

Atomo HIV Self Test

Summary of Performance and Usability



Overall Diagnostic Performance

The diagnostic performance of the Atomo HIV rapid diagnostic test has been evaluated by several independent laboratories and found to demonstrate excellent performance.

An aggregated summary of all relevant testing is presented below, including both CTS (European) and African data.



	Diagnostic Performance
Overall Sensitivity	99.6% (1315/1320)
Overall Specificity	99.7% (1939/1945)



European Laboratory Evaluation in Accordance with Common Technical Specifications (CTS) for CE Marking

Evaluation sites

- Institute of Tropical Medicine, Antwerp, Belgium (WHO Reference Laboratory)
- German Red Cross, Berlin, Germany

Institute of Tropical Medicine

Foundation of Public Utility

Department of Clinical Sciences – HIV/STD Reference Laboratory



Sensitivity & Specificity

Sample Type	Performance
Overall Sensitivity	99.4% (820/825)
Overall Specificity	99.6% (1619/1625)

Seroconversion (early infection):

- Atomo HIV Self Test was tested with 18 seroconversion panels and compared to any data available on other CE marked HIV rapid tests.
- Atomo HIV Self Test detected the **same number of positives** when compared to the performance of the most sensitive tests for each panel.
- Atomo HIV Self Test **detected 40% more positives** than the performance of the least sensitive tests for each panel.



South African Evaluations, 2016 - 2017

Extensive laboratory evaluation has also been conducted in South Africa.

Evaluation site

- Global Clinical & Viral Laboratory (Global Labs), Durban, South Africa

Sample Type	Performance
Overall Sensitivity	100% (495/495)
Overall Specificity	100% (320/320)



Overall In-field Performance

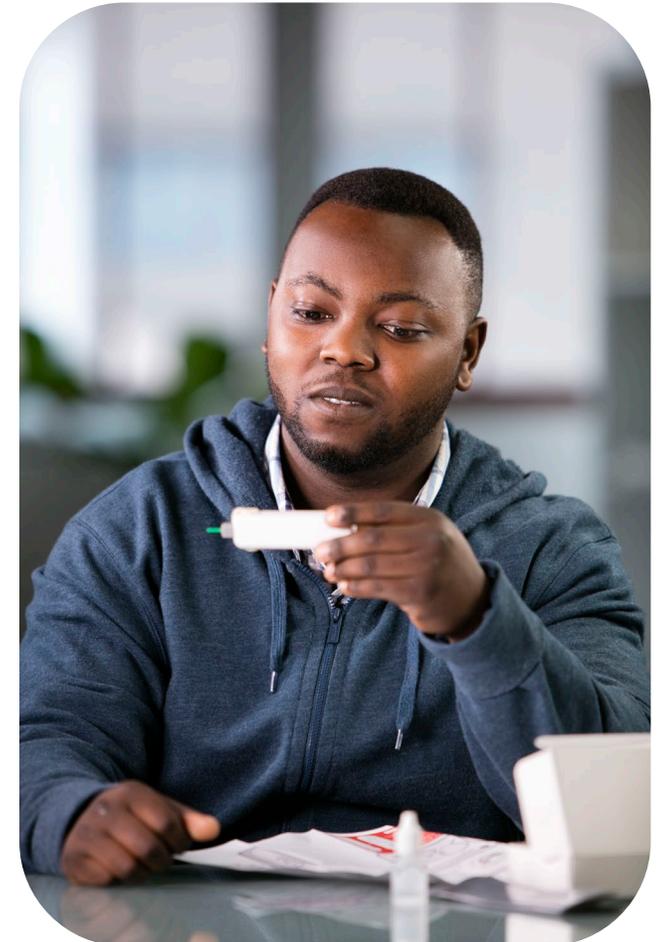
Three in-field evaluations have been performed with the Atomo HIV Self Test in both a high prevalence region (Kenya) and a low prevalence region (Australia).

Details of the studies are provided over the following slides.

In-field performance evaluations are based on self test users performing the test for the first time and comparing results to a laboratory standard or approved test algorithm.

Atomo HIV Self Test has demonstrated excellent performance in the hands of first time users. An aggregated summary of all relevant testing is presented below.

	Overall In-field Performance	In-field Concordance with Approved Test Algorithm
Sensitivity	94.3% (33/35)	100% (33/33)
Specificity	95.2% (866/910)	99.4% (884/889)



In-Field Evaluation 1 - Kenya, 2016

The Kenya Medical Research Institute (KEMRI) supports the Kenyan National AIDS and STI's Control Programme (NASCO). KEMRI evaluated the acceptability and in-field diagnostic performance of the Atomo HIV Self Test in two separate studies.

Study 1 target group: general adult population with different levels of educational attainment; including university students and the general population in remote village settings.

Diagnostic Performance

Atomo HIV Self Test showed **100% concordance** with the approved professional use test algorithm.

	In-field performance (test performed & interpreted by first time self test user)	Concordance with approved test algorithm* (interpretation by professional)
Sensitivity (positive participants)	20/22 (90.9%)	20/20 (100%)
Specificity (negative participants)	160/181 (88.4%)	160/160 (100%)

*Unigold™ rapid test



In-Field Evaluation 1 - Kenya, 2016 (cont.)

Acceptability

The acceptability of the Atomo HIV Self Test was also assessed through study data and participant questionnaires:

Key Metrics / Acceptability	
Participants found it easy to understand the test requirements	93%
Participants were able to complete the test correctly first time (unsupervised)	89%
Participants recommended the use of the product	94%

“We conclude that Atomo HIV Self Test has exceeded the minimum usability standards required of a self-test intended for use in environments with high HIV prevalence rates. This report recommends its introduction into the Kenyan market.”

Usability Evaluation of the Atomo HIV Self Test in Kenya for Qualitative Detection of Antibodies to HIV, KEMRI, January 2017



In-Field Evaluation 2 - Kenya, 2017

The second KEMRI study again evaluated the acceptability and in-field diagnostic performance of the Atomo HIV Self Test but with a different target user group.

Study 2 target group: adult population with a bias towards Ugandan migrants living in or visiting Kenya.

Diagnostic Performance

	In-field performance (test performed by first time self test user)	Concordance with approved test algorithm* (interpretation by professional)
Sensitivity (positive participants)	13/13 (100%)	13/13 (100%)
Specificity (negative participants)	195/217 (89.9%)	213/217 (98.2%)

*Unigold and Determine™ HIV-1/2 rapid test



In-Field Evaluation 2 - Kenya, 2017 (cont.)

Acceptability

The acceptability of the Atomo HIV Self Test was also assessed through study data and a questionnaire:

Key Metrics / Acceptability	
Participants found it easy to understand the test requirements	99%
Participants were able to complete the test with all steps performed in the correct sequence	92%
Participants recommended the use of the product	99%
Participants expressed willingness to purchase the test	96%



In-Field Evaluation 3 - Australia, 2017

A third study was conducted at a primary healthcare facility in Sydney, Australia (Holdsworth House). The study evaluated the usability and performance of Atomo HIV Self Test.

Study 3 target group: people at risk of HIV infection.

Diagnostic Performance

Note: there were no HIV positive participants in the study due to the low HIV prevalence in Australia.

	In-field performance (test performed by first time self test user)	Concordance with approved test algorithm* (interpretation by professional)
Sensitivity (positive participants)	N/A	N/A
Specificity (negative participants)	511/512 (99.8%)	511/512 (99.8%)

*4th generation Siemens ADVIA Centaur XPT Immunoassay System



African In-Field HIV Self Test Performance Study Comparison

Comparing published performance of Atomo HIV Self Test and OraQuick HIV Self Test in Kenya

	Atomo HIV Self Test *	OraQuick HIV Self Test #
In field Sensitivity	100% (33/33)	89.7% (26/29)
False negative (error rate in-field)	0%	10.3%
In field Specificity	98.9% (373/377) against rapid test	99.4% (173/174) against rapid test 98% (48/49) against ELISA
Storage conditions	2 - 30°C	2 – 27°C
Time to result	15 mins	20 mins
Technology	3 rd Generation	2 nd Generation (longer detection window)

*Based on two usability evaluations of the Atomo HIV Self Test in Kenya conducted by Kenya Medical Research Institute, 2016 & 2017

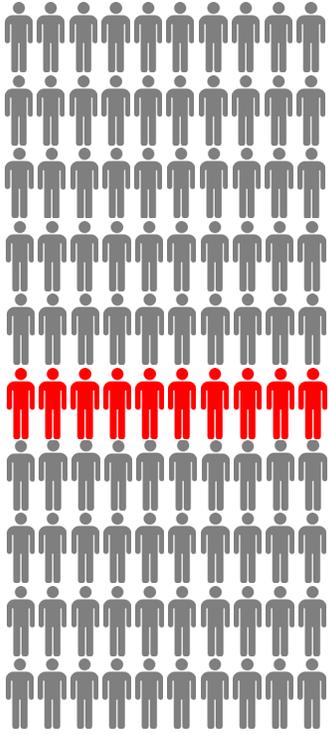
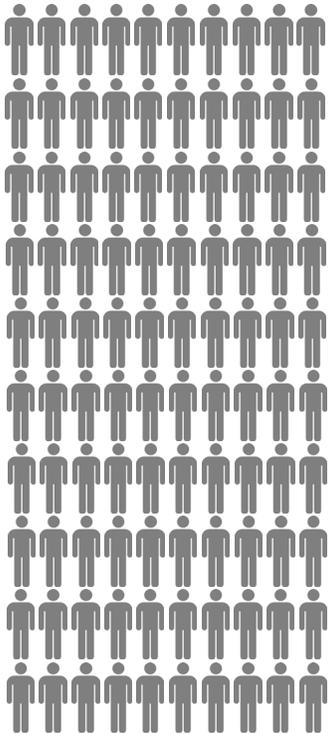
Accuracy of Oral HIV Self-tests in Kenya, 3ie Grantee Final Report. Washington, DC: International Initiative for Impact Evaluation (3ie), 2014



In-Field HIV Self Test Concordance - Performance Comparison

Comparing published performance of Atomo HIV Self Test and OraQuick HIV Self Test in Kenya

Atomo HIV Self Test
Sensitivity
100%



OraQuick HIV Self Test
Sensitivity
89.7%

10 in every 100 HIV positive self-test users are at risk of receiving a **false negative** result with OraQuick. This could delay onset of treatment and greatly increase the risk of HIV transmission in the community.

