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## Evaluation of the performance of BioPlex R 2200 HIV Ag-Ab for HIV primary infection serodiagnosis in an infectious disease setting

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**Background:** Early and accurate identification of primary infection may permit early treatment of patients with beneficial consequences on both single patient clinical progression and whole community, for the high transmission rates of the infection associated with this phase. The aim of the study was to evaluate the performances of the multiplex flow immunoassay BioPlex® 2200 (Bio-Rad) for primary HIV infection serodiagnosis, in comparison with routinely assays used in an infectious disease centre. BioPlex® 2200 Bio-Rad is a V generation screening assay since allows the simultaneous detection of antibodies to HIV-1 (groups M and O), HIV-2 and the HIV-1 p24 antigen, with a separated result report for each analyte.

**Material/methods:** The comparison was conducted on clinical samples from 58 primary HIV-1 infections. The routine algorithm for serodiagnosis consisted in a screening assay with Architect HIV Ag/Ab (Abbott) to be confirmed with Western Blot (WB, New-Lav I, Bio-Rad) or with HIV-1 RNA test

(RealTime HIV-1, Abbott), in case of a negative WB result. Avidity test was used for recent infection diagnosis, where there was not available a negative HIV Ab screening test in the previous 6 months.

**Results:** According to Fiebig staging of primary infections, of the 58 tested, 12 infections were classified as Fiebig II/III (positive Architect HIV Ag/Ab test, negative WB and positive HIV-1 RNA assay), 19 as Fiebig IV (positive Architect HIV Ag/Ab test, indeterminate WB), 23 as Fiebig V (positive Architect HIV Ag/Ab, positive WB but without p31 band reactivity) and 4 as Fiebig VI (positive Architect HIV Ag/Ab, positive WB with p31 band reactivity and a low avidity test index or a documented negative screening HIV-1 test in the previous 6 months). In comparison with the currently used screening test, BioPlex® 2200 showed a sensitivity of 100%, but at variance with this assay, BioPlex® 2200 had the power to discriminate, among the 12 infections previously classified as Fiebig II/III, 8 Fiebig II (showing only a positive p24 antigen index) and 4 Fiebig III (with a positive index for both p24 and HIV-1 Ab). In all Fiebig IV infections, with only one exception, the p24 antigen was detected together with the antibody. Median HIV-1 RNA Log cp/ml was higher in Fiebig II as compared to Fiebig III (6.88 vs 6.02,  $p=0.027$ ) and Fiebig IV samples (6.14,  $p=0.005$ ). A positive correlation was observed between HIV-1 RNA values and p24 antigen indexes (where antigen was detected alone), measured by BioPlex® 2200 ( $r = 0.629$ ,  $p=0.003$ , in Spearman tests).

**Conclusions:** The BioPlex® 2200 assay, at least with an equal sensitivity with respect to the IV generation Architect assay, may allow a better discrimination of the first phases of HIV infection, contributing to a more accurate staging of primary HIV infection.