Soluble receptor fms-like tyrosine kinase-1 testing: analytical performances of the new B•R•A•H•M•S sFlt-1 KRYPTOR automated immunoassay

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Objective

Soluble fms-like tyrosine kinase-1 (sFlt-1) participates to the physiopathology of pre-eclampsia by complexing the placental growth factor (PlGF) and blunting its biological action. Measurement of sFlt-1 levels contributes to the risk assessment of pre-eclampsia but only few automated assays for sFlt-1 testing are available. The aim of our study was to evaluate the analytical performances of the Thermo Scientific B•R•A•H•M•S sFlt-1 KRYPTOR immunoassay on KRYPTOR® compact PLUS instrument, a recently developed automated immunoassay.

Methods

Imprecision of the B•R•A•H•M•S sFlt-1 KRYPTOR (Thermo Scientific) immunoassay was determined with three levels of manufacturer's control materials and seven pools of serum covering a broad spectrum of sFlt-1 concentrations, ran in duplicates two times a day for 5 days. The linearity of the sFlt-1 assay was determined through a 20 points dilution test. Matrix commutability was evaluated in paired EDTA and serum samples collected from second and third trimester pregnant women (n=47). PlGF concentrations were also determined in this set of patient samples with the B•R•A•H•M•S PlGF KRYPTOR immunoassay.

Results

The between run coefficients of variation (CV) for the quality control materials were 0. 8, 1. 1 and 1. 0% for mean concentrations of 1540, 2988 and 9666 pg/mL, respectively. The 20 points dilution test covered a range of concentrations ranging from 92391 to 41 pg/mL and demonstrated a reduced mean bias of 6. 2%, confirming the linearity of the assay. In the pregnant women samples, the median concentrations of sFlt-1 in serum and EDTA were respectively 1072 pg/mL (range: 166. 3 - 3400) and 1122 pg/mL (326 – 3099). The Spearman correlation coefficient between the 2 matrixes was 0. 97 and Passing and Bablok regression analysis showed a slope of 0. 97 and an intercept of 30. 31. For PlGF, the median concentrations in serum and EDTA were respectively 220. 3 pg/mL (range: 88. 6 – 928. 3) and 214. 5 pg/mL (76. 3 – 948. 4). The Spearman correlation coefficient between serum and EDTA was 0. 96 and Passing and Bablok regression analysis between the 2 matrixes showed a slope of 0. 94 and an intercept of 8. 02. The ratios between sFlt-1 and PlGF were not significantly different between serum and EDTA.

Conclusion

Our study demonstrated that the sFlt-1 automated immunoassay developed on the B•R•A•H•M•S KRYPTOR® compact PLUS has excellent analytical performances. Furthermore, a limited bias was observed between serum and EDTA samples, indicating the potential matrix commutability.