New line immunoassay (LIA) for HIV detection

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**Background:** Most national and international algorithms include immunoblotting - Western Blot (WB) or LIA to confirm HIV infection. The advantage of WB is a wide range of native HIV purified proteins, which increases the reliability of diagnostics especially during early seroconversion. The use of recombinant proteins and synthetic peptides in LIA reduces a frequency of indeterminate results obtained in lysate-based WB. A new LIA (MilaBlot-HIV) based on wide range of recombinant antigens and synthetic peptide is able to differentiate HIV-1 group M and O, HIV-2 antibody. In this study the MilaBlot-HIV was evaluated and compared to well-established tests.

**Materials/methods:** The MilaBlot-HIV based on HIV-1 group M antigens applied on a nitrocellulose strip: env (gp160, gp120, gp41), pol (p51/66, p31), gag (p24 and p17). HIV-1 group O antigen is present as discrete line. Antigen gp36 and synthetic peptide gp105 used to detect antibodies to HIV-2. Built-in three quality control lines ensure that the procedure was performed correctly, cutoff line assist in the grading of the reaction. Detection of anti-HIV antibodies is carried out using mouse antihuman IgG labeled with alkaline phosphatase. Specimens: 11 seroconversion panels of ZeptoMetrix Corporation, USA and BBI Diagnostics, USA; 189 well known HIV positive samples and 958 well known negative samples including 477 blood donor, 233 pregnant, 248 somatic patients.

**Results:** In comparison with INNO-LIA HIV I/II Score, Innogenetic, Belgium the MilaBlot-HIV has the similar sensitivity with panels PRB926 (2 out of 6 determined as positive (2/6)); HIV6247 (0/8), HIV9032 (5/14) and superior in sensitivity to panels PRB965 (2/6) against (1/6), HIV9017 (2/6) against (1/6), HIV9018 (1/11) against (0/11). When WB (BioRad, France) and WB (Cambridge Biotech, UK) were used as reference tests MilaBlot-HIV sensitivity was identical with panels HIV9077 (10/24), HIV9021 (0/17), HIV9030 (0/17) and exceeds in sensitivity with panels HIV9079 (12/25) against (11/25) and PRB955 (1/5) against (0/5). The diagnostic sensitivity of the MilaBlot-HIV was established 100%, total specificity - 99.8% with the well known samples.

**Conclusions:** MilaBlot-HIV – new confirmation kit for anti-HIV-1,2 status by immunoblotting. The kit permits earlier HIV detection comparable to the reference tests and demonstrate high diagnostic efficiency.