PERFORMANCE OF THE LIAISON® XL AUTOMATED IMMUNOASSAY PLATFORM FOR BLOOD DONOR SCREENING ON VIRAL AND TREPONEMA MARKERS

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Introduction: Sensitivity and specificity are of utmost importance when screening blood donors for viral and bacteriological blood borne infections. Assay platforms designed for this purpose need to have high throughput, easy management and appropriate analysis menu. Recently a new such platform has been introduced: LIAISON® XL from DiaSorin S.p.A, Saluggia, Italy. This platform offers all the markers needed for infection screening of blood donors.

We have carried out a performance evaluation of this platform, including Hepatitis B surface antigen (HBsAg), Hepatitis B core antibodies (anti-HBc), Hepatitis C antibodies (HCV ab), HTLV-1/2 antibodies, Human T-lymphotropic virus types 1 and 2 (HTLV-1/2) and Treponema pallidum antibodies.

Material and Methods: For sensitivity, selected panels of samples, previously analysed on the Architect (Abbott Laboratories, Abbott Park, Illinois, USA; gold standard for this evaluation) immunoanalyses were used. These samples were confirmed positive for the tested markers (see table below).

Specificity was assessed by analysis of samples from blood donors, previously run on the Architect platform and found non-reactive for each marker. Over 1,000 donor samples (both new and regular donors) were tested in the evaluation, except for anti-HTLV-1/2 and anti-HBTC where 366 and 342 samples were tested respectively. The reactive donor samples were retested when possible (if volumes were sufficient). Previously non-specific reactive (Architect) samples were also run for every tested marker, as well as samples with autoimmune antibodies (rheumatoid factor, RF, n=30) and antibodies for other infections (Borrelia and Epstein Barr Virus, EBV n=32).

Results: 372 samples positive for the tested markers (HBsAg n=51, anti-HBc n=52, anti-HCV n=75, Treponema-Ab n=55, anti-HTLV-1 n=82, anti-HIV-2 n=28, anti-HTLV-1 n=28 anti-HTLV-2 n=5) have been tested, and found positive, indicating a high sensitivity.

At least 342 first time blood donors, that were negative on the Architect® have been tested, and in addition at least 700 regular blood donors, negative in routine screening. Only a few false positive samples have been detected (table below). Some of the previously false reactive samples became negative when tested with LIAISON® XL. Overall, the specificity fulfills the requirements of blood donor screening.

Sensitivity and Specificity


False-reactive samples (Abbott Architect)


Conclusion: The LIAISON® XL immunoassay instrument from DiaSorin is an easy to use, fully automated analyzer. The assays have excellent sensitivity and high specificity for blood borne infections viruses (i.e. Hepatitis B, Hepatitis C, HIV-1, HIV-2, HTLV-1 and HTLV-2) and bacteria (T. pallidum). It offers a rational and high-quality screening platform for large scale use.