Comparative study of a new HIV combo screening assay with enhanced sensitivity.

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Background: Early HIV detection is a key to safeguard the blood transfusion. The goal of the study was to assess the ability of "DS-EIA-HIV-AGAB-SCREEN" to reduce diagnostic window period.

Methods: A total of 30 seroconversion panels, dilution series of 1st international reference reagent were tested to evaluate the sensitivity of the new assay. To investigate the ability to detect different HIV-1 subtypes the commercial SeraCare Life Sciences (375 West St., West Bridgewater, MA 02379, USA) world wide performance panel WWRP 302 (M) were tested. Results were compared to data of further state of the art CE-marked HIV antigen/antibody combination assays, HIV antibody assays and HIV p24 antigen tests.

Results: The lower detection limit of "DS-EIA-HIV- AGAB- SCREEN" assay for HIV-1 p24 ANTIGEN 1st international reference reagent was calculated to be 0.5 U/ml. Thus the sensitivity of the best CE marked HIV combination tests makes 4-2 U/ml. The new assay showed a statistically significant better sensitivity in seroconversion panels to the compared tests. Compared to nucleic acid amplification techniques, detection of HIV infection by "DS-EIA-HIV- AGAB-SCREEN" assay is on average only delayed by about 3,4 days. Compared with most sensitive

HIV combo assays “DS-EIA-HIV- AGAB-SCREEN” identified infection relative to NAT by a mean of 1,21 day earlier (maximum 13 days). The assay demonstrated good enough specificity and sensitivity along with broad subtype detection. The “DS-EIA-HIV- AGAB-SCREEN” detects all major HIV-1 subtypes including subtypes A, B, C, D, E, F, G, B/D, as well as group O and HIV-2 type. The specificity of the test was evaluated with samples of unselected blood donors (n=5000), clinical patients (n=200) and potentially cross-reacting specimens (n=100) and was equal 99.6 %.

Conclusion: The assay performance represents the “state-of-the-art” technology for serologic blood screening of HIV infection. “DS-EIA-HIV-AGAB-SCREEN” combo assay can significantly reduce the diagnostic window.