Performance of 9 rapid diagnostic HIV tests on a wide panel of whole blood samples

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Rapid diagnostic HIV tests (RDTs) are now used in and outside laboratories or as self-tests, to improve HIV diagnosis coverage. RDTs performances are classically tested on serum, and more rarely on whole blood, limiting interpretation on a "real life" use. Moreover, most of the RDTs tested only detect antibodies (3rd generation). We tested the performance of 9 RDTs, including two detecting p24 and antibodies (4th generation) on a large panel of fresh and reconstituted whole blood samples, corresponding to diverse clinical status and representative of the wide genetic diversity of HIV.

Seven 3rd generation RDTs and two 4th generation RDTs were tested (Table 1). The specificity of the tests was evaluated on 200 negative samples collected from patients in our sexually transmitted disease clinic. The sensitivity was evaluated on 300 positive samples referenced in our National Reference Center (NRC) collections. These latter were representative of HIV diversity, including HIV-1/O and HIV-2; and 50 were collected during the primary HIV infection (PHI) phase. We validated a method of whole blood reconstitution that corresponded to a mix of selected serum (frozen collection) with fresh cells (separated from fresh whole blood), to mimic whole blood.

Our method of reconstituted whole blood allowed us to evaluate RDTs close to real-life conditions, on a large panel of samples in terms of genetic diversity and clinical status. No difference was observed for diagnosis of HIV-1/M infections; nonetheless, divergent HIV-1/O samples remains of concern, with only 2 tests detecting them all. Use of 4th generation RDT can significantly increase the diagnosis of primary infection, but results are largely depending on the test used, the HIV BioTechMed Rapid-4 being worse than some 3rd generation RDTs.