APPLICATION OF A NEW BIOCHIP ARRAY PLATFORM TO THE SIMULTANEOUS SCREENING OF DRUGS OF ABUSE IN URINE AND ORAL FLUID IN UNDER 20 MINUTES

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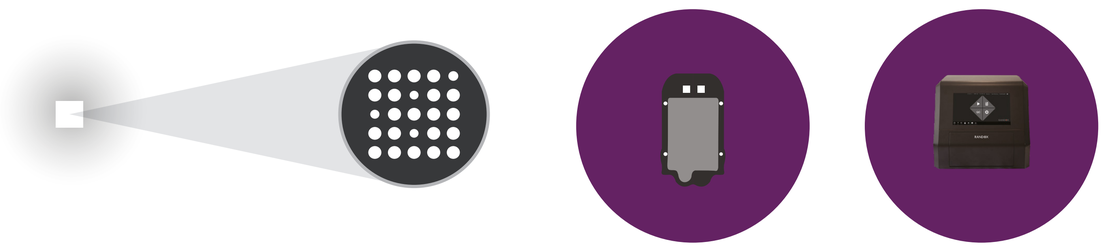
Introduction

Biochip array technology enables multi-analytical screening of drugs of abuse from a single undivided sample in under 20 minutes with the new biochip analyser Evidence MultiSTAT. This study reports the analytical evaluation of this application to the simultaneous screening of drugs of abuse in urine (creatinine included) and oral fluid.

Methodology

The DOA Array Urine and DoA Array Oral Fluid II were used (EV4193, EV4279, Randox Toxicology Ltd., Crumlin, UK), simultaneous competitive chemiluminescent immunoassays on a biochip surface were applied to the fully automated Evidence MultiSTAT analyser, which processes a self-contained cartridge containing all the components required for the assays (EV4115, Randox Toxicology Ltd, Crumlin, UK). Sampling against a cut-off sample, the results are qualitative. The NeoSal Oral Fluid Collection System was used for oral fluid (Neogen Corporation, Lansing, USA).



Biochip (9 mm x 9 mm) | Discrete Test Regions | MultiSTAT Cartridge | Fully Automated MultiSTAT analyser

Test Menu and Cut-Offs

DOA Array Urine

Cut-offs (Urine)			
Aanlyte	Cut-Off (ng/mL)	Analyte	Cut-off (ng/mL)
AB-PINACA	2.5	JWH-018	20
α-PVP	5	6-MAM	10
Amphetamine	200	Methadone	300
Barbiturates	200	Methamphetamine	200
Benzodiazepines I	150	Opiate	200
Benzodiazepines II	150	Oxycodone	50
Benzoylecgonine/Co-caine	150	THC	20
Buprenorphine	1	Tramadol	5
ETG	750	Tricyclic Antidepressants (TCA)	150
Fentanyl	2	UR-144	10
Creatinine	20 mg/dL		

DOA Array Oral Fluid II

Cut-offs (Oral Fluid)			
Aanlyte	Cut-Off (ng/mL)	Analyte	Cut-off (ng/mL)
α-PVP	2.5	LSD	1.5
Amphetamine	60	6-MAM	3
Barbiturates	60	Methadone	5
Benzodiazepines I	15	Methamphetamine	70
Benzodiazepines II	15	Opiate	15
Benzoylecgonine/Co-caine	30	Oxycodone	10
Buprenorphine	1.5	PCP	7
Fentanyl	1.5	Tramadol	5
JWH-018	20	THC	5
Ketamine	65	UR-144	25

Results

DOA Array Urine

Repeatability

Repeatability was determined by assessing control material prepared at the cut-off and at ±50% of the cut-off. Each sample was assessed against the cut-off material twice a day for 10 days, resulting in n=20 results for each sample. The percentage agreement was calculated for the number of samples that correctly reported negative and positive.

Assay		-50% cut-off	Cut-off	+50% cut-off	Agreement (%)
AB-PINACA	+	0	8	19	97.5
	-	20	12	1	
α-PVP	+	0	10	20	100
	-	20	10	0	
Amphetamine	+	0	7	20	100
	-	20	13	0	
Barbiturates	+	0	8	20	100
	-	20	12	0	
Benzodiazepines I	+	0	12	20	100
	-	20	8	0	
Benzodiazepines II	+	0	11	20	100
	-	20	9	0	
Benzoylecgonine/ Cocaine	+	0	12	20	100
	-	20	8	0	
Buprenorphine	+	0	8	20	100
	-	20	12	0	
ETG	+	0	8	19	97.5
	-	20	12	1	
Fentanyl	+	0	13	20	100
	-	20	7	0	
JWH-018	+	0	12	20	100
	-	20	8	0	
6-MAM	+	0	14	20	100
	-	20	6	0	
Methadone	+	0	12	20	100
	-	20	8	0	
Methamphetamine	+	0	12	20	100
	-	20	8	0	
Opiate	+	0	12	20	100
	-	20	8	0	
Oxycodone	+	0	7	20	100
	-	20	13	0	
THC	+	0	14	20	100
	-	20	6	0	
Tramadol	+	0	12	20	100
	-	20	8	0	
TCA	+	0	11	20	100
	-	20	9	0	
UR-144	+	0	9	20	100
	-	20	11	0	
Creatinine	+	0	10	20	100
	-	20	10	0	

Accuracy

Accuracy was determined by assessing spiked samples at varying concentrations (50 spiked positive samples prepared at concentrations greater than the cut-off, 10 negative spiked samples prepared at concentrations lower than the cut-off and 40 blank negative samples). Each sample was assessed against the cut-off material to determine a positive or negative result. The percentage agreement was calculated as the percentage of correct reports out of the total number of samples analysed (n=100).

Assay		Spike +	Spike -	Agreement (%)
AB-PINACA	+	50	0	100
	-	0	50	
α-PVP	+	50	0	100
	-	0	50	
Amphetamine	+	50	0	100
	-	0	50	
Barbiturates	+	50	0	100
	-	0	50	
Benzodiazepines I	+	50	0	100
	-	0	50	
Benzodiazepines II	+	50	0	100
	-	0	50	
Benzoylecgonine/ Cocaine	+	50	0	100
	-	0	50	
Buprenorphine	+	46	0	96
	-	4	50	
ETG	+	50	0	100
	-	0	50	
Fentanyl	+	50	0	100
	-	0	50	
JWH-018	+	50	0	100
	-	0	50	
6-MAM	+	50	0	100
	-	0	50	
Methadone	+	50	0	100
	-	0	50	
Methamphetamine	+	50	0	100
	-	0	50	
Opiate	+	50	0	100
	-	0	50	
Oxycodone	+	50	0	100
	-	0	50	
THC	+	44	0	94
	-	6	50	
Tramadol	+	50	0	100
	-	0	50	
TCA	+	50	0	100
	-	0	50	
UR-144	+	50	0	100
	-	0	50	
Creatinine	+	100	0	100
	-	0	50	

EV4193 180618 pl

DOA Array Oral Fluid II

Repeatability

Control material prepared at the cut-off and ±50% cut-off was assessed. Each sample was assessed against the cut-off material twice a day for 10 days (n=80 for each sample). The percentage agreement was calculated for the number of samples that reported negative and positive correctly.

Assay		-50% cut-off	Cut-off	+50% cut-off	Agreement (%)
α-PVP	+	0	34	79	99.4
	-	80	46	1	
Amphetamine	+	0	36	80	100
	-	80	44	0	
Barbiturates	+	0	45	80	100
	-	80	35	0	
Benzodiazepines I	+	0	42	80	100
	-	80	38	0	
Benzodiazepines II	+	0	30	80	100
	-	80	50	0	
Benzoylecgonine/ Cocaine	+	0	38	80	100
	-	80	42	0	
Buprenophine	+	0	37	79	99.4
	-	80	43	1	
Fentanyl	+	0	69	80	100
	-	80	11	0	
JWH-018	+	0	47	80	100
	-	80	33	0	
Ketamine	+	0	58	79	99.4
	-	80	22	1	
LSD	+	0	37	80	100
	-	80	43	0	
6-MAM	+	1	61	79	98.6
	-	79	9	1	
Methadone	+	0	74	80	100
	-	80	6	0	
Methamphetamine	+	0	59	80	100
	-	80	21	0	
Opiate	+	0	60	80	100
	-	80	20	0	
Oxycodone	+	1	15	80	99.4
	-	79	65	0	
PCP	+	0	37	79	99.4
	-	80	43	1	
Tramadol	+	0	73	80	100
	-	80	7	0	
THC	+	0	53	80	100
	-	80	27	0	
UR-144	+	0	12	80	100
		80	68	0	

Accuracy

Spiked samples at varying concentrations were assessed (50 spiked positive samples prepared at concentrations >cut-off, 10 negative spiked samples prepared at concentrations <cut-off and 40 blank negative samples). Each sample was assessed against the cut-off material to determine a positive or negative result. The percentage agreement was calculated as the percentage of correct reports out of the total number of analysed samples (n=100).

Assay		Spike +	Spike -	Agreement (%)
α-PVP	+	50	0	100
	-	0	50	
Amphetamine	+	50	0	100
	-	0	50	
Barbiturates	+	50	0	100
	-	0	50	
Benzodiazepines I	+	50	0	100
	-	0	50	
Benzodiazepines II	+	49	0	99
	-	1	50	
Benzoylecgonine/ Cocaine	+	49	0	99
	-	1	50	
Buprenophine	+	49	0	99
	-	1	50	
Fentanyl	+	50	0	100
	-	0	50	
JWH-018	+	50	10	90
	-	0	40	
Ketamine	+	45	0	95
	-	5	50	
LSD	+	50	0	100
	-	0	50	
6-MAM	+	50	1	99
	-	0	49	
Methadone	+	50	0	100
	-	0	50	
Methamphetamine	+	50	0	100
	-	0	50	
Opiate	+	50	0	100
	-	0	50	
Oxycodone	+	49	0	99
	-	1	50	
PCP	+	49	0	99
	-	1	50	
Tramadol	+	50	0	100
	-	0	50	
THC	+	50	2	98
	-	0	48	
UR-144	+	50	0	100
	-	0	50	

EV4279 010218 ml

Conclusion

Data indicate optimal analytical performance and applicability of the Evidence MultiSTAT system to the simultaneous screening of drugs of abuse in <20 minutes in urine and oral fluid.