

Validation of CEDIA and DRI drugs of abuse immunoassays for urine screening on a Thermo Scientific Indiko Plus analyser



UNIVERSITÄTS
KLINIKUM FREIBURG

Institute of Forensic Medicine
Forensic Toxicology



Katharina M. Köhler, Raija Hammer, Kathrin Riedy, Volker Auwärter and Merja A. Neukamm

Institute of Forensic Medicine, Forensic Toxicology, Medical Center – University of Freiburg, Germany

Introduction

Abstinence control for drugs of abuse and ethanol is often demanded for driving licence re-granting during medical and psychological assessment (MPA). For this purpose, a reliable screening method for urine samples is needed. Cloned Enzyme Donor Immuno Assays (CEDIA®) and DRI® immunoassays were validated on a Thermo Scientific Indiko Plus.

Experimental

Thermo Scientific Indiko Plus



Capacity: Up to 350
photometric tests / hour

On-Board Sample
capacity: Max. 54

Immunological tests

Cloned Enzyme Donor Immuno Assay (CEDIA®) Cannabinoids, Opiates, Cocaine, Amphetamine OFT, Methamphetamine OFT, Benzodiazepines

DRI® Ecstasy, Ethyl glucuronide

Validation

The immunological cut-offs were adapted to the minimum detectable concentrations required in the MPA guidelines (MPA cut-offs). Cut-off values and sensitivities were determined using real urine samples with confirmed concentrations of the analytes in the range of the required MPA-cut-offs (confirmation with GC-MS or LC-MS/MS), samples were diluted or spiked if necessary.

MPA cut-offs (ng/ml urine)

Cannabinoids THC-COOH **10** (after hydrolysis)

Opiates morphine (codeine, dihydrocodeine) **25** (after hydrolysis)

Cocaine benzoylecgonine **30**

Amphetamines amphetamine, methamphetamine, MDMA, MDEA, MDA **50**

Methadone EDDP **50**

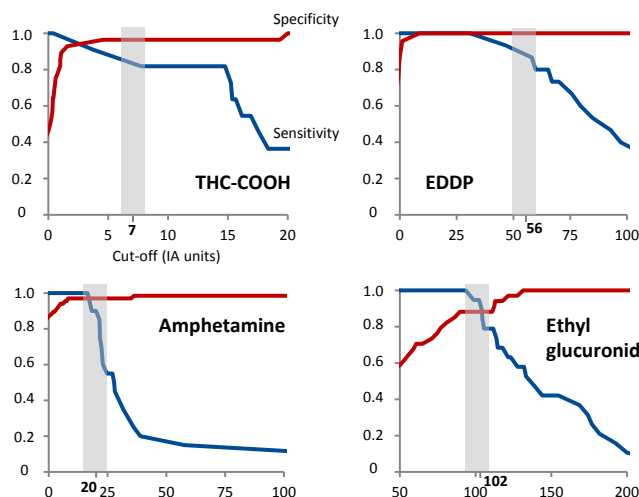
Benzodiazepines diazepam, nordazepam, oxazepam, hydroxylalprazolam, hydroxybromazepam, 7-aminoflunitrazepam **50**

Ethyl glucuronide **100**

Results

Cut-off selection

The forensic cut-off was chosen at the highest value resulting in a sensitivity higher or equal to 90 % (less than 10 % false negatives corresponding to the MPA cut-off).



Results

Sensitivity

Parameter	Cut-off	Sensitivity	N	Concentration range (ng/ml)
Cannabinoids	7	91%	28	2 – 19
Opiates	16	100%	27	3 – 75*
Benzoylecgonine	32	100%	42	3 – 40
Amphetamine	20	90%	32	7 – 92
Methamphetamine	30	100%	25	3 – 55
Ecstasy	34	100%	33	5 – 61
EDDP	56	93%	20	12 – 130
Benzodiazepines	48	95%	43	8 – 92**
Ethyl glucuronide	102	95%	32	70 – 190

Table 1) Cutoff given in IA units, N = number of samples, sensitivity = true positives / all positives, true positives = concentration above the MPA cut-off

* Morphine ** sum of benzodiazepines

Specificity

Parameter	Estimated specificity	N	Number of false positives
Cannabinoids	96%	28	1
Opiates	100%	22	0
Benzoylecgonine	100%	27	0
Amphetamine	97%	67	2
Methamphetamine	87%	23	3
Ecstasy	96%	23	1
EDDP	100%	23	0
Benzodiazepines	100%	31	0
Ethyl glucuronide	88%	34	4

Table 2) The specificity was estimated using confirmed negative urine samples.

estimated specificity: true negatives / all negatives

Quality controls

Within-run precision

Bias

Parameter	Target Concentration [ng/ml]			Precision (CV)			Bias		
	Low	Middle	High	Low	Middle	High	Low	Middle	High
Cannabinoids	9.5	12.5	16	2.4%	1.0%	0.9%	99%	113%	101%
Opiates	28	37.5	47	2.0%	1.4%	1.4%	102%	104%	107%
Benzoylecgonine	28	37.5	47	1.1%	2.9%	1.5%	118%	117%	125%
Amphetamine	20	25	50	3.8%	6.5%	2.5%	113%	110%	111%
Methamphetamine	50	37.5	78	1.5%	7.6%	0.7%	103%	82%	102%
Ecstasy	37.5	50	75	6.1%	4.1%	2.8%	103%	92%	107%
EDDP	37.5	50	75	6.1%	4.1%	2.8%	103%	92%	107%
Benzodiazepines	38	50	63	2.4%	2.3%	3.5%	103%	100%	101%
Ethyl glucuronide	75	100	375	4.8%	4.5%	0.9%	93%	103%	94%

Conclusion

The CEDIA® and DRI® assays on the Thermo Scientific Indiko Plus analyser show sufficient sensitivity with acceptable specificity and precision for drugs of abuse screening in urine and meet the German MPA requirements.

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Contact

Merja A. Neukamm, Institute of Forensic Medicine, Forensic Toxicology
Albertstr. 9, D-79104 Freiburg, Germany
merja.neukamm@uniklinik-freiburg.de