

AtomoRapid™ HIV

TEST DEVICE





Overview **Overview**



Atomo Diagnostics has developed the world's first integrated blood based HIV Self Test device that offers untrained users a simple at-home HIV screening test result in just 15 minutes.

After several years of use in the field, improvements over previous solutions are well quantified:



Accurate results:

99.6% Sensitivity (ability to correctly identify HIV positive samples), and 99.6% Specificity (ability to correctly identify HIV negative samples).



Rapid:

The test uses one-fifth the volume of blood necessary for other tests and provides a result in just 15 minutes.



Easy to use:

Atomo's completion rate for first-time, untrained users is 97%. The average for "bits in a box" test is around 90%.

Atomo has taken that 10% error rate and reduced it to less than 3%.

In Africa alone, this would save

40,000 lives per year.

Atomo is currently seeking FDA approval for North American markets. Atomo's proven track record of regulatory approval includes the Therapeutics Goods Administration (Australia), the European CE Mark, and the World Health Organization (WHO).



MARKET

Reach

Atomo sells its rapid HIV Self Test devices through distribution agreements with international healthcare companies in 130 countries around the world including:

EUROPE

Owen Mumford (United Kingdom / EU)- (branded as the Simplitude ByMe HIV Self Test) in over 30 European countries. Sales commenced in February 2019.

LMIC

Mylan/Viatris- low and middleincome countries (LMICs)-(branded as the Mylan HIV Self Test) in more than one hundred countries across Africa, Asia, the Middle East, the Commonwealth of Independent States (CIS), and Latin America. Sales commenced in July 2019.

AFRICA

lyzea Health (South Africa) $(branded\,as\,the\,lyeza\,l\,Test\,HIV\,Self$ Test) in private sector markets in South Africa, Swaziland, Lesotho and Mozambique, sales of which commenced in September 2016.

AUSTRALIA

Atomo HIV Self Test was approved in November 2018, for sale in Australia in April 2019.



ADVANCED

Technology

The Atomo Self Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. Designed to be used by untrained lay users in a private setting as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique.

- The device requires a sample size of 10uL.
- The test consists of a paper test strip inside a plastic cartridge. The test is performed by placing a small drop of blood on the test strip and then applying drops of test fluid (diluent).
- When the test is completed, two lines can appear on the paper strip. A visible Control Line indicates that the diluent was added and migrated successfully, and that the test reagents are functioning correctly. The Test Line will only become visible if the applied sample contains antibodies to HIV.

Easy Interpretation of Result

The test result is displayed clearly in just 15 minutes.

Easy Blood Delivery

Blood is delivered cleanly to the test strip by simply rotating the blood collection unit.



Accurate Blood Collection

The easy-to-use blood collection unit is designed to collect exactly the right sample volume ($10\mu l$), ensuring optimal test performance.

Built-in Safety Lancet

The auto-retracting safety lancet eliminates the risk of hazardous sharps injuries by locking the needle inside the device after use for safe disposal.



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