Poster presentation
Diagnostics in virology

Abstract: P1080

Citation: Clinical Microbiology and Infection. Volume 16 Supplement No. 2, Page S297

Advantages of the state-of-the-art ELISA test at verification of an early HIV infection

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Background: One of the problems of EIA diagnostic HIV infection associated with the reliable confirmation of the screening assays results. The basic difficulties are connected with confirmation screening result at early stage of seroconversion because immune blot assays (WB) are not intended for detection of presence p24 antigen - early serological a marker of an HIV infection. The other problem is "indeterminate" WB result. The aim of present study was to evaluate EIA test "DS-EIA-HIV-Ab/Ag-spectrum" as a supplemental assay for confirmation of the HIV positive results at early stage of seroconversion.

Materials: The "DS-EIA-HIV-Ab/Ag-spectrum" is an *in vitro* qualitative EIA for the detection of antibodies to individual proteins of HIV 1 (including HIV 1 group 0), HIV 2 and HIV-1 p24 antigen in human serum or plasma. Wells of microtiter plate are separately coated by recombinant proteins comprising diagnostic relevant epitopes of HIV 1 structural proteins gp41 and HIV-1 group 0 gp 41, gp120, p24, p31 and gp36 of HIV 2 and mouse monoclonal antibodies to HIV 1 p24. Sensitivity of the test was evaluated by 16 commercial available seroconversion panel (total n = 167) [ZeptoMetrix and BBI (USA)].

Results: EIA test "DS-EIA-HIV-Ab/Ag-spectrum" permits confirmation of earlier detection of HIV infection. This assay is able to confirm 100 out of 167 seroconversion specimens as HIV positive. 28 of them were positive for p24 antigen only. The delay of HIV infection detection by EIA test "DS-EIA-HIV-Ab/Ag-spectrum" in comparison with detection of HIV virus RNA is 1.2 days. WB can confirm only 13 samples out of 167 as HIV positive and 54 samples as indeterminate. The delay of HIV infection detection in comparison with detection of HIV virus RNA is 18-19 days.

Conclusion: The received results demonstrated high diagnostic efficiency of new supplemental assay. Opportunity of detection p24 antigen and high specificity allow to confirm screening results from early stages of HIV infection and reducing number indeterminate results received by WB.