Quantification of Corticosteroids and Androgens in Serum, utilizing Waters MassTrak™ Steroid Serum Sets 2 & Sets 3 for Clinical Research

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Background: Steroid hormones encompass a large class of small molecules that play a central role in metabolic processes, such as the regulation of sexual characteristics, blood pressure, and inflammation. Enzymes that form part of the steroid biosynthetic pathway are pivotal in these metabolic processes, and their dysfunction can be examined through the correct measurement of steroid hormones in a clinical research setting. The availability of lyophilized calibrators and QCs reduces sample preparation time, aids in method harmonization, and assists with metrological traceability in accordance with ISO15189:2022, when used alongside an analytically selective chromatographic method.

Clinical Research Method: A quantitative clinical research method utilizing Waters MassTrak Steroid Serum Sets 2 and 3, Cals & QCs and Waters Oasis™ PRiME HLB µElution plate technology for the extraction of testosterone, androstenedione, 17-hydroxyprogesterone (17- OHP), dehydroepiandrosterone sulfate (DHEAS), Cortisol, 11-deoxycortisol and 21-deoxycortisol from human serum samples. Chromatographic separation was performed on an ACQUITY™ UPLC™ I Class Plus (FL-I) System, using an ACQUITY UPLC HSS T3 Column, accompanied by a Xevo™ TQ-S micro Mass Spectrometer.

Results: Accuracy (±6%) and precision (±10%) have been confirmed through comparison to External Quality Assurance (EQA) LC-MS/MS schemes, panels and QC material for all seven steroid hormones. All analytes were assessed at the low, medium and high concentrations for each MassTrak Steroid Serum Set, which yielded excellent results across the range (±10%). Deming and Linear regression analysis were performed. No statistically significant bias was observed for each compound, with a mean method bias of ±1.3% for Set 2 and ±1.0% for Set 3. The clinical research method was shown to be linear for all analytes over the calibration ranges specified, furthermore, calibration lines created using Set 2 and Set 3 were analysed over a five-day period and were linear with a co-efficient of determination of (r2) > 0.999 for all analytes. Analytical sensitivity using Signal:Noise (S/N) of the low calibrator (Calibrator 1) of each set, was >10:1 for each analyte across several analytical runs.

Conclusion: This evaluation has demonstrated that the MassTrak Steroid Serum Calibrator and Quality Control Sets 2 and 3 can provide precise and accurate quantification of steroid hormones in serum. An analytically sensitive and selective clinical research method has been developed for the analysis of testosterone, androstenedione, 17- OHP, DHEAS, cortisol, 11-deoxycortisol and 21-deoxycortisol in serum using Waters I-Class Xevo TQ-S micro system.

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