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Letter to the Editor

Calibration of qualitative HBsAg assay results for quantitative HBsAg monitoring

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ABSTRACT

Evidence is accumulating that quantitative hepatitis B surface antigen monitoring may be useful in managing patients with chronic HBV infection on certain treatment regimens. Based on these results with the Abbott Architect qualitative and quantitative HBsAg assays, it seems feasible to convert qualitative to quantitative HBsAg values for this purpose.

Evidence is accumulating for the value of quantitative hepatitis B surface antigen (qHBsAg) testing and monitoring for understanding and predicting the natural clearance of HBsAg in chronic hepatitis B-infected (CHB) and treatment-naïve patients [1–4], and assessing the likely responses to interferon- and nucleos(t)ide analogue-based therapies [4–6]. The use of qHBsAg monitoring has been recently recommended in national guidelines for the management of chronic hepatitis B (HBV) infection [7].

The Abbott Architect (Abbott Diagnostics, Abbott Park, IL, USA) is a popular platform for high throughput qualitative HBsAg (HBsAg Qualitative II kit, B2G220) testing. A quantitative version of this kit (HBsAg, B6C3G0) offers qHBsAg testing. During the evaluation and the validation of the Architect qHBsAg assay, for introduction into our routine diagnostic service, we noticed a remarkable linearity of the Architect qualitative HBsAg (qlHBsAg) assay. Previous studies have calibrated qlHBsAg assays using qHBsAg assays for specific internal and research use [8,9], so we decided to investigate this further to determine if these qlHBsAg results could be accurately and consistently converted to qHBsAg results.

Our evaluation of the qlHBsAg vs qHBsAg Abbott Architect assays took place in two stages. First, from our archived samples, we selected high HBsAg concentration serum samples from each of the HBV A, B and C genotypes (the most common HBV genotypes in this Alberta population). These were diluted to give a wide linear range and tested in parallel on the qlHBsAg and qHBsAg assays (Fig. 1). Note that the linear regression curves are relatively similar across the three different HBV genotypes, so for the rest of this analysis we are assuming that the different HBV genotypes give similar results.

The second stage of this exercise took place once the qHBsAg assay was formally introduced into routine service. Each week, for 5 consecutive weeks, samples received routinely (about 5–10 samples/week) for qHBsAg (for which an automatic or manual 1:500 dilution is required as per manufacturer's instructions) were also run at a 1:500 dilution on the qlHBsAg assay. The resulting qHBsAg (IU/mL) (x-axis) and qlHBsAg S/CO (signal to cut-off) ratio (y-axis) values were plotted and a linear regression curve was fitted. For each of the subsequent weeks after the first week, the 1:500 diluted qlHBsAg S/CO value was inserted into the previous week's linear regression equation to obtain a 'calculated' qHBsAg result for each sample. Note that this 1:500 dilution step (which is not routinely required) for the qlHBsAg assay is important to obtain this calculated qHBsAg value in this way.

Examples of these results, including the linear regression curve obtained from the full 5 weeks of qlHBsAg/qHBsAg data (Fig. 2A) are shown in Fig. 2B–F. Although there is some variation in the calculated vs measured qHBsAg values derived from the 5-week linear regression curve, the overall comparison over this 5-week period is reasonably close (all R^2 values > 0.93). Note that the weekly calculated vs measured qHBsAg values cover variable ranges, depending on the clinical samples received for qHBsAg testing during each week. Based on these results, we would like to suggest that a mean of these linear regression curves may be useful for converting qlHBsAg values to qHBsAg values – especially in laboratories that are already running the qlHBsAg assay, where the introduction of the relatively low volume qHBsAg assay may not be deemed particularly cost-effective.

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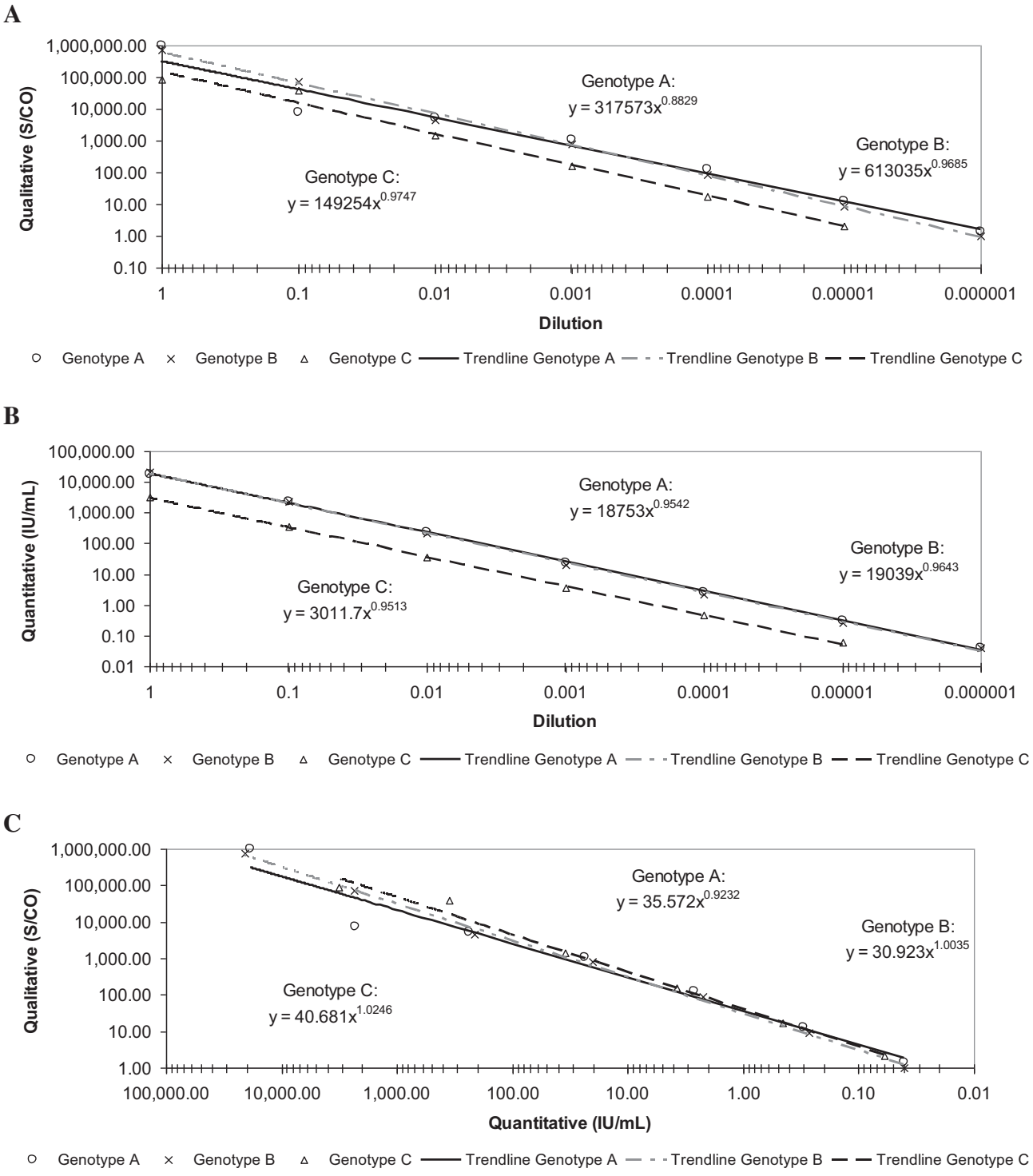

Fig. 1. Plots showing the linearity of the qualitative (A) and quantitative HBsAg (B) assay performance with serial dilutions of serum samples of HBV genotypes A, B and C. Combined plots relating the qualitative (qlHBsAg) to the quantitative (qHBsAg) assays for each HBV genotype A, B and C (C): $y = 35.572x^{0.9232}$, $y = 30.923x^{1.0035}$ and $y = 40.681x^{1.0246}$, respectively.