

## DIAGNOSTIC ACCURACY OF EIGHT HIV RDTs AND TWO SIMPLE CONFIRMATORY ASSAYS FROM FIVE SUB-SAHARAN AFRICAN COUNTRIES

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### Background:

WHO pre-qualified HIV rapid diagnostic tests (RDT) showed very good performance in initial evaluations on an international panel of specimens, however reports from several African countries highlight performance issues that seem to vary geographically. We aimed to evaluate the performance of eight HIV RDTs and two simple confirmatory assays individually using specimens from five sub-Saharan African countries.

### Methods:

Specimens collected in six sites in five sub-Saharan African countries were tested at HIV reference laboratory at the Institute of Tropical Medicine, Antwerp, with state of the art reference tests and with eight RDT and two confirmatory assays. Weighted analysis was carried out to adjust for sampling strategies.

### Results:

A total of 2785 samples collected from August 2011 to January 2015 in the 6 sites were tested at the ITM. All RDTs showed very high sensitivity, ranging from 98.9% for First Response HIV 1-2.0 to 100% for Determine HIV 1/2, SD Bioline HIV 1/2 3.0 and INSTI HIV antibody test. Specificity varied from 90.4% for First Response HIV 1-2.0 test to 99.7% for HIV 1/2 STAT-PAK. The specificity also varied greatly with the origin of specimens. The level of concordance between the users was high. For confirmatory assays, the total sensitivity and specificity was 100% and 98.2% for ImmunoComb II HIV 1&2 CombFirm (IC) and 99.9% and 97.5% for Geenius HIV 1/2. Indeterminate rates were 8.9 % for IC and 9.4% for Geenius HIV 1/2.

### Conclusion:

Overall, the performances of individual RDTs were lower than in the WHO evaluations and only HIV 1/2 Stat-Pak would have passed the suggested thresholds of >99% sensitivity and >98% specificity. However, acceptable RDT-based algorithms could be found when combining them according to WHO-recommended algorithms. These results confirm the geographical differences in HIV RDT performance and highlight the importance of designing locally-adapted algorithms following the latest WHO recommendations, particularly in a context of increasing testing coverage with the test and treat strategy.