Forensic abstinence control with KIMS immunoassays for drugs of abuse and ethyl glucuronide in urine on a cobas c 501 analyzer

Merja A. Neukamm1, Arsham Bahrami1, Volker Auwärter2, Felix M. P. Mehne2 and Eva Höss2

1Institute of Forensic Medicine, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg
2Roche Diagnostics GmbH, Penzberg

Introduction

For the medico-psychological assessment (MPA) during driving license re-granting in Germany, abstinence control including urine samples is required. In these programs, even small amounts of markers for drug or alcohol abuse have to be detected. Thus, the concentrations of the target compounds are very low, and, in consequence, the sensitivity of the applied screening method has to be much higher than for clinical use. Modified drugs of abuse and ethyl glucuronide immunoassays were evaluated for precision, accuracy, on-board calibration stability, cross reactivity, sensitivity and specificity.

Kinetic interaction of microparticles in solution (KIMS)

No drugs in urine
Aggregation of microparticles
Light scattering

Experimental

Sensitivity, Specificity and Cut-offs

For sensitivity and specificity, the immunoassay values of at least 100 negative and 50 positive samples per substance class* were compared with the quantitative LC-MS/MS or GC-MS values using ROC (receiver operating characteristic) analysis. At least 10 positive samples for each of the MPA-target analytes were included.

Results

Calibration stability: 28 days for all analytes except amphetamines (21 days)

For on-board calibration stability, the low and middle quality control samples were analyzed with n = 5 repetitions at day 0 and with n = 1 repetitions at day 7, 14, 21, and 28. Inter-day precision and accuracy were determined with n = 20 repetitions each at five consecutive days. For cross reactivity, a Roche negative calibrator was spiked with one of the analytes at concentrations yielding immunoassay values within the calibration range of the assay.

Conclusion

The presented kinetic interaction of microparticles in a solution (KIMS) immunoassays on a cobas c 501 provide a new method to reliably detect drug or alcohol consumption in abstinence control programs requiring high sensitivity.

Literature


Contact

Merja A. Neukamm, Institute of Forensic Medicine, Forensic Toxicology, Albertstr. 9, D-79104 Freiburg, Germany
Fax +49 761 203 6827
merja.neukamm@uniklinik-freiburg.de

[Image of the cobas c501 analyzer]

[Image of sensitivity and specificity graph]

[Table of drug concentrations and detection rates]

[Diagram of kinetic interaction of microparticles]