



Performance and Usability of INSTI, a Blood-based Rapid HIV Self Test for Qualitative Detection of HIV Antibodies in Intended Use Populations in Kenya

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Background: HIV self testing is rapidly gaining acceptance as an effective method to reach undiagnosed individuals in sub-Saharan Africa, however there is very little documented data on performance of blood-based self tests in diverse intended-use populations. The self testing concept was approved in Kenya in 2015, but no products were available.

Methods: The Kenya Medical Research Institute (KEMRI) completed a study of the blood-based 60-second INSTI HIV Self Test to measure its performance, usability and readability in 688 consenting adults with broad demographic diversity, from Matayos, Bumuturu, Khunyangu, Aterait and Asinge villages in Busia County, Western Kenya. All subjects participated in the performance study, comparing INSTI results to 4th generation EIA results from venous blood collected from each subject. Portions of the study subjects also participated in qualitative usability and readability studies to assess label comprehension, ease of use and result interpretation. The study was conducted between 22nd March and 11th April 2017, under ethics approval by the KEMRI Ethical Review Committee.



Results: Compared to the bioelisa HIV-1+2 Ag/Ab (Biokit S.A., Barcelona, Spain) EIA test, the specificity of the INSTI HIV Self test was 99.26% and sensitivity was 98.51%. Negative predictive value was 98.89% and positive predictive value was 99.00% for the study population. From the 350 subjects in the usability study, 98.00% found the test instructions easy to follow; 99.71% successfully added the blood droplet into INSTI bottle 1; 97.71% indicated willingness to use the test again; and 98.29% would recommend the kit to a partner. For the 91 subjects in the readability study, 100% correctly interpreted the positive, negative and invalid results, while 65.93% were unsure how to interpret the weak positive result.

Conclusions: INSTI is unique for its use of a “hanging” fingerstick blood drop, without the need for a collection device. This first field study of such a fingerstick blood-based self test provides strong evidence that the INSTI HIV Self Test is accurate, acceptable and easy to use by self testers with diverse backgrounds in sub-Saharan Africa. Modifications to the kit instructions to include a visual of a weak positive result would provide a more consistent interpretation.