

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

HOW LOW CAN WE GO?

PRICING FOR HIV VIRAL LOAD TESTING IN LOW- AND MIDDLE-INCOME COUNTRIES

Viral load testing is the gold standard in HIV treatment monitoring and is recommended by the World Health Organization (WHO).¹ Routine in wealthy countries, its cost and complexity have, until now, formed a barrier to its scale up in developing countries. However, price reductions, strategies of specimen collection (such as dried blood spots), the decision to pool samples, as well as new point-of-care technologies that are coming to market, are making it possible to implement viral load monitoring in resource-limited settings.^{2,3}

Médecins Sans Frontières (MSF) is actively involved in addressing barriers to viral load scale up in its projects. Through a grant from UNITAID, MSF is facilitating viral load scale up in seven countries, and is currently undertaking a project to determine the optimal use of various viral load technologies in HIV projects in these countries. In July 2013, the MSF report *Putting HIV Treatment to the Test*⁴ included instrument and consumable prices for viral load and CD4 point-of-care tests.

However, the information in *Putting HIV Treatment to the Test* only tells part of the story of the cost of viral load monitoring. This briefing paper will provide additional important information, including:

- Data on the costs of implementing viral load to the point of delivery, highlighting data from six countries
- Results from a study revealing the estimated cost of manufacturing for reagents (including production overheads) for viral load tests
- An analysis of the major drivers of viral load costs and where prices can come down, using expert opinion and quantitative analysis

The data in this brief is preliminary, and explores only the most salient points and findings, with full results to be published in 2014. The findings reveal that, while prices are coming down for viral load testing, given the relatively low cost of manufacture (of laboratory-based tests especially), and opportunities to achieve economies of scale, there is still considerable room for price decreases through negotiations with large volumes (based on reliable forecasting), and by optimising throughput (efficiency) of each instrument, to reduce the per test costs.



People wait to be examined at Thyolo District Hospital, Malawi.

While prices for viral load testing are coming down, there is still considerable room for price decreases given the relatively low cost of manufacture, and opportunities to achieve economies of scale, through negotiations with large volumes, and by optimising throughput of each instrument to reduce the per test costs.

WHY SCALE UP VIRAL LOAD TESTING?

The 2013 WHO Guidelines on laboratory monitoring of people receiving antiretroviral therapy (ART) recommend viral load monitoring at six months after treatment initiation, at 12 months, and every 12 months thereafter.¹ Viral load is the gold standard for quantifying the levels of HIV in the blood and thus determines the success of ART. This knowledge enables care providers to detect problems that need addressing far earlier than immunological monitoring of CD4 cell counts, and this in turn allows adherence problems

to be addressed more rapidly and successfully. Viral load monitoring also identifies those people whose treatment is indeed failing and therefore need to be switched to alternative options. On a programmatic level, viral load monitoring can facilitate a more rational and effective use of funds as it allows targeted adherence support interventions to help people stay on first-line regimens longer, which cost a fraction of second- and third-line options.⁵

Innovations in viral load monitoring are also simplifying testing. Using ‘dried

blood spots’ helps expand access to viral load testing as it allows for more feasible sample transportation from remote sites. Use of pooled samples to test for viral load – whereby blood samples from multiple people are mixed together and one test conducted on the pooled sample – has been shown in several studies to reduce costs related to viral load monitoring.^{3,6} New viral load point-of-care diagnostics under development also hold the promise to simplify monitoring and bring diagnostics closer to the patient and accelerate clinical decision making.

“My latest viral load count is undetectable. Antiretroviral treatment is life-long so it’s encouraging to be told that the treatment is working well for me. It helps to know that whatever the difficulties, I am controlling the virus. I am proud that my viral load is undetectable, and I tell others about it. It helps me plan for tomorrow and I am confident I will live a normal life.”

Fanelwa Gwashu, 42, lives with her two children in Khayelitsha, South Africa, where she runs a treatment adherence club. She has been on antiretroviral treatment for nine years.



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USER COSTS: SIX COUNTRY CASE STUDIES

We conducted a survey among select individual programs. Six countries (Kenya, Lesotho, Malawi, Swaziland, Thailand, and Zimbabwe), using four different viral load laboratory-based testing platforms (supplied by Abbott, Biocentric, bioMérieux, and Roche), provided comprehensive prices, including sample collection consumables, transportation costs, lab consumables, instrument costs, reagent costs, and human resources. These categories are defined in the appendix (available online at www.msfacecess.org/how-low-can-we-go). In four of these countries (Lesotho, Malawi, Swaziland, and Zimbabwe), MSF is supporting the Ministry of Health in scaling up viral load testing with the support of UNITAID.

Below are the key preliminary findings from this survey (see Table 1 and Figures 1 and 2):

- ❖ Comprehensive cost per viral load test ranged from US\$24.90 to \$44.07.
- ❖ The largest contributor to price was the cost of the reagents and consumables (other non-device products required for running the test) – consistently more than half and up to 83% of overall costs.
- ❖ Publicly-available data put the costs for reagents and consumables negotiated by the Clinton Health Access Initiative (CHAI) in Kenya at only \$10.50* per test, suggesting that the price of reagents and consumables is very flexible. This illustrates the extent of price discrepancies, with some countries paying considerably more than prices available through negotiations with manufacturers, based on volumes. Improved negotiating power could halve the current prices countries are paying for reagents and consumables, leading to significant price reductions to the overall costs of performing viral load testing.
- ❖ If countries responding to our survey had access to the lowest price available, the range of comprehensive costs, including implementation, would drop to \$16.78–\$29.14.**
- ❖ The price per test was also dependent on the volume of tests run on each instrument. The closer to maximal capacity the device is used, the cheaper the cost per test, with the steepest decrease in cost falling between 25% and 50% efficiency.

“The costs of consumables are malleable and often driven by volume.”
Procurement specialist

Investing in scalable technology to improve cost efficiency:

“Establishing automated systems have allowed for high throughput and continual sample processing.”

Professor Wendy Stevens, Director of National Priority Programs for the National Health Laboratory Services, South Africa



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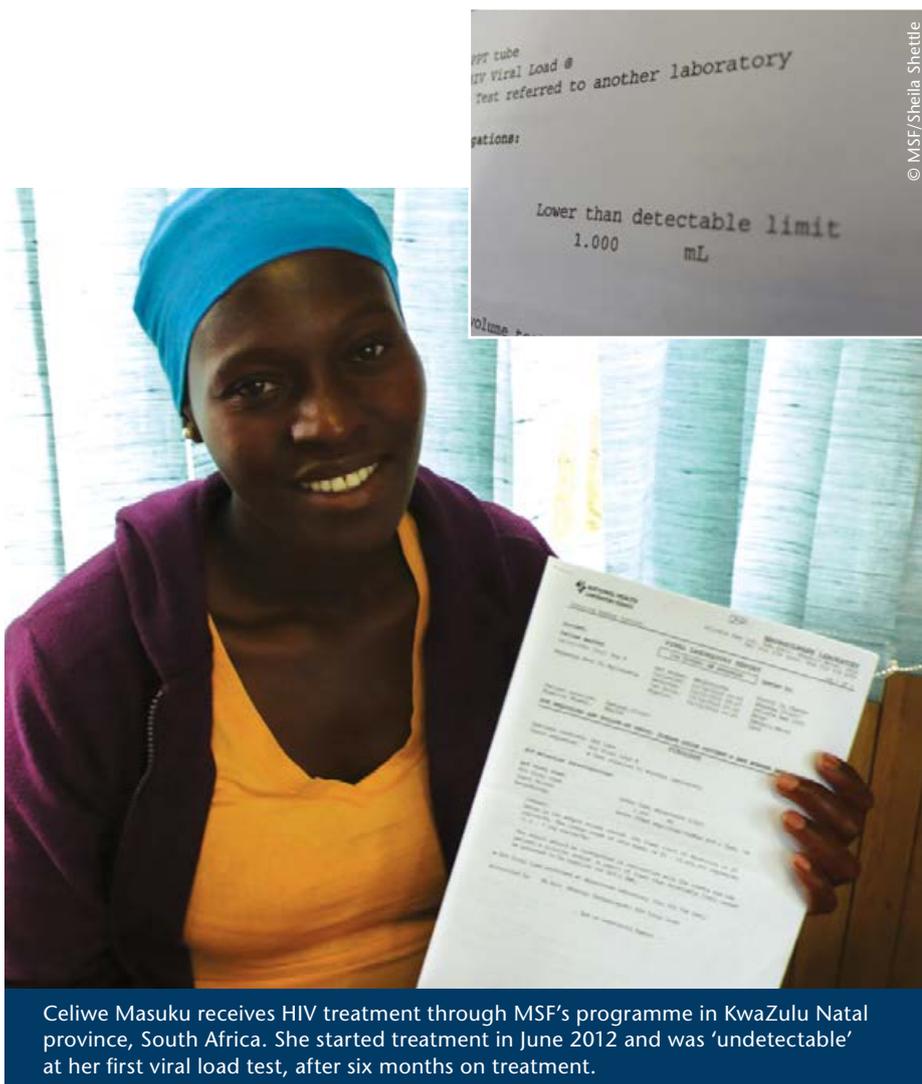
A health worker takes a finger prick blood sample, Swaziland.

* This cost includes reagent cost to port only (CIF). For other costs, such as customs, handling costs and transport to government stores, the price is \$11 per test.

** This assumes \$10.50 for the costs of laboratory reagents and consumables and excludes the one site where outsourced testing did not allow for disaggregation of laboratory costs.

TABLE 1: OVERALL COSTS PER VIRAL LOAD TEST IN THE SIX COUNTRIES SURVEYED

Country	Health sector	Laboratory health care level	Comprehensive cost of VL test	Cost of reagents / consumables	Reagents / consumables as % of comprehensive cost
National programmes					
Kenya	Public	National	\$43.42	\$24.79	57.10%
Thailand	Public	Regional	\$44.07	\$36.38	82.60%
MSF project site					
Lesotho	MSF (testing outsourced)	District	\$34.17	\$20.23	59.20%
Malawi	Public/MSF	District	\$35.38	\$23.13	65.40%
Swaziland	Public/MSF	District	\$24.90	\$18.62	74.80%
Zimbabwe	Public/MSF	District	\$39.03	\$22.86	58.60%



Celiwe Masuku receives HIV treatment through MSF's programme in KwaZulu Natal province, South Africa. She started treatment in June 2012 and was 'undetectable' at her first viral load test, after six months on treatment.

Continuously searching for ways to boost efficiency:

"In opting to send samples to the nearest processing facility—even when these are in neighbouring provinces—additional gains in reduced transport costs have been made. Significant workflow re-engineering was done to make maximum use of instrumentation."

Professor Wendy Stevens,
Director of National
Priority Programs for the
National Health Laboratory
Services, South Africa

FIGURE 1: BREAKDOWN OF AVERAGE COST PER VIRAL LOAD TEST

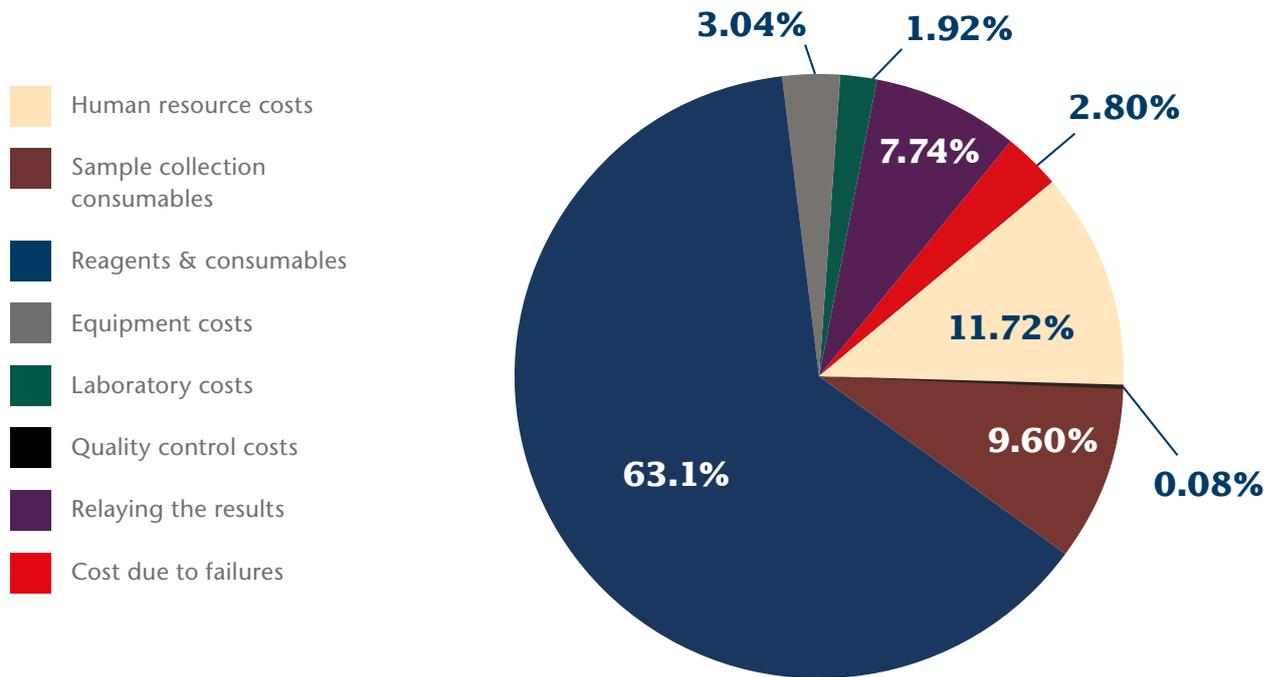
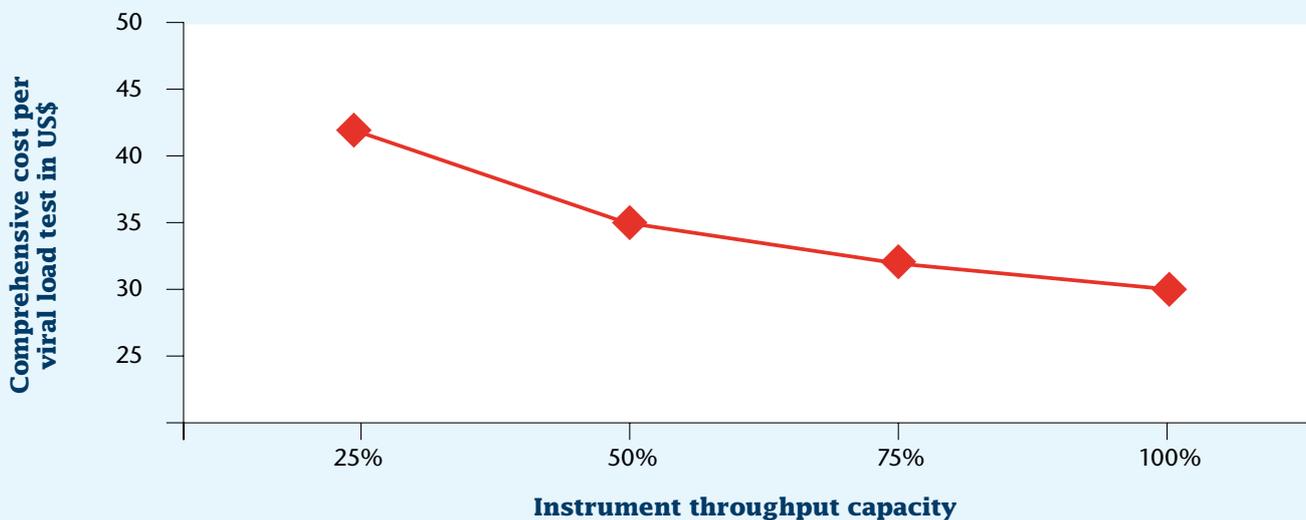


FIGURE 2: EFFECT OF THROUGHPUT ON VIRAL LOAD COSTS PER TEST



Comprehensive costs per viral load test from six reported sites, MSF preliminary data 2013

“The placement of machines and their subsequent throughput impacts the costs per tests. For now, the larger machines need to be centralised to maintain high efficiency and lower prices.”

Diagnostics specialist

MANUFACTURING COSTS

In 2013, MSF commissioned a study to assess the manufacturing costs for six* viral load products in order to understand the potential magnitude for price decreases of viral load tests. The consultants assessed the raw costs of reagents, reagent containers, viral load platform raw materials, intellectual property, and final product assembly and manufacturing overhead. Manufacturing costs were based on the production of one million tests annually – typical for an automated production line at peak production.

Below are the results of this research (See table 2):

- Costs associated with intellectual property are significant, with royalty payments for intellectual property (in the case of laboratory-based tests by Abbott and Roche, Armored RNA supplied by Ambion) for some viral load technologies accounting for a considerable portion (between 19% and 63%) of the total manufacturing cost.
- Due to expensive moulding costs necessary to produce an integrated and complex cartridge, the manufacturing costs of point-of-care tests are almost twice as high as the cost of high-throughput laboratory-based tests. While point-of-care tests will be important in certain clinical contexts, the lowest manufacturing costs per test for high-volume sites will be achieved with laboratory-based viral load.
- The estimated cost of manufacture for reagents and consumables ranged from US \$1.23–\$4.37 for laboratory-based tests. While this cost does not consider potential payments for licences and royalties for intellectual property, distribution or support services, the dramatic gap between the real costs of manufacture and the actual prices paid by countries for reagents and consumables demonstrates the potential for significant and rapid price decreases.

*Biocentric was not included in the analysis as it is an open platform and sources its reagents and instrumentation from multiple external manufacturers.

“From a country perspective, [countries] rarely know prices being paid in the region and globally. Countries may not have the full context as to why prices vary between countries and what factors into prices.”
Diagnostics specialist

TABLE 2: ESTIMATED MANUFACTURING COSTS OF EXEMPLAR VIRAL LOAD TESTS

	Reagent costs	Moulding costs	Reagent container costs	Final assembly costs	IP costs	Total	IP cost as percentage of total
Laboratory-based tests							
Abbott RealTime HIV-1 assay	\$2.38	\$0.02	\$0.07	\$0.06	\$4.25	\$6.77	63%
Roche CAP/CTM HIV-1 assay	\$4.37	\$0.07	\$0.03	\$0.04	\$1.80	\$6.31	29%
BioMerieux NucliSens EasyQ HIV-1 assay	\$1.23	\$0.00	\$0.35	\$0.04	\$0.00	\$1.61	0%
Cavidi ExaVir Load assay	\$2.49	\$0.00	\$0.22	\$0.05	\$0.00	\$2.76	0%
Point-of-care tests							
Alere Q HIV Test	\$1.56	\$4.01	\$0.00	\$1.50	\$2.26	\$9.33	24%
Diagnostics for the Real World SAMBA test	\$1.62	\$3.29	\$0.00	\$1.50	\$2.26	\$8.67	26%
Wave 80 Biosciences EOSCAPE-HIV test	\$1.56	\$3.50	\$0.00	\$0.00	\$1.20	\$6.26	19%
Lumora “BART” test	\$1.62	\$0.00	\$1.27	\$0.95	\$1.00	\$4.84	21%

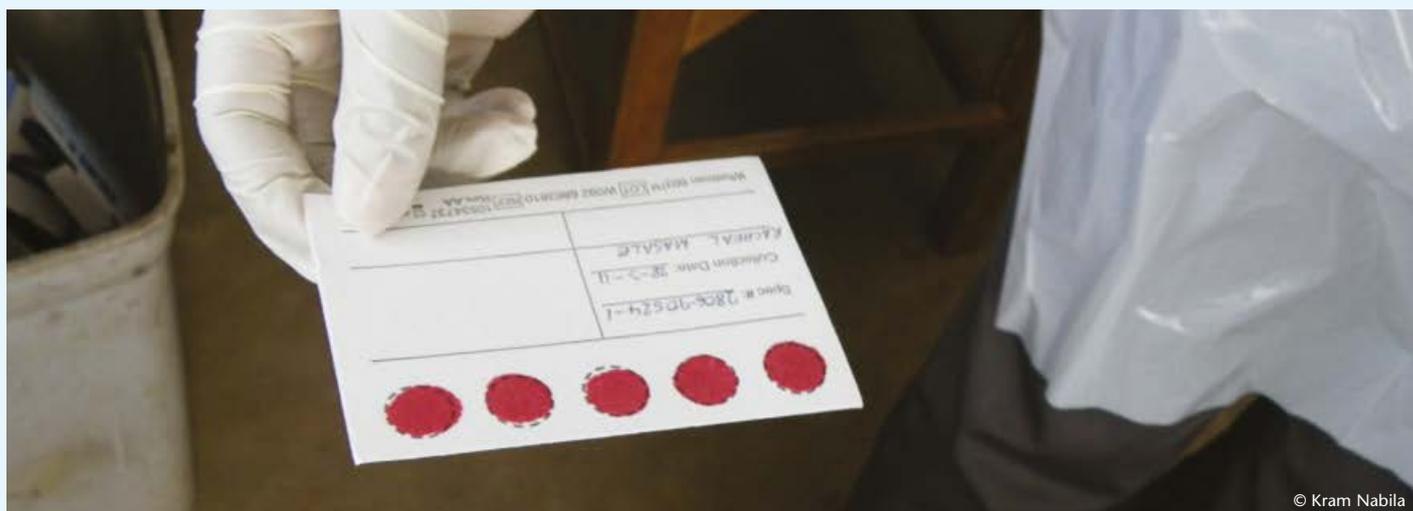
CAN THE PRICE OF VIRAL LOAD TESTING BE REDUCED?

The preliminary data presented in this issue brief demonstrates several important opportunities to reduce costs of viral load testing and optimise ART services. The Global Fund, PEPFAR and countries can negotiate for lower viral load prices by pooling their procurement. Furthermore, as the primary cost of viral load monitoring is due to the cost of reagents and consumables, ensuring that laboratory-based viral load instruments are used at maximal capacity will decrease price per test. In addition, as countries increase the number of viral load tests that are performed and improve forecasting, increased purchasing power can be used to further negotiate lower prices. A cost analysis of manufacturing viral load tests indicates that viral load prices can be significantly further reduced, allowing room for price decreases through negotiation and competition as additional manufacturers enter the market. Bringing viral load testing to scale should occur within a broader context that supports referral networks, while enabling for complementary expansion of point-of-care testing to further decentralise care.

Preventing monopolies for better cost efficiencies:

“South Africa contracted two viral load suppliers to each provide 50% of the viral load testing, creating in-country competition.”

Professor Wendy Stevens,
Director of National Priority Programs for the National Health Laboratory Services, South Africa



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A health worker takes a dried blood spot test card for testing, Malawi.

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WHAT NEEDS TO HAPPEN

Viral load prices are expected to decrease in the short to medium term as countries develop stronger price negotiations, increase and pool their bulk procurement and scale up throughputs. However, more is needed to achieve the cost reduction potential of viral load:

- ❖ **Governments and other purchasers should increase pricing transparency.** Because few contract prices are publicly available, countries face information ambiguities when they negotiate with manufacturers and distributors for products and service agreements. Increasing pricing transparency will help more programmes be in a better position to access the best prices.
- ❖ **Countries and donors should take steps to encourage competition.** In high volume situations, donors and affected governments can encourage competition between contractors and negotiate for lower prices (including for maintenance) and better services when instruments are procured from more than one company. Furthermore, by including leasing or reagent rental options, countries can invest in and update technology more easily, rather than with an instrument purchase, which will continue to depreciate and lock countries into using that platform for a number of years. Some countries would benefit from impartial assistance in developing these service level and contract agreements.
- ❖ **Funders should provide support for countries to implement WHO guidelines for HIV treatment monitoring,** particularly as viral load expansion will yield economies of scale. Right now, the Global Fund, PEPFAR, and high volume countries like South Africa have the opportunity to pool procurement, which will increase purchasing power and result in lower prices.
- ❖ **Countries should adopt measures to improve care and increase cost-efficiency of viral load testing** by rapid scale up to leverage economies of scale and use larger volumes and information, such as cost of manufacture, to negotiate for better prices. Countries can also invest in innovation, such as pooling samples for viral load testing to increase efficiencies. To increase task shifting and allow for greater decentralisation, methods such as fingerprick dried blood spots performed by lay workers are currently being validated. Point-of-care viral load technologies are designed to be simple and easy to use and can be performed by any health worker.
- ❖ **Countries should increase referral network efficiencies to optimise the mix of point-of-care and lab-based tools.** To ensure an optimum mix of point-of-care and lab-based viral load technologies, there is a need to improve referral networks and processes, including sample delivery and delivery of results to patients through pre-existing referral networks. This not only decreases the cost of the viral load testing through reduced transport costs and reductions in missing data, but also improves service delivery by providing results more rapidly. Mobile- and electronic-health technologies can provide clinics and patients with their results in a faster and less costly manner, and automatically feed results into patient databases for easy retrieval and tracking of both individuals and programmes over time.
- ❖ **Addressing the cost of intellectual property (IP):** Royalties paid by manufacturers to third parties to secure licensing of intellectual property are a significant cost for some viral load technologies. IP should be licensed at a lower cost when the final products are sold to low- and middle-income countries, and any cost savings should be passed on to purchasers. Looking ahead to the development of new viral load tests, global health actors should support strategies, such as pooling patents from third parties, with reasonable royalty payments, in order to enable the development of open diagnostic platforms and to ensure affordability.

“Low volumes, intellectual property restrictions... and placement decisions that lead to non-optimal utilisation of machines drive up viral load testing costs.”

Diagnosics specialist



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