ASSESSMENT OF NEW LIAISON® XL MUREX AUTOMATED IMMUNOASSAYS FOR THE DETECTION OF HBsAg, anti-HCV AND HIV MARKERS IN HUMAN SERUM/PLASMA

INTRODUCTION

LIAISON® XL is a fully automated chemiluminescence analyzer, performing the complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes) as well as the measurement and evaluation. LIAISON® XL test Menu offer a wide range of immunoassay specialties and adopt a “Flash” chemiluminescence technology (CLIA) with paramagnetic microparticle solid phase. The same proven technology is used for LIAISON®.

LIAISON® XL murex HIV Ab/Ag assay employs HIV-1, HIV-1 group O, and HIV-2 antigens and anti-p24 monoclonal antibodies in two coupled reagent cartridges. Information of the overall Ab/Ag reactivity and detail of the specific reactivity for anti-HIV / HIV p24 antigen is provided.

LIAISON® XL murex HCV Ab assay employs two recombiant antigens (core and NS4) and a third HCV antigen (biotinylated NS3).

The LIAISON® XL murex HBsAg Quant assay employs a set of anti-HBs monoclonal antibodies. Reliable detection of genotypes and sensitivity against mutants is assured by using Mabs against highly conserved epitopes of the inner region of HBsAg.

METHODS

SPECIFICITY

Blood Donors

More than 5000 blood donor specimens collected in two donation centers, i.e. ETS NORMANDIE, Rouen - Bois Guillaume and ETS NORD DE FRANCE -Lille (France), were tested with the three LIAISON® XL murex assays. A sample of 100 from first-time donors was also included in the evaluation.

Hospital patients

A study was performed on more than 2000 samples from the hospital laboratory routine, with a prevalence of HBsAg (0.70 %), HIV Ag/Ab (0.10 %) and anti-HCV (1.7%). This allows to assess specificity performance in a typical routine population.

SENSITIVITY

Diagnostic sensitivity was assessed with:

- HIV Ag/Ab: 562 anti-HIV-1 (including different subtypes), 100 anti-HIV-2 and 52 HIV p24 positive specimens.
- anti-HCV: 678 anti-HCV positive specimens (294 of whom encompassing genotypes 1, 2, 3, 4, 4 non-a, 5, 6).
- HBsAg: 424 HBsAg positive specimens. Additionally 10 of the most common HBsAg mutants, cloned and expressed in the HeLa cell line, have been tested with commercially available HBsAg assays.

Serocversion panels were tested for all kits. The results obtained for the panels, characterized by PCR testing and non reactive first sample (19 for HIV, 28 for anti-HCV, 26 for HBsAg) were further analyzed by calculating range, mean and median of the timing of detection in term of error evaluation to detect by analyte from the onset, i.e. PCR reactivity.

Results:

- Development of an immunoassay for the detection of HCV antibodies in human serum/plasma specimens, for use on the new LIAISON® XL analyzers. Enrietti S., De Luca M., Capuano F., Zanin D., Enrietti S., Anrò V., Morena S., Pallavicini L. DiaSorin Spa, Via Crescentino, Saluggia (VC), Italy – Poster presented at SMMI Congress - Milan, Italy (8-12 June 2010).
- Development of a combined immunoassay for the detection of HIV-1(2) antigen and antibodies, for use on the new LIAISON® XL analyzers. Zanin D., Momin S., Pallavicini L. DiaSorin SpA, Sr. Crocifisso, Saluggia (VC), Italy – Poster presented at SIMTI Congress - Milan, Italy (8-12 June 2010).
- Assessment of a new Liaison® XL automated immunoassay for the quantitative and highly specific detection of HBsAg in human serum/plasma. Capuano F., Anrò V., Petrarucchi M., Enrietti S., Pallavicini L. DiaSorin SpA, Sr. Crocifisso, Saluggia (VC), Italy – Poster presented at ECCMID Congress - Milan, Italy (10 May 2011).
- A novel panel of recombiant Hepatitis B Surface Antigen mutants. Sarasso C., Dianzani U., Chioschetti A., Rigamonti V., Del Corso A., Capuano F. and Obemio S.J. - “M. Department of Medical Sciences, Università del Piemonte Orientale A. Avogadro, Novara, Italy” – Department of Biotechnology and Biosciences, University of Milano-Bicocca, Milan, Italy – Poster presented at 4th European Congress of Virology, Copenhagen (CO), Italy (7-11 April 2010).

Conclusions:

All three LIAISON® XL murex assays showed a sensitivity comparable to the best assays currently available on the market, with an excellent specificity. Therefore they can be used as an aid in the detection of HIV / HCV / HBV infection in clinical settings and in screening test for donated blood and plasma.