POSTER

Therapeutic Drug Monitoring on COBAS® INTEGRA 400 – Evaluation Results

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SUMMARY

The COBAS® INTEGRA 400 (Roche Diagnostics GmbH) is a random access analyzer with a consolidated test menu for routine clinical chemistry, specific proteins, drugs of abuse screening and therapeutic drug monitoring (TDM) and different measuring technologies. It was the aim of the present study to evaluate the suitability of this instrument as dedicated analyzer for TDM. Eight assays based on three different technologies were included: Acetaminophen (enzymatic method), Amikacin/Phenytoin/Free Phenytoin/Lidocaine (fluorescence polarization immunoassays; FPIA), Digitoxin/Digoxin (kinetic interaction of microparticles in solution; KIMS). The study comprised the determination of imprecision according to NCCLS EP-T protocol, method comparison and linearity studies. The assays were compared with the corresponding methods on AxSYM® or TDx® analyzers (Abbott Laboratories). For Acetaminophen and Amikacin COBAS® INTEGRA 700 was used as additional comparison instrument. The results are summarized in a table (table 6). Precision results are well acceptable with within-run CVs < 5% and total CVs < 6% except for Digitoxin and Digoxin which show a somewhat higher imprecision at low concentrations. Results obtained for Acetaminophen and Amikacin on COBAS® INTEGRA 400 and 700 show excellent agreement. A good comparability is also found between COBAS® INTEGRA 400 and AxSYM or TDx methods with slight systematic deviations for Acetaminophen, Amikacin and Free Phenytoin. The lower correlation coefficient for the digoxin method comparison can be attributed to two discrepant samples. Linearity throughout the range studied which covered > 80% of the measuring range was confirmed for the five assays tested (Digitoxin, Digoxin, Lidocaine, Free Phenytoin, Phenytoin) based on the acceptance criteria of ± 10% deviation of the measured values from the theoretical values. Based on the analytical performance of the TDM tests studied it can be concluded that the COBAS® INTEGRA 400 is very well suited for routine TDM analysis.