Performance of a new chemiluminescent assay to detect and quantify anti-HBs antibodies

Charlotte PRONIER, Diane LE BAYON, Anne DELEPINE, Gisèle LAGATHU, Anne MAILLARD, Thoai Duong LY, Vincent THIBAULT1, 2
1 Virology Department – Rennes University 1 – Pontchaillou Hospital Rennes 1 INSERM U1085 – IRSET – Rennes – FRANCE
2 Biomnis, Ivry-sur-Seine, FRANCE

OBJECTIVE
✓ to assess the performance of Liaison XL Murex Anti-HBs Plus (DiaSorin)
✓ to compare anti-HBs quantification with Roche Elecsys anti HBs II and Abbott Architect assays
✓ to appraise anti-HBs quantification after natural or vaccine-induced immunization

BACKGROUND
• Quantification of anti-HBs antibodies (HBsAb) is a key parameter to assess vaccination efficacy or to monitor hepatitis B immunoglobulin protection level in liver transplanted patients.
• Reliability of HBsAb quantification depends on technique standardization accuracy
• Naturally acquired or vaccine induced antibodies are not identical and may not be similarly quantified

RESULTS
1 Overall agreement rate between DiaSorin and Roche qualitative results (n=563)

<table>
<thead>
<tr>
<th></th>
<th>DiaSorin</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>223</td>
<td>39.6%</td>
</tr>
<tr>
<td>POSITIVE</td>
<td>10</td>
<td>1.6%</td>
</tr>
<tr>
<td>Total</td>
<td>233</td>
<td>41.2%</td>
</tr>
</tbody>
</table>

The overall agreement between both techniques was 96.6% [95-98%]

2 Standardisation of both Roche and DiaSorin techniques against the WHO standard

DiaSorin IU/mL

3 Passing-Bablok analysis on 225 values within the quantification range for both techniques

4 Bland-Altman analysis on 225 samples within the quantification range for both techniques

The mean bias between the two techniques is 10.7 IU/L [-3.15 - 24.6]

5 Distribution of HBsAb quantification differences expressed as a percentage of DiaSorin over Roche (n=225)

6 Difference of quantification according to HBV serological profiles (p<0.5; ns): naturally acquired HBsAb are quantified similarly as vaccine induced Ab.

The values obtained with DiaSorin were on average 15% higher than with Roche (median 11%)

7 Difference of DiaSorin quantification compared to Roche Cobas and Abbott Architect on 100 samples randomly selected to cover the entire range of linearity

CONCLUSIONS
✓ the DiaSorin assay possesses at least comparable performances as the Roche test.
✓ The 96.6% qualitative agreement between both techniques is satisfactory. The few qualitative discordant results did not favor one assay over the other when tested on a third party assay.
✓ Standardization to the WHO standard was excellent as well as linearity. The overall correlation between Roche and DiaSorin on clinical samples was good whatever the encountered serological profile.
✓ A limited comparison with the Abbott Architect confirms previous data and tends to indicate an imperfect standardization of Abbott assay to the international unit.

METHODS

The methods were:
• ROCHE Elecsys Anti-HBs II as our routine technique and used to determine the serological profiles, HBsAb BioMerieux Vidas was used to confirm most discordant samples.
• The material consisted of several categories of samples:
  - 100 HBV vaccines (fresh and frozen)
  - 100 past HBV infection (fresh and frozen)
  - Up to 200 hundred serum samples from patients and health care workers from daily submissions for routine anti-HBs testing without any selection (fresh).
  - 100 positive specimens (selected and provided by DiaSorin, frozen)
  - WHO International Standard – Second International Standard for anti-hepatitis B surface antigen (anti-HBs) - (provided by DiaSorin)
  - 5-10 samples with high anti-HBs titers, serially diluted, to check the recovery test with both methods.

Contact : vincent.thibault@chu-rennes.fr