INTRODUCTION OF AN AUTOMATIC INSTRUMENTAL DILUTION FOR HIGH TITER SPECIMENS IN HBsAg QUANTITATIVE ASSAY

M. Petruzzello, F. Capuano, S. Morena, S. Enrietti, L. Pallavicini - Product Development Department - DiaSorin SpA, Italy

OBJECTIVE

LIAISON® XL murex HBsAg Quant assay is designed for a sensitive detection of acute HBV infections including HBsAg escaping mutants, moreover its quantitation supports the role of HBsAg as a predictive marker for the anti-HBV treatment response. Quantitation of HBsAg has an increasingly clinical utility as a biomarker for the prognosis and response in therapy in cases of chronic Hepatitis B.

A new assay protocol for an auto-dilution of out of range specimens was developed and then assessed.

METHODS

A new assay protocol was developed for the LIAISON® XL murex HBsAg Quant assay to allow the user to select on board dilution of specimens containing HBsAg concentrations above the assay range (>150 IU/mL). These samples can be automatically diluted using the specific Specimen Diluent loaded in the ancillary reagent area of the LIAISON® XL instrument. The recommended dilution factor is 1:400. Assay range is set from 0.030 to 150 IU/mL, where best precision and manual dilutions occurred.

The same kit can be used for monitoring the therapy and to screen hospitalized patients and donors population, with clear cost benefit for the laboratory and reduction of turn-around time.

RESULTS

AUTO-DILUTION ACCURACY

The linear regression slope on a set of 17 samples serially auto-diluted 1:200 – 1:400 – 1:800 was obtained.

<table>
<thead>
<tr>
<th>Term Obtained 95%C.I.</th>
<th>Slope 1:200</th>
<th>1.02</th>
<th>0.96-1.01</th>
</tr>
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<tbody>
<tr>
<td>Slope 1:400</td>
<td>1.00</td>
<td>0.97-1.01</td>
<td></td>
</tr>
<tr>
<td>Slope 1:800</td>
<td>0.98</td>
<td>0.96-1.03</td>
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AUTO-DILUTION PRECISION

Precision on five replicates between manual and auto-dilution was obtained.

Table 4: CV% (mean)

<table>
<thead>
<tr>
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<th>CV%</th>
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<tbody>
<tr>
<td>Auto-dilution</td>
<td>4.8% 2.6% 3.6% 2.3% 1.6% 1.9% 1.3% 2.1% 3.6% 2.6%</td>
</tr>
<tr>
<td>Manual-dilution</td>
<td>1.7% 1.3% 0.9% 0.6% 1.3% 2.0% 1.3% 1.7% 2.9% 1.5%</td>
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Based on the above linear regression data and the Analysis of variance for repeated measures among tested auto-dilutions (ANOVA – C.I.95%) no significant trends between tested auto-dilutions occurred.

DISCUSSION

Potential errors due to manual handling of samples. The LIAISON® XL murex HBsAg Quant direct two-step sandwich CLIA assay ensures reliable data showing high analytical performance in the quantitative determination of HBsAg in serum/plasma specimens. The same kit can be used for monitoring the therapy and to screen hospitalized patients and donors population, with clear cost benefit for the laboratory and reduction of turn-around time.

CONCLUSIONS

A new assay protocol for an auto-dilution of out of range specimens was developed and then assessed. The LIAISON® XL murex HBsAg Quant assay exhibits acceptable linearity of auto versus manual-dilution.

CV% values obtained for the automated dilution ranged from 1.3% to 4.8%, thus demonstrating the high precision of the new assay protocol for the auto-dilution.

As a result of DiaSorin’s commitment to quality and continuous improvement, updates have been introduced to the LIAISON® XL murex HBsAg Quant assay (Catalog Number 310250). The LIAISON® XL murex HBsAg Quant Specimen Diluent (Catalog Number 310252) can be used as ancillary reagent managed automatically by the LIAISON® XL instrument.

The data supports the adequacy of the auto-dilution choice in the LIAISON® XL murex HBsAg Quant system for patient samples higher than 150 IU/mL. Recently, quantitation of HBV has a growing clinical utility in the monitoring of therapy in the case of chronic Hepatitis B, therefore it has been suggested the use of HBsAg as a biomarker for the prognosis and response to therapy in cases of chronic Hepatitis B.

The option of manually dilute the sample is still feasible in the LIAISON® XL murex HBsAg Quant system.