

Performance Evaluation of the HE4 as a Serum Tumor Marker for Ovarian Carcinoma

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Abstract : Background: Ovarian carcinoma is the fourth most common cause of cancer-related death in women worldwide. HE4, a novel marker for ovarian cancer could be used for monitoring recurrence or progression of disease in patients with invasive epithelial ovarian carcinoma. It is further intended to be used in conjunction with CA 125 to estimate the risk of epithelial ovarian cancer in women presenting with an adnexal mass. In this study, we aim to evaluate the analytical performance and clinical utility of HE4 assay using Architect i 2000SR(Abbott Diagnostics, USA). Methods: The precision was evaluated according to Clinical and Laboratory Standards Institute(CLSI) EP5 guideline. Three levels of control materials were analyzed twice a day in duplicate manner over 20 days. We calculated within run and total coefficient of variation (CV) at each level of control materials. The linearity was evaluated based on CLSI EP6 guideline. Five levels of calibrator were prepared by mixing high and low level of calibrators. For 43 women with adnexal masses, HE4 and CA 125 were measured and Risk of ovarian malignancy (ROMA) scores were calculated. The patients' medical records were reviewed to determine the clinical utility of HE4 and ROMA score. Results: In a precision study, the within-run and total CV were 2.0 % and 2.3% for low level of control material, 1.9% and 2.4% for medium level and 0.5 % and 1.1% for high level, respectively. The linear range of HE4 was 14.63 to 1475.15pmol/L. Of the 43 patients, two patients in pre-menopausal group showed the ROMA score above the cut-off level (7.3%). One of them showed CA 125 level within the reference range, while the HE4 was higher than the cut-off. Conclusion: The overall analytical performance of HE4 assay using Architect showed high precision and good linearity within clinically important range. HE4 could be an useful marker for managing patients with adnexal masses.

Keywords : HE4, CA125, ROMA, evaluation, performance

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