00256 Combination of New and Old Hepatocellular Carcinoma Biomarkers: Evaluation of Protein-induced by Vitamin K Absence or Antagonist II (PIVKA-II) and Alphafetoprotein (AFP) on Abbott i1000SR

Tan Si Yu, Ng Wai Yoong, Yap Mei Mei, Chan Wai Ting, Yeo Chin Pin

Singapore General Hospital

Aims: Hepatocellular carcinoma (HCC) has been ranked the third leading cause of cancer death in the world. To improve detection of HCC, new biomarkers such as the 'Protein-Induced by Vitamin K Absence or Antagonist II' (PIVKA-II) have been proposed to be used together with current ones, eg alphafetoprotein (AFP) for improved detection of HCC. In this study, PIVKA-II and AFP tests on Abbott i1000SR were evaluated for technical performance with a comparison of AFP against the Roche cobas e602.

Methodology: PIVKA-II and AFP-A (Abbott) were evaluated for imprecision, linearity, limits of detection and carryover according to CLSI guidelines. Routine clinical test specimens (n=62) for AFP (AFP-R, Roche e602) were later tested on the Abbott test platform (AFP-A, PIVKA-II) to investigate correlations between test analytes.

Result: Both the Abbott PIVKA-II and AFP-A assays gave imprecisions (within CVs 0.9-3.4%, total CVs 1.9-3.9%) , linearity, limits of detection (PIVKA-II LoD 1.44 mAu/mL; AFP-A LoD 1.05 ng/mL) and carryover performance to be concordant with manufacturer's claims. There was a negative bias (-7.1% Altman-Bland) for AFP-A compared to AFP-R. Passing-Bablok regression was AFP-A = 0.89 AFP-R + 0.24 (n = 62; Spearman's rs2 =1.0). Different methodologies and reaction monoclonals likely account for the bias seen. Generally PIVKA-II levels trended positively with AFP (-A, -R) levels. For those with low AFP-R levels (<7.1 ng/mL, n = 12), PIVKA-II levels ranged from 14.5 - 46.5 mAU/mL, consistent with upper limits of 32.0 and 50.9 mAU/mL in apparently healthy Japanese and Europeans studied.

Conclusion: The overall performance was satisfactory with a demonstrated negative bias of AFP-A compared to AFP-R. Further clinical studies with detailed pathology will better show the association of PIVKA-II and AFP and their usefulness in our patient population.