

NEW BIOCHIP ARRAY PLATFORM FOR THE SIMULTANEOUS SCREENING OF DRUGS OF ABUSE IN ORAL FLUID IN UNDER 20 MINUTES

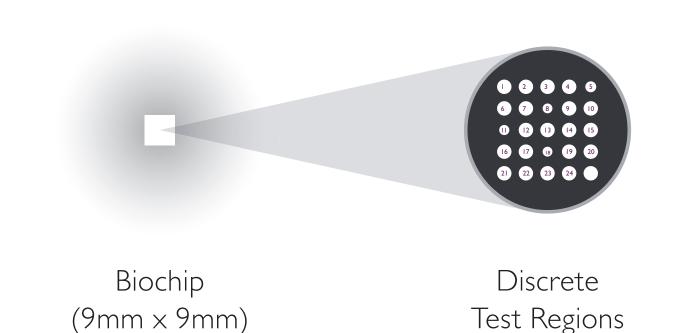
Darragh J., Anderson V., Vance P., Cardwell S., Doone D., Dicks J., Speers A., Dyttus O., Rodríguez M.L., Benchikh M.E., McConnell R.I., FitzGerald S.P. Randox Toxicology Ltd, 55 Diamond Road, Crumlin, County Antrim BT294QY, United Kingdom e-mail: scientific.publications@randox.com

Introduction

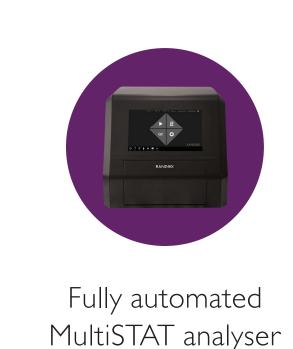
Oral fluid collection is quick, simple, non-invasive and can be easily observed. Biochip array technology enables multi-analytical screening of drugs of abuse from a single oral fluid sample in under 20 minutes with the new biochip analyser Evidence MultiSTAT, which leads to drug test consolidation and time and labor effective screening. This study reports the analytical evaluation of this application.

Methodology

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. Sampling against a cut-off sample, the results are qualitative.







Results

Cut-offs

Matrix: oral fluid

Assay	Cut-off	Assay	Cut-off
α-PVP	2 ng/mL	6-MAM	2 ng/mL
Amphetamine	50 ng/mL	Methadone	4 ng/mL
Barbiturates	50 ng/mL	Methamphetamine	50 ng/mL
Benzodiazepines I	10 ng/mL	Opiates	10 ng/mL
Benzodiazepines II	10 ng/mL	Oxycodone	8 ng/mL
BZG/Cocaine	20 ng/mL	PCP	5 ng/mL
Buprenorphine	I ng/mL	THC	2 ng/mL
Fentanyl	I ng/mL	Synthetic Cannabinoids (JWH-018)	5 ng/mL
Ketamine	50 ng/mL	Synthetic Cannabinoids (UR-144)	10 ng/mL
LSD	I ng/mL	Tramadol	4 ng/mL

Accuracy

Assessment of spiked samples at different concentrations: 50 negative samples spiked at concentrations >cut-off, I0 negative samples spiked at concentrations <cut-off and 40 blank negative samples.

The agreement (%) was calculated as the percentage of correct report

The agreement (%) was calculated as the percentage of correct reports out of the total number of samples analysed (n=100).

Assay		Spike +	Spike -	Agreement (%)	Assay		Spike +	Spike -	Agreement (%)
lpha-PVP	+	50	0	100	100 6-MAM	+	50		99
	-	0	50			-	0	49	
Amphetamine	+	50	0	100	Methadone	+	50	0	100
I	-	0	50			-	0	50	
Barbiturates	+ 50 0 Tes 100 Methamphetamine	Methamphetamine	+	50	0	100			
	-	0	50		l	-	0	50	. 0 0
Benzodiazepines I	+	50	0	100	00 Opiates	+	50	0	100
201.20 010.20 011.00 1	-	0	50			-	0	50	100
Benzodiazepines II	+	50	0	100 Oxycodone	+	49	0	99	
201120 d1020p11100 11	-	0	50		O/Y COGOTIC	-	I	50	
BZG/Cocaine	+	49	0	99	PCP	+	50	0	99
	-	I	50			-	0	50	• •
Buprenorphine	+	49	0	99	99 THC	+	50	0	100
2 s.p. 3.73. p.m.3	-	1	50	, ,		-	Ο	50	. 00
+ Fentanyl	+	50	0	100	Synthetic Cannabinoids (JWH-018)	+	50	0	100
. 6 66 7 .	-	0	50	. • •		-	0	50	
+ Ketamine	+	50	Ī	100	Synthetic Cannabinoids	+	50	0	100
	- 0 49 (UR-144)	-	0	50	. 3 3				
LSD	+	50	0	100	Tramadol	+	50	0	100
	_	0	50	100		_	0	50	100

Precision

Assessment of control material prepared at the cut-off and $\pm 50\%$ of the cut-off. Each sample was assessed twice a day for 10 days on 2 different analysers (n=80). The agreement (%) was calculated for the number of samples that reported negative and positive correctly.

Assay		<50%	Cut-off	>50%	Agreement (%)
α-PVP	+	0	34	79	99.4
	- +	80 0	46 36	80	
Amphetamine	-	80	44	0	100
Darbituratos	+	0	45	80	LOO
Barbiturates	-	80	35	0	100
Benzodiazepines I	+	0	42	80	100
	- +	80	38	0 80	
Benzodiazepines II	_	80	50	0	100
BZG/Cocaine	+	0	38	80	100
bZG/Cocaine	-	80	42	Ο	100
Buprenorphine	+	0	37	79	99.4
	+	80 0	43 69	80	
Fentanyl	-	80		0	100
V atamain a	+	0	58	79	00.4
Ketamine	-	80	22	I	99.4
LSD	+	0	37	80	100
	- +	80	43 61	0 79	
6-MAM	_	79	9		99
Matlandana	+	0	74	80	100
Methadone	-	80	6	0	100
Methamphetamine	+	0	59	80	100
	- +	80 0	2 I 60	0 80	
Opiates	_ _	80	20	0	100
	+		15	80	00.4
Oxycodone	-	79	65	Ο	99.4
PCP	+	0	37	79	99.4
	- +	80	43 53	80	
THC	_	80	27	0	100
Cynthatic Canadain aide	+	0	47	80	
Synthetic Cannabinoids (JWH-018)	-	80	33	0	100
Synthetic Cannabinoids	+	0	12	80	100
(UR-144)	-	80	68	0	
Tramadol	+	0	73	80	100
	-	80	/	0	
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Authentic oral fluid samples assessment

n=90	Evidence MultiSTAT						
Assay			+	-	Agreement (%)		
Amphetamine (cut-off: 50 ng/mL)	LC/MS	+ -	I 5	0 84	94		
Benzodiazepines (cut-off: 10 ng/mL)	LC/MS	+ -	10 4	T 75	94		
BZG/Cocaine (cut-off: 20 ng/mL)	LC/MS	+ -	30 I I	2 47	86		
6-MAM (cut-off: 2 ng/mL)	LC/MS	+ -	52 9	0 29	90		
Methadone (cut-off: 4 ng/mL)	LC/MS	+ -	64 2	0 24	98		
Methamphetamine (cut-off: 50 ng/mL)	LC/MS	+ -	0	0 90	100		
Opiates (cut-off: 2 ng/mL)	LC/MS	+ -	55 8	0 27	91		

Conclusion

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Data indicate that the Evidence MultiSTAT system enables simultaneous screening of twenty drug classes in <20 minutes in oral fluid with extremely sensitive cut-offs and reproducible and accurate qualitative results.