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ORAL PRESENTATIONS
Therapeutic Drug Monitoring

22. Comparison of the ARK Immunoassay to the Seradyn Fluorescence Polarization Immunoassay for Measurement of Serum Topiramate

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Background: Topiramate is a newer anticonvulsant used to treat ailments such as epilepsy and migraine headaches, with off-label application in bipolar disorder, post-traumatic stress, and other conditions. Compared to older antiepileptic agents, topiramate has a favorable pharmacokinetic profile and mild side effects including weight loss and somnolence. The therapeutic range is wide, 2–20 mg/mL (6–60 mmol/L); serum topiramate analysis is most likely to aid in determining individuals' optimal levels, addressing therapeutic failure or drug-drug interactions, and assessing compliance. We compared topiramate measurement by fluorescence polarization immunoassay (FPIA, Seradyn) on an Abbott TDx/FLx_ instrument, to a novel immunoassay (ARKTM Topiramate Assay, ARK Diagnostics) performed on an Olympus AU680 automated analyzer. Precision, linearity, limit of quantitation, carryover, spike recovery, and endogenous interferences were tested for the ARK assay, followed by comparison of 120 patient samples analyzed using both methods. The analytical calibration ranges for the FPIA and ARK assays are 2.0–32.0 mg/mL and 2.0–60.0 mg/mL, respectively. For the ARK assay, precision within the calibration range showed mean concentrations between 97.9–102.4% of nominal values, with all coefficients of variation (CVs) below 4.0%. Precision below the calibration range was acceptable: CVs were 13.5% and 6.1% at 0.5 and 1.0 mg/mL, respectively. Lipemia, hemoglobin, and other endogenous interferences did not significantly affect analysis, and no carryover was seen. Agreement between the ARK immunoassay and FPIA method was very good; comparison of patient and spiked samples across the analytical range displayed a mean difference of 1.0% (67.7%) between the two assays. In summary, the ARK topiramate immunoassay provides robust analytical performance and comparability to existing FPIA methods, and is compatible with high-throughput automated chemistry analyzers.