests COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L
Kit sizes	48 tests/kit	48 tests/kit	72 tests/kit	72 tests/kit
Internal control(s)	Yes	Quantitation Standard	Yes	Quantitation Standard
Compatible with EQA and which?	Yes: QCMD			
Mean time between failures	COBAS AmpliPrep Instrument: 114 days COBAS TaqMan Analyser: 236 days COBAS TaqMan 48 Analyser: 850 days			
Transport and storage	Reagents: 2-8ºC Disposables: room temperature			
Fridge at -80°C required?	No			
Shelf life (of each item in the kit)	Average 6 months, dependant on earliest expiry of components.			
Performance protocol (steps)	As per Instructions for Use.			
Non-proprietary components required outside of the kit	As per Instructions for Use.			
Regulatory approval	WHO-PQ, CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD (plasma).	WHO-PQ, CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD (plasma).	CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD.	CE-IVD, US-FDA-IVD, Canada-IVD, Japan-IVD.
In-country approvals	Not provided.			
USAGE				
Technical skill required	Medium-highly trained, precision pipetting required.			
Applicable settings	Low- to highly-resourced settings.			
Laboratory set-up	Specialized; 1 dedicated area required for the COBAS AmpliPrep/COBAS TaqMan with docking station; preferably 2 dedicated areas for the COBAS AmpliPrep/COBAS TaqMan 48 System option.			
Waste disposal requirements	According to individual country regulations.			

Continued overleaf ⋰

02 | PRICING

EARLY INFANT DIAGNOSIS						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep Instrument	Sample preparation	3051315001		COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, v2.0	6693083190	$520.38
COBAS TaqMan Analyser	Amplification and detection	3121453001		COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	$19
COBAS TaqMan 48 Analyser	Amplification and detection	3279332001				
cobas p 630 Instrument	Automated pre-analytical solution for primary tube handling					
COBAS AmpliPrep/COBAS TaqMan System	1 COBAS AmpliPrep Instrument PLUS 1 COBAS TaqMan Analyser	3051315001 AND 3121453001	$150,000			
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001	$80	None		
SPU of 12x24/Cob.AmpliP		3155525001	$93			
Tube-S Box of 12x24/Cob.AmpliP		3137040001	$90			
Tip-K 1,2 mm ID Box of 12x36		3287343001	$55			
Cost per device			**$150,000**	**Cost per test result (includes reagents, controls and disposables)**		**$12.50**

HIV VIRAL LOAD						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep Instrument	Sample preparation	3051315001		COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0	5212294190	$350.00
COBAS TaqMan Analyser	Amplification and detection	3121453001		COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	$19
COBAS TaqMan 48 Analyser	Amplification and detection	3279332001				
cobas p 630 Instrument	Automated pre-analytical solution for primary tube handling					
COBAS AmpliPrep/COBAS TaqMan System	1 COBAS AmpliPrep Instrument PLUS 1 COBAS TaqMan Analyser	3051315001 AND 3121453001	$150,000			
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001	$80	None		
SPU of 12x24/Cob.AmpliP		3155525001	$93			
Tube-S Box of 12x24/Cob.AmpliP		3137040001	$90			
Tip-K 1,2 mm ID Box of 12x36		3287343001	$55			
Cost per device			**$150,000**	**Cost per test result (includes reagents, controls and disposables)**		**$9.40**

HCV QUAL						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep Instrument	Sample preparation	3051315001		COBAS AmpliPrep/COBAS TaqMan HCV Qualitative Test, v2.0	5480477190	Price will depend on country income level and volume commitments
COBAS TaqMan Analyser	Amplification and detection	3121453001				
COBAS TaqMan 48 Analyser	Amplification and detection	3279332001				
cobas p 630 Instrument	Automated pre-analytical solution for primary tube handling			COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	$19
COBAS AmpliPrep/COBAS TaqMan System	1 COBAS AmpliPrep Instrument PLUS 1 COBAS TaqMan Analyser	3051315001 AND 3121453001	$150,000			
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001	$80	None		
SPU of 12x24/Cob.AmpliP		3155525001	$93			
Tube-S Box of 12x24/Cob.AmpliP		3137040001	$90			
Tip-K 1,2 mm ID Box of 12x36		3287343001	$55			
Cost per device			**$150,000**	**Cost per test result**		**Dependent on income level & volume commitments**

HCV VIRAL LOAD						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep Instrument	Sample preparation	3051315001		COBAS AmpliPrep/COBAS TaqMan HCV 72 Tests	5532264190	Price will depend on country income level and volume commitments
COBAS TaqMan Analyser	Amplification and detection	3121453001		COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	$19
COBAS TaqMan 48 Analyser	Amplification and detection	3279332001				
cobas p 630 Instrument	Automated pre-analytical solution for primary tube handling					
COBAS AmpliPrep/COBAS TaqMan System	1 COBAS AmpliPrep Instrument PLUS 1 COBAS TaqMan Analyser	3051315001 AND 3121453001	$150,000			
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001	$80	None		
SPU of 12x24/Cob.AmpliP		3155525001	$93			
Tube-S Box of 12x24/Cob.AmpliP		3137040001	$90			
Tip-K 1,2 mm ID Box of 12x36		3287343001	$55			
Cost per device			**$150,000**	**Cost per test result**		**Dependent on income level & volume commitments**

03 | TIERED AND VOLUME-BASED PRICING

Price will depend on country income level and volume commitments.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Outright purchase, leasing and rental are available dependent on country, contractual volume commitment with mitigation risk assessment.
Installation	Yes, included in acquisition cost.
Training	Yes, included in acquisition cost.
Maintenance (including instrument swap)	Information not provided.
Length(s) of warranty and additional costs for extended warranty / care plan	Standard Manufacture Warranty (12 months): includes parts, travel and labour. Extended Warranty (months 13-24): up to 2 preventive maintenance visits. Excludes break down and repair visits.
Warranty components	Parts, travel and labour.
Turnkey option	Information not provided.
in-country / regional technical support availability	Roche provides in-country/regional technical support either directly through Roche or by a Roche distributor.

05 | CONTACT INFO

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LAB-BASED HIV VL, HCV VL & HCV GT
SACACE BIOTECHNOLOGIES

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPE
Company	**Sacace Biotechnologies**		
Product	**HIV REAL-TM QUANT DX**	**HCV REAL-TM QUANT DX**	**HCV GENOTYPE PLUS REAL-TM**
	ASSAY		
Intended use (as per regulatory approval)	Quantitative detection of HIV-1 RNA. Provides prognostic information regarding likelihood of treatment response to antiretroviral therapy.	Quantitative detection of HCV RNA. Provides prognostic information regarding likelihood of treatment response to interferon monotherapy, interferon plus ribavirin combination therapy and peginterferon plus ribavirin combination therapy.	Genotyping of HCV virus genotypes 1-6.
Principle of the assay	Quantitative Real-Time PCR using fluorescently-labelled probes and dual color detection.	Quantitative Real-Time PCR using fluorescently-labelled probes and dual color detection.	Real time PCR with 2-channel fluorescent detection.
Target	Pol	5'UTR region	
Genotypes and/ or subtypes	All relevant genotypes: all subtypes of HIV-1 M-group (A, B, C, D, AE, F, G, AA-GH)	1a, 1b, 2, 3, 4, 5a, 6	
Type of result	Quantitative		Genotype
Linear range	48 - 10,000,000 IU/mL	13 - 10,000,000 IU/mL	N/A
Output	Viral load		Genotype
DNA or RNA specific?	RNA specific		
Polyvalency	Not provided		
	PERFORMANCE		
Sensitivity - analytical and clinical (source)	48 IU/mL with 1.0 mL sample	13 IU/mL with 1.0 mL sample	1,000 IU/mL
Specificity - analytical and clinical (source)	100%	100%	100%
Bias (source)	Not provided		
Intra-assay precision (source)	CV % = 0.71	CV % = 0.86	N/A
Inter-assay precision (source)	CV % = 0.82	CV % = 1.37	N/A
	SAMPLE		
Sample preparation (steps)	Whole blood collected in EDTA should be separated into plasma and cellular components by centrifugation at 800-1,600 x g for 20 min within six hours. The isolated plasma has to be transferred into a sterile polypropylene tube.		
Sample type	Plasma		
Sample volume	100 - 1,000 µL		
Sample stability	Plasma may be stored at 2-8°C for an additional 3 days. Alternatively, plasma may be stored at -18°C for up to one month or 1 year when stored at -70°C.		
Nucleic acid extraction method	Automatic or manual. Any commercial RNA/DNA isolation kit, if CE-IVD validated for viral nucleic acids extraction from plasma, could be used. Manual: Sacace MagnoVirus Automated: Sacace SaMag Nucleic Acids Automatic Extractor		Automated or manual. Manual (any nucleic acid extraction kit; Sacace recommend their own one) or automated (e.g. NucliSens easyMAG (bioMérieux)).
Time to result	3 hours		
Capacity	96 samples per run		
Batching?	96 samples per plate		
Throughput per end-user per hour and/or 8hr day	96 samples per day using SaMag automatic nucleic acid extractor.		50 samples per day.

Product	HIV REAL-TM QUANT DX	HCV REAL-TM QUANT DX	HCV GENOTYPE PLUS REAL-TM
INSTRUMENT			
Size of device	SaMag: 100 x 70 x 52 cm SaCycler-96: 210 x 540 x 540 mm		
Weight of device	SaMag: 70kg SaCycler-96: 27kg		
Robustness	Possibility to resume in case of power failure.		
Environmental requirements	SaMag: 30 to 80% RH (non condensing) SaCycler-96: Room temperature (~25°C) max; humidity 50-80%		
Power requirements	AC power; possibility to resume in case of power failure		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	N/A		
Ease of use	Keypad and integrated barcode reader for easy set-up.		
Display languages	English		
Built-in memory storage capacity	Yes, and possibility to resume in case of power failure		
Connectivity options	None		
Interpretation of result	Using provided PC software "RealTime_PCR"		
Instrument lifespan	100,000 hours of LED		
Other non-proprietary equipment required	PC with windows operating system (supplied).		
Regulatory approval	CE-IVD		
KIT			
Kit components	Calibrators, high positive control, low positive control, negative control, internal exogenous control		Internal and external (positive and negative).
Kit sizes	1 box		
Internal control(s)	Yes		
Compatible with EQA and which?	The kit was validated using the 2nd WHO International Reference Panel Preparation for HIV-1 Subtypes for NAT (Main), NIBSC code: 12/224.	The kit was validated using the 4th WHO International Standard for HCV for Nucleic Acid Amplification Techniques, NIBSC code: 06/102 15.	
Mean time between failures	Not provided		
Transport and storage	All components of the kit are lyophilized, the kit can be shipped at room temperature and stored at 2-8°C.		Shipped at 2-8°C and stored at -20°C.
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	The user just has to add 50µL of extracted viral RNA into the PCR tubes containing lyophilized reagents and transfer the 0.2mL PCR tube to the Real Time PCR instrument (no need to prepare PCR mastermix).		In addition mastermix must be prepared (mix, buffer, taq and MMLV enzymes), as kit is in liquid form.
Non-proprietary components required outside of the kit	Not provided		
Regulatory approval	CE-IVD	CE-IVD	None
In-country approvals	Not provided		
USAGE			
Technical skill required	Medium-highly trained, precision pipetting required at low volumes.		
Applicable settings	Low- to highly-resourced settings.		
Laboratory set-up	Specialised, 1-2 dedicated areas are required.		
Waste disposal requirements	Not provided		

Continued overleaf

Lab-based HIV VL & HCV VL – Sacace Biotechnologies continued

02 | PRICING

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
SaCycler-96	Real Time PCR instrument, 96-well plate, 5 channels	SC-96I	$20,000	HIV Real-TM Quant Dx	Assay kit	V0-96/3FRT	$20 (without extraction)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
SaMag	Automatic Nucleic Acid Extractor		$14,000	None			
Cost per device			**$34,000**	**Cost per test result**			**>$20**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
SaCycler-96	Real Time PCR instrument, 96-well plate, 5 channels	SC-96I	$20,000	HCV Real-TM Quant Dx	Assay kit	V1-96/3FRT	$20 (without extraction)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
SaMag	Automatic Nucleic Acid Extractor		$14,000	None			
Cost per device			**$34,000**	**Cost per test result**			**>$20**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Training	Provided through local distibutor or directly at Sacace facilities in Como.
Warranty components	1 year on instruments.

05 | CONTACT INFO

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Product Specialist

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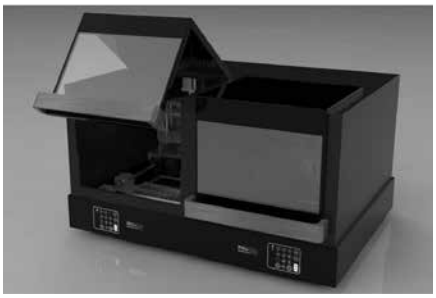

SaMag (automatic NA extraction)

SaCycler - 96
(Real TIme PCR)

LAB-BASED HIV VL, HCV VL & HCV GT
SIEMENS

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPING
Company	**Siemens**		
Product	**VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)**	**VERSANT HCV RNA 1.0 ASSAY (KPCR)**	**VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)**
ASSAY			
Intended use (as per regulatory approval)	Quantitation of HIV-1 RNA.	Quantitation of HCV RNA.	Line probe assay that identifies HCV genotypes 1 to 6 and subtypes a and b of genotype 1. Additional subtype information is available in a majority of cases. Intended to be used to guide the selection of treatment type and length for individuals being considered for antiviral treatment who are chronically infected with HCV. Thus intended to be used with samples known to be positive for HCV RNA.
Principle of the assay	Kinetic PCR		Line Probe Assay (LiPA) that utilizes the reverse-hybridization technology.
Target	HIV-1 RNA pol	Highly conserved HCV 5' untranslated region (5' UTR).	5'UTR and core region of the HCV genome.
Genotypes and/ or subtypes	HIV-1: group M (A-H, CRF01_ AE, CRF02_AG), group O	Genotypes 1-6 (1A, 1B, 2A, 2B, 2C, 3A, 4A, 5A, 6A)	Detects genotypes 1-6 and subtypes 1a vs 1b, and subtypes 6 (c-I).
Type of result	Quantitative		Qualitative
Linear range	37 - 11,000,000 copies/mL	15 - 100,000,000 IU/mL (64.5 copies/mL - 430,000,000 copies/mL)	N/A
Output	Viral load		Genotype
DNA or RNA specific?	RNA		
Polyvalency	HBV, CT/GC, CMV, EBV, HSV 1&2, HHV-6, Adenovirus, BKV, VZV, Parvovirus B19, JCV		N/A
PERFORMANCE			
Sensitivity - analytical and clinical (source)	LOD: 37 copies/ml (80IU/ ml) as determind following the CLSI MM6-A and CLSI EP17-A guidelines.	Limit of detection: 15 IU/mL (64.5 copies/mL); Analytical Sensitivity was also determined using the 3rd WHO HCV RNA International Standard diluted into pooled human serum or plasma using three reagent lots. The LoD was 7.5 IU/mL for plasma (95% CI: 6.5 - 9.6 IU/mL) and 19.4 IU/mL for serum (95% CI: 16.4 - 24.7 IU/mL).	HCV viral loads as low as 2,106 IU/mL produce reliable genotype results.
Specificity - analytical and clinical (source)	99.7% (n=1,0551); 95% lower one-sided confidence limit: 99.3%	100% (n = 1,054; 95% lower one-sided confidence limit: 99.7%).	N/A
Bias (source)	Not provided		N/A
Intra-assay precision (source)	Not provided		N/A
Inter-assay precision (source)	Not provided	Total Precision (including lot to lot variation) • 2 log IU/mL: 23.8 - 30.4% (0.11–0.13 log SD) • 3 - 4 log IU/mL: 22.8 - 23.6% (0.10 log SD) • 5 - 8 log IU/mL: 26.5 - 35.6% (0.11 - 0.15 log SD)	N/A
SAMPLE			
Sample preparation (steps)	Fully automated sample extraction using proprietary beads and sample prep module.		Manual (using the QIAGEN QIAamp DSP Virus Kit REF 60704) or fully automated sample extraction using proprietary beads and sample prep module.
Sample type	Plasma	Serum and plasma	
Sample volume	500µL		
Sample stability	Whole EDTA blood: ≤6 hours at room temperature or ≤24 hours at 2-8°C before centrifigation. Plasma: ≤24 hours at room temperature or ≤5 days at 2-8°C.		Store the extracted RNA at 2 - 8°C until processed with the VERSANT Amplification 2.0 Kit (LiPA). If the RNA is not processed immediately within approximately 30 minutes of extraction then store RNA samples at -60° to -80°C.

Continued overleaf

Lab-based HIV VL & HCV VL – Siemens continued

Product	VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)	VERSANT HCV RNA 1.0 ASSAY (KPCR)	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)
SAMPLE			
Nucleic acid extraction method	Automated (using proprietary beads)		Manual or automated.
Time to result	≤6 hours for a full plate (96 tests): - Sample preparation system setup: <10 minutes - Sample extraction: <3 hours - Amplification and detection: <3 hours		Variable depending on work flow.
Capacity	96 tests per run: 89 clinical samples, 4 calibrators, 3 controls =178 clinical samples/shift		Autoblot 3000H: 20 samples/run AutoLiPA 48: 48 samples/run
Batching?	Yes, flexible run sizes of 1-96 tests per batch		Yes
Throughput per end-user per hour and/or 8hr day	96 tests per run: 89 clinical samples, 4 calibrators, 3 controls =178 clinical samples/shift		Not provided
INSTRUMENT			
Size of device	VERSANT sample prep module (depth includes autoload tray): W 112.4 x D 100.6 x H 90.5 cm VERSANT amplification/detection module: W 36.8 x D 53.4 x H 45.7 cm		Autoblot 3000H: W 55.9 x H 45.7 x D 19.1 cm AutoLiPA 48: W 80.4 (w) x H 46 x D 45.9 cm
Weight of device	VERSANT Sample prep module: 155kg VERSANT Amplification/detection module: 25kg		Autoblot 3000H: 15.9kg AutoLiPA 48: 47kg
Robustness	Extremely robust		
Environmental requirements	Temperature: 18 - 30°C Humidity: 30 - 80% non-condensing Altitude: 0 - 2,000m Noise: <65 dB (SP module) / <75 dB, 1m distance (AD module)		Autoblot 3000H: • Temperature: 5 - 40°C • Maximum RH: 80% for temperatures ≤31°C decreasing linearly to 50% RH at 40°C • Altitude ≤2,000m AutoLiPA 48: • 15 - 30°C for operation; -10 to 50°C temperature for non-operation • RH of 20 - 90%
Power requirements	100 - 120 V AC at 50 - 60 Hz ± 5% or 200 V - 240 V AC		Autoblot 3000H: • 100 - 240 V, 50 - 60Hz, 3.2 amp max • MAINS supply voltage fluctuations up to ±10% of the nominal voltage • Transient overvoltages typically present on the MAINS supply AutoLiPA 48: 100 - 120 V and 220 - 240 V; 50 - 60 Hz
Time to battery charge	N/A		Not provided
Battery duration (hours)	N/A		Autoblot 3000H: Equipped with a rechargeable lithium battery that has a shelf-life of one year.
Alternative charging options	No		
Ease of use	Communication: 9 pin port; 4 COM ports; 2 network cards for communcations between SP and AD modules and for use with a LIS; Windows-based software; LIS-compatible user interface that manages up to 2 separate Analysers (Siemens configuration is not designed for Microsoft Windows domain network environment); Software production complies to ISO 13485; License: Windows XP.		Not provided
Display languages	English		
Built-in memory storage capacity	160 GB hard drive		Not provided
Connectivity options	LIS Interface capability		Not provided
Interpretation of result	Target not detected <37 copies/mL; viral load or >11,000,000 copies/mL	Target not detected <15 IU/mL; viral load or >1 x 10^8 IU/mL	Visual interpretation with interpretation chart or automated with LIPAScan software.
Instrument lifespan	Not provided		Not provided
Other non-proprietary equipment required	Computer and barcode scanner (supplied).		Scanner for LiPAScan software (optional)
Regulatory approval	CE-IVD Directive 98/79/EC		CE-IVD Directive 98/79/EC

Product	VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)	VERSANT HCV RNA 1.0 ASSAY (KPCR)	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)
KIT			
Kit components	VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 1 & 2 and VERSANT Sample Preparation 1.0 Reagents Kit (Box 1 & 2)	VERSANT HCV RNA 1.0 (kPCR) Kit, IVDD Box 1 & 2 and VERSANT Sample Preparation 1.0 Reagents Kit (Box 1 & 2)	HCV Amplification 2.0 Kit (LiPA) HCV Genotype 2.0 Assay (LiPA)
Kit sizes	96 tests/kit		40 tests/kit
Internal control(s)	Yes: internal controls; negative, low positive and high positive controls.		Yes: VERSANT HCV Control 2.0 Kit (LiPA)
Compatible with EQA and which?	Yes		Not provided
Mean time between failures	Not provided		
Transport and storage	Sample prep reagent kit, Box 1: 15-30°C; Box 2: 2-8°C; kPCR Reagent kit, Box 1: -30 to -10°C; kPCR Calibrators and controls kit, Box 2: -90 to -60°C.		HCV Amplification 2.0 Kit (LiPA): -25 to -15°C HCV Genotype 2.0 Assay (LiPA): 2 - 8°C
Fridge at -80°C required?	Yes		No
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	(1) Load dedicated sample prep reagents into a trough (2) place reagents on the module, (3) load plasma samples on to sample carrier, (4) place sample carriers on auto load tray of VERSANT sample prep module - from that point on it is fully automated.		Not provided
Non-proprietary components required outside of the kit	Plastics (e.g. tips and plates)		QIAGEN QIAamp DSP Virus Kit (REF 60704) if manual extraction is preferred
Regulatory approval	WHO prequalified; CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC
In-country approvals	Not provided		
USAGE			
Technical skill required	Yes, qualified in molecular practices		
Applicable settings	Highly-resourced settings		
Laboratory set-up	System concept supports either 1- or 2-room technologies		Bench top systems
Waste disposal requirements	Per local regulations and requirements		

02 | PRICING

HIV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
kPCR Sample Prep Sub-system	Automated sample preparation	10282928		VERSANT Sample Preparation 1.0 Reagents Box 1	Sample preparation	10286026	$10 - 14
kPCR Amp/Detect Instrument	Amplification and detection	10282939		VERSANT Sample Preparation 1.0 Reagents Box 2	Sample preparation	10286027	
				VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 1	Amplification and detection	10375763	$43 - 58
				VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 2	Amplification and detection	10375764	
				Test panel HIV-1 RNA (KPCR) (RUO)	3 positive controls and 1 negative	10282417	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
VERSANT KPCR SW V3.1 Install kit and KPCR TDEF software CD V3.2	Installation	10814064 10816436		Disposable tips 1mL Filtered (8 x 480 tips per case)		10282929	
BACK-UPS	Uninterrupted power supply	10638181		Disposable tips 300µL Filtered (12 x 480 tips per case)		10282930	
kPCR SP Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702391		Sample Prep Reagent Trough kit per 20 sleeves of 6 containers		10489008	
kPCR AD Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702393		Ultra clear cap strips (120 strips of 8)		10283000	
				96 Deep well plate 2mL (case of 60 plates)		10283255	
				PCR plates barcoded (25)		10282998	
				Waste bag biohazard (200)		10282938	
Cost per device			**$166,000 - 221,600**	**Cost per test result**			**$54 - 72**

Continued overleaf

HCV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
kPCR Sample Prep Sub-system	Automated sample preparation	10282928		VERSANT Sample Preparation 1.0 Reagents Box 1	Sample preparation	10286026	$10 - 14
kPCR Amp/Detect Instrument	Amplification and detection	10282939		VERSANT Sample Preparation 1.0 Reagents Box 2	Sample preparation	10286027	
				VERSANT HCV RNA (kPCR) kit, IVDD Box 1	Amplification and detection	10375763	$62 - 86
				VERSANT HCV RNA (kPCR) kit, IVDD Box 2	Amplification and detection	10375764	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
VERSANT KPCR SW V3.1 Install kit and KPCR TDEF software CD V3.2	Installation	10814064 10816436		Disposable tips 1mL Filtered (8 x 480 tips per case)		10282929	
BACK-UPS	Uninterrupted power supply	10638181		Disposable tips 300µL Filtered (12 x 480 tips per case)		10282930	
kPCR SP Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702391		Sample Prep Reagent Trough kit per 20 sleeves of 6 containers		10489008	
kPCR AD Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702393		Ultra clear cap strips (120 strips of 8)		10283000	
				96 Deep well plate 2mL (case of 60 plates)		10283255	
				PCR plates barcoded (25)		10282998	
				Waste bag biohazard (200)		10282938	
Cost per device			**$166,000 - 221,600**	**Cost per test result**			**$72 - 100**

HCV GENOTYPING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
AutoLiPA 48 INSTRUMENT	Line probe assay	10313066	$39,375 - 50,000	VERSANT HCV LiPA 2.0 Amplification Kit (IVD) (40 tests)	Amplification	10325050	$1,250 - 2,500
Autoblot 3000H Instrument	Line probe assay	10315618	$17,200 - 20,000	VERSANT HCV LiPA 2.0 Genotype Kit (IVD) (40 tests)	Genotyping	10325052	$3,250 - 10,250
LiPAScan Software (optional)	Software	10291328	$3,125 - 4,375	VERSANT HCV LiPA 2.0 Control Kit (IVD)	Controls	10325051	$812.50 - 1,250
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Auto LiPA 30 Strips Tray		10330923		None			
Auto LiPA 48 Strips Tray		10325628					
AutoBlot 3000 Strips Tray		10315381					
VERSANT LiPA Scan Reading Template		10329226					
Cost per device			**$57,000 - 70,000**	**Cost per test result**			**$132 - 350**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Available.
Installation	Complete installation provided by trained Siemens personnel.
Training	Dedicated training on instrument. Electronic training is widely available using Siemens Personalized Education Program (PEP).
Maintenance	Routine preventative maintenance required, and provided by Siemens with service contract.
Length(s) of warranty and additional costs for extended warranty / care plan	One year warranty provided for instrumentation.
Warranty components	Information not provided.
Turnkey option	Information not provided.
in-country / regional technical support availability	Available in all countries where Siemens products are sold.

05 | CONTACT INFO

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KPCR

LIPA

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GLOSSARY AND ABBREVIATIONS

INCOTERM GLOSSARY

Incoterms are an internationally recognised collection of terms that specify the responsibility of the buyer and seller in a purchase.[31] The terms used in this report include the following:

EXW (Ex works): Where the seller is responsible for the product, the export packing, and the monitoring and labelling.

FCA (Free carrier): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES).

CPT (Carriage paid to): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES), freight forwarder documentation fees, inland freight to main carrier, original terminal charges, vessel loading charges, ocean/air freight, and nominate export forwarder.

CIF (Cost, insurance, and freight): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES), freight forwarder documentation fees, inland freight to main carrier, original terminal charges, vessel loading charges, ocean/air freight, nominate export forwarder, and marine insurance. In general, companies specify the port to which the product will be delivered.

AIDS: Acquired Immunodeficiency Syndrome.

ART: Antiretroviral treatment.

ARV: Antiretroviral medicine to treat HIV/AIDS.

Bundled price: When a company sells a package or set of goods or services (in this case tests for different diseases or analytes that are run on the same platform) for a lower price than they would charge if the customer bought them separately.

CD4 count: The absolute number of CD4 positive T lymphocytes (T lymphocytes are CD3 positive immune cells) in the blood. CD4 count is measured in cells per microliter (cells/µL) of blood; equivalent to cells per cubic millimetre (cells/mm3). A normal, healthy value for a CD4 count is usually above 500 cells/µL.

CD4 percentage: The percentage of CD4 positive versus CD3 positive lymphocytes in the blood. A normal, healthy value for a CD4% is usually above 29%. Since CD4 counts can vary naturally from day to day, CD4% is a more accurate measurement of the health of the immune system. Children under the age of five years should be tested using CD4% because the number of lymphocytes can be higher in children and therefore using CD4% is more accurate.

CDC: Centers for Disease Control and Prevention in the US.

CE: Conformite Europeenne. Europe's regulatory agency for medical drugs and devices.

Clinical: Based on signs, symptoms, morbidities and diseases.

CMV: Cytomegalovirus.

CRF: Circulating Recombinant Form.

CT/NG or CT/GC: Chlamydia trachomatis and Neisseria gonorrhoeae.

DBS: Dried blood spot. A spot of blood that is preserved on filter paper through a process of desiccation.

DNA: Deoxyribonucleic acid. The genetic material of living organisms.

DRM: Drug resistance mutation. Genetic mutations of the HIV genome that result in resistance to antiretroviral drugs so that viral replication is no longer suppressed.

EBV: Epstein–Barr virus.

EID: Early infant diagnosis. According to current WHO guidelines, the first diagnostic test should be performed by a virological test when the infant is six weeks of age.

ELISA: Enzyme-linked immunosorbent assay. Also called enzyme immunoassay (EIA).

FDA: Food and Drug Administration. The US FDA is the USA's regulatory agency for medical drugs and devices.

FRET: Fluorescence resonance energy transfer.

FS: Fingerstick, also termed fingerprick. A lancet is used to prick or cut the fingertip to get a drop of capillary blood.

GMP: Good Manufacturing Practice. A production and testing practice that helps to ensure a quality product.

HBV and HCV: Hepatitis B virus and hepatitis C virus.

HIV: Human Immunodeficiency Virus.There are two types of HIV: HIV-1 and HIV-2. HIV-1 is more widespread and more virulent.

HPV: Human papillomavirus.

Immunologic: Based on the measurement of the immune system (e.g. for HIV the CD4 count or percentage and the change in the CD4 count or percentage over time). Clinico-immunological monitoring is based on both clinical and immunological measurement.

IVD: In vitro diagnostic.

kPCR: Kinetic polymerase chain reaction.

LDC: Least-Developed Countries, according to the United Nations classification.

LTR: Long terminal repeat. A conserved region of the HIV genome that is repeated on both ends.

mAb: Monoclonal antibody. A type of mono-specific antibody that binds to only one antigen or epitope.

MRSA: Methicillin-resistant Staphylococcus aureus.

NASBA: Nucleic Acid Sequence Based Amplification.

N/A: Not applicable.

PMTCT: Prevention of mother-to-child transmission. Providing treatment to mothers who are HIV-positive and their infants to prevent vertical infection in utero, intra-partum and post-partum.

POC: Point-of-care.

RAP: Reagent agreement plan. Reagent agreement or reagent rental where products sold (in this case diagnostics or monitoring tests) are increased in price to include an amount to cover the amortized cost of an instrument platform, including maintenance costs, or other equipment. These costs are amortized over the useful life of the instrument system. A RAP requires accurate monthly volume forecasting.

RLS: Resource-limited settings.

Continued overleaf

RNA: Ribonucleic acid. Similar to DNA but is used to transmit information from DNA (transcription) to proteins (translation).

RT: Reverse transcriptase. An enzyme than transcribes RNA into DNA.

rt-PCR or q-PCR: Real-time or quantitative polymerase chain reaction. A form of PCR that is quantitative.

RUO: Research use only. Usually in connection with the fact that a product has not yet received FDA regulatory approval.

Serologic: Based on the measurement of antibodies in the blood.

SOP: Standard operating procedure.

SVR: Sustained virological response

TB: Tuberculosis. A disease caused by the pathogen Mycobacterium tuberculosis. MDR- and XDR-TB are multidrug-resistant and extensively drug-resistant TB, respectively.

TBD: To be determined.

TGA: Therapeutic Goods Administration. Australia's regulatory agency for medical drugs and devices.

Total cost of ownership: The fully loaded sum of the direct and indirect costs of a product or system (in this case test result, including reagents, calibrators and controls, equipment, servicing and set-up and logistics).

UNITAID: UNITAID is a global health initiative in great part financed by a solidarity levy on airline tickets. UNITAID uses innovative financing to increase funding for greater access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries. It is hosted and administered by WHO.

Virologic: Based on the measurement of the virus or a component of the virus (e.g. for HIV, p24 or RNA).

VL: Viral load.

VLT: Viral load test.

WHO: World Health Organization.

ACKNOWLEDGEMENTS:

MSF gratefully acknowledges the support of UNITAID as co-funders of two MSF projects: (1) An HIV-focused project to evaluate EID, VL and CD4 diagnostic platforms in eight resource-constrained countries; and (2) An HCV co-infection project aimed at transforming care in seven countries with the introduction of improved drugs and the simplification of the diagnostic and monitoring algorithm.

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