

PERFORMANCE OF HIV DIAGNOSTIC ALGORITHMS AT SIX SITES IN FIVE SUB-SAHARAN AFRICAN COUNTRIES

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Background:

In resource-constrained settings, HIV testing algorithms are based on the use of rapid diagnostic screening tests, allowing high accuracy HIV diagnosis in decentralized testing sites by non-skilled personnel and same day results. Local design and evaluation of the testing algorithm performance is recommended, but rarely performed.

Methods:

We compared the on-site performance of the HIV testing algorithms at six sites in five sub-Saharan African countries. In each site, at least 220 positive and 220 negative clients by the on-site algorithm had a specimen sent to the HIV reference laboratory at Institute of Tropical Medicine, Belgium, for testing by a state of art testing algorithm for resource rich settings.

Results:

Between August 2011 and January 2015, more than 14 000 clients were tested for HIV at the six HIV counseling and testing sites and 2786 were included in the study. HIV positivity rate at the testing sites ranged from 8.0% in Baraka (DRC) to 63.7% in Conakry (Guinea). When adjusted to account for the under-representation of negative results by the study design, the sensitivity of the testing algorithms ranged from 89.5% in Arua (Uganda) to 100% in Douala (Cameroon) and Conakry (Guinea). The specificity of the algorithm used was lowest in Douala (98.3 %) and highest in Conakry (100 %). Overall, 24 (1 %) clients would have been misclassified, ranging from 0-8 per site (0-1.7%), with 16 false positive and 8 false negative results. Six false negative specimens were re-tested on-site with a back-up sample and were found positive. Thirteen false positive specimens were similarly re-tested and 9 remained positive.

Conclusion:

Several sites showed performance below the expectations, with unacceptably high false positive and negative results. Lot validation, respecting incubation time, correct labelling, testing on plasma versus whole blood can reduce the risk of false results. Beside all the quality issues, careful selection of HIV RDTs and algorithms should be conducted regularly in order to keep misclassification as low as possible. Strategies such as retesting at the start of antiretroviral therapy are needed to identify false positive individuals in existing HIV-positive cohorts.