

Correspondence

To the Editors

Precision of hepatitis B virus pregenomic RNA test: a concern on novel biomarker for hepatitis B

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Dear Editors,

Hepatitis B virus (HBV) infection is an important problem. In paediatrics, the estimated global prevalence is 1.3% and the important clinical concern is management of chronic HBV infection¹. Indolfi G, *et al* noted that treatment for children with high rates of HBV replication was required and follow-up monitoring by biomarker was necessary¹. A novel biomarker is pregenomic RNA, which is associated with efficacy and prognosis of chronic hepatitis treatment^{2,3}. Regarding this new biomarker, pre-analytical conditions can affect the laboratory analysis. Degradation of RNA due to heat is possible. In a temperature-controlled condition, the stability of the test is acceptable⁴. At room temperature, Rattanachaisit P, *et al* found that there was a continuous decrease of RNA level in blood specimen when time passes⁴. However, the decrease is small, less than 0.5 log₁₀ copies/mL, and may not be clinically significant⁴.

In the clinical laboratory, another important issue to be addressed is precision of the test. A precise test should provide closeness of the analytical results to each other. Adding to the previous study of stability, the authors reappraise on imprecision of using pregenomic RNA test at room temperature. From within run analysis (N = 40), coefficient of variance (CV) is equal to 13.95%. Hence, the precision rate is 86.05%. Since CV from analysis is high, it can imply that the test is not precise. In conclusion, pregenomic RNA test is imprecise and interpretation of pregenomic RNA should recognize the possible problem from imprecision. Applying the imprecision value to the previous reported cutoff for clinical significant change, the adjusted cut-off for a significant RNA level change for clinical monitoring should extend to 0.57 log₁₀ copies/mL.

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