



# HIV Self-Testing Crucial Growth Drivers for Chembio, Orasure

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DUSSELDORF, GERMANY – Representatives of Chembio Diagnostics and Orasure Technologies said Tuesday that growing demand for HIV self-testing has become an important driver of growth for their companies.

On the sidelines of the Medica world medical forum in Dusseldorf, Germany, Krishnan Allampallam, global marketing director of Chembio Diagnostics, said the World Health Organization's [recent prequalification](#) for its Sure Check HIV Self-Test represents an important milestone for the firm. Chembio's self-test is a single-use immunochromatographic lateral flow test for the detection for antibodies to HIV types 1 and 2.

"This helps us promote the test in low-resource countries that require WHO prequalification," Allampallam said. "It opens up many markets for us."

Olivia Njathi, who works in East Africa international sales for OraSure Technologies, said the firm's HIV self-test, which has been available internationally for several years, is already getting high adoption in African countries, driven in part by the platform's affordability and use of an oral swab instead of a fingerstick for sample collection.

Affordability has been enabled by a deal the firm inked in 2017 with the Bill & Melinda Gates Foundation, which facilitated making the test available at about \$2 per user. With further financial support by Unitaid, the tests are available free of charge to users in some low-resource countries, Njathi said.

Chembio has not yet established pricing for its HIV self-test.

In spite of growing evidence about the success of HIV self-testing program, the hurdles are high [for approval](#) of home-use infectious disease diagnostic tests. To date only the OraQuick In-Home HIV Test has been cleared by the US Food and Drug Administration for patients to perform their own testing at home.

Having an early mover advantage in the HIV self-testing market has translated to sales growth for the firm. In the third quarter of 2019, the firm sold approximately 1.5 million HIV self-tests, and sales of self-tests were the [primary motivation](#) for the firm to continue to project double-digit revenue growth through the end of this year for its international HIV franchise.

Chembio anticipates recent regulatory approvals will lead to greater product sales within global geographic markets, Allampallam said, adding that in Africa, country agencies in charge of administering and purchasing tests had recommended that Chembio seek WHO prequalification. Further, the firm recently received WHO prequalification approval for its [Malaysian manufacturing facility](#), allowing the production of Stat-Pak HIV 1/2 tests in that country.

Self-administered tests run the risk of patients collecting samples incorrectly, but OraSure is leveraging that risk in its favor — instead of using blood as a sample, its test uses saliva, Njathi said. HIV patients

can't run the risk of getting a false-negative result with oral fluids, while blood sampling done by hesitant patients can lead to inaccuracy in testing, she said.

"There can be a lot of challenges associated with getting enough blood for self-testing," Allampallam said. "With less blood, the testing platform needs to be more sensitive, but providing a small volume of blood also makes testing easier."

He noted that Chembio has designed the collection mechanism in its HIV self-test to draw specifically 2.5 microliters, while other blood-based HIV tests require larger volumes of blood.

To ensure accuracy, the collection device on Chembio's test uses capillary force as part of a design that the firm has patented, Allampallam said.

Allampallam pointed to a 2014 [PLoS One study](#), which reported that fingerstick whole-blood home-use tests were more sensitive than home-use oral fluid tests. The comparison in the study included one of Chembio's oral fluid tests.

Allampalam and Njathi's comments came on the [heels of a report](#), published this week in [JAMA Internal Medicine](#), suggesting that HIV prevention programs should include an HIV self-testing mail distribution program to their portfolios of prevention services for high-risk populations.

Aside from OraSure and Chembio, firms that have been granted prequalification status by the WHO for HIV tests include [Mylan](#) and Atomo Diagnostics. [Abbott](#) also received WHO prequalification approval for its m-Pima HIV-1/2 VL viral load diagnostic test.

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