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The new EIA assay for reliable confirmation of HIV infection

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Background: The diagnostic of HIV infection is based on antibodies detection to different proteins of human immunodeficiency virus (HIV) type 1, 2 and HIV 1 antigen p 24 in sera specimens. One of the problems of EIA diagnostic HIV infection associated with the reliable confirmation of the screening assays results. The aim of present study was to evaluate new EIA test "DS-EIA-HIV-Ab/Ag-spectrum" as a supplemental assay for verification of the HIV positive results.

Methods: Wells of microtiter plate were separately coated by recombinant proteins comprising diagnostic relevant epitopes of HIV 1 structural proteins gp41, gp120, p24, p31 and gp36 of HIV 2 and mouse monoclonal antibodies to HIV 1 p24. Sensitivity of new test was evaluated by well defined sera samples from HIV-infected patients (n=800) and commercial available panels of sera. For specificity evaluation of the new assay, specimens of healthy blood donors (n =910), pregnant women (n=130), patients with other infections (n=224), patients with noninfectious diseases (n=64) and samples with indeterminate results (IND) in Western Blot (WB) (n=154) were investigated.

Results: EIA test "DS-EIA-HIV-Ab/Ag-spectrum" is able to confirm all tested anti-HIV positive sera as positive. The new assay allow additionally detect HIV p24 antigen in the serum samples at concentration not less then 5pg/ml. Ninety nine sera with WB IND were tested as HIV positive in new assay at the initially testing and confirmed as HIV positive in WB dynamic observation. Forty five of them were positive for p24 antigen only. Diagnostic specificity of the new test has been estimated at 99,5%.

Conclusions: The received results demonstrated high diagnostic efficiency of new supplemental assay. Opportunity of definition p24 antigen and high specificity allow reducing number IND received by WB.