DIAGNOSTIC CHARACTERISTICS OF HYPERSENSITIVE IMMUNOENZYME ASSAY KIT TO HIV-INFECTION

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The problem of early diagnosis of human immunodeficiency virus remains relevant and can be solved by introducing the highly sensitive 4th generation ELISA test kits in the laboratory practice. The advantage of this analysis is simultaneous determination of serum antigen p24 HIV-1 and HIV-specific total antibody (IgG, IgM, IgA), that can detect the infection in the early stages of development.

In Private Joint Stock Company «Scientific and Production Company Diaproph-Med» a modified version of the test kit of the 4th generation DIA-HIV-Ag/Ab hypersensitivity was developed, which uses a mixture of synthetic analogs of viral antigens in the immune-enzyme conjugates at two stages of reaction. Significant amplification of specific signal is achieved by introducing a streptavidin which is conjugated to horseradish peroxidase polymeric form. The analytical sensitivity of the test kit to identify the 1st International Standard WHO HIV p24 (NIBSC) was 0.78 IU/ml. The ability to test kit to detect early HIV infection has been examined for 9 seroconversion panels of sera (7 production ZeptoMetrix Corp. and 2 – SeraCare Life Sciences, USA) and is comparable to its peers, the leading manufacturers of test kits. The diagnostic characteristics of the test kit tested on standard panels, including dilution of serum of HIV-infected people, and not diluted sera with antibodies to HIV-1 (1 869 samples) and HIV-2 (41 sample). In these studies, the test kit detected HIV in a large ratio OD/cut off compared to similar commercial test kits for the 4th generation. The diagnostic specificity of the test kit DIA-HIV-Ag/Ab according to the results obtained in the study of blood donors from various transfusion services in Ukraine (93 788 researches) was 99.95%.

**Key words:** HIV ELISA test kit of the 4th generation, the diagnostic sensitivity and specificity.

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