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**ANALYTICAL PERFORMANCE EVALUATION OF A NEW ASSAY FOR URINARY FREE CORTISOL ASSESSMENT IN LIQUID CHROMATOGRAPHY-TANDEM MASS SPECTROMETRY**

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Background and aim: According to current guidelines, urinary free cortisol (UFC) is the first-line biochemical test for screening endogenous Cushing syndrome. Due to its higher selectivity and specificity compared to radioimmunoassays (RIA), liquid chromatography-tandem mass spectrometry (LC-MS/MS) has become the reference technique for UFC assessment in clinical practice. Aim of the study was to evaluate the analytical performance of a new UFC LC-MS/MS assay and to compare results with those obtained with a RIA method currently used in our laboratory.

Methods: The LC-MS/MS assay and analytical system were the ISBN UFC kit and a Nexera X2 series UHPLC (Shimadzu, Kyoto, Japan)-4500 MD triple quadrupole MS detector (ABSciex, Darmstadt, Germany) respectively.

Results: The LC-MS/MS method was linear up to 5000 nmol/L. The limit of detection (LOD), defined as the lowest concentration generating a signal to noise ratio (S/N) >3, was 3 nmol/L. The limit of quantification (LOQ), defined as the minimum concentration of cortisol measurable with an imprecision of at least 20%, was 6 nmol/L. Within-run and between-run coefficients of variation were <6% and 10% over a broad range of values (5 sample pools, 10 repetitions). Linear regression analysis between RIA and LC-MS/MS on 50 samples yielded a correlation coefficient of 0.88. The RIA method showed a positive proportional bias of 56% compared to the HPLC-MS/MS assay. Results obtained from two external quality assessment schemes (UK NEQAS) showed excellent agreement (mean specimens bias <15%), with mean values from 44 laboratories using the same method.

Conclusion: The new commercial UFC LC-MS/MS assay display optimal analytical performance in terms of precision, sensitivity and accuracy, and seems hence suitable for routine use as replacement of RIA assays.

Fassnacht M, et al. Management of adrenal incidentalomas: European Society of Endocrinology Clinical Practice Guideline in collaboration with the European Network for the Study of Adrenal Tumors. Eur J Endocrinol 2016;175:G1-G34.