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Poster Session V

Molecular and non-molecular diagnostics of viruses

EVALUATION OF THE NEW ASSAY LIAISON XL MUREX HBSAG QUANT FOR THE QUANTIFICATION OF HEPATITIS B SURFACE ANTIGEN IN PATIENTS WITH CHRONIC HEPATITIS B

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Objectives. Recent technologic innovations have allowed for the quantitative assessment of the hepatitis B surface antigen (HBsAg) levels in serum and HBsAg quantification has been applied for monitoring chronic HBV infection during its natural history as well as for the prediction of response to treatment. The LIAISON XL Murex HBsAg Quant assay (XL, DiaSorin, Saluggia, I) is the newest CE approved chemiluminescence immunoassay to detect HBsAg in the setting of blood transfusion as well as to quantify HBsAg level for clinical purposes using onboard dilution. The assay is standardized against the World Health Organization Second International Standard with an analytical sensitivity of 0.03 IU/mL and a dynamic range up to 150 IU/mL. The aim of the study was to evaluate XL performances and compare the new system with the first licensed quantitative Architect HBsAg immunoassay (ArC, Abbott Diagnostics, IL, US, onboard dilution), as gold standard.

Methods. Sequential serum samples (n=152) from 14 patients with chronic HBe-negative hepatitis B (CHB), the majority of them infected with HBV genotype D and undergoing antiviral treatment, were retrospectively tested with both the two assays. The 2nd WHO Standard 00/588 for HBsAg was used to assess assay performance.

Results. Correlation between XL and ArC results was high ($r=0.95$, $p<0.0001$) and by Bland-Altman analysis the agreement between the two assays was close (mean difference between ArC and XL: 0.21 ± 0.15 log IU/mL, 95% CI: $-0.07-0.5$ log IU/mL). In the study-series, mean levels of HBsAg as detected by XL and ArC were not significantly different (2.8 and 3.0, log IU/mL, respectively). In patients undergoing antiviral treatment with NUCs median baseline viral load before antiviral treatment was very similar with the two methods (3.7 and 3.9 log IU/mL with XL and ArC). At one year of antiviral treatment viral load decrease from baseline was 0.3 logs with both the two methods. Performance of XL against the 2nd WHO was excellent ($r=0.998$, $p<0.0001$, 95% CI: 0.993-0.999).

Conclusions. The current study shows high correlation and agreement between quantitative HBsAg measurement with XL and ArC. XL accurately and reliably quantified HBsAg in clinical samples from patients with HBV chronic hepatitis either at baseline or during antiviral therapy. Therefore, XL, the first HBsAg quantitative immunoassay also approved for blood banks, can be used in clinical practice for monitoring HBsAg titers for the best definition and management of HBV chronic hepatitis either in naïve patients or during antiviral therapy.