Evaluation of the HISCL M2BPGi assay performance

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Background: The *Wisteria floribunda* agglutinin-positive human Mac-2 binding protein (WFA^+-M2BP) is a novel marker for the assessment of liver fibrosis. A number of clinical studies showed that WFA^+-M2BP reflects the progression of liver fibrosis. Furthermore, a study targeting patients with hepatitis C suggested that WFA^+-M2BP is useful in predicting for the development of hepatocellular carcinoma. A WFA^+-M2BP assay reagent, HISCL M2BPGi, for the glycan-lectin reaction was released by Sysmex Corporation (Kobe, Japan) in 2013. In this study, we evaluated basic performance of the reagent and correlations between HISCL M2BPGi level and that of other non-invasive liver fibrosis markers.

Methods: Precision was determined for two levels of quality control (QC). Intra-day precision was tested using ten replicate measurements for each QC. For inter-day precision, each QC level was measured in duplicate every day over a 2-week period. Linearity was tested using pooled serum. To determine the sample stability, pooled serum was stored at various temperatures (room temperature, 4°C, -20°C, and -80°C) and a freeze-thaw cycle was repeated. To determine correlations, we used serum samples for other fibrosis markers.

Results: The coefficients of variation for intra- and inter-day precision ranged from 1.2% to 2.1% and 4.2% to 5.9%, respectively. Linearity was confirmed up to 11 cut off index. Although samples stored at room temperature were unstable, other storage conditions and the freeze-thaw cycle did not influence M2BPGi level. The concordances between M2BPGi and hyaluronic acid, collagen type IV, collagen type IV 7S, and platelets were 71.3%, 62.4%, 78.2%, and 50.5%, respectively.

Conclusion: The performance of the reagent was sufficient for routine measurements. The correlation between M2BPGi and other markers was generally good. However, some M2BPGi levels were mismatched with those of other markers. In those cases, further examination is necessary.

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