Comparison of two analyzers for the quantification of anti-HBs antibodies using ELISA method

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Introduction

The quantification of anti-HBs antibodies is necessary to see if a patient has a sufficient concentration of antibodies to protect him effectively against Hepatitis B. Other factors have to be taken into account, such as quantification of HBs antigen and anti-HBc antibodies. However; we will focus on anti-HBs antibodies quantification. In order to manage a procedure of validation, the main part is to compare the instrument we want to check with another available in the laboratory. The method in question is ELISA: Enzyme Linked Immuno-Sorbent Assay. In this case, the method is based on the sandwich principle. Two automated systems using ELISA method are compared: BEP 3 System from Siemens and VIDAS from Biomérieux. The only difference between these two systems is the detection: BEP 3 uses a colored reaction product and VIDAS uses a fluorescence measure. After checking the systems performances, such as repeatability and reproducibility, the same samples are analyzed by the BEP 3 and the VIDAS respectively. Patients' samples used for this comparison are chosen so as to be homogeneous in the covering of the all measuring range.

Experimental conditions

For this technic, critical values in concentration are around 10 IU/l for the cut-off and around 100 IU/l . Above 100 IU/l it is considered that the concentration of antibodies is sufficient to neutralize the Hepatitis B virus. The range of concentration is between 10 to 150 IU/l and composed of 20 sera. 10 sera were taken above 150 IU/l and finally, 10 sera were under 10 IU/l (negative values). Sera were frozen and samples dates were between February 4th, 2013 and March 20th, 2013.

Results and discussion

Results were satisfying for low values and then results were further extended. On the XY graph (see figure 1), VIDAS results are on the x-axis and BEP 3 results on the y-axis. The goal is to have a line with a slope equal to 1 and a y-intercept equal to 0. For the comparison, values above 100 are not considered so relevant and there is no clinical interest to check above this limit since results will always be positive. We can see that one serum, near 128 with BEP, is around 71 with VIDAS, and it could explain the low quality of the regression ($R^2 = 0.56$ and $R^2a = 0.57$). In addition, the study of residuals does not allow concluding on the linearity. However, this serum is not abnormal with the Grubbs test at 5%. Concerning negative sera, some of them are discordant (see table 1). Indeed, 3 sera are undetermined and 1 is positive by VIDAS.

Conclusion

Especially for low values, the concordance between the two methods was accurate. However, on the 10 negative sera, 1 was positive with VIDAS, which is the contrary of the BEP result. We can notice that samples which were discordant were near the cut-off, so it can explain the discrepancy between the systems. There is also a difference of sensitivity; a colorimetric detection is less sensitive than one by fluorescence. We can also notice that a patient who has a very low concentration of antibodies or no antibodies at all will not have a real different diagnostic.

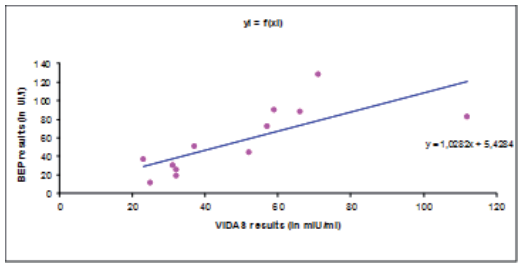

Figure 1 : XY representation of BEP and VIDAS results, the linear regression with a near one slope, the y-intercept near 0 and the discrepancy at 71 on x-axis.

		BEP	
		+	-
VIDAS	+	30	1
	Indeterminate result	0	3
	-	0	6
	TOTAL	30	10

Table 1 : Sign table of two methods with positive sera found positive by both techniques and for negative sera, some discordances appear.

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