Evaluation of KIMS immunoassays on a cobas c 501

for drugs of abuse and ethyl glucuronide
in urine and serum

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Introduction

Reliable urine screenings for drugs of abuse and alcohol consumption are essential for the implementation of abstinence control programs. For the medico-­psychological assessment (MPA) during driving license re-­grantsing a high sensitivity of the applied screening methods is highly important, as very low drug concentrations have to be detected. On the other hand, in clinical settings, drug intoxications have to be detected rapidly by analysis of blood/serum. Immunoassays are typically used for drug screenings and have to be adapted to the range of expected concentrations where appropriate.

Experimental

Sensitivity, Specificity and Cut-offs

For sensitivity and specificity, the IA-values of >100 negative and 50 positive samples per substance class* were compared with the quantitative LC–MS/MS or GC–MS values. Methadone: 22, EDDP: 28 positive samples. For the sensitivity the result of the confirmatory analysis was regarded as positive if the measured concentration reached or exceeded a concentration of 60% of the respective MPA limit (supposed measurement uncertainty 40%).

For precision and accuracy, a Roche negative calibrator was spiked with one of the analytes at concentrations yielding immunoassay values within the calibration range of the assay.

Cut-off

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Cut-off (ng/ml IA-units)

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Precision and Accuracy

Between +/- 12 % for low, middle and high quality controls (5 days, n = 20 each)

Calibration stability

28 days for all analytes except amphetamines (21 days)

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Cross reactivity

Cannabinoids %

-9-Carboxy-11-nor-Δ9 THC-glucuronide 34

11-Hydroxy-Δ9 THC 14

Opiates

Methadone 99

6-Acetylmorphine 71

Codeine-glucuronide 61

Dihydrocodeine 55

Morphone-6-glucuronide 47

Cocaine (metabolites)

Egoninmethylerster 0.003

Amphetamines (and NPS)

6-(2-Aminopropyl)-benzofuran 150

± MDA 130

± MDA 110

4-Fluoromethamphetamine 92

± MBDB-HCl 68

Amphetamine 46

Methenilidate 0.31

Methadone

Levomepromazine 4.3

EDDP

Methadone 0.033

Benzoalazepines

α-Hydroxyalprazolam 92

Flubromazolam 91

Oxazepam 76

α-Hydroxybromazepam 75

Lorazepam 70

7-Aminolflunitrazepam 66

Ethyl glucuronide

Ethyl sulfate 0.011

Conclusion

The modified KIMS immunoassays on a cobas c 501 can be applied to reliably and sensitively detect drug or alcohol consumption in abstinence control programs and drugs of abuse in clinical intoxication cases.

Literature


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