

Evaluation of KIMS immunoassays on a cobas c 501 analyzer 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-granting 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.

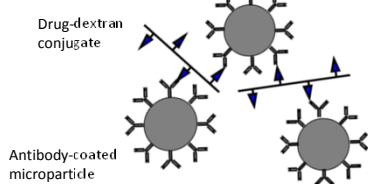


Roche cobas c 501

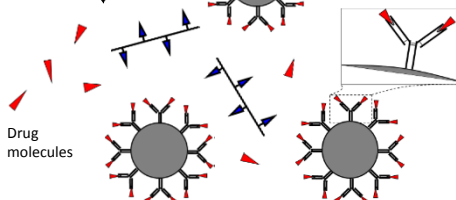
Experimental

Kinetic interaction of microparticles in solution (KIMS)

No drugs present
Aggregation of microparticles
Light scattering ↑



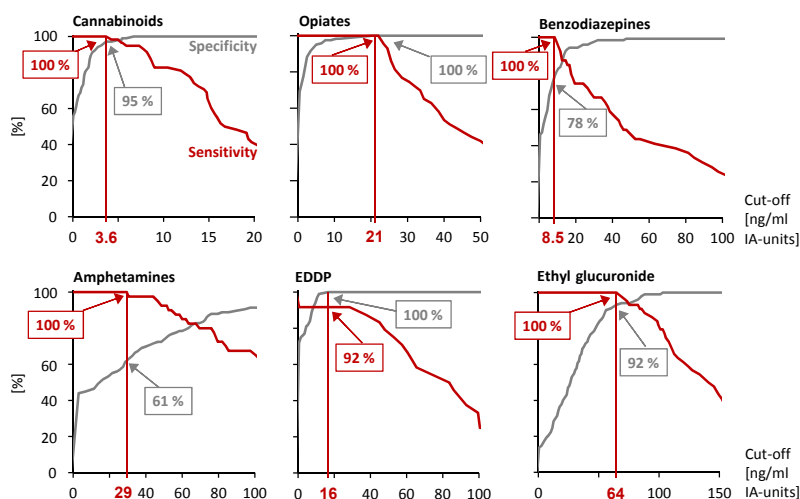
Drugs present
Inhibition of aggregation
Light scattering ↓



Parameters

Parameters	MPA limits	Clinical cut-offs
	Urine [ng/ml]	Serum [IA-units]
Cannabinoids	10	50
Opiates	25	-
Cocaine	30	300
Amphetamines	50	300
Methadone	50	300
Benzodiazepines	50	200
Barbiturates	-	200
Ethyl glucuronide	100	-

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%).

Precision and Accuracy

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

Calibration stability

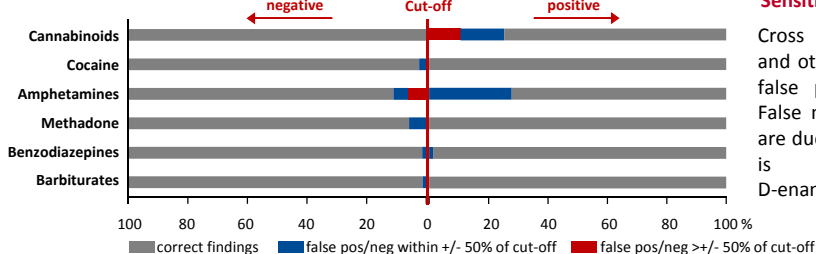
28 days for all analytes except amphetamines (21 days)

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.

Cross reactivity

Substance	%
Cannabinoids	
9-Carboxy-11-nor-Δ ⁹ THC-glucuronide	34
11-Hydroxy-Δ ⁹ THC	14
Opiates	
Morphine-3-glucuronide	38
Codeine	99
6-Acetylmorphine	71
Codeine-6-glucuronide	61
Dihydrocodeine	55
Morphine-6-glucuronide	47
Cocaine (metabolite)	
Ecgoninmethylester	0.003
Amphetamines (and NPS)	
6-(2-Aminopropyl)-benzofurane	150
± MDMA	130
± MDA	110
4-Fluoromethamphetamine	92
± MBDB-HCl	68
Amphetamine	46
Methylphenidate	0.31
Methadone	
Levomepromazine	4.3
EDDP	
Methadone	0.033
Benzodiazepines	
α-Hydroxyalprazolam	92
Flubromazolam	91
Oxazepam	76
α-Hydroxybromazepam	75
Lorazepam	70
7-Aminoflunitrazepam	66
Ethyl glucuronide	
Ethyl sulfate	0.011

Serum



Sensitivity and Specificity

Cross reactivity to THC metabolites and other cannabinoids might lead to false positive cannabinoid findings. False negative amphetamine findings are due to the applied antibody which is stereoselective for the D-enantiomers of the amphetamines.

n > 50 of positive and negative samples

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

M.A. Neukamm, A. Bahrami, V. Auwärter, F.M.P. Mehne, E. Höss: Evaluation of KIMS immunoassays on a **cobas c 501** analyzer for drugs of abuse and ethyl glucuronide testing in urine for forensic abstinence control, *Drug Testing and Analysis* 2017, 9, 1217-1223

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