



# 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

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**

 [msfacecess.org/undetectable](http://msfacecess.org/undetectable)

### 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 antiretroviral medicines through its Untangling the Web reports and pushing for the uptake of policies that promote access to affordable, quality-assured treatments.

 [utw.msfacecess.org](http://utw.msfacecess.org)

### 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.

 [msfacecess.org/diagnosis-treatment-hepatitis-c-technical-landscape](http://msfacecess.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.<sup>32</sup> 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.<sup>3</sup> 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.<sup>32</sup> Other reasons for infant HIV infection include late ART initiation in mothers, and mothers inadequately adhering to ART during pregnancy and breast-feeding.<sup>13</sup> As infant mortality peaks at 2-3 months

of age in infected infants, early treatment is imperative to prevent illness and death<sup>14,15</sup>, and may also reduce the latent HIV-1 reservoir<sup>16</sup>, 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.<sup>17</sup>

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.<sup>18</sup>



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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](http://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<sup>9</sup> – 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'<sup>1,2</sup>, 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<sup>3,4</sup> 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<sup>5,6</sup>, 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<sup>3</sup>. 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.



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# 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 <sup>1</sup>
<b>Alere Pima Analyser</b> <i>Well-established and fairly widely implemented in resource-limited settings; cartridge-based</i>	<b>\$6 – 12</b>
<b>BD FACSPresto</b> <i>Market launched and quality assured, fully decentralisable, batching is possible; measures CD4 count, CD4 % and Hb; cartridge-based</i>	<b>&lt;\$10</b>
<b>Millipore Muse Auto CD4/CD4% system</b> <i>Not yet commercially available; measures both CD4 count and CD4 %; flow cytometry-based</i>	<b>~\$5</b>
<b>Omega Visitect CD4</b> <i>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</i>	<b>\$5.20</b>
<b>Sysmex Partec CyFlow miniPOC</b> <i>Is higher throughput than the other POC CD4 tests; measures CD4 count, CD4 % and total lymphocyte count; flow cytometry-based</i>	<b>\$3.15</b>
POINT-OF-CARE HIV AND HCV VIROLOGICAL TESTS	
<b>Alere q HIV 1/2 Detect (EID)</b> <i>Market launched and quality assured, fully decentralisable; cartridge-based</i>	<b>\$15 - 25</b>
<b>Cepheid Xpert HIV-1 qual (EID), Xpert HIV-1 Viral Load and Xpert HCV Viral Load</b> <i>Market launched and quality assured; GeneXpert is modular and near POC; but not fully decentralisable, cartridge-based</i>	<b>&lt;\$20</b>
<b>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</b> <i>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</i>	<b>\$17 - 28</b>
<b>Molbio Diagnostics Truenat HIV and Truenat HCV (viral load)</b> <i>Not yet market launched; may be launched in India first; cartridge-based</i>	<b>\$15</b>
<b>NWGHF LYNX HIV p24 Antigen Test</b> <i>Not yet market launched; non-molecular test, simple, affordable and fully decentralisable; cartridge-based</i>	<b>\$6.50 - 15</b>
<b>NWGHF/Quidel Savanna Quantitative RealTime HIV-1 Assay</b> <i>Not yet market launched; 50μL plasma (capillary whole blood separated by plasma separator) and 200μL plasma options; cartridge-based</i>	<b>\$11</b>
LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS	
<b>Abbott ARCHITECT HCV Ag</b> <i>The only fully automated, highly sensitive, commercially available, quality approved, HCV core antigen test; chemiluminiscent microparticle immunoassay</i>	<b>\$25 - 50</b>
<b>Abbott RealTime HIV-1 Qualitative (EID), RealTime HIV-1 (viral load) and RealTime HCV (viral load) and RealTime HCV Genotype II</b> <i>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</i>	<b>HIV: \$13 – 30 HCV: \$13 – 35</b>
<b>Biocentric Generic HIV DNA Cell (EID), Generic HIV Charge Virale and Generic HCV Charge Virale</b> <i>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</i>	<b>EID: \$13 HIV: \$15 HCV: \$23</b>
<b>bioMérieux NucliSENS EasyQ HIV-1</b> <i>Only platform that has received regulatory approval to use DBS as a sample type for HIV viral load</i>	<b>\$23</b>
<b>Cavidi ExaVir Load</b> <i>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</i>	<b>\$12 - 25</b>

Continued overleaf 

••• What this means for programmes continued

LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS (continued)	COST PER TEST IN USD <sup>1</sup>
<b>Hologic Aptima HIV-1 Quant Dx Assay and Aptima HCV Quant Dx Assay</b> <i>New automated platform for HIV and HCV; awaiting market launch of HCV test</i>	<b>HIV: \$10 - 25</b>
<b>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)</b> <i>Different options available for HIV and HCV viral load testing; platform not widely used in low-resource settings</i>	<b>\$16 - 45</b>
<b>Roche CAP/CTM HIV-1 Qualitative (EID), CAP/CTM HIV-1 (viral load), CAP/CTM HCV Qualitative and CAP/CTM HCV (viral load)</b> <i>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</i>	<b>EID: \$12.50</b> <b>HIV: \$9.40</b> <b>HCV: dependent on country income level and volume commitments</b>
<b>Sacace HIV Real-TM Quant Dx, HCV Real-TM Quant Dx and HCV Genotype Plus Real-TM</b> <i>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</i>	<b>&gt;\$20</b>
<b>Siemens VERSANT HIV-1 RNA Assay, VERSANT HCV RNA Assay (viral load) and VERSANT HCV Genotype 2.0 Assay</b> <i>Widely used for HCV viral load and genotyping, but not widely found in low-resource settings; expensive</i>	<b>HIV: \$54 – 72</b> <b>HCV: \$72 – 100</b> <b>GT: \$132 – 350</b>

(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 haemoglobin). 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<sup>7</sup>, 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.<sup>8</sup> 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.<sup>9</sup>

## 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, Cavid (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.<sup>10</sup>

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.<sup>11</sup> Additional cost modelling studies that include the now-lower prices for HIV viral load and second line treatment are expected imminently.

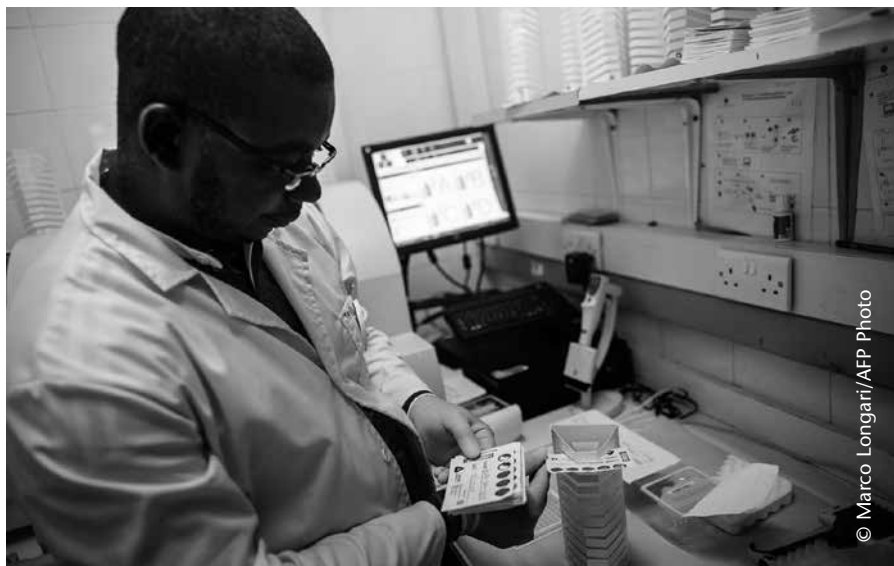
As countries start to implement and scale-up HCV testing programmes, it will be useful to be able to use existing molecular platforms for HCV testing. Abbott, Biocentric, Qiagen, Roche, Sacace and Siemens all have test kits for HCV RNA that may be run on

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.<sup>12</sup> 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.<sup>7</sup>



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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.<sup>19</sup> 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<sup>20</sup>, 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.<sup>8,21</sup> 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 1 mL 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.<sup>22</sup> 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.<sup>8,10</sup>

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.<sup>23</sup> 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.



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# 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<sup>24</sup>.

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 in 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<sup>25</sup>. 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<sup>26</sup>. 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.<sup>27</sup>

## 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.<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup> 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).<sup>\*</sup> 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.

<sup>\*</sup>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 € 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.





## 02 | PRICING

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

Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
Pima Analyser	1 Pima Analyser device	260300003	\$5,500	Pima CD4 100X cartridge kit	100 Pima CD4 foil sealed test cartridges with 1 product insert	260100100	\$595
	1 power transformer			Pima CD4 2.5X cartridge kit	25 Pima CD4 foil sealed test cartridges with 1 product insert	260100025	
	1 EU power cable			Fingerprick Sample Collection Kit for 100 Pima CD4 tests	4 units of safety lancets (x28)	260400199	\$80
	1 Pima Analyser User Guide				4 units of gauze swabs (x25)		
	1 Pima bead standard (260400011)				1 unit of alcoholic swabs (x100)		
Pima Instrument & Accessory Pack	1 Pima Analyser	260300004	\$6,050	Pima Printer Paper 1	4 units of plasters (x26)	260400009	\$32
	1 Power transformer				1 safety-lancet user guide		
	1 EU cable				Pima Printer Paper 2		
	1 Pima Analyser User Guide			Pima Bead Std	1 normal cartridge	260400011	\$50
	1 Pima Bead standard (260400011)				1 low cartridge		
	1 Pima Bag (260400001)				1 Pima bead standard user guide		
	1 Pima Printer (260400007)						
1 Connectivity Pack (260400015)							
<b>Instrument Accessories</b>		<b>Reference number</b>	<b>FCA (\$)</b>	<b>Non-proprietary equipment and consumables</b>		<b>Reference number</b>	<b>FCA (\$)</b>
Pima Instrument Bag	1 Pima Analyser bag	260400001	\$180	None			
Pima Printer	1 Pima Printer	260400007	\$350				
	1 Pima Printer User Guide						
Pima Connectivity Pack 1	1 Roll thermal paper 1, coated, non-adhesive						
	1 Pima Connectivity Pack	260400015	\$550				
Alere Solar Solution	1 User Manual						
	1 Solar Panel	260400040	\$1,750				
Alere Power Pack	1 Power Pack (260400015)						
	1 User Manual	260400017	\$1,150				
<b>Cost per device</b>			<b>\$6,000 – \$12,000</b>	<b>Cost per test result</b>		<b>\$6 – \$12</b>	

## 03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

## 04 | MAINTENANCE, WARRANTY & TRAINING

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

## 05 | CONTACT INFO

Rozanne Tzuk  
Alere, 1 Dan Street  
North Industrial Area, POB 360, Yayne  
70650, Israel

**Website:** www.alere.com  
**Tel:** +972 - 8 - 942 - 9201 (ext. 206)  
**Email:** rosanne.tzuk@alere.com





# POINT-OF-CARE CD4 BD

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

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

Continued overleaf

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

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



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## 03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

Continued overleaf ❖❖❖

## 04 | MAINTENANCE, WARRANTY & TRAINING

	Description
<b>Leasing or reagent rental</b>	Reagent rental programme available. Please inquire.
<b>Installation</b>	No installation required.
<b>Training</b>	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.
<b>Maintenance</b>	No maintenance required. All inclusive warranty for 3 years, including instrument swap.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	3 Years all inclusive. Warranty extension available for additional 2 years for a fixed price.
<b>Warranty components</b>	<ul style="list-style-type: none"> <li>- All inclusive in warranty.</li> <li>- No preventive maintenance required.</li> <li>- Instrument performs self-check each time it is turned on.</li> <li>- No calibration required (factory calibrated).</li> <li>- Internal self calibration performed as needed.</li> <li>- Warranty includes replacement of units.</li> <li>- No internal cleaning required.</li> <li>- No on site repair needed.</li> <li>- Instrument will be swapped by local depot center.</li> <li>- Local dedicated POC coordinator will manage logistics and any issues related to instrument performance.</li> <li>- All parts are fully tested and reliable for the warranty period.</li> </ul>
<b>Turnkey option</b>	No (no installation required).
<b>in-country / regional technical support availability</b>	<ul style="list-style-type: none"> <li>- In-country technical support team and depot center available for repair and swap.</li> <li>- In addition, in-country POC coordinator available to coordinate and support all BD FACSPresto activities, including logistics, order placement and swaps.</li> </ul>

## 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					
<b>ASSAY</b>		<b>INSTRUMENT</b>		<b>KIT</b>					
<b>Intended use (as per regulatory approval)</b>	Enumeration of CD4 absolute count and CD4 percentage of lymphocytes.	<b>Size of device</b>	H 22 x W 20 x D 28 cm	<b>Kit components</b>	Reagent cocktail, cell lyses.				
<b>Principle of the assay</b>	Flow Cytometry, green laser, forward scatter, two color fluorescence.	<b>Weight of device</b>	4kg	<b>Kit sizes</b>	100, 500 and 1000 test kits.				
<b>Type of result</b>	Quantitative	<b>Robustness</b>	TBD after testing in Cameroon.	<b>Internal control(s)</b>	Not provided.				
<b>Linear range</b>	TBD	<b>Environmental requirements</b>	Temperature: 16 - 35 °C	<b>Compatible with EQA and which?</b>	TBD				
<b>Output</b>	CD4 count and percentage	<b>Power requirements</b>	100 - 200 VAC, 50/60 Hz, 80 W, 15 VDC, 5A	<b>Mean time between failures</b>	TBD				
<b>T-cell specific?</b>	Yes	<b>Time to battery charge</b>	TBD	<b>Transport and storage</b>	2 - 8 °C				
<b>Polyvalency</b>	Not at this time	<b>Battery duration (hours)</b>	TBD	<b>Fridge at -80°C required?</b>	No				
<b>PERFORMANCE</b>		<b>Alternative charging options</b>	External battery in development.	<b>Shelf life (of each item in the kit)</b>	12 months				
<b>Accuracy (source)</b>	Clinical study in process.	<b>Ease of use</b>	5 USB ports available. Data station on board. Touch screen. Histograms and Scatterplots displayed. No printer included, printer must be Microsoft 7 compatible.	<b>Performance protocol (steps)</b>	Two steps, no wash protocol.				
<b>Bias - CD4 counts, adults (source)</b>									
<b>Bias - CD4 counts &amp; %, children (source)</b>									
<b>Intra-assay precision, counts &amp; % (source)</b>						<b>Display languages</b>	English	<b>Non-proprietary components required outside of the kit</b>	None
<b>Inter-assay precision, counts &amp; % (source)</b>						<b>Built-in memory storage capacity</b>	Unlimited, Dell computer.	<b>Regulatory approval</b>	Not applied for yet as clinical study is still in process.
<b>SAMPLE</b>		<b>Connectivity options</b>	5 USB ports for accessories or for interface.	<b>In-country approvals</b>	Not applied for yet as clinical study is still in process.				
<b>Sample preparation</b>	Two steps, no wash, 30 minutes.	<b>Interpretation of result</b>	Auto acquisition; automated and manual gating.	<b>USAGE</b>					
<b>Sample type</b>	Venous blood.	<b>Instrument lifespan</b>	10 years	<b>Technical skill required</b>	HS Diploma.				
<b>Sample volume</b>	10µL	<b>Other non-proprietary equipment required</b>	Pipettes, vortex.	<b>Applicable settings</b>	Small hospital or clinic laboratory.				
<b>Sample stability</b>	48 hours	<b>Regulatory approval</b>	Not applied for yet as clinical study is still in process.	<b>Laboratory set-up</b>	Hospital lab, clinic lab, ambulatory care lab.				
<b>Time to result</b>	4 minutes			<b>Waste disposal requirements</b>	Liquid waste is bleached.				
<b>Capacity</b>	15 tests per hour								
<b>Batching?</b>	Yes								
<b>Throughput per end-user per hour and/or 8hr day</b>	15 Samples per hour / 120 per day, not including sample prep time								

Continued overleaf

## 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					
<b>Cost per device</b>			<b>~\$18,000</b>	<b>Cost per test result</b>		<b>~\$5</b>

## 03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

## 04 | MAINTENANCE, WARRANTY & TRAINING

	Description
<b>Leasing or reagent rental (RAP)</b>	Not provided.
<b>Installation</b>	Not provided.
<b>Training</b>	(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.
<b>Maintenance (including instrument swap)</b>	Distributors will handle servicing the instruments.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	One year warranty.
<b>Warranty components</b>	All parts and service.
<b>Turnkey option</b>	Not provided.
<b>in-country / regional technical support availability</b>	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		
	<b>ASSAY</b>		<b>SAMPLE</b>		
<b>Intended use (as per regulatory approval)</b>	Estimation of CD4+ T-cell count to be used as an aid to initiation in the treatment of HIV infection.	<b>Sample preparation (steps)</b>	None		
<b>Principle of the assay</b>	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/ $\mu$ L).	<b>Sample type</b>	Capillary and venous (EDTA) whole blood		
		<b>Sample volume</b>	30 $\mu$ L		
		<b>Sample stability</b>	Less than 24 hour old blood sample		
		<b>Time to result</b>	40 minutes		
		<b>Capacity</b>	N/A		
		<b>Batching?</b>	Possible		
		<b>Throughput per end-user per hour and/or 8hr day</b>	Up to 120 samples/day		
		<b>INSTRUMENT (OPTIONAL AX-2X STRIP READER)</b>			
		<b>Size of device</b>	W 123 x H 113 x D 109 mm		
		<b>Weight of device</b>	600g		
<b>Robustness</b>	Robust				
<b>Type of result</b>	Semi-quantitative	<b>Environmental requirements</b>	5 - 45°C		
<b>Linear range</b>	To be determined.	<b>Power requirements</b>	12V DC / 100-240 V, 50 Hz AC/DC supplied plug pack		
<b>Output</b>	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/ $\mu$ L, for example, 350 CD4+ T cells/ $\mu$ L.	<b>Time to battery charge</b>	N/A		
		<b>Battery duration (hours)</b>	N/A		
<b>T-cell specific?</b>	Yes	<b>Alternative charging options</b>	12 V DC Battery Pack, 12 V DC Rechargeable Solar Battery Pack		
<b>Polyvalency</b>	No	<b>Ease of use</b>	3.4 LCD colour touch screen (pictogram & keypad). USB printer is optional.		
<b>PERFORMANCE</b>		<b>Display languages</b>	English, French, Portugese, Spanish, Italian, German		
<b>Accuracy (source)</b>	Not provided	<b>Built-in memory storage capacity</b>	1,000 Patient Records		
		<b>Connectivity options</b>	Multiple data export options		
<b>Bias - CD4 counts, adults (source)</b>	N/A	<b>Interpretation of result</b>	Above or below cut-off reference (e.g. 350 cells/ $\mu$ L)		
<b>Bias - CD4 counts &amp; %, children (source)</b>	N/A	<b>Instrument lifespan</b>	5 years (reader)		
<b>Intra-assay precision, counts &amp; % (source)</b>	N/A (single use test)	<b>Other non-proprietary equipment required</b>	None		
<b>Inter-assay precision, counts &amp; % (source)</b>	To be determined	<b>Regulatory approval</b>	Not available for reader.		

Continued overleaf

KIT		USAGE	
<b>Kit components</b>	CD4 strip test, running buffer, lancets, swabs, micro-pipette, desiccant, instructions for use.	<b>Technical skill required</b>	Trained health professional or health care worker.
<b>Kit sizes</b>	25 & 100 test packs	<b>Applicable settings</b>	Primary Health Care level zero and above.
<b>Internal control(s)</b>	A procedural control is built in to the test.	<b>Laboratory set-up</b>	None required
<b>Compatible with EQA and which?</b>	No	<b>Waste disposal requirements</b>	Disposal by incineration of infectious disease materials; simple trash for other materials.
<b>Mean time between failures</b>	N/A		
<b>Transport and storage</b>	Indicative transport and storage under ambient temperatures to be confirmed by ongoing long term stability data.		
<b>Fridge at -80°C required?</b>	No		
<b>Shelf life (of each item in the kit)</b>	To be determined by on going long term stability trial data.		
<b>Performance protocol (steps)</b>	(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.		
<b>Non-proprietary components required outside of the kit</b>	None		
<b>Regulatory approval</b>	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)		
<b>In-country approvals</b>	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
<b>Cost per device</b>	<b>\$3,500</b>	<b>Cost per test result</b>	<b>\$5.2</b>

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\$)
<b>Leasing or reagent rental (RAP)</b>	N/A	
<b>Installation</b>	For optional reader: 1/2 day.	Included
<b>Training</b>	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.
<b>Maintenance</b>	Optional instrument is maintenance-free. Swap out if required during 12-month warranty period.	
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	N/A	
<b>Warranty components</b>	N/A	
<b>Turnkey option</b>	N/A	
<b>In-country / regional technical support availability</b>	Yes. Initially from Cape Town.	

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# POINT-OF-CARE CD4 SYSMEX PARTEC

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	SYSMEX PARTEC GmbH	Product	CYFLOW MINIPOC	
<b>ASSAY</b>		<b>SAMPLE</b>		
<b>Intended use (as per regulatory approval)</b>	Determination of CD4 absolute and CD4%.	<b>Sample preparation (steps)</b>	(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).	
<b>Principle of the assay</b>	Single platform flow cytometry based on TVAC.		(2) The ready-to-use prefilled buffer solution "Buffer 1" has to be added (no pipetting required).	
<b>Type of result</b>	Quantitative, absolute count and percentage.		(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.	
<b>Linear range</b>	5 - 5,000 cells/µL		(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.	
<b>Output</b>	CD4 absolute (CD4+ T-lymphocytes/µL), CD4% (CD4+ T-lymphocytes among all lymphocytes).		<b>Sample type</b>	Venous EDTA whole blood.
<b>T-cell specific?</b>	Yes, fluorochrome conjugated CD4/CD45 mAb.		<b>Sample volume</b>	20µL
<b>Polyvalency</b>	No	<b>Sample stability</b>	48 hours at 2 - 8°C	
<b>PERFORMANCE</b>		<b>Time to result</b>	3 Minutes for counting analysing and saving (sample attached to the instrument) plus 15 minutes incubation time outside the instrument.	
<b>Accuracy (source)</b>	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)	<b>Capacity</b>	20 Tests per hour, one sample run on the instrument at a time.	
		<b>Batching?</b>	Batching samples for incubation is possible.	
		<b>Throughput per end-user per hour and/or 8hr day</b>	Approx. 20 tests per hour = 160 tests per day.	
		<b>INSTRUMENT</b>		
<b>Bias - CD4 counts, adults (source)</b>	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)	<b>Size of device</b>	W 270 x D 188 x H 240 mm	
		<b>Weight of device</b>	6.2kg	
		<b>Robustness</b>	Robust, no laser alignment after transport necessary.	
		<b>Environmental requirements</b>	Temperature: 15 - 30°C (operative) Humidity: 20 - 85% relative (non-condensing)	
		<b>Power requirements</b>	100/230 VAC power supply - 50/60 Hz. Battery Pack available	
		<b>Time to battery charge</b>	3 hours	
<b>Bias - CD4 counts &amp; %, children (source)</b>	Mean absolute bias = <1% (PLOS ONE DOI:10.1371/journal.pone.0116663 February 17, 2015)	<b>Battery duration (hours)</b>	4-5 hours	
		<b>Alternative charging options</b>	- Set to connect with car battery is standard equipment - Battery Pack available - Solar Panel for Battery Pack also available	
<b>Intra-assay precision, counts &amp; % (source)</b>	<±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)	<b>Ease of use</b>	- Built-in computer - "5.7" TFT colour touchscreen - Automated analysis - Automated data saving - Built-in thermal printer	
		<b>Display languages</b>	English, French, Spanish and German.	
<b>Inter-assay precision, counts &amp; % (source)</b>	CD4>200 cells/µL: ≤10% CD4>200 cells/µL: ≤15% (internal study)	<b>Built-in memory storage capacity</b>	Data storage of approximately 20,000 data sets.	
		<b>Connectivity options</b>	USB	
		<b>Interpretation of result</b>	- CD4 in cells/µL - CD4% - Lymphocytes in cells/µL	
		<b>Instrument lifespan</b>	8 Years is expected.	
		<b>Other non-proprietary equipment required</b>	No	
		<b>Regulatory approval</b>	- 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	
<b>Kit components</b>	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	<b>Technical skill required</b>	Technical skill required for laboratory staff: nurse or lab technician.
		<b>Applicable settings</b>	Technology can be used at all levels of the health system, including central, regional, district and mobile labs, and some primary sites.
<b>Kit sizes</b>	20 tests/kit	<b>Laboratory set-up</b>	Clean desk or table.
<b>Internal control(s)</b>	Supports internal QC (Partec Count Check Beads as non-biological controls).	<b>Waste disposal requirements</b>	According to the local regulations.
<b>Compatible with EQA and which?</b>	Yes, with CD4 EQA programmes.		
<b>Mean time between failures</b>	Proprietary.		
<b>Transport and storage (include temperature)</b>	Recommended transport temperature: 2 - 35°C, do not freeze Recommended storage temperature: 2 - 8°C, do not freeze		
<b>Fridge at -80°C required?</b>	No		
<b>Shelf life (of each item in the kit)</b>	Minimum 6 months.		
<b>Performance protocol (steps)</b>	(1) Sample staining, (2) Incubation (15 min), (3) Adding buffers, (4) Sample run, (5) Data analysis and results (automated).		
<b>Non-proprietary components required outside of the kit</b>	None.		
<b>Regulatory approval</b>	- CE (TÜV) IVD (Directive 98/79/EG) - Not eligible as POC for GF ERPD - Submission of product dossier for WHO PQ is on-going		
<b>In-country approvals</b>	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*			
<b>Cost per device</b>			<b>~\$11,000</b>	<b>Cost per test result</b>		<b>\$3.15*</b>

\*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 ⇨

### 03 | TIERED AND VOLUME-BASED PRICING

Available on request.

### 04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US\$) (FCA)
<b>Leasing or reagent rental (RAP)</b>	Reagent rental options can be inquired in a partnership approach with the local distributor.	Upon request.
<b>Installation</b>	The CyFlow miniPOC Instructions for Use (IFU) provides all the information for set-up, instrument operation and maintenance.	N/A
<b>Training</b>	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.
<b>Maintenance (including instrument swap)</b>	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).
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	Common Warranty: 12 months (preventive maintenance and service contracts optionally available on request).	Upon request.
<b>Warranty components</b>	Common Warranty: 12 months on all parts except filters, mirrors, other quartz or glass parts, disposables, as long as not otherwise stated.	Not provided.
<b>Turnkey option</b>	Available on request.	Upon request.
<b>In-country / regional technical support availability</b>	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.

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# POINT-OF-CARE HIV EID ALERE

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ALERE	Product	ALERE Q HIV 1/2 DETECT
<b>ASSAY</b>		<b>SAMPLE</b>	
<b>Intended use (as per regulatory approval)</b>	EID and acute stage adult diagnosis.	<b>Sample preparation</b>	None
<b>Principle of the assay</b>	Multi-plexed real time PCR.	<b>Sample type</b>	Whole blood (capillary or venous EDTA) & plasma EDTA.
<b>Target</b>	Proprietary	<b>Sample volume</b>	25µL
<b>Genotypes and/or subtypes</b>	HIV-1 (M/N), HIV-1 (O) & HIV-2	<b>Sample stability</b>	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).
<b>Type of result</b>	Qualitative	<b>Nucleic acid extraction method</b>	Automated (in cartridge)
<b>Linear range</b>	N/A	<b>Time to result</b>	52 minutes
<b>Output</b>	Detected or not detected.	<b>Capacity</b>	1 test at a time
<b>DNA or RNA specific?</b>	RNA	<b>Batching?</b>	No
<b>Polyvalency</b>	In development	<b>Throughput per end-user per hour and/or 8hr day</b>	8/day
<b>PERFORMANCE</b>		<b>INSTRUMENT</b>	
<b>Sensitivity - analytical and clinical (source)</b>	Venous blood: 98.98% Capillary blood: 98.65% Plasma: 99.57% (V&V Studies Pack insert)	<b>Size of device</b>	20 x 21 x 30 cm
<b>Specificity - analytical and clinical (source)</b>	100% (V&V Studies Pack Insert)	<b>Weight of device</b>	7.8 kg
<b>Bias (source)</b>	N/A	<b>Robustness</b>	Very robust.
<b>Intra-assay precision (source)</b>	N/A	<b>Environmental requirements</b>	Temperature: 10 - 40°C Humidity: 0 - 85% Altitude: 0 - 2,000 m NN
<b>Inter-assay precision (source)</b>	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 IIIIB) 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).	<b>Power requirements</b>	100 - 240 V at 50 - 60 Hz
		<b>Time to battery charge</b>	Recommended: overnight
		<b>Battery duration (hours)</b>	8 hours
		<b>Alternative charging options</b>	External battery.
		<b>Ease of use</b>	Touch screen, optional USB printer.
		<b>Display languages</b>	English, French, German.
		<b>Built-in memory storage capacity</b>	1,000 tests
		<b>Connectivity options</b>	USB cellular modem with datapoint connectivity.
		<b>Interpretation of result</b>	Printed as detected or not detected.
		<b>Instrument lifespan</b>	Alere guarantee 10 years.
		<b>Other non-proprietary equipment required</b>	No
		<b>Regulatory approval</b>	GF ERPD & CE-IVD

Continued overleaf ⇨

## ❖ Point-of-Care HIV EID – Alere continued

KIT		USAGE	
<b>Kit components</b>	50 foiled cartridges	<b>Technical skill required</b>	No
<b>Kit sizes</b>	50 tests	<b>Applicable settings</b>	Point-of-care and small laboratories.
<b>Internal control(s)</b>	Yes	<b>Laboratory set-up</b>	None required.
<b>Compatible with EQA and which?</b>	Compatible WHO panel	<b>Waste disposal requirements</b>	Standard biohazard waste disposal.
<b>Mean time between failures</b>	Proprietary		
<b>Transport and storage</b>	4 - 30°C		
<b>Fridge at -80°C required?</b>	No		
<b>Shelf life (of each item in the kit)</b>	6 months (currently)		
<b>Performance protocol (steps)</b>	None		
<b>Non-proprietary components required outside of the kit</b>	No		
<b>Regulatory approval</b>	CF ERPD & CE-IVD		
<b>In-country approvals</b>	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 however 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
<b>Cost per device</b>			<b>\$25,000</b>	<b>Cost per test result</b>			<b>≥\$14.95 - 25</b>



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

### 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
<b>Company</b>	Cepheid		
<b>Product</b>	XPRT HIV-1 QUAL	XPRT HIV-1 VIRAL LOAD	XPRT HCV VIRAL LOAD
<b>ASSAY</b>			
<b>Intended use (as per regulatory approval)</b>	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.
<b>Principle of the assay</b>	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.		
<b>Target</b>	3'-end of 5' LTR		5' UTR
<b>Genotypes and/or subtypes</b>	HIV-1, Group M Subtypes A-H, AB, AE, AG, J, K, Group N, Group O.		Genotypes 1-6
<b>Type of result</b>	Qualitative	Quantitative	Quantitative
<b>Linear range</b>	N/A	40 – 10,000,000 HIV-1 copies/mL	10 – 100,000,000 HCV IU/ml
<b>Output</b>	HIV infected / HIV uninfected	copies/mL	IU/mL
<b>DNA or RNA specific?</b>	TNA	TNA (RNA from plasma)	RNA
<b>Polyvalency</b>	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).		
<b>PERFORMANCE</b>			
<b>Sensitivity - analytical and clinical (source)</b>	Not provided.		

Product	XPRT HIV-1 QUAL	XPRT HIV-1 VIRAL LOAD	XPRT HCV VIRAL LOAD																									
<b>PERFORMANCE (CONTINUED)</b>																												
<b>Specificity - analytical and clinical (source)</b>	<p><b>Analytical specificity:</b></p> <ul style="list-style-type: none"> <li>- Evaluated by adding cultured organisms at <math>5 \times 10^5</math> 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.</li> <li>- Tested organisms are listed: <i>Candida albicans</i>, 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, <i>Staphylococcus aureus</i>. None of the organisms tested showed cross reactivity or interference with the HIV-1 detection.</li> </ul> <p><b>Clinical specificity:</b></p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- 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.</li> <li>- The specificity was 100% (1014/1014), 95% CI: 99.6-100.0.</li> </ul>	<p><b>Analytical specificity:</b></p> <ul style="list-style-type: none"> <li>- Evaluated by adding cultured organism at <math>5 \times 10^4</math> 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).</li> <li>- Tested organisms are listed: HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, <i>Candida albicans</i>, 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, Banzai virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, <i>Staphylococcus pidermis</i>, <i>Staphylococcus aureus</i>. None of the organisms tested showed cross reactivity and all HIV-1 positive replicates resulted in a titer within <math>\pm 0.5</math> log of the HIV-1 positive control.</li> </ul> <p><b>Clinical specificity:</b></p> <ul style="list-style-type: none"> <li>- Evaluated using 109 EDTA plasma specimens from HIV-1 negative blood donors.</li> <li>- None of the 109 specimens tested were detected equating to 100% specificity (95% CI = 96.7-100.0).</li> </ul>	<p><b>Analytical specificity:</b></p> <ul style="list-style-type: none"> <li>- Evaluated by adding potentially cross-reacting organisms at <math>1 \times 10^5</math> CFU/mL, copy/mL or TCID<sub>50</sub>/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 <math>\pm 0.5</math> log from a HCV positive control.</li> <li>- In addition to the species listed here, HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, <i>Candida albicans</i>, 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, Banzai virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, <i>Staphylococcus epidermis</i>, <i>Staphylococcus aureus</i>, 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.</li> </ul>																									
<b>Bias (source)</b>	Not provided.																											
<b>Intra-assay precision (source)</b>	Not provided.																											
<b>Inter-assay precision (source)</b>	<p>VQA Reference Standard:</p> <ul style="list-style-type: none"> <li>- WB: 88 - 96% <math>\geq 200</math> copies/mL</li> <li>- DBS: 100% <math>\geq 800</math> copies/mL</li> </ul> <p>WHO Reference Standard:</p> <ul style="list-style-type: none"> <li>- WB: 100% <math>\geq 420</math> copies/mL</li> <li>- DBS: 96 - 100% <math>\geq 1,000</math> copies/mL</li> </ul>	<p>Total precision:</p> <ul style="list-style-type: none"> <li>- 1.6 log<sub>10</sub> cp/mL: SD 0.25, CV 62.5%</li> <li>- 3 log<sub>10</sub> cp/mL: SD 0.09, CV 20.5%</li> <li>- 5 log<sub>10</sub> cp/mL: SD 0.08, CV 17.8%</li> <li>- 7 log<sub>10</sub> cp/mL: SD 0.10, CV 22.6%</li> </ul>	<p>Total precision:</p> <ul style="list-style-type: none"> <li>- 1.0 log<sub>10</sub> cp/mL: SD 0.21, CV 51.7%</li> <li>- 2.7 log<sub>10</sub> cp/mL: SD 0.09, CV 22.1%</li> <li>- 5.4 log<sub>10</sub> cp/mL: SD 0.11, CV 25.8%</li> <li>- 8.2 log<sub>10</sub> cp/mL: SD 0.13, CV 30.5%</li> </ul>																									
<b>SAMPLE</b>																												
<b>Sample preparation (steps)</b>	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.																									
<b>Sample type</b>	Whole Blood or DBS	EDTA, EDTA-PPT plasma, ACD plasma	EDTA, EDTA-PPT plasma or serum																									
<b>Sample volume</b>	100µL WB or 1 DBS (50-70µL)	1 mL plasma	1 mL serum or plasma																									
<b>Sample stability</b>	<ul style="list-style-type: none"> <li>• EDTA-anticoagulated whole blood may be stored at <ul style="list-style-type: none"> <li>- 31-35°C for <math>\leq 8</math> hours</li> <li>- 15-30°C for <math>\leq 24</math> hours</li> <li>- 2-8°C for <math>\leq 72</math> hours</li> </ul> </li> <li>• DBS cards may be stored at <ul style="list-style-type: none"> <li>- <math>\leq 31-35^\circ\text{C}</math> for <math>\leq 8</math> weeks</li> <li>- 2-25°C or -15°C or colder for up to 12 weeks</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Whole blood may be held at <ul style="list-style-type: none"> <li>- 15-30°C for <math>\leq 8</math> hours</li> <li>- 2-8°C for <math>\leq 72</math> hours</li> </ul> </li> <li>• After centrifugation, plasma may be held at <ul style="list-style-type: none"> <li>- 2-8°C for <math>\leq 6</math> days</li> <li>- 15-30°C for <math>\leq 24</math> hours</li> </ul> </li> <li>• Plasma specimens are stable frozen (<math>\leq -18^\circ\text{C}</math> and <math>\leq -70^\circ\text{C}</math>) for 6 weeks.</li> <li>• Plasma specimens are stable for <math>\leq 3</math> freeze/thaw cycles.</li> </ul>	<ul style="list-style-type: none"> <li>• Whole blood may be held at <ul style="list-style-type: none"> <li>- 15-35°C for <math>\leq 6</math> hours</li> <li>- 2-8°C for up to 72 hours</li> </ul> </li> <li>• After centrifugation, plasma and serum may be held at <ul style="list-style-type: none"> <li>- 2-8°C for <math>\leq 3</math> days</li> <li>- 15-35°C for <math>\leq 24</math> hours</li> </ul> </li> <li>• Plasma and serum specimens are stable frozen (-70 to -18°C) for 6 weeks.</li> <li>• Plasma and serum specimens are stable for <math>\leq 3</math> freeze/thaw cycles.</li> </ul>																									
<b>Nucleic acid extraction method</b>	Automated																											
<b>Time to result</b>	90 minutes		105 minutes																									
<b>Capacity</b>	<table border="1"> <thead> <tr> <th>Time (hours)</th> <th>8</th> <th>10</th> <th>12</th> <th>24</th> </tr> </thead> <tbody> <tr> <td>1 module</td> <td>6</td> <td>7</td> <td>8</td> <td>16</td> </tr> <tr> <td>2 modules</td> <td>12</td> <td>14</td> <td>16</td> <td>32</td> </tr> <tr> <td>4 modules</td> <td>24</td> <td>28</td> <td>32</td> <td>64</td> </tr> <tr> <td>16 modules</td> <td>96</td> <td>112</td> <td>128</td> <td>256</td> </tr> </tbody> </table>			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
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																								
<b>Batching?</b>	No																											
<b>Throughput per end-user per hour and/or 8hr day</b>	<p><b>8hr throughput/m<sup>2</sup>:</b></p> <table border="1"> <tbody> <tr> <td>1 module</td> <td>190</td> </tr> <tr> <td>2 modules</td> <td>250</td> </tr> <tr> <td>4 modules</td> <td>289</td> </tr> <tr> <td>16 modules</td> <td>494</td> </tr> </tbody> </table>			1 module	190	2 modules	250	4 modules	289	16 modules	494																	
1 module	190																											
2 modules	250																											
4 modules	289																											
16 modules	494																											

Continued overleaf 

## ❖ Point-of-Care HIV EID, HIV VL, HCV VL – Cepheid continued

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
<b>INSTRUMENT</b>			
<b>Size of device</b>	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		
<b>Weight of device</b>	1 module: 8.16 kg 4 modules: 12 kg 16 modules: 57 kg		
<b>Robustness</b>	Systems are robust with minimal maintenance/cleaning. In routine use at many TB centres globally.		
<b>Environmental requirements</b>	15 - 30°C		
<b>Power requirements</b>	220-240V, 50-60 Hz - 110V version also available		
<b>Time to battery charge</b>	N/A		
<b>Battery duration (hours)</b>	N/A		
<b>Alternative charging options</b>	Solar panel installations have been demonstrated as well as inverters linked to arrays of lead/acid batteries.		
<b>Ease of use</b>	No internal printer. USB printer can be added to print all of the parameters mentioned.		
<b>Display languages</b>	Choice of English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin selected at installation.		
<b>Built-in memory storage capacity</b>	None, other than laptop, or desktop computer.		
<b>Connectivity options</b>	Ethernet, Wifi and USB ports. Communications protocols for HL7 and ASTM standards are included in the GeneXpert software. Remote Xpert software available for download.		
<b>Interpretation of result</b>	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 <sup>7</sup> 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 <sup>8</sup> IU/mL - HCV not detected - Invalid, Error or 'No Result', if the process is interrupted by the user
<b>Instrument lifespan</b>	7 Years (except for the computer, which may require updating before this time).		
<b>Other non-proprietary equipment required</b>	Printer, as needed.		
<b>Regulatory approval</b>	FDA Approved	FDA Approved	FDA Approved
<b>KIT</b>			
<b>Kit components</b>	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
<b>Kit sizes</b>	10 tests per kit		
<b>Internal control(s)</b>	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)	
<b>Compatible with EQA and which?</b>	Yes, any.		
<b>Mean time between failures</b>	Not provided.		
<b>Transport and storage</b>	2 - 8°C shipping initially until sufficient stability data supports transport at 2 - 28°C, storage at 2 - 8°C.		
<b>Fridge at -80°C required?</b>	No	No, unless for long term storage of plasma.	
<b>Shelf life (of each item in the kit)</b>	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
<b>KIT (CONTINUED)</b>			
<b>Performance protocol (steps)</b>	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 100µL of 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 1 mL of plasma into the sample chamber using the transfer pipette provided; (3) Load cartridge onto GeneXpert and run.	
<b>Non-proprietary components required outside of the kit</b>	If using DBS: <ul style="list-style-type: none"> <li>DBS Collection Kit (Filter paper cards, e.g., Whatman 903, Munktell or equivalent, lancets and swabs).</li> <li>Eppendorf ThermoMixer C (Eppendorf order number 5382 000.015).</li> <li>Eppendorf SmartBlock (Eppendorf order number 5309 000.007).</li> </ul>	Blood collection tube, centrifuge.	
<b>Regulatory approval</b>	CE-IVD marked	CE-IVD marked	CE-IVD marked
<b>In-country approvals</b>	Pending		
<b>USAGE</b>			
<b>Technical skill required</b>	Basic		
<b>Applicable settings</b>	All		
<b>Laboratory set-up</b>	Minimal		
<b>Waste disposal requirements</b>	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 (\$)
<i>GeneXpert Desktop Instruments</i>	<i>Modules</i>			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			
GeneXpert XVI	4	GXXVI-4-D	\$30,680				
GeneXpert XVI	8	GXXVI-8-D	\$44,120				
GeneXpert XVI	12	GXXVI-12-D	\$57,560	Xpert HIV-1 VL At launch: \$19.10 >50,000 tests: \$16.80 >750,000 tests: \$15.05 >1.5 million tests: \$14.20			
GeneXpert XVI	16	GXXVI-16-D	\$71,000				
<i>GeneXpert Laptop Instruments</i>	<i>Modules</i>						
GeneXpert II	2	GXII-2-D	\$12,030	Xpert HCV VL At launch: \$19.20 >50,000 tests: \$17.10 >750,000 tests: \$15.55 >1.5 million tests: \$15.05			
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):				For DBS(EID):			
• Eppendorf ThermoMixer C		Eppendorf order number 5382 000.015		Collection kit (filter paper cards, lancets, swabs)			
• Eppendorf SmartBlock		Eppendorf order number 5309 000.007					
Centrifuge							
<b>Cost per device</b>		<b>GXIV-4-D</b>	<b>\$17,000</b>	<b>Cost per test result</b>		<b>\$19.10 - 19.90</b>	

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\$)
<b>Leasing or reagent rental (RAP)</b>	Not for High Burden Developing Country Programme.	
<b>Installation</b>	1-2 hrs for GX-1 to -16 modules 3-5 days for Infinity 80	
<b>Training</b>	<ol style="list-style-type: none"> <li>2-3 hours of training required</li> <li>Languages available: English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin</li> <li>On site training is available</li> <li>Training tools are available</li> <li>Weblink to training materials is available</li> </ol>	N/A
<b>Maintenance (including instrument swap)</b>	Robust system, minimal maintenance required. Daily wiping down of the instrument is recommended.	N/A
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	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
<b>Warranty components</b>	Parts and labour	
<b>Turnkey option</b>	No information provided.	
<b>In-country / regional technical support availability</b>	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

	<b>HIV EARLY INFANT DIAGNOSIS</b>	
<b>Company</b>	<b>Diagnostics for the Real World, Ltd</b>	
<b>Product</b>	<b>SAMBA HIV-1 QUAL TEST</b>	<b>SAMBA II HIV-1 QUAL WHOLE BLOOD TEST</b>
<b>ASSAY</b>		
<b>Intended use (as per regulatory approval)</b>	Qualitative detection of HIV-1 as an aid in the diagnosis of HIV-1 infection in paediatric samples for early infant diagnosis.	
<b>Principle of the assay</b>	<p>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.</p>	<p>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.</p>
<b>Target</b>	Proviral DNA and RNA	
<b>Genotypes and/or subtypes</b>	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.)	
<b>Type of result</b>	Qualitative, Yes or No result.	
<b>Linear range</b>	N/A. Limit of detection: 400 copies/mL of HIV-1 RNA.	
<b>Output</b>	Yes or No result.	
<b>DNA or RNA specific?</b>	Proviral DNA and RNA.	
<b>Polyvalency</b>	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.
<b>PERFORMANCE</b>		
<b>Sensitivity - analytical and clinical (source)</b>	Clinical sensitivity: 95.7 - 100%. (From three independent clinical evaluations in Kenya, Uganda and Zimbabwe.)	TBD
<b>Specificity - analytical and clinical (source)</b>	Clinical specificity: 99.2 - 100%. (From three independent clinical evaluations in Kenya, Uganda and Zimbabwe.)	TBD
<b>Bias (source)</b>	N/A	TBD
<b>Intra-assay precision (source)</b>	N/A	TBD
<b>Inter-assay precision (source)</b>	N/A	TBD
<b>SAMPLE</b>		
<b>Sample preparation (steps)</b>	Whole blood using a capillary based blood collection system.	
<b>Sample type</b>	Whole blood (capillary or venous).	
<b>Sample volume</b>	150µL sample input, assay requires 100µL	
<b>Sample stability</b>	4 - 30°C for up to 8 hours	
<b>Nucleic acid extraction method</b>	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
<b>SAMPLE</b>		
<b>Time to result</b>	~ 2 hours	
<b>Capacity</b>	4 samples per run (simultaneously)	1 sample per run
<b>Batching?</b>	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.
<b>Throughput per end-user per hour and/or 8hr day</b>	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).
<b>INSTRUMENT</b>		
<b>Size of device</b>	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
<b>Weight of device</b>	SAMBAprep: 53 kg SAMBAamp: 3.8 kg	Display module: 2.1 kg Assay module: 9.9 kg
<b>Robustness</b>	Suitable for resource-limited settings.	
<b>Environmental requirements</b>	Temperature: 15 - 35°C Relative humidity: 20 - 95%	Temperature: 10 - 40 °C Relative humidity: ≤80% up to 31°C, decreasing linearly to 50% RH at 40°C
<b>Power requirements</b>	100 - 250 V, 50 - 60 Hz	
<b>Time to battery charge</b>	N/A	
<b>Battery duration (hours)</b>	N/A	
<b>Alternative charging options</b>	None	Can be charged via solar panel or car battery.
<b>Ease of use</b>	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.
<b>Display languages</b>	English	
<b>Built-in memory storage capacity</b>	None	100,000 test results can be stored by the display module.
<b>Connectivity options</b>	None	Display module includes a built-in ethernet port and USB port.
<b>Interpretation of result</b>	Visual results on a test-strip.	Automated camera read out with visual verification step.
<b>Instrument lifespan</b>	Expected: 3 years; ideal: 5 years.	TBD
<b>Other non-proprietary equipment required</b>	None	None
<b>Regulatory approval</b>	CE-marked. Pre-submission stage for WHO PQ.	CE-marked. Pre-submission stage for WHO PQ.
<b>KIT</b>		
<b>Kit components</b>	<b>SAMBA HIV-1 Qual Test Extraction kit (4001-24):</b> QB Cartridge 1 (4001A), QB Cartridge 2 (4001B), QB Cartridge 3 (4001C), Output Tube (4001D). <b>SAMBA HIV-1 Qual Test Amplification kit (4000-24):</b> 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).
<b>Kit sizes</b>	24 tests/kit	12 tests/kit
<b>Internal control(s)</b>	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
<b>Compatible with EQA and which?</b>	CDC Proficiency testing panel, Rush University EQA panel, others to be determined.	
<b>Mean time between failures</b>	Proprietary	TBD
<b>Transport and storage</b>	2 - 37°C for long term storage -10 - 55°C shipping stability (for 1 month) No cold chain transport required	
<b>Fridge at -80°C required?</b>	No	
<b>Shelf life (of each item in the kit)</b>	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
<b>KIT</b>		
<b>Performance protocol (steps)</b>	(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 amplification 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
<b>Non-proprietary components required outside of the kit</b>	Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab.	
<b>Regulatory approval</b>	ERPD Category 3, pre-submission stage for WHO PQ	CE-IVD for test kits planned for submission.
<b>In-country approvals</b>	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.
<b>USAGE</b>		
<b>Technical skill required</b>	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.
<b>Applicable settings</b>	Hospitals, clinics and large healthcare centres with electricity.	All levels of hospitals and healthcare setting with electricity or provision for solar power.
<b>Laboratory set-up</b>	None except for electricity.	None except for electricity or provision for solar power.
<b>Waste disposal requirements</b>	Sample tube to be disposed of in infectious waste. All other cartridges can be disposed of in laboratory waste.	

<b>HIV VIRAL LOAD</b>		
Company	<b>Diagnostics for the Real World, Ltd</b>	
Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI Q PLASMA TEST
<b>ASSAY</b>		
<b>Intended use (as per regulatory approval)</b>	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.	
<b>Principle of the assay</b>	<p>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.</p>	<p>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.</p>

Continued overleaf ❖❖❖

Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI Q PLASMA TEST
<b>ASSAY</b>		
<b>Target</b>	HIV-1 RNA	
<b>Genotypes and/or subtypes</b>	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.)	
<b>Type of result</b>	Semi-Quantitative (>/< 1,000 ± 0.3 log copies/mL).	
<b>Linear range</b>	N/A. Cut-off at 1,000 copies/mL (± 0.3 log assay variation).	
<b>Output</b>	Viral load >/< 1,000 ± 0.3 log copies/mL.	
<b>DNA or RNA specific?</b>	RNA	
<b>Polyvalency</b>	Only HIV test portfolio.	Development stage: SAMBA II CT/NG Duplex test, SAMBA II Flu A/B Duplex test.
<b>PERFORMANCE</b>		
<b>Sensitivity - analytical and clinical (source)</b>	Overall concordance: 98%, 94.8%, 95.9%, 96.4% (In independent clinical evaluations performed in Malawi, Uganda, Kenya and Zimbabwe, respectively.)	TBD
<b>Specificity - analytical and clinical (source)</b>	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
<b>Bias (source)</b>	N/A	TBD
<b>Intra-assay precision (source)</b>	N/A	TBD
<b>Inter-assay precision (source)</b>	N/A	TBD
<b>SAMPLE</b>		
<b>Sample preparation (steps)</b>	As per vendor instructions (laboratory and vendor specific).	
<b>Sample type</b>	Plasma	
<b>Sample volume</b>	300µL sample input, assay requires 200µL	
<b>Sample stability</b>	15 - 30°C for up to 12 hours or 2 - 8°C for up to 5 days	
<b>Nucleic acid extraction method</b>	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).
<b>Time to result</b>	~ 90 mins	
<b>Capacity</b>	4 samples per run (simultaneously)	1 sample per run
<b>Batching?</b>	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.
<b>Throughput per end-user per hour and/or 8hr day</b>	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).
<b>INSTRUMENT</b>		
<b>Size of device</b>	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
<b>Weight of device</b>	SAMBAprep: 53 kg SAMBAamp: 3.8 kg	Display module: 2.1 kg Assay module: 9.9 kg
<b>Robustness</b>	Suitable for resource-limited settings.	
<b>Environmental requirements</b>	Temperature: 15 - 35°C Relative humidity: 20 - 95%	Temperature: 10 - 40 °C Relative humidity: ≤80% up to 31°C, decreasing linearly to 50% RH at 40°C
<b>Power requirements</b>	100 - 250 V, 50 - 60 Hz	
<b>Time to battery charge</b>	N/A	
<b>Battery duration (hours)</b>	N/A	
<b>Alternative charging options</b>	None	Can be charged via solar panel or car battery.
<b>Ease of use</b>	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
<b>INSTRUMENT</b>		
<b>Display languages</b>	English	
<b>Built-in memory storage capacity</b>	None	100,000 test results can be stored by the display module.
<b>Connectivity options</b>	None	Display module includes a built-in ethernet port and USB port.
<b>Interpretation of result</b>	Visual results on a test-strip.	Automated camera read out with visual verification step.
<b>Instrument lifespan</b>	Expected: 3 years; ideal: 5 years.	TBD
<b>Other non-proprietary equipment required</b>	Centrifuge to process plasma.	
<b>Regulatory approval</b>	CE-marked. Pre-submission stage for WHO PQ.	CE-marked. Pre-submission stage for WHO PQ.
<b>KIT</b>		
<b>Kit components</b>	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).
<b>Kit sizes</b>	12 tests/kit	
<b>Internal control(s)</b>	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
<b>Compatible with EQA and which?</b>	CDC Proficiency testing panel, Rush University EQA panel, others to be determined.	
<b>Mean time between failures</b>	Proprietary	TBD
<b>Transport and storage</b>	2 - 37°C for long term storage -10 - 55°C shipping stability (for 1 month) No cold chain transport required	
<b>Fridge at -80°C required?</b>	No	
<b>Shelf life (of each item in the kit)</b>	12 months	12 months (based on component stability study data, kit stability in progress).
<b>Performance protocol (steps)</b>	<ol style="list-style-type: none"> <li>(1) Sample collection</li> <li>(2) Insert sample and cartridges into SAMBAprep machine</li> <li>(3) Push start button</li> <li>(4) Upon completion of run, place tube containing extracted sample into SAMBAamp</li> <li>(5) Load SAMBAamp cartridge</li> <li>(6) Transfer extracted sample into reagent tube</li> <li>(7) Push start button</li> <li>(8) When beep sounds transfer sample to the SAMBAamp cartridge</li> <li>(9) Amplification cartridge at completion of ampfication step (beep will sound), rotate cartridge manually, plunge detection buffer</li> <li>(10) Read test results visually at end of detection</li> </ol>	<ol style="list-style-type: none"> <li>(1) Scan test kit on the display module</li> <li>(2) Scan patient tracking card on the display module</li> <li>(3) Load cartridges and sample on the machine</li> <li>(4) Press start</li> <li>(5) Verify and print results</li> </ol>
<b>Non-proprietary components required outside of the kit</b>	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.
<b>Regulatory approval</b>	ERPD Category 3. Dossier submitted to WHO PQ.	CE-IVD for test kits planned for submission. Pre-submission stage to WHO PQ.
<b>In-country approvals</b>	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.
<b>USAGE</b>		
<b>Technical skill required</b>	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.
<b>Applicable settings</b>	Hospitals, clinics and large healthcare centres with electricity.	All levels of hospitals and healthcare setting with electricity or provision for solar power.
<b>Laboratory set-up</b>	None except for electricity.	None except for electricity or provision for solar power.
<b>Waste disposal requirements</b>	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		
<b>Cost per device</b>			<b>\$37,000*</b>	<b>Cost per test result</b>		<b>\$17- 23**</b>

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 system for venipuncture		
<b>Cost per device</b>			<b>\$25,000 - 30,000*</b>	<b>Cost per test result</b>		<b>\$20-28**</b>

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

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**SAMBA****SAMBA II**

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

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

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

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

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## 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			
<b>Cost per device</b>			<b>\$9,000</b>	<b>Cost per test result</b>			<b>\$15</b>

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



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## 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
<b>Company</b>	Northwestern Global Health Foundation	Quidel / Northwestern Global Health Foundation	
<b>Product</b>	LYNX HIV P24 ANTIGEN TEST	SAVANNA QUANTITATIVE REALTIME HIV-1 ASSAY	
<b>ASSAY</b>			
<b>Intended use (as per regulatory approval)</b>	Birth to 18 months but no evaluations 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.	
<b>Principle of the assay</b>	Qualitative p24 antigen based immunochromatographic assay.	An in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of HIV-1.	
<b>Target</b>	p24 antigen	HIV-1	
<b>Genotypes and/or subtypes</b>	HIV-1 (expected to be all subtypes, but still in the process of verifying).	HIV-1 (all subtypes)	
<b>Type of result</b>	Qualitative	Quantitative	
<b>Linear range</b>	N/A	200 - 1,000,000 copies/mL	1,000 - 1,000,000 copies/mL
<b>Output</b>	Control line and/or test line	Copies/mL of HIV-1 in plasma	
<b>DNA or RNA specific?</b>	Neither, p24 antigen.	RNA	
<b>Polyvalency</b>	None.	TB and Rif resistance tests under development.	
<b>PERFORMANCE</b>			
<b>Sensitivity - analytical and clinical (source)</b>	TBD pending external/independent evaluations.		
<b>Specificity - analytical and clinical (source)</b>			
<b>Bias (source)</b>			
<b>Intra-assay precision (source)</b>			
<b>Inter-assay precision (source)</b>			
<b>SAMPLE</b>			
<b>Sample preparation (steps)</b>	(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
<b>Sample type</b>	Capillary whole blood.	Plasma	
<b>Sample volume</b>	80µL	200µL	165µL of whole blood collected in plasma separator yielding 50µl of plasma.
<b>Sample stability</b>	TBD		
<b>Nucleic acid extraction method</b>	N/A	Fully automated.	
<b>Time to result</b>	51 minutes	60 minutes	
<b>Capacity</b>	Instrument will accommodate 1 test at a time.	The instrument is random access and will accommodate 2 tests.	
<b>Batching?</b>	No	Random access	
<b>Throughput per end-user per hour and/or 8hr day</b>	11-12 tests per 8 hr day.	14 tests per Instrument per 8 hr day.	

Continued overleaf ❖❖❖

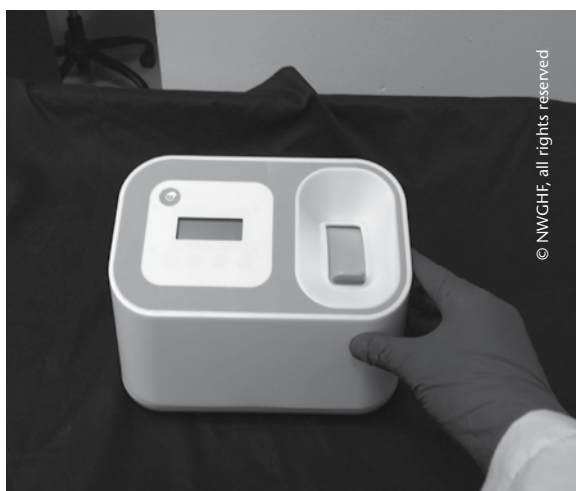
Product	LYNX HIV P24 ANTIGEN TEST	SAVANNA QUANTITATIVE REALTIME HIV-1 ASSAY	
<b>INSTRUMENT</b>			
<b>Size of device</b>	20.2 x 15.6 x 13.4 cm	W 24 x H 59 x D 62 cm	
<b>Weight of device</b>	1.7 kg	TBD	
<b>Robustness</b>	Completely enclosed for operation in dusty environments. Comply with EN 60529.		
<b>Environmental requirements</b>	15 - 35°C	15°C - 40°C	
<b>Power requirements</b>	Powered by AC mains or 12V DC with internal rechargeable Li-ion battery.	Powered by AC or DC mains with external battery backup.	
<b>Time to battery charge</b>	<1 hour	TBD	
<b>Battery duration (hours)</b>	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.	
<b>Alternative charging options</b>	No	TBD	
<b>Ease of use</b>	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.	
<b>Display languages</b>	N/A (none displayed)	1. English; 2. French; 3. Spanish; 4. Portuguese	
<b>Built-in memory storage capacity</b>	None	Yes	
<b>Connectivity options</b>	Optional reader with connectivity.	Internal modem or wired data connection. Data can be sent via cellular, data cable or USB.	
<b>Interpretation of result</b>	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.	
<b>Instrument lifespan</b>	TBD		
<b>Other non-proprietary equipment required</b>	No	Centrifuge	No
<b>Regulatory approval</b>	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	
<b>KIT</b>			
<b>Kit components</b>	TBD	Cartridge	Lancet, plasma separator, cartridge.
<b>Kit sizes</b>	10	Multiple	
<b>Internal control(s)</b>	Yes, control line on strip test.	Internal controls will verify proper conditions and assay performance for amplification.	
<b>Compatible with EQA and which?</b>	TBD	Cartridge is compatible with Virology Quality Assurance (VQA) and UK National External Quality Assessment Service (NEQAS).	
<b>Mean time between failures</b>	TBD	Target: 10,000 tests per module.	
<b>Transport and storage</b>	No cold chain or humidity control is required for shipping and transport.		
<b>Fridge at -80°C required?</b>	No		
<b>Shelf life (of each item in the kit)</b>	Target: 12-18 months at temperatures up to 30 - 40°C and humidity up to 70 - 90%.		
<b>Performance protocol (steps)</b>	(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	
<b>Non-proprietary components required outside of the kit</b>	Phlebotomy consumables (gloves, lancet, alcohol swab, gauze pad).	Phlebotomy consumables (gloves, lancet if finger/needle plus EDTA Vacutainer, alcohol swab, gauze pad).	
<b>Regulatory approval</b>	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	
<b>In-country approvals</b>	None		
<b>USAGE</b>			
<b>Technical skill required</b>	All staff levels, but feasibility studies are still being done to assess this.		
<b>Applicable settings</b>	For use in sites that perform dried blood spot (DBS) collection or local laboratories.	ART clinics, clinics, hospitals.	
<b>Laboratory set-up</b>	No laboratory required.	Centrifuge required to separate whole blood into plasma.	No laboratory required.
<b>Waste disposal requirements</b>	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			
<b>Cost per device</b>		<b>\$1,000 - 2,000</b>	<b>Cost per test result</b>		<b>\$6.50 - 15</b>

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					
<b>Cost per device</b>		<b>~\$10,000</b>	<b>Cost per test result</b>		<b>~\$11</b>

### 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
<b>Leasing or reagent rental (RAP)</b>	Leasing, capital purchase and reagent rental options anticipated.		Leasing, capital purchase and reagent rental options anticipated.
<b>Installation</b>	None required.	N/A	None required.
<b>Training</b>	- 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
<b>Maintenance</b>	None required. Instrument swap during warranty rather than performing on-site service and maintenance.	N/A	TBD
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	1-2 years; with instrument swap if processor breaks down within the year.		1-2 years
<b>Warranty components</b>	Local distributor for instrument swap.		Local distributor for instrument swap.
<b>Turnkey option</b>	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.
<b>In-country / regional technical support availability</b>	Via local distributors.		Via local distributors.

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# LAB-BASED HCV CORE ANTIGEN ABBOTT (ARCHITECT)

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ABBOTT	Product	ARCHITECT HCV AG
<b>ASSAY</b>		<b>SAMPLE</b>	
<b>Intended use (as per regulatory approval)</b>	Quantitative determination of HCV core antigen.	<b>Sample preparation (steps)</b>	(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.
<b>Principle of the assay</b>	Two-step immunoassay using Chemiluminescent Microparticle Immunoassay (CMIA) technology (with flexible assay protocols, referred to as Chemiflex)		(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: <ul style="list-style-type: none"> <li>• they contain fibrin, red blood cells, or other particulate matter,</li> <li>• they require repeat testing, or</li> <li>• they were frozen and thawed.</li> </ul>
<b>Type of result</b>	Quantitative		(3) Transfer clarified specimen to a sample cup or secondary tube for testing.
<b>Linear range</b>	0.00 - 20,000.00		(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.
<b>Output</b>	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: <ul style="list-style-type: none"> <li>• Specimens with concentration values &lt;3.00 fmol/L are considered nonreactive for HCV Ag</li> <li>• Specimens with concentration values ≥3.00 fmol/L are considered reactive for HCV Ag</li> <li>• Specimens with concentration values ≥3.00 fmol/L to &lt;10.00 fmol/L should be retested in duplicate</li> </ul>	<b>Sample type</b>	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).
<b>Polyvalency</b>	ARCHITECT anti-HCV among others: <a href="https://www.abbottdiagnostics.com/en-us/products/ARCHITECT-i2000SR.html#test-menu">https://www.abbottdiagnostics.com/en-us/products/ARCHITECT-i2000SR.html#test-menu</a>	<b>Sample volume</b>	The minimum sample volume for a single test is 158µL Each Additional Test requires 108µL
<b>PERFORMANCE</b>		<b>Sample stability</b>	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. <ul style="list-style-type: none"> <li>• 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.</li> <li>• Avoid more than two freeze/thaw cycles.</li> <li>• Specimens may be shipped at 2-8°C (wet ice), or -20°C or colder (dry ice).</li> </ul>
<b>Sensitivity (source)</b>	≤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)]	<b>Time to result</b>	Time to the 1st result: 36 minutes
		<b>Capacity</b>	100 tests/hour
		<b>Batching</b>	Yes
		<b>Throughput</b>	100 tests/hour
<b>Specificity (source)</b>	≥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)]	<b>INSTRUMENT</b>	
		<b>Size of device</b>	i1 000SR: 125.1 H x 149.9 W x 76.2cm D i2000SR: 121.9 H x 154.9 W x 124.5cm D
		<b>Weight of device</b>	i1 000SR: 288kg i2000SR: 490.3kg
<b>Intra-assay precision (source)</b>	<10% total CV (package insert)	<b>Environmental requirements</b>	Water requirements: Type II or better, to dilute buffer concentrate
		<b>Power requirements</b>	i1 000: AC 110-240V ±10%, 47-63 Hz i2000: AC 180-264V, 47-63 Hz
		<b>Regulatory approval</b>	CE Marked, available in 150+ countries

Continued overleaf

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

Company	ABBOTT	Product	ARCHITECT HCV AG
	<b>KIT</b>		<b>KIT</b>
<b>Kit components</b>	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	<b>Non-proprietary components required outside of the kit</b>	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.abbottiagnostics.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)
<b>Kit sizes</b>	100 tests		
<b>Internal control(s)</b>	3 Bottles (8 mL each) of ARCHITECT HCV Ag Controls (Negative, Positive 1 and 2)		
<b>Transport and storage</b>	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.	<b>Regulatory approval</b>	CE Marked
		<b>In-country approvals</b>	Available in all countries that accept a CE-mark and in countries that require registration (approx. 60 countries, excluding the USA and China)
		<b>USAGE</b>	
<b>Refridgeration at -80°C required?</b>	No	<b>Technical skill required</b>	Medium to highly trained lab personnel
<b>Shelf life (of each item in the kit)</b>	Shelf life upon manufacture: 12 months	<b>Applicable settings</b>	From low- to highly-resourced settings
<b>Performance protocol (steps)</b>	2	<b>Laboratory set-up</b>	Two dedicated areas are recommended: Sample Preparation Area and Instruments Run Area
		<b>Waste disposal requirements</b>	According to the regulations of each country

## 02 | PRICING

Instrument		Reference number	FCA (\$)	Cartridge/reagents	Reference number	FCA (\$)
Abbott ARCHITECT i2000SR	Immunoassay Analyser	03M74-02		ARCHITECT HCV Ag Reagent Kit	6L47	
Abbott ARCHITECT i2000SR	Stand Alone Base RSH Kit (60 carriers, 8 RSH trays), Two-toned color	02J47-12		ARCHITECT HCV Ag Calibrators	6L47-02	
				ARCHITECT HCV Ag Controls	6L47-11	
				Negative (1 x 8mL) Control 1 (1 x 8mL) Control 2 (1 x 8mL)		
Instrument Accessories		Reference number	FCA (\$)	Non-proprietary equipment and consumables	Reference number	FCA (\$)
ARCHITECT i Pre-Trigger Solution	4 x 975 mL	06E23-65		Pipettes		
ARCHITECT i Trigger Solution	4 x 975 mL	06C55-60		Pipette tips		
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				
<b>Cost per instrument</b>			<b>Not provided</b>	<b>Cost per test result</b>		<b>\$25 - \$50</b>
				<b>Cost per person (test result plus instrumentation and other materials)</b>		<b>\$200</b>

### 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
<b>Installation</b>	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.
<b>Training</b>	Comprehensive Integration: <ul style="list-style-type: none"> <li>• Validation Expertise,</li> <li>• Certified Training.</li> </ul> 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 <a href="http://www.abbottdiagnostics.com">www.abbottdiagnostics.com</a> .
<b>Maintenance (including instrument swap)</b>	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: <ul style="list-style-type: none"> <li>• Schedule maintenance procedures during times of slower workflow.</li> <li>• Verify adequate supplies are on board the system, or available to load, prior to initiating a maintenance procedure.</li> <li>• 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.</li> </ul>
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	Generally a warranty is provided, depending on the country and contract details
<b>Turnkey option</b>	No
<b>in-country / regional technical support availability</b>	Yes, please contact the local representative or find country-specific contact information on <a href="http://www.abbottdiagnostics.com">www.abbottdiagnostics.com</a> . 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
<b>Company</b>	Abbott			
<b>Product</b>	ABBOTT REALTIME HIV-1 QUALITATIVE	ABBOTT REALTIME HIV-1	ABBOTT REALTIME HCV	ABBOTT REALTIME HCV GENOTYPE II
<b>ASSAY</b>				
<b>Intended use</b>	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.
<b>Principle of the assay</b>	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.
<b>Target</b>	HIV-1 RNA polymerase	HIV-1 RNA polymerase	5' UTR of HCV genome	5' UTR for GT 1-6, NS5b for subtypes 1a, 1b
<b>Genotypes and/or subtypes</b>	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 <a href="http://www.nature.com/naturemedicine">http://www.nature.com/naturemedicine</a> ).	Genotypes 1-6	Genotypes 1, 1a, 1b, and 2 - 6
<b>Type of result</b>	Qualitative	Quantitative	Quantitative	Qualitative
<b>Linear range</b>	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
<b>Output</b>	"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
<b>DNA or RNA specific?</b>	TNA extraction	RNA selective extraction	RNA	RNA
<b>Polyvalency</b>	HIV-1 viral load, HCV, HCV GT, HBV, HPV, CT/NG, CMV, MTB detection; MTB RIF/INH Resistance			
<b>PERFORMANCE</b>				
<b>Sensitivity - analytical and clinical (source)</b>	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
<b>Specificity - analytical and clinical (source)</b>	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)
<b>Bias (source)</b>	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
<b>Intra-assay precision (source)</b>	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
<b>Inter-assay precision (source)</b>	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				
<b>Sample preparation</b>	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).			
<b>Sample type</b>	Plasma, DBS	Plasma, DBS (RUO) HIV VL on DBS in development for CE Mark in 2016.	Serum, plasma	
<b>Sample volume</b>	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
<b>Sample stability</b>	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.
<b>Nucleic acid extraction method</b>	Manual and automated extraction.			
<b>Time to result</b>	5.4 - 7.7 hours	5.4 - 7.6 hours		5.25 hours
<b>Capacity</b>	1 - 96 samples/run including 2 controls	1 - 96 samples/run including 3 controls		24 samples/run including 2 controls
<b>Batching?</b>	Yes	Yes, flexible sample input with mPLUS available		Yes
<b>Throughput per end-user per hour and/or 8hr day</b>	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
<b>INSTRUMENT</b>				
<b>Size of device m2000sp</b>	179 L x 187 H x 124.4 cm D			
<b>Size of device m24sp</b>	88.1 L x 75.9 H x 69.6 cm D (not available for HIV-1 Qualitative)			
<b>Size of device m2000rt</b>	34 L x 49 H x 45 cm D			
<b>Weight of device m2000sp</b>	326.8 kg instrument and cabinet			
<b>Weight of device m24sp</b>	84kg (not available for HIV-1 Qualitative)			
<b>Weight of device m2000rt</b>	34.1kg			
<b>Robustness</b>	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.			
<b>Environmental requirements</b>	<p><b>Sample Prep:</b>            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: &lt;8,000 lux (direct sunlight can interfere with the PosID)</p> <p><b>Real Time PCR:</b>            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</p>			
<b>Power requirements</b>	100-240 V			
<b>Time to battery charge</b>	GE UPS (Uninterruptable Power Supply) specified; depends on how long it will take to be charged when attached to the system.			
<b>Battery duration (hours)</b>	GE (General Electric) unit to last at least 20 minutes			
<b>Alternative charging options</b>	No, lab mains power only			
<b>Ease of use</b>	High ease of use: data station, keypad, mouse, printer, and bar code scanner.			
<b>Display languages</b>	m2000: English, French, Spanish, Italian, German, Portuguese, Russian, and Chinese m24: French, Italian, German, Spanish, and Portuguese (not for HIV-1 Qualitative)			
<b>Built-in memory storage capacity</b>	2 MB			
<b>Connectivity options</b>	Yes, connectivity via Laboratory Information Systems available and interface to mobile system in development; AbbottLink available.			
<b>Interpretation of result</b>	"HIV-1 Detected" or "Not Detected"	Viral load provided without interpretation		Qualitative result
<b>Instrument lifespan</b>	At least 10 years; through preventive maintenance and total call procedures they can be kept in operation indefinitely.			
<b>Other non-proprietary equipment required</b>	Centrifuge, vortex mixer. In addition, for manual extraction, dry heating blocks.			
<b>Regulatory approval</b>	CE-marked, WHO-prequalification with assay	CE-marked, FDA approved, WHO-prequalification with assay; DBS is RUO	CE-marked, FDA approved	
<b>KIT</b>				
<b>Kit components</b>	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	
<b>Kit sizes</b>	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)
<b>Internal control(s)</b>	Yes; processed through sample extraction until detection with each sample.			
<b>Compatible with EQA and which?</b>	Amenable to EQA			
<b>Mean time between failures</b>	384.2 days / 0.95 Calls Per Year			
<b>Transport and storage</b>	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
<b>Fridge at -80°C required?</b>	No			
<b>Shelf life (of each item in the kit)</b>	Shelf life upon manufacture: 18 months			

Product	ABBOTT REALTIME HIV-1 QUALITATIVE	ABBOTT REALTIME HIV-1	ABBOTT REALTIME HCV	ABBOTT REALTIME HCV GENOTYPE II
<b>KIT</b>				
<b>Performance protocol</b>	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.			
<b>Non-proprietary components required outside of the kit</b>	Yes, see package insert for details (e.g. pipette tips)			
<b>Regulatory approval</b>	CE-marked, WHO prequalified	CE-marked, FDA approved, WHO pre-qualified	CE-marked, FDA approved	
<b>In-country approvals</b>	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.	
<b>USAGE</b>				
<b>Technical skill required</b>	Medium-highly trained. Precision pipetting required at low volumes.			
<b>Applicable settings</b>	From low- to highly-resourced settings			
<b>Laboratory set-up</b>	Two dedicated areas are recommended: Sample Preparation Area and Amplification Area			
<b>Waste disposal requirements</b>	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 (\$)
<i>m2000sp</i>	Sample Extraction, up to 96 samples	09K14-002	\$162,000	<i>m</i> Sample Preparation Systems DNA (4x24 Preps) (RealTime HIV-1 qualitative)	Sample preparation, extraction reagent	06K12-024	
<i>m2000rt</i>	Amplification and detection	09K15-001	\$45,000	Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	04N66-090	
				Abbott RealTime HIV-1 Qualitative Control Kit CE	1 kit (2 levels with 12 replicates per level)	04N66-080	
				Abbott RealTime HIV-1 Qualitative Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	04N66-066	
				<i>m</i> 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 RealTime HIV-1 Qualitative <i>m2000</i> 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 Vessels)		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					
<i>m</i> Systems Wrench (1 each)		01N71-001					
Optical Calibration Kit (1 each)		04J71-093					
<b>Cost per device</b>			<b>\$207,000</b>	<b>Cost per test result</b>		<b>\$13 - 30</b>	

Continued overleaf 

<b>HIV VIRAL LOAD</b>							
<b>Instrument</b>		<b>Reference number</b>	<b>FCA (\$)</b>	<b>Cartridge/reagents</b>		<b>Reference number</b>	<b>FCA (\$)</b>
<i>m24sp</i> (not available in US)	Sample Extraction, up to 24 samples	03N06-001	\$80,000	<i>m</i> Sample Preparation Systems RNA (4x24 Preps) (viral load)	Sample preparation, extraction reagent	04J70-024	
<i>m2000sp</i>	Sample Extraction, up to 96 samples	09K14-002	\$162,000	Abbott RealTime HIV-1 Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	02G31-90	
<i>m2000rt</i>	Amplification and detection	09K15-001	\$45,000	Abbott RealTime HIV-1 Control Kit CE	1 kit (3 levels with 8 replicates per level)	02G31-080	
				Abbott RealTime HIV-1 Calibrator Kit CE	1 kit (2 levels with 12 replicates per level)	02G31-070	
				Abbott RealTime HIV-1 Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	02G31-066	
				Abbott RealTime HIV-1 Amplification Reagent Kit FDA	1 kit (96 tests; 4 x 24 tests/pack)	06L18-090	
				Abbott RealTime HIV-1 Control Kit FDA	1 kit (3 levels with 8 replicates per level)	06L18-080	
				Abbott RealTime HIV-1 Calibrator Kit FDA	1 kit (2 levels with 12 replicates per level)	06L18-070	
				<i>m</i> 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	
<b>Instrument Accessories</b>		<b>Reference number</b>	<b>FCA (\$)</b>	<b>Non-proprietary equipment and consumables</b>		<b>Reference number</b>	<b>FCA (\$)</b>
RealTime HIV-1 Application CD-ROM CE	Application CD ROM	01L68		None			
RealTime 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 <i>m2000sp</i> and <i>m24sp</i>	04J71-010					
Disposable Tips (DiTis): 200µL (2304 Tips)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-017					
5mL Reaction Vessles (2000 Vessles)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-020					
200 mL Reagent Vessles (90 Vessels)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-060					
96 Deep Well Plates (32 Plates)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-030					
96-Well Optical Reaction Plates (20 Plates)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-070					
Optical Adhesive Covers (100 Covers)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-075					
Master Mix Tubes/Caps (150 Tubes/Caps)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-080					
Splash Free Support Base (5 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	09K31-001					
13mm Sample Racks	needed for <i>m2000sp</i> and <i>m24sp</i>	04J72-082					
<i>m</i> Systems Wrench (1 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	01N71-001					
Optical Calibration Kit (1 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-093					
1.4 mL Internal Control Vial	needed for <i>m24sp</i>	03N19-001					
1.4 mL Internal Control Vial Cap	needed for <i>m24sp</i>	03N20-001					
* please note: Abbott RealTime HIV-1 Amplification Reagent Kit FDA does not include manual extraction							
<b>Cost per device</b>			<b>\$207,000</b>	<b>Cost per test result</b>			<b>\$13 - 30</b>

HCV VIRAL LOAD							
Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
<i>m24sp</i>	Sample Extraction, up to 24 samples	03N06-001	\$80,000	Abbott RealTime HCV Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	04J86-090	
<i>m2000sp</i>	Sample Extraction, up to 96 samples	09K14-002	\$162,000	Abbott RealTime HCV Control Kit CE	1 kit (3 levels with 8 replicates per level)	04J86-080	
<i>m2000rt</i>	Amplification and detection	09K15-001	\$45,000	Abbott RealTime 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 <i>m2000sp</i> and <i>m24sp</i>	04J71-010					
Disposable Tips (DiTis): 200µL (2304 Tips)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-017					
5mL Reaction Vessles (2000 Vessels)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-020					
200 mL Reagent Vessles (90 Vessels)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-060					
96 Deep Well Plates (32 Plates)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-030					
96-Well Optical Reaction Plates (20 Plates)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-070					
Optical Adhesive Covers (100 Covers)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-075					
Master Mix Tubes/Caps (150 Tubes/Caps)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-080					
Splash Free Support Base (5 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	09K31-001					
13mm Sample Racks	needed for <i>m2000sp</i> and <i>m24sp</i>	04J72-082					
mSystems Wrench (1 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	01N71-001					
Optical Calibration Kit (1 each)	needed for <i>m2000sp</i> and <i>m24sp</i>	04J71-093					
1.4 mL Internal Control Vial	needed for <i>m24sp</i>	03N19-001					
1.4 mL Internal Control Vial Cap	needed for <i>m24sp</i>	03N20-001					
<b>Cost per device</b>			<b>\$207,000</b>	<b>Cost per test result</b>			<b>\$13 - 35</b>

HCV GENOTYPING							
Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
<i>m2000sp</i>	Sample Extraction, up to 96 samples	09K14-002	\$162,000	Abbott RealTime HCV Genotype II Amplification Reagent Kit CE	24 tests	08K24-90	
<i>m2000rt</i>	Amplification and detection	09K15-001	\$45,000	Abbott RealTime HCV Control Kit CE	4 positive, 4 negative	08K24-80	
Instrument Accessories		Reference number	FCA (\$)	Non-proprietary equipment and consumables		Reference number	FCA (\$)
Abbott RealTime HCV Genotype II <i>m2000</i> -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 Vessels)		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					
<b>Cost per device</b>			<b>\$207,000</b>	<b>Cost per test result</b>			<b>Not provided</b>

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**03 | TIERED AND VOLUME-BASED PRICING**

No Information Provided

**04 | MAINTENANCE, WARRANTY & TRAINING**

	Description
<b>Leasing or reagent rental (RAP)</b>	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.
<b>Installation</b>	Provided: installation performed by Abbott service engineer or third party engineer certified by Abbott following internal SOP.
<b>Training</b>	<p>Provided:</p> <ul style="list-style-type: none"> <li>• Training done at customer site for up to 6 people.</li> <li>• Averages [m2000sp: training 3 days duration; m2000rt: 2 days; m2000sp and m2000rt: 4 days together] and is dependent on the number of assays.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• Languages: English, French, Portuguese, Spanish.</li> <li>• Done in real conditions / using true samples / using samples and material from the laboratory.</li> <li>• Content of training: <ul style="list-style-type: none"> <li>- m2000 System Overview, Hardware Overview.</li> <li>- Good Laboratory Practices, Set-up RealTime extraction for all assays, RNA/DNA Extraction reagents.</li> <li>- Review of RealTime results.</li> <li>- Perform maintenance, decontamination procedure, troubleshooting, lamp replacement, optical calibration, and contamination check.</li> </ul> </li> <li>• End user lab technician is certified by Abbott.</li> </ul> <p>Additional training on top of the 2 sessions will be on demand and charged.</p>
<b>Maintenance</b>	<ul style="list-style-type: none"> <li>• During the warranty period: repair is assured.</li> <li>• Following year 1 of the service contract, maintenance includes <ul style="list-style-type: none"> <li>- Preventive maintenance</li> <li>- Repair visits</li> <li>- Phone support by molecular expert (Abbott Molecular engineer or third party engineer certified by Abbott)</li> </ul> </li> <li>• Preventive maintenance = 1 PM/year <ul style="list-style-type: none"> <li>- Software is upgraded as required</li> <li>- Phone support is available from 9am-5pm (depending on the country)</li> </ul> </li> <li>• Repair maintenance is available 5 days/week from 9am-5pm <ul style="list-style-type: none"> <li>- Spare parts are included</li> <li>- Can be purchased upfront or paid monthly/annually</li> </ul> </li> </ul>
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	Warranty = 12 months
<b>Warranty components</b>	Installation, repair, spare parts, labour, initial training, phone support.
<b>Turnkey option</b>	Available on request.
<b>in-country / regional technical support availability</b>	Depends on country. Service assumed by Abbott Molecular service engineer or distributor service people certified by Abbott.

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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
<b>Company</b>	Biocentric		
<b>Product</b>	GENERIC HIV DNA CELL	GENERIC HIV CHARGE VIRALE	GENERIC HCV CHARGE VIRALE
<b>ASSAY</b>			
<b>Intended use (as per regulatory approval)</b>	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.
<b>Principle of the assay</b>	Real time PCR assay with fluorescence detection.	Real time RT-qPCR with fluorescence detection.	
<b>Target</b>	HIV-1 LTR (Long Terminal Repeat).		Not disclosed.
<b>Genotypes and/or subtypes</b>	HIV-1: Group M, B and non B subtypes, including CRF.		Genotypes 1 to 6.
<b>Type of result</b>	Qualitative and quantitative.	Quantitative	
<b>Linear range</b>	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
<b>Output</b>	Detection of HIV-1 DNA or quantitation of HIV-1 DNA copies/10 <sup>6</sup> cells.	RNA viral load in copies/mL or IU/mL.	
<b>DNA or RNA specific?</b>	DNA	RNA	
<b>Polyvalency</b>	HIV-2 viral load, M. tuberculosis and drug resistance, HBV viral load.		
<b>PERFORMANCE</b>			
<b>Sensitivity - analytical and clinical (source)</b>	Input whole blood volume of 200µL: 40 copies/10 <sup>6</sup> 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
<b>Specificity - analytical and clinical (source)</b>	100%	100%	
<b>Bias (source)</b>	N/A	δ= -0.12 to 0.22 copies/mL (from: clinical comparative studies)	
<b>Intra-assay precision (source)</b>	Samples tested in duplicate (n = 172): Spearman, r = 0.940; p<0.0001	<2%	
<b>Inter-assay precision (source)</b>	<5%	<6%	
<b>SAMPLE</b>			
<b>Sample preparation (steps)</b>	Prepare DBS.	Prepare plasma.	
<b>Sample type</b>	Venous or capillary whole blood or PBMCs or DBS (RUO).	Plasma (EDTA or citrated) or DBS (RUO).	Plasma (EDTA or citrated).
<b>Sample volume</b>	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
<b>Sample stability</b>	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
<b>Nucleic acid extraction method</b>	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)		
<b>Time to result</b>	4 hours	3.5 hours, including RNA isolation	
<b>Capacity</b>	180 - 360 patient samples per kit.		
<b>Batching?</b>	Yes		
<b>Throughput per end-user per hour and/or 8hr day</b>	One working day = 40 samples	One working day: - one Arrow extractor = 40 samples - two Arrow extractors = 82 samples	

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



## 02 | PRICING

EARLY INFANT DIAGNOSIS							
Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
<i>Fluorocycler</i>	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 (\$)
<i>Arrow or GenoXtract</i>	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						
<b>Cost per device</b>			<b>\$42,000</b>	<b>Cost per test result</b>			<b>\$13.05</b>

HIV VIRAL LOAD							
Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
<i>Fluorocycler</i>	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 (\$)
<i>Arrow or GenoXtract</i>	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						
<b>Cost per device</b>			<b>\$42,000</b>	<b>Cost per test result</b>			<b>\$14.9</b>

HCV VIRAL LOAD							
Instrument		Reference number	FCA (\$)	Cartridge/reagents		Reference number	FCA (\$)
<i>Fluorocycler</i>	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 (\$)
<i>Arrow or GenoXtract</i>	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						
<b>Cost per device</b>			<b>\$42,000</b>	<b>Cost per test result</b>			<b>\$22.60</b>

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

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**03 | TIERED AND VOLUME-BASED PRICING**

No tiered or volume-based pricing provided.

**04 | MAINTENANCE, WARRANTY & TRAINING**

	Description	Cost (\$)
<b>Leasing or reagent rental (RAP)</b>	3 year contract leasing for 1 thermocycler and one 12-sample automated extraction instrument.	Approx. \$1,300/month
<b>Installation</b>	On request.	
<b>Training</b>	(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
<b>Maintenance</b>	Full on-site servicing (preventive and curative) as well as instrument swap, if necessary.	\$5,500/year
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	- 12 months warranty. - Extended warranty included in maintenance program.	Not provided.
<b>Warranty components</b>	On Thermocycler and Automated Extraction instrument.	Not provided.
<b>Turnkey option</b>	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
<b>In-country / regional technical support availability</b>	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
<b>ASSAY</b>		<b>PERFORMANCE</b>	
<b>Intended use</b>	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.	<b>Bias (source)</b>	Not provided.
<b>Principle of the assay</b>	Real time NASBA isothermal signal amplification using molecular beacons for detection.	<b>Intra-assay precision (source)</b>	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)
<b>Target</b>	HIV-1 RNA gag	<b>Inter-assay precision (source)</b>	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)
<b>Genotypes and/or subtypes</b>	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).	<b>Accuracy (source)</b>	Plasma: <0.25 10Log DBS: <0.30 10Log (bioMérieux)
<b>Type of result</b>	Quantitative	<b>SAMPLE</b>	
<b>Linear range</b>	25 - 10,000,000 copies/mL	<p>Blood collection and plasma preparation:</p> <ul style="list-style-type: none"> <li>- Blood should be collected in sterile tubes by normal venipuncture techniques using EDTA as an anticoagulant and should be handled with the proper precautions.</li> <li>- After centrifugation (e.g. 10 minutes at 1,500 x g), the obtained plasma specimen should be used as sample input.</li> <li>- No special specimen preparation or fasting of the patient is necessary.</li> <li>- No adverse effects were observed using EDTA as the anticoagulant.</li> <li>- Any deviations from the described procedures should be validated by users in their own laboratory setting.</li> </ul> <p>DBS Collection:</p> <ul style="list-style-type: none"> <li>- 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).</li> <li>- Note: Fill each printed circle with a SINGLE application of blood. Prevent spotting outside the circles.</li> <li>- Note: Avoid touching or smearing the blood spots.</li> <li>- Two spots are needed for the nucleic acid extraction procedure.</li> <li>- 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.</li> <li>- Dry the filter paper for at least 3 hours (and for a maximum of overnight) at room temperature (15 to 30 °C).</li> </ul>	
<b>Output</b>	Time-to-result: 2.5 - 3 hours		
<b>DNA or RNA specific?</b>	RNA		
<b>Polyvalency</b>	HPV; ARGENE molecular menu: immunocompromised, meningitis, respiratory diseases RT-PCR kits.		
<b>PERFORMANCE</b>		<b>Sample preparation (steps)</b>	
<b>Sensitivity - analytical and clinical (source)</b>	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 copies 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)	<b>Sample type</b>	EDTA plasma or dried blood spot (venous EDTA or capillary (without anticoagulant) whole blood spotted on card).
<b>Specificity - analytical and clinical (source)</b>	Observed specificity: N = 261 (1mL EDTA plasma) = 100% [95% CI (98.6 - 100)] N = 129 (0.1mL EDTA plasma) = 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)		

Continued overleaf

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
<b>SAMPLE</b>		<b>INSTRUMENT</b>	
<b>Sample volume</b>	Plasma: 0.1 / 0.5 / 1 mL DBS: 2 spots of 50µL each	<b>Power requirements</b>	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)
<b>Sample stability</b>	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 desiccant 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.	<b>Time to battery charge</b>	N/A
		<b>Battery duration (hours)</b>	N/A
		<b>Alternative charging options</b>	N/A
		<b>Ease of use</b>	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.
<b>Nucleic acid extraction method</b>	Semi-automated	<b>Display languages</b>	English, German, Italian, Spanish, French.
<b>Time to result</b>	Less than 3 hours, from sample to result (sample acquisition, extraction, amplification, detection).	<b>Built-in memory storage capacity</b>	Storage on the computer (capacity of 250 GB).
<b>Capacity</b>	Can be configured to run 8 - 1,000 tests/day but only 8 - 140 tests/day if only one instrument is used.	<b>Connectivity options</b>	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.
<b>Batching?</b>	Yes. Maximum run size: NucliSENS EasyMAG = 24 samples NucliSENS miniMAG = 12 samples NucliSENS EasyQ Analyser = 48 samples	<b>Interpretation of result</b>	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").
		<b>Instrument lifespan</b>	Approximately 8 years depending on usage conditions, usage frequency, and systems environment.
<b>Throughput per end-user per hour and/or 8hr day</b>	Around 140 samples can be tested per 8-hour shift if 1 EasyMAG and 1 EasyQ are used.	<b>Other non-proprietary equipment required</b>	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".
		<b>Regulatory approval</b>	CE-IVD
<b>INSTRUMENT</b>		<b>KIT</b>	
<b>Size of device</b>	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	<b>Kit components</b>	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
<b>Weight of device</b>	MiniMAG: ±3.6 kg EasyMAG: ±125 kg EasyQ: ±20.5 kg	<b>Kit sizes</b>	48 tests
<b>Robustness</b>	Yes, refer to mean-time between failures: EasyMAG = 384 days; EasyQ = 5 years.	<b>Internal control(s)</b>	Yes
<b>Environmental requirements</b>	MiniMAG: - Temperature: 4 – 45°C Easy Mag: - Temperature: 15 - 30°C - Relative humidity: ≤80%, non-condensing at 30°C DB - Altitude: 0 - 2,500 meters above sea level EasyQ: - Temperature: 10 - 40°C - 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)	<b>Compatible with EQA and which?</b>	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.
		<b>Mean time between failures</b>	EasyMAG: 384 days; EasyQ: 5 years

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
KIT		USAGE	
<b>Transport and storage</b>	Amplification reagents: 2-8°C Extraction reagents (buffers 1, 2 and lysis buffer): 2-30°C Buffer 3 and magnetic silica: 2-8°C	<b>Technical skill required</b>	Medium-highly trained, precision pipetting required at low volumes.
<b>Fridge at -80°C required?</b>	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.	<b>Applicable settings</b>	Technology can be used at regional / central level or national reference (or comparable) laboratories. Access to decentralized settings via DBS.
<b>Shelf life</b>	>210 days: buffers 1, 2, 3; magnetic silica; lysis buffer; disposables >150 days: amplification reagents >120 days: extraction reagents	<b>Laboratory set-up</b>	Specialized; 2-3 dedicated areas required.
<b>Performance protocol (steps)</b>	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.	<b>Waste disposal requirements</b>	Containers for solid waste, container for liquid waste, waste plastic bags.
<b>Non-proprietary components required outside of the kit</b>	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".		
<b>Regulatory approval</b>	WHO PQ, CE-IVD (plasma and EDTA + capillary DBS)		
<b>In-country approvals</b>	Please refer to bioMérieux for country-specific registration information.		



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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 (\$)
				<b>For miniMAG</b>			
				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	
				<b>For EasyMAG</b>			
				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	
				<b>For EasyQ</b>			
				EasyQ 8-Tube Caps		285051	
				EasyQ 8-Tube Strips		285048	
				<b>For DBS</b>			
				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	
<b>Cost per device</b>				<b>Cost per test result</b>			<b>±\$23.40*</b>

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

**03 | TIERED AND VOLUME-BASED PRICING**

No information provided.

**04 | MAINTENANCE, WARRANTY & TRAINING**

	<b>Description</b>
<b>Leasing or reagent rental (RAP)</b>	None provided.
<b>Installation</b>	Installation of the instrument, as per bioMérieux recommendations and procedures, consists of: <ul style="list-style-type: none"> <li>- Unpacking the instrument</li> <li>- Bench positioning</li> <li>- Configuration of the instrument</li> <li>- Verification of the instrument</li> <li>- Validation of the functioning of the instrument</li> </ul>
<b>Training</b>	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: <ul style="list-style-type: none"> <li>- Principles of the technique</li> <li>- Use of the system</li> <li>- Interpretation of the results</li> </ul> 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: <ul style="list-style-type: none"> <li>- Worksheet materials explaining the steps to follow depending on the protocols used (simple front &amp; quick user guide). These worksheets are available on the CD-ROM sent with the kit.</li> <li>- How-to-use video available for the use of DBS.</li> </ul> Webinars can be organized on a case by case basis.
<b>Maintenance</b>	Maintenance performed during the warranty period as per bioMérieux recommendations and procedures consists of: <ul style="list-style-type: none"> <li>- 2 preventive maintenances for Nuclisens EasyMag</li> <li>- 1 preventive maintenance for Nuclisens EasyQ</li> <li>- Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions</li> </ul> Preventive and corrective maintenance is provided by the bioMérieux legal representative in the country of destination following bioMérieux procedures and recommendations. Any warranty extension is studied on a case by case basis.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	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: <ul style="list-style-type: none"> <li>- 2 preventive maintenances for the Nuclisens EasyMag and 1 for the Nuclisens EasyQ</li> <li>- Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions.</li> </ul> Any warranty extension will be studied on a case by case basis and a quotation will be issued.
<b>Warranty components</b>	Included: <ul style="list-style-type: none"> <li>- Instrument, parts and labour, within the frame of our ongoing Export Sales General Conditions.</li> <li>- Travelling expenses.</li> </ul> Excluded: <ul style="list-style-type: none"> <li>- Disposables and replacement items with a normal life expectancy of less than 1 year (such as, but not limited to, batteries, lamps and tubing).</li> </ul>
<b>Turnkey option</b>	Yes, to be discussed on a case by case basis.
<b>In-country / regional technical support availability</b>	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
	<b>ASSAY</b>	<b>INSTRUMENT</b>	<b>KIT</b>
<b>Intended use (as per regulatory approval)</b>	For determination of the activity of the enzyme reverse transcriptase (RT), as a marker of retroviral replication.	<b>Size of device</b>	Footprint on bench: <0.6 sqm
<b>Principle of the assay</b>	Determination of RT activity	<b>Weight of device</b>	12 kg
<b>Target</b>	Reverse Transcriptase (RT)	<b>Robustness</b>	Very robust
<b>Genotypes and/or subtypes</b>	HIV-1 and HIV-2 and all subtypes	<b>Environmental requirements</b>	Laboratory
<b>Type of result</b>	Quantitative	<b>Power requirements</b>	AC power
<b>Linear range</b>	200 - 600,000 copies/mL		
<b>Output</b>	fg RT/mL and RNA copy equivalents/mL	<b>Time to battery charge</b>	N/A
<b>DNA or RNA specific?</b>	N/A		
<b>Polyvalency</b>	No	<b>Battery duration (hours)</b>	N/A
	<b>PERFORMANCE</b>		
<b>Sensitivity - analytical and clinical (source)</b>	200 copies/mL	<b>Alternative charging options</b>	N/A
<b>Specificity - analytical and clinical (source)</b>	>99.5%	<b>Ease of use</b>	N/A
<b>Bias (source)</b>	Not provided	<b>Display languages</b>	N/A
<b>Intra-assay precision (source)</b>	4-8% CV		
<b>Inter-assay precision (source)</b>	2-3% CV	<b>Built-in memory storage capacity</b>	N/A
<b>Sample preparation (steps)</b>	Prepare plasma from whole blood.		
<b>Sample type</b>	EDTA + Citrate plasma	<b>Connectivity options</b>	N/A
<b>Sample volume</b>	1 mL		
<b>Sample stability</b>	≤6 months at -20°C, >6 months at -80°C	<b>Interpretation of result</b>	N/A
<b>Nucleic acid extraction method</b>	N/A		
<b>Time to result</b>	48 hrs	<b>Instrument lifespan</b>	N/A
<b>Capacity</b>	32 samples per run	<b>Other non-proprietary equipment required</b>	ELISA plate reader, incubator, end-over-end mixing table, vortex, computer
<b>Batching?</b>	Yes		
<b>Throughput per end-user per hour and/or 8hr day</b>	30-60 tests over 2 days	<b>Regulatory approval</b>	N/A
			<b>USAGE</b>
			<b>Kit components</b>
			Reagents + consumables
			<b>Kit sizes</b>
			32 samples / kit
			<b>Internal control(s)</b>
			HIV-I rRT Standard
			<b>Compatible with EQA and which?</b>
			Yes, eg. NRL Australia and HUQAS Kenya
			<b>Mean time between failures</b>
			No equipment failures recorded to date
			<b>Transport and storage</b>
			-14 to -25°C
			<b>Fridge at -80°C required?</b>
			No
			<b>Shelf life (of each item in the kit)</b>
			2 years at customer
			<b>Performance protocol (steps)</b>
			Detailed in IfU, 21 steps over 2 days
			<b>Non-proprietary components required outside of the kit</b>
			Pipette tips
			<b>Regulatory approval</b>
			CE-IVD marked
			<b>In-country approvals</b>
			Botswana, Zambia, Zimbabwe, Kenya, Uganda, Lesotho, India, Philippines and more.
			<b>Technical skill required</b>
			Lab Technician
			<b>Applicable settings</b>
			Near-POC / district hospital level
			<b>Laboratory set-up</b>
			Simple, not specialized, single work area, freezing required.
			<b>Waste disposal requirements</b>
			Follow local SOPs for hazardous waste handling.



## 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			
<b>Cost per device</b>			<b>\$4,500</b>	<b>Cost per test result</b>			<b>\$12-25</b>

## 03 | TIERED AND VOLUME-BASED PRICING

No information provided.

## 04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (\$)
<b>Leasing or reagent rental (RAP)</b>	Purchase, leasing and reagent rental options can be offered.	Offered and negotiated upon request.
<b>Installation</b>	Wherever CavidI has representation, installation is free of charge. If a new market, costs can be negotiated.	None
<b>Training</b>	<ul style="list-style-type: none"> <li>• 4-5 days of training is needed</li> <li>• English and Portuguese available</li> <li>• On-site training available</li> <li>• Training tools are available as a training package/tools for before, under and after training.</li> <li>• End-users are considered proficient after training</li> <li>• Comprehensive training material is available for trainers and users.</li> </ul>	Free of charge in countries where CavidI has representation. If a new market, costs can be negotiated.
<b>Maintenance (including instrument swap)</b>	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.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	The ExaVir equipment is guaranteed (unlimited warranty) as long as the site is active.	None
<b>Warranty components</b>	Warranty covers all components of the ExaVir equipment.	N/A
<b>Turnkey option</b>	Can be offered upon request.	N/A
<b>In-country / regional technical support availability</b>	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
<b>Company</b>	<b>Hologic</b>	
<b>Product</b>	<b>APTIMA HIV-1 QUANT DX ASSAY</b>	<b>APTIMA HCV QUANT DX ASSAY</b>
<b>ASSAY</b>		
<b>Intended use</b>	<p>Detection and quantitation of HIV-1 RNA.</p> <p>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.</p> <p>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.</p>	<p>Detection and quantitation of HCV RNA.</p> <p>Indicated for use as an aid in the diagnosis of active HCV infection in the following populations:</p> <ul style="list-style-type: none"> <li>- Individuals with antibody evidence of HCV infection with evidence of liver disease</li> <li>- individuals suspected of being actively infected with HCV following antibody evidence</li> <li>- individuals at risk of HCV infection with antibodies to HCV</li> </ul> <p>Detection of HCV RNA indicates that the virus is replicating and, therefore, is evidence of active infection.</p> <p>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.</p> <p>Not intended for use as a screening test for the presence of HCV in blood or blood products.</p>
<b>Principle of the assay</b>	Real-Time TMA	
<b>Target</b>	HIV-1 Pol and LTR	HCV 5' UTR
<b>Genotypes and/or subtypes</b>	HIV-1 group M (A, B, C, D, F, G, H, CRF01_AE, CRF02_AG), group N, and group O	Genotypes 1-6
<b>Type of result</b>	Qualitative and quantitative	
<b>Linear range</b>	LOD = 13.1 copies Linear Range for Quantitation = 30 - 10e6 copies/mL	Performance characteristics have not yet been established.
<b>Output</b>	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
<b>DNA or RNA specific?</b>	RNA	
<b>Polyvalency</b>	<p>Available: Chlamydia diagnosis, Gonorrhoea diagnosis, Chlamydia/Gonorrhoea combined diagnosis, Trichomonas vaginalis diagnosis, and HPV diagnosis and genotyping.</p> <p>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.</p>	
<b>PERFORMANCE</b>		
<b>Sensitivity - analytical and clinical (source)</b>	13.1 copies/mL (95% detected in 500mL plasma) (package insert)	Performance characteristics have not yet been established.
<b>Specificity - analytical and clinical (source)</b>	100% (CI 99.4 - 100% in 500mL plasma) (package insert)	
<b>Bias (source)</b>	<0.05 log copies/mL (package insert)	
<b>Intra-assay precision (source)</b>	Within 0.05 log SD and <1.93% CV (package insert)	
<b>Inter-assay precision (source)</b>	Within 0.09 log SD and <3.75% CV (package insert)	

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
<b>SAMPLE</b>		
<b>Sample preparation</b>	Plasma and serum: after centrifugation, uncap primary blood tube and load onto system.	
<b>Sample type</b>	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.	
<b>Sample volume</b>	≥1.2mL in primary tubes, 700mL in specimen aliquot tubes, and 240mL with a 1:3 dilution in specimen aliquot tubes.	
<b>Sample stability</b>	<p>Whole blood is stable for 24hrs at 2-30°C prior to centrifugation.</p> <p>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.</p> <p>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.</p>	<p><b>Target:</b></p> <p>Whole blood is stable for 6hrs at 2-30°C prior to centrifugation.</p> <p>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.</p> <p>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.</p> <p>Note: Performance characteristics have not yet been established.</p>
<b>Nucleic acid extraction method</b>	Automated (platform is completely automated from sample to result).	
<b>Time to result</b>	Time to first 5 results is 2hr and 41 minutes, with additional 5 results every 5 minutes.	
<b>Capacity</b>	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.	
<b>Batching?</b>	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.	
<b>Throughput per end-user per hour and/or 8hr day</b>	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.	
<b>INSTRUMENT</b>		
<b>Size of device</b>	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.	
<b>Weight of device</b>	345kg. UPS (optional): 34.5kg.	
<b>Robustness</b>	<ul style="list-style-type: none"> <li>• Direct tube sampling capability of primary tube and no processing of sample prior to loading onto the instrument.</li> <li>• 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.</li> <li>• A reagent identification system (barcode or other) to automatically link reagent lot and expiration date information to the sample report.</li> <li>• Positive Sample Identification with ability to load samples and let the system run by itself automatically.</li> <li>• Reagent dispense verification and liquid level sensing capability to verify proper dispense of sample and reagents into reaction tube.</li> <li>• The ability to automatically decontaminate and remove amplification reaction tubes from the assay processing area without operator intervention in a closed system.</li> <li>• Ability to perform maintenance steps automatically at times scheduled by operator.</li> </ul>	
<b>Environmental requirements</b>	<p>Environment: indoor use only. Can be placed in general purpose lab and independent molecular lab not required</p> <p>Sunlight: No direct sunlight - sunlight may mislead optical sensors and affect performance</p> <p>Dust: No excessive dust</p> <p>Altitude: ≤2,000m above sea level</p> <p>Temperature: Ambient Operating 15–30°C; Storage 5–45°C; Transport -20–70°C</p> <p>Relative Humidity: Operating 20-85% non-condensing; Storage 10-90% non-condensing; Transport 10-90% non-condensing</p> <p>Pollution Degree: 2</p> <p>Installation Class: 2</p>	
<b>Power requirements</b>	<p>Voltage: 100-240 + 10% VAC</p> <p>Frequency: 50-60Hz, single phase</p> <p>Current Input: Minimum of 15 amp circuit (dedicated); 20 amp circuit (dedicated if used with optional UPS)</p> <p>Current Draw: Average 700W; Peak 1400W; 100 VAC circuit draws 13 amps, 240 VAC circuit draws 5.4 amps</p> <p>Fuse: Thermal circuit breaker</p>	
<b>Time to battery charge</b>	N/A	
<b>Battery duration</b>	N/A	
<b>Alternative charging options</b>	N/A	
<b>Ease of use</b>	The Panther has a touchscreen monitor connected to the system and a printer is included.	
<b>Display languages</b>	English	
<b>Built-in memory storage capacity</b>	250 GB	
<b>Connectivity options</b>	Panther hosts bi-directional LIS connectivity.	

Continued overleaf 

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
<b>INSTRUMENT</b>		
<b>Interpretation of result</b>	Reported Aptima HIV-1 Quant Dx Results / Quantitative Interpretation / Qualitative Interpretation. 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
<b>Instrument lifespan</b>	7-10 years	
<b>Other non-proprietary equipment required</b>	No other third party equipment is required.	
<b>Regulatory approval</b>	N/A	
<b>KIT</b>		
<b>Kit components</b>	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	
<b>Kit sizes</b>	100 tests	
<b>Internal control(s)</b>	Internal control is formulated into the TCR and run in every sample.	
<b>Compatible with EQA and which?</b>	Acrometrix, QCMD, WHO standard	
<b>Mean time between failures</b>	Average = 1,200 hours globally. This reflects new vs experienced 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.	
<b>Transport and storage</b>	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.	
<b>Fridge at -80°C required?</b>	No	
<b>Shelf life (of each item in the kit)</b>	Maximum shelf life = 18 months post manufacturing.	Product currently under development. Performance characteristics have not been established.
<b>Performance protocol</b>	<ol style="list-style-type: none"> <li>1. Centrifuge blood tube to separate plasma or serum</li> <li>2. Prepare reagents, load onto Panther rack, and load on Panther</li> <li>3. Load samples onto Panther rack, uncap tubes, and load on Panther</li> <li>4. If samples do not have barcodes, manually enter sample ID into system</li> <li>5. Close Panther door and Panther will start assay processing and report results when complete</li> </ol>	
<b>Non-proprietary components required outside of the kit</b>	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.	
<b>Regulatory approval</b>	CE-IVD certified (Nov 2014). Submitted for WHO Prequalification, US FDA PMA and China FDA.	Will be submitted for the following: CE/IVD (expected in 2015), US FDA, and China FDA.
<b>In-country approvals</b>	Several planned.	
<b>USAGE</b>		
<b>Technical skill required</b>	Minimal skill level, no pipetting needed.	
<b>Applicable settings</b>	Can be run in general laboratory with minimal infrastructure requirements.	
<b>Laboratory set-up</b>	General purpose laboratory.	
<b>Waste disposal requirements</b>	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			
<b>Cost per device</b>			<b>\$150,000 - 175,000</b>	<b>Cost per test result</b>			<b>\$10-25</b>

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			
<b>Cost per device</b>			<b>\$150,000 - 175,000</b>	<b>Cost per test result</b>			<b>Price available upon commercialization</b>

## 03 | TIERED AND VOLUME-BASED PRICING

No information provided.

Continued overleaf

## 04 | MAINTENANCE, WARRANTY & TRAINING

	Description
<b>Leasing or reagent rental (RAP)</b>	Instrument purchase or reagent rental are available based on contractual volume commitments.
<b>Installation</b>	Included in instrument purchase or reagent rental, estimated at less than 3 days.
<b>Training</b>	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.
<b>Maintenance</b>	Year 1: full warranty Year 2 and beyond: service contract available for purchased instruments or included in reagent rental
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	12 month warranty included in instrument purchase. Annual service contract offered after warranty period. Instrument service and support included in reagent rental.
<b>Warranty components</b>	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
<b>Turnkey option</b>	N/A
<b>in-country / regional technical support availability</b>	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	
<b>Company</b>	Qiagen			
<b>Product</b>	<b>ARTUS HI VIRUS-1 RG RT-PCR</b>	<b>ARTUS HI VIRUS-1 QS-RGQ</b>	<b>ARTUS HCV RG RT-PCR</b>	<b>ARTUS HCV QS-RGQ</b>
<b>ASSAY</b>				
<b>Intended use</b>	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.	
<b>Principle of the assay</b>	Real time PCR			
<b>Target</b>	HIV-1 RNA LTR		HCV RNA, 240 nt region of the 5' UTR	
<b>Genotypes and/or subtypes</b>	HIV-1: Group M (A-H)		HCV genotypes 1–6	
<b>Type of result</b>	Quantitative			
<b>Linear range</b>	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
<b>Output</b>	Viral load			
<b>DNA or RNA specific?</b>	No			
<b>Polyvalency</b>	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.
<b>PERFORMANCE</b>				
<b>Sensitivity - analytical and clinical (source)</b>	4.5 IU/μL (analytical)	34.4 copies/mL (analytical)	33.6 IU/mL (analytical)	21.6 IU/mL (analytical)
<b>Specificity - analytical and clinical (source)</b>	Not provided			
<b>Bias (source)</b>	Not provided			
<b>Intra-assay precision (source)</b>	Not provided			
<b>Inter-assay precision (source)</b>	Not provided			
<b>SAMPLE</b>				
<b>Sample preparation (steps)</b>	Not provided			
<b>Sample type</b>	Plasma			
<b>Sample volume</b>	500μL	1,000μL	500μL	1,000μL
<b>Sample stability</b>	Not provided			
<b>Nucleic acid extraction method</b>	Manual (QIAamp DSP Virus Kit)	Automated	Manual (QIAamp DSP Virus Kit)	Automated
<b>Time to result</b>	5–6 hours			
<b>Capacity</b>	≤96 samples			
<b>Batching?</b>	Yes, flexible batch size.			
<b>Throughput per end-user per hour and/or 8hr day</b>	≤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
<b>INSTRUMENT</b>				
<b>Size of device</b>	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
<b>Weight of device</b>	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)
<b>Robustness</b>	Not provided			
<b>Environmental requirements</b>	For indoor use only			
<b>Power requirements</b>	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
<b>Time to battery charge</b>	N/A			
<b>Battery duration (hours)</b>	N/A			
<b>Alternative charging options</b>	None			
<b>Ease of use</b>	None	Touch screen	None	Touch screen
<b>Display languages</b>	English			
<b>Built-in memory storage capacity</b>	None			
<b>Connectivity options</b>	Q!Alink software (for automated data transfer between QIAsymphony RGQ and LIMS).			
<b>Interpretation of result</b>	None			
<b>Instrument lifespan</b>	Not provided			
<b>Other non-proprietary equipment required</b>	Vortex mixer, Benchtop centrifuge			
<b>Regulatory approval</b>	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
<b>KIT</b>				
<b>Kit components</b>	2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)			
<b>Kit sizes</b>	24 or 96 reactions	24 or 72 reactions	24 or 96 reactions	24 or 72 reactions
<b>Internal control(s)</b>	Yes			
<b>Compatible with EQA and which?</b>	Yes, QCMD			
<b>Mean time between failures</b>	Not provided			
<b>Transport and storage</b>	Store the kit at -20°C, with some variation by reagent, transport on dry ice.			
<b>Fridge at -80°C required?</b>	No			
<b>Shelf life (of each item in the kit)</b>	All reagents are stable until the expiration date stated on the label			
<b>Performance protocol (steps)</b>	Not provided			
<b>Non-proprietary components required outside of the kit</b>	None			
<b>Regulatory approval</b>	CE-IVD	CE-IVD	CE-IVD	CE-IVD
<b>In-country approvals</b>	Not provided			
<b>USAGE</b>				
<b>Technical skill required</b>	Medium to highly trained, precision pipetting required at low volumes.			
<b>Applicable settings</b>	Mid- to highly-resourced settings	Highly-resourced settings	Mid- to highly-resourced settings	Highly-resourced settings
<b>Laboratory set-up</b>	3 dedicated areas are required	2 dedicated areas are required	3 dedicated areas are required	2 dedicated areas are required
<b>Waste disposal requirements</b>	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			
<b>Cost per device</b>			<b>Not provided</b>	<b>Cost per test result</b>			<b>\$16 - 45</b>

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**03 | TIERED AND VOLUME-BASED PRICING** | No information provided.

**04 | MAINTENANCE, WARRANTY & TRAINING**

	QSRGQ		ROTORGENE Q	
	Description	Cost (\$)	Description	Cost (\$)
<b>Leasing or reagent rental (RAP)</b>	Possible	N/A	Possible	N/A
<b>Installation</b>	<ul style="list-style-type: none"> <li>• Installation of the system hardware and software</li> <li>• Introductory training</li> <li>• Help customer to get started quickly</li> </ul>	\$7,000 - 9,000	<ul style="list-style-type: none"> <li>• Installation of the system hardware and software</li> <li>• Introductory training</li> <li>• Help customer to get started quickly</li> </ul>	\$2,000 - 3,000
<b>Training</b>	<ul style="list-style-type: none"> <li>• 2-5 days required</li> <li>• English + local languages, if available</li> <li>• On site training possible</li> <li>• Training tools available</li> <li>• Certified user after training completed</li> </ul>	~\$1,500 - 3,000 per day	<ul style="list-style-type: none"> <li>• 1-2 days required</li> <li>• English + local languages, if available</li> <li>• On site training possible</li> <li>• Training tools available</li> <li>• Certified user after training completed</li> </ul>	~\$1,500 - 3,000 per day
<b>Maintenance (including instrument swap)</b>	<ul style="list-style-type: none"> <li>• Inspection of all components of the equipment</li> <li>• Bring the instrument to its optimal performance</li> <li>• Ensure instrument is performing according to specification</li> </ul>	\$5,000 - 7,000	<ul style="list-style-type: none"> <li>• Inspection of all components of the equipment</li> <li>• Bring the instrument to its optimal performance</li> <li>• Ensure instrument is performing according to specification</li> </ul>	\$1,500 - 1,900
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	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
<b>Warranty components</b>	Parts, labour, travel	N/A	Parts, labour, shipping	N/A
<b>Turnkey option</b>	N/A			
<b>in-country / regional technical support availability</b>	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
<b>Company</b>	Roche Molecular Diagnostics			
<b>Product</b>	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
<b>ASSAY</b>				
<b>Intended use (as per regulatory approval)</b>	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.
<b>Principle of the assay</b>	Real Time PCR.			
<b>Target</b>	GAG and LTR (dual target) and HIV-2.	GAG and LTR (dual target).	HCV	HCV
<b>Genotypes and/or subtypes</b>	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.	
<b>Type of result</b>	Qualitative	Quantitative	Qualitative	Quantitative
<b>Linear range</b>	N/A	20 - 1,000,000 copies/mL (33 - 16,700,000 IU/mL)	N/A	15 - 100,000,000 IU/mL
<b>Output</b>	Qualitative result	Quantitative viral load result	Qualitative result	Quantitative viral load result
<b>DNA or RNA specific?</b>	DNA and RNA (TNA)	RNA		
<b>Polyvalency</b>	CMV Viral Load, B*5701, Chlamydia trachomatis (COBAS TaqMan 48 Analyser), Mycobacterium tuberculosis (COBAS TaqMan 48 Analyser), HBV.			
<b>PERFORMANCE</b>				
<b>Sensitivity - analytical and clinical (source)</b>	100% (Instructions For Use)	100% (Instructions For Use)	100% (Instructions For Use)	100% (Instructions For Use)
<b>Specificity - analytical and clinical (source)</b>	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)
<b>Bias (source)</b>	Not provided.			
<b>Intra-assay precision (source)</b>	Not provided.			
<b>Inter-assay precision (source)</b>	Not provided.			

Continued overleaf

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
<b>SAMPLE</b>				
<b>Sample preparation (steps)</b>	(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 transferring 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.		
<b>Sample type</b>	Plasma or dried blood spots (DBS)	Plasma	Plasma or serum	
<b>Sample volume</b>	Plasma: 1mL (850mL gets processed) DBS: 1 spot (60–70µL)	1mL (850mL gets processed)	1mL (650mL gets processed)	1mL (650mL gets processed)
<b>Sample stability</b>	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.
<b>Nucleic acid extraction method</b>	Automated (docked and undocked options).			
<b>Time to result</b>	5-8 hours			
<b>Capacity</b>	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)
<b>Batching?</b>	Yes. System can perform additional batches with its interleaved capability.			
<b>Throughput per end-user per hour and/or 8hr day</b>	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			
<b>INSTRUMENT</b>				
<b>Size of device</b>	W 165 x D 74.5 x H 93.5 cm			
<b>Weight of device</b>	310 kg			
<b>Robustness</b>	Not provided.			
<b>Environmental requirements</b>	Ambient room temperature (15 - 32 °C).			
<b>Power requirements</b>	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)			
<b>Time to battery charge</b>	N/A			
<b>Battery duration (hours)</b>	N/A			
<b>Alternative charging options</b>	None			
<b>Ease of use</b>	Data Station			
<b>Display languages</b>	English			
<b>Built-in memory storage capacity</b>	Not provided.			
<b>Connectivity options</b>	Yes			
<b>Interpretation of result</b>	Automatic interpretation of data.			
<b>Instrument lifespan</b>	Depends on number of samples run.			
<b>Other non-proprietary equipment required</b>	Vortex mixer (and Thermomixer for DBS).	Vortex mixer		
<b>Regulatory approval</b>	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
<b>KIT</b>				
<b>Kit components</b>	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
<b>Kit sizes</b>	48 tests/kit	48 tests/kit	72 tests/kit	72 tests/kit
<b>Internal control(s)</b>	Yes	Quantitation Standard	Yes	Quantitation Standard
<b>Compatible with EQA and which?</b>	Yes: QCMD			
<b>Mean time between failures</b>	COBAS AmpliPrep Instrument: 114 days COBAS TaqMan Analyser: 236 days COBAS TaqMan 48 Analyser: 850 days			
<b>Transport and storage</b>	Reagents: 2-8°C Disposables: room temperature			
<b>Fridge at -80°C required?</b>	No			
<b>Shelf life (of each item in the kit)</b>	Average 6 months, dependant on earliest expiry of components.			
<b>Performance protocol (steps)</b>	As per Instructions for Use.			
<b>Non-proprietary components required outside of the kit</b>	As per Instructions for Use.			
<b>Regulatory approval</b>	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.
<b>In-country approvals</b>	Not provided.			
<b>USAGE</b>				
<b>Technical skill required</b>	Medium-highly trained, precision pipetting required.			
<b>Applicable settings</b>	Low- to highly-resourced settings.			
<b>Laboratory set-up</b>	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.			
<b>Waste disposal requirements</b>	According to individual country regulations.			



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## 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			
<b>Cost per device</b>			<b>\$150,000</b>	<b>Cost per test result (includes reagents, controls and disposables)</b>		<b>\$12.50</b>

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			
<b>Cost per device</b>			<b>\$150,000</b>	<b>Cost per test result (includes reagents, controls and disposables)</b>		<b>\$9.40</b>

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			
<b>Cost per device</b>			<b>\$150,000</b>	<b>Cost per test result</b>		<b>Dependent on income level &amp; volume commitments</b>

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			
<b>Cost per device</b>			<b>\$150,000</b>	<b>Cost per test result</b>		<b>Dependent on income level &amp; volume commitments</b>

### 03 | TIERED AND VOLUME-BASED PRICING

Price will depend on country income level and volume commitments.

### 04 | MAINTENANCE, WARRANTY & TRAINING

	Description
<b>Leasing or reagent rental (RAP)</b>	Outright purchase, leasing and rental are available dependent on country, contractual volume commitment with mitigation risk assessment.
<b>Installation</b>	Yes, included in acquisition cost.
<b>Training</b>	Yes, included in acquisition cost.
<b>Maintenance (including instrument swap)</b>	Information not provided.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	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.
<b>Warranty components</b>	Parts, travel and labour.
<b>Turnkey option</b>	Information not provided.
<b>in-country / regional technical support availability</b>	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
<b>Company</b>	Sacace Biotechnologies		
<b>Product</b>	HIV REAL-TM QUANT DX	HCV REAL-TM QUANT DX	HCV GENOTYPE PLUS REAL-TM
<b>ASSAY</b>			
<b>Intended use (as per regulatory approval)</b>	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.
<b>Principle of the assay</b>	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.
<b>Target</b>	Pol	5'UTR region	
<b>Genotypes and/or subtypes</b>	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	
<b>Type of result</b>	Quantitative		Genotype
<b>Linear range</b>	48 - 10,000,000 IU/mL	13 - 10,000,000 IU/mL	N/A
<b>Output</b>	Viral load		Genotype
<b>DNA or RNA specific?</b>	RNA specific		
<b>Polyvalency</b>	Not provided		
<b>PERFORMANCE</b>			
<b>Sensitivity - analytical and clinical (source)</b>	48 IU/mL with 1.0 mL sample	13 IU/mL with 1.0 mL sample	1,000 IU/mL
<b>Specificity - analytical and clinical (source)</b>	100%	100%	100%
<b>Bias (source)</b>	Not provided		
<b>Intra-assay precision (source)</b>	CV % = 0.71	CV % = 0.86	N/A
<b>Inter-assay precision (source)</b>	CV % = 0.82	CV % = 1.37	N/A
<b>SAMPLE</b>			
<b>Sample preparation (steps)</b>	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.		
<b>Sample type</b>	Plasma		
<b>Sample volume</b>	100 - 1,000 µL		
<b>Sample stability</b>	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.		
<b>Nucleic acid extraction method</b>	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)).	
<b>Time to result</b>	3 hours		
<b>Capacity</b>	96 samples per run		
<b>Batching?</b>	96 samples per plate		
<b>Throughput per end-user per hour and/or 8hr day</b>	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
<b>INSTRUMENT</b>			
<b>Size of device</b>	SaMag: 100 x 70 x 52 cm SaCycler-96: 210 x 540 x 540 mm		
<b>Weight of device</b>	SaMag: 70kg SaCycler-96: 27kg		
<b>Robustness</b>	Possibility to resume in case of power failure.		
<b>Environmental requirements</b>	SaMag: 30 to 80% RH (non condensing) SaCycler-96: Room temperature (-25°C) max; humidity 50-80%		
<b>Power requirements</b>	AC power; possibility to resume in case of power failure		
<b>Time to battery charge</b>	N/A		
<b>Battery duration (hours)</b>	N/A		
<b>Alternative charging options</b>	N/A		
<b>Ease of use</b>	Keypad and integrated barcode reader for easy set-up.		
<b>Display languages</b>	English		
<b>Built-in memory storage capacity</b>	Yes, and possibility to resume in case of power failure		
<b>Connectivity options</b>	None		
<b>Interpretation of result</b>	Using provided PC software "RealTime_PCR"		
<b>Instrument lifespan</b>	100,000 hours of LED		
<b>Other non-proprietary equipment required</b>	PC with windows operating system (supplied).		
<b>Regulatory approval</b>	CE-IVD		
<b>KIT</b>			
<b>Kit components</b>	Calibrators, high positive control, low positive control, negative control, internal exogenous control		Internal and external (positive and negative).
<b>Kit sizes</b>	1 box		
<b>Internal control(s)</b>	Yes		
<b>Compatible with EQA and which?</b>	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.
<b>Mean time between failures</b>	Not provided		
<b>Transport and storage</b>	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.
<b>Fridge at -80°C required?</b>	No		
<b>Shelf life (of each item in the kit)</b>	12 months		
<b>Performance protocol (steps)</b>	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.
<b>Non-proprietary components required outside of the kit</b>	Not provided		
<b>Regulatory approval</b>	CE-IVD	CE-IVD	None
<b>In-country approvals</b>	Not provided		
<b>USAGE</b>			
<b>Technical skill required</b>	Medium-highly trained, precision pipetting required at low volumes.		
<b>Applicable settings</b>	Low- to highly-resourced settings.		
<b>Laboratory set-up</b>	Specialised, 1-2 dedicated areas are required.		
<b>Waste disposal requirements</b>	Not provided		

Continued overleaf 

## 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			
<b>Cost per device</b>			<b>\$34,000</b>	<b>Cost per test result</b>		<b>&gt;\$20</b>	

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			
<b>Cost per device</b>			<b>\$34,000</b>	<b>Cost per test result</b>		<b>&gt;\$20</b>	

## 03 | TIERED AND VOLUME-BASED PRICING

No information provided.

## 04 | MAINTENANCE, WARRANTY & TRAINING

	Description
<b>Training</b>	Provided through local distributor or directly at Sacace facilities in Como.
<b>Warranty components</b>	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)

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

## 01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPING
<b>Company</b>	Siemens		
<b>Product</b>	<b>VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)</b>	<b>VERSANT HCV RNA 1.0 ASSAY (KPCR)</b>	<b>VERSANT HCV GENOTYPE 2.0 ASSAY (LiPA)</b>
<b>ASSAY</b>			
<b>Intended use (as per regulatory approval)</b>	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.
<b>Principle of the assay</b>	Kinetic PCR		Line Probe Assay (LiPA) that utilizes the reverse-hybridization technology.
<b>Target</b>	HIV-1 RNA pol	Highly conserved HCV 5' untranslated region (5' UTR).	5'UTR and core region of the HCV genome.
<b>Genotypes and/or subtypes</b>	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-l).
<b>Type of result</b>	Quantitative		Qualitative
<b>Linear range</b>	37 - 11,000,000 copies/mL	15 - 100,000,000 IU/mL (64.5 copies/mL - 430,000,000 copies/mL)	N/A
<b>Output</b>	Viral load		Genotype
<b>DNA or RNA specific?</b>	RNA		
<b>Polyvalency</b>	HBV, CT/GC, CMV, EBV, HSV 1&2, HHV-6, Adenovirus, BKV, VZV, Parvovirus B19, JCV		N/A
<b>PERFORMANCE</b>			
<b>Sensitivity - analytical and clinical (source)</b>	LOD: 37 copies/ml (80IU/ml) as determined 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.
<b>Specificity - analytical and clinical (source)</b>	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
<b>Bias (source)</b>	Not provided		N/A
<b>Intra-assay precision (source)</b>	Not provided		N/A
<b>Inter-assay precision (source)</b>	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
<b>SAMPLE</b>			
<b>Sample preparation (steps)</b>	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.
<b>Sample type</b>	Plasma	Serum and plasma	
<b>Sample volume</b>	500µL		
<b>Sample stability</b>	Whole EDTA blood: ≤6 hours at room temperature or ≤24 hours at 2-8°C before centrifugation. 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

Product	VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)	VERSANT HCV RNA 1.0 ASSAY (KPCR)	VERSANT HCV GENOTYPE 2.0 ASSAY (LiPA)
<b>SAMPLE</b>			
<b>Nucleic acid extraction method</b>	Automated (using proprietary beads)		Manual or automated.
<b>Time to result</b>	≤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.
<b>Capacity</b>	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
<b>Batching?</b>	Yes, flexible run sizes of 1-96 tests per batch		Yes
<b>Throughput per end-user per hour and/or 8hr day</b>	96 tests per run: 89 clinical samples, 4 calibrators, 3 controls =178 clinical samples/shift		Not provided
<b>INSTRUMENT</b>			
<b>Size of device</b>	VERSANT sample prep module (depth includes autoloader 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
<b>Weight of device</b>	VERSANT Sample prep module: 155kg VERSANT Amplification/detection module: 25kg		Autoblot 3000H: 15.9kg AutoLiPA 48: 47kg
<b>Robustness</b>	Extremely robust		
<b>Environmental requirements</b>	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%
<b>Power requirements</b>	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
<b>Time to battery charge</b>	N/A		Not provided
<b>Battery duration (hours)</b>	N/A		Autoblot 3000H: Equipped with a rechargeable lithium battery that has a shelf-life of one year.
<b>Alternative charging options</b>	No		
<b>Ease of use</b>	Communication: 9 pin port; 4 COM ports; 2 network cards for communications 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
<b>Display languages</b>	English		
<b>Built-in memory storage capacity</b>	160 GB hard drive		Not provided
<b>Connectivity options</b>	LIS Interface capability		Not provided
<b>Interpretation of result</b>	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 <sup>8</sup> IU/mL	Visual interpretation with interpretation chart or automated with LiPAScan software.
<b>Instrument lifespan</b>	Not provided		Not provided
<b>Other non-proprietary equipment required</b>	Computer and barcode scanner (supplied).		Scanner for LiPAScan software (optional)
<b>Regulatory approval</b>	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)
<b>KIT</b>			
<b>Kit components</b>	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)
<b>Kit sizes</b>	96 tests/kit		40 tests/kit
<b>Internal control(s)</b>	Yes: internal controls; negative, low positive and high positive controls.		Yes: VERSANT HCV Control 2.0 Kit (LiPA)
<b>Compatible with EQA and which?</b>	Yes		Not provided
<b>Mean time between failures</b>	Not provided		
<b>Transport and storage</b>	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
<b>Fridge at -80°C required?</b>	Yes		No
<b>Shelf life (of each item in the kit)</b>	12 months		
<b>Performance protocol (steps)</b>	(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
<b>Non-proprietary components required outside of the kit</b>	Plastics (e.g. tips and plates)		QIAGEN QIAamp DSP Virus Kit (REF 60704) if manual extraction is preferred
<b>Regulatory approval</b>	WHO prequalified; CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC
<b>In-country approvals</b>	Not provided		
<b>USAGE</b>			
<b>Technical skill required</b>	Yes, qualified in molecular practices		
<b>Applicable settings</b>	Highly-resourced settings		
<b>Laboratory set-up</b>	System concept supports either 1- or 2-room technologies		Bench top systems
<b>Waste disposal requirements</b>	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	
<b>Cost per device</b>			<b>\$166,000 - 221,600</b>	<b>Cost per test result</b>			<b>\$54 - 72</b>

Continued overleaf 

❖ Lab-based HIV VL & HCV VL – Siemens continued

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	
<b>Cost per device</b>			<b>\$166,000 - 221,600</b>	<b>Cost per test result</b>			<b>\$72 - 100</b>

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					
<b>Cost per device</b>			<b>\$57,000 - 70,000</b>	<b>Cost per test result</b>			<b>\$132 - 350</b>

**03 | TIERED AND VOLUME-BASED PRICING**

No information provided.

**04 | MAINTENANCE, WARRANTY & TRAINING**

	Description
<b>Leasing or reagent rental (RAP)</b>	Available.
<b>Installation</b>	Complete installation provided by trained Siemens personnel.
<b>Training</b>	Dedicated training on instrument. Electronic training is widely available using Siemens Personalized Education Program (PEP).
<b>Maintenance</b>	Routine preventative maintenance required, and provided by Siemens with service contract.
<b>Length(s) of warranty and additional costs for extended warranty / care plan</b>	One year warranty provided for instrumentation.
<b>Warranty components</b>	Information not provided.
<b>Turnkey option</b>	Information not provided.
<b>in-country / regional technical support availability</b>	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.<sup>31</sup> 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/ $\mu$ L) of blood; equivalent to cells per cubic millimetre (cells/ $\text{mm}^3$ ). A normal, healthy value for a CD4 count is usually above 500 cells/ $\mu$ L.

**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* ❖

❖ *Glossary and Abbreviations continued*

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

**RT:** Reverse transcriptase. An enzyme that 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.

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## **DISCLAIMER:**

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## MSF Access Campaign

Médecins Sans Frontières  
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