

DIAGNOSTIC EFFICIENCY OF ENZYME IMMUNOASSAYS FOR EARLY DETECTION OF HIV INFECTION

OBJECTIVES: The main method of laboratory diagnostics of HIV infection at the present time is detection of antibodies or simultaneous detection of antibodies and HIVp24 antigen by enzyme immunoassay. In recent years a significant progress has been achieved in reduction of diagnostic window period due to increasing of assay sensitivity. The aim of present study was to carry out comparative assessment of performance characteristics of screening assays of HIV infection, and to evaluate their diagnostic efficiency.

METHODS: Five ELISAs, one of third generation, three of fourth generation with different level of sensitivity at HIV-1 p24 antigen detection and one assay intended only for HIV-1 p24 detection were used in this comparative study. All assays were CE-marked. Sensitivity of the kits was estimated by testing with standard "HIV-1 p24 ANTIGEN 1st international reference reagent" (NIBSC, UK) and "HIV Antigen Sensitivity Panel No.801" (BBI, USA). The ability of the assays to detect HIV infection during seroconversion was evaluated by using of 22 seroconversion panels (total n=225) from ZeptoMetrix and SeraCare (USA).

RESULTS: 22 seroconversion panels have been tested, and according to the results, assay intended for detection of HIV-1 p24 only with sensitivity 0.025 IU/ml detects p24 antigen an average on the 13th day with a delay of about 0.25 day compared with the detection of viral RNA. Fourth generation assay with sensitivity 0.25 IU/ml detects p24 antigen an average on the 15th day, assay with sensitivity 0.5 IU/ml detects p24 antigen an average on the 16th day, assay with sensitivity 1.25 IU/ml detects p24 antigen an average on the 18th day with a delay of about 2.25-days, 2.75-days and 5.78-days compared with the detection of viral RNA. Third-generation assay identify the first positive result an average on the 24th day with a delay of about 10.91-day compared with the detection of viral RNA.

CONCLUSION: There is a direct correlation between assay sensitivity at HIV-1 p24 detection and reduction of seroconversion window period. The assay with highest level of sensitivity at HIV-1 p24 antigen detection (0.025 IU/ml) able to reduce seroconversion window period almost equally with NAT assay.