P0028
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HIV biomarkers, resistance and diagnostics

Performance evaluation of BIO-FLASH HIV 1+2 Ag/Ab on Biokit's BIO-FLASH® analyser

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Background: Two related retrovirus, human immunodeficiency virus 1 and 2 (HIV-1 and HIV-2) are the etiological agents of the acquired immunodeficiency syndrome (AIDS). BIO-FLASH HIV 1+2 Ag/Ab is a fourth generation chemiluminescent two-step immunoassay that uses recombinant antigens with sequences belonging to both HIV-1 (gp41 and gp41gO) and HIV-2 (gp36), as well as monoclonal antibodies against HIV p24. It is designed for the simultaneous detection of HIV-1/HIV-2 antibodies and HIV p24 antigen and allows an early diagnosis of HIV infection. The aim of this study was to evaluate the performance of the assay on the BIO-FLASH® analyser.

Material/methods: Specificity was assessed by testing 6702 fresh unselected serum and plasma samples from three different blood banks (Banc de Sang i Teixits de Catalunya (Spain), EFS Pyrénées-Méditerranée site de Montpellier (France) and DRK Blutspendedienst Baden-Württemberg-Hessen (Germany)), plus 200 non-selected serum samples of hospitalized patients. Sensitivity was assessed by testing 658 pre-characterized positive frozen samples from Hospital routine and Viral Testing Screening Laboratories, including samples of the different anti-HIV-1 subtypes, anti-HIV-2, p24 antigen, cell culture supernatants subtypes, as well as fresh samples (less than 1 day after extraction). In addition 30 commercial seroconversion panels were analysed. Samples were evaluated in three different sites: Biokit, EFS Pyrénées-Méditerranée and Paul-Ehrlich-Institut. Other relevant characteristics like analytical sensitivity, sample matrix, precision, cross-reactivity, endogenous interferences, time to first result, throughput, repeatability and reagent on-board stability, were also assessed.

Results: Overall, diagnostic specificity and sensitivity were 99.8% (6691/6702) and 100% (658/658) respectively. Also 100% specificity was found with hospitalized patients (191/191). The sensitivity in seroconversion panels was equivalent or superior to other currently CE marked HIV Ag/Ab screening assays. The analytical sensitivity of the assay for HIV-1 p24 antigen was 0.38 IU/mL. The test also showed high detection sensitivity for p24 antigen and anti-HIV-1 antibody subtypes (inclusive group O). Serum (including serum separator tube) and 9 different plasma anticoagulants showed equivalent results. Total precision %CV was found to be between 3.1% and 5.7%. The assay showed expected results for all clinical conditions in the cross-reactivity study and demonstrated to be free of interference for haemoglobin (up to 5 g/L), bilirubin (up to 0.18 g/L), and triglycerides (up to 13 g/L). Time to first result was 42 minutes and throughput was 61 test/hour. No significant lot-to-lot differences were found for reagent and calibrators. Reagent on-board stability was verified up to 13 weeks.

Conclusions: In terms of specificity, sensitivity, precision, cross-reactivity, endogenous interferences, analytical sensitivity and repeatability the assay shows an excellent performance. The robustness of the BIO-FLASH HIV 1+2 Ag/Ab together with the features of the BIO-FLASH® analyser (random access, easy-to use, and full automation) makes it an excellent choice for routine use in a clinical or blood bank laboratory.