

## Introduction

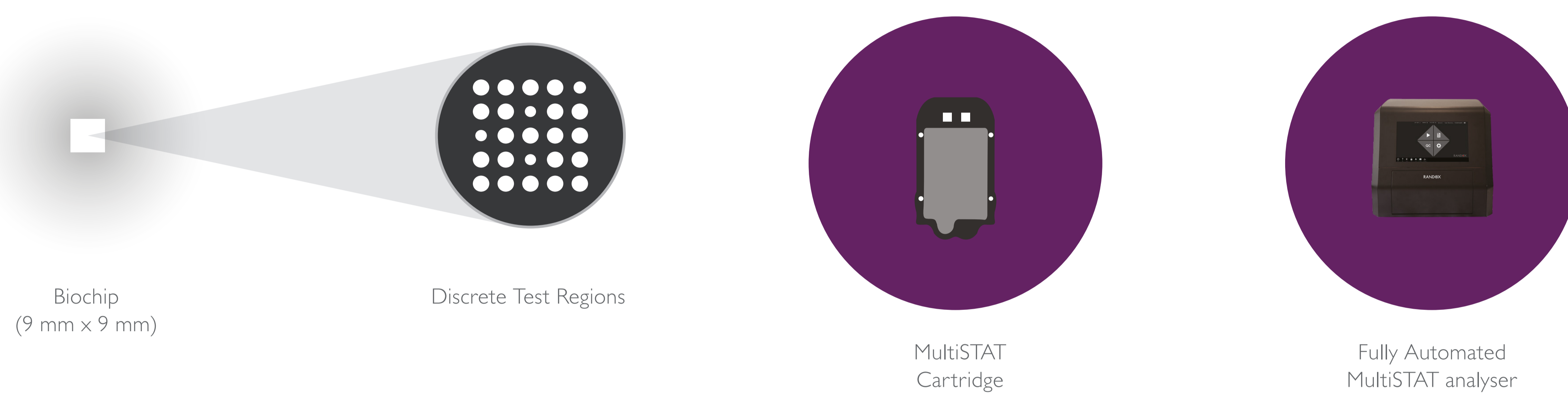
Rapid drug screening is of vital importance in the drug testing process. Biochip array technology allows multi-analytical screening, which increases the screening capacity. By applying this technology to the biochip analyser Evidence MultiSTAT, multiple drugs of abuse [AB-PINACA, alpha-pyrrolidinopentiophenone (alpha-PVP), amphetamine, barbiturates, benzodiazepines, benzoylecgonine/cocaine, buprenorphine, ethyl glucuronide (ETG), fentanyl, 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 6-monoacetylmorphine (6-MAM), methadone, methamphetamine, opiate, oxycodone, tramadol, tetrahydrocannabinol (THC), UR-144 and creatinine] are simultaneously detected from a single urine sample in under 20 minutes.

Optimal repeatability and accuracy of the system were previously reported. This study presents data from the screening of authentic urine samples (including positive and negative samples) using this new biochip platform.

## Methodology

Simultaneous competitive chemiluminescent immunoassays on a biochip surface applied to the Evidence MultiSTAT analyser were employed. Sampling 25µl of urine against a cut-off sample, the results obtained are qualitative.

Different authentic urine sample sets from a rehabilitation center in USA (set1 n=30, set2 n=98 and set3 n=52) were assessed. A qualitative result was determined for each of the drug classes and the results presented as percentage agreement to liquid chromatography tandem mass spectrometry (LC-MS/MS).



## Results

The multi-analytical screening of authentic samples (including positive and negative samples) showed the following percentage agreement with LC-MS/MS:

### Authentic Samples Set 1

Set 1 (n=30)							
Assay	MultiSTAT cut-offs (ng/mL)	LC-MS/MS cut-offs (ng/mL)	Positive/positive	Positive/negative	Negative/positive	Negative/negative	Agreement (%)
Amphetamine	200	300	1	2	0	27	<b>93</b>
Benzodiazepines	150	200	3	1	0	26	<b>97</b>
Benzoylecgonine/cocaine	150	100	21	4	2	3	<b>80</b>
Buprenorphine	1	10	0	0	2	28	<b>93</b>
Methadone	300	200	2	1	0	27	<b>97</b>
Methamphetamine	200	1000	1	2	0	27	<b>93</b>
Opiate	200	100	9	1	0	20	<b>97</b>
Oxycodone	50	100	7	0	0	23	<b>100</b>
THC	20	40	18	2	0	10	<b>93</b>

Screening of samples set 1 for 6-MAM showed that the samples were negative for this drug with 100% agreement between MultiSTAT platform (cut-off: 10 ng/mL) and a commercially available urine dip test (cut-off: 2 ng/mL).

### Authentic Samples Set 2

Set 2 (n=98)							
Assay	MultiSTAT cut-offs (ng/mL)	LC-MS/MS cut-offs (ng/mL)	Positive/positive	Positive/negative	Negative/positive	Negative/negative	Agreement (%)
α-PVP	5	5	2	2	0	94	<b>98</b>
Amphetamine	200	200	3	1	0	94	<b>99</b>
Barbiturates	200	200	0	0	0	98	<b>100</b>
Benzodiazepines 1	150	150	0	1	0	97	<b>99</b>
Benzodiazepines 2	150	150	0	0	0	98	<b>100</b>
Benzoylecgonine/cocaine	150	150	54	7	0	37	<b>93</b>
Buprenorphine	1	1	0	0	0	98	<b>100</b>
Fentanyl	2	2	3	0	0	95	<b>100</b>
JWH-018	20	20	0	0	0	98	<b>100</b>
6-MAM	10	10	2	0	0	96	<b>100</b>
Methadone	300	300	9	0	0	89	<b>100</b>
Methamphetamine	200	200	1	1	0	96	<b>99</b>
Opiate	200	200	5	0	0	93	<b>100</b>
Oxycodone	50	50	12	1	0	85	<b>99</b>
Tramadol	5	5	0	0	0	98	<b>100</b>
THC	20	15	51	18	0	29	<b>82</b>

### Authentic Samples Set 3

Set 3 (n=52)							
Assay	MultiSTAT cut-offs (ng/mL)	LC-MS/MS cut-offs (ng/mL)	Positive/positive	Positive/negative	Negative/positive	Negative/negative	Agreement (%)
Benzodiazepines	150	150	0	5	0	47	<b>90</b>
Benzoylecgonine/cocaine	150	150	32	2	0	18	<b>96</b>
Methadone	300	300	4	0	0	48	<b>100</b>
Methamphetamine	200	200	3	1	0	48	<b>98</b>
Opiate	200	200	11	0	0	41	<b>100</b>
THC	20	15	35	0	0	17	<b>100</b>

17.082.127RDF, 18.183.127RDF, 18.184.127RDF

All samples screened positive for creatinine (> 20mg/dL) indicating that no sample dilution occurred.

## Conclusion

The data indicate favorable agreement of biochip array technology applied to the Evidence MultiSTAT with LC-MS/MS. By using this biochip platform, multiple drugs of abuse and creatinine can be screened in less than 20 minutes from a single urine sample. This system represents a reliable new analytical tool for urine drug testing.