DRUGS OF ABUSE ARRAY ORAL FLUID II

—evidence—
MULTISTAT

INTENDED USE

The Evidence MultiSTAT DOA Oral Fluid II Assays are tests for the qualitative determination of the parent molecule and metabolites of drugs in human oral fluid. They are competitive enzyme immunoassays run on the automated biochip array analyser, Evidence MultiSTAT.

FOR FORENSIC USE ONLY. Not for use in diagnostic procedures

The Evidence MultiSTAT DOA Oral Fluid II Assays provide only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method[1]. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Cat. No. EV4279

Containing the following components:

1.	Oral Fluid Test Cartridge	12 x 1 Cartridge
2.	Oral Fluid Cut Off	6 x 1 ml
3.	Oral Fluid Positive Control	4 x 1 ml
4.	Reconstitution Buffer	2 x 10 ml
5.	Sample Droppers	24 x Dropper

Cat. No. EV4116

Containing the following components:

1.	MultiSTAT Tip Cartridge	12 x 1 Tip Cartridge

CLINICAL SIGNIFICANCE

Drug abuse in any form gives rise to serious negative consequences not only for the abuser by devastating their mental and physical health, but also to the whole of society. It is an indirect and direct cause of many crimes and also in the spread of diseases. It is very costly, with costs related to crimes, medical care, treatment and welfare programs for addicted individuals and wasted working hours [1]. Oral fluid can provide a quick and non-invasive specimen for drug testing [2], with its usefulness as an aid in clinical diagnosis and for therapeutic drug monitoring now established [3]. It offers the advantage of less potential for sample adulteration and substitution [2] and in many cases drug in oral fluid represents the physiologically active fraction. Oral fluid testing has been successfully used as an alternative to blood testing in pharmacokinetic and pharmacotoxicologic studies [3].

PRINCIPLE

The Evidence MultiSTAT analyser is a fully automated Biochip Array System. It performs simultaneous detection of multiple analytes from a single sample. The core technology is the Randox Biochip, a solid-state device containing an array of discrete test regions containing immobilized antibodies specific to different DOA compound classes. A competitive chemiluminescent immunoassay is employed for the DOA assays with the drug in the specimen and drug labelled with horseradish peroxidase (HRP) being in direct competition for the antibody binding sites. Increased levels of drug in a specimen will lead to reduced binding of drug labelled with HRP and thus a reduction in chemiluminescence being emitted.

The light signal generated from each of the test regions on the biochip is detected using digital imaging technology and compared to that from the cut

off material. The classification of test analyte present in the sample is determined from the cut off material.

LIMITATION

Note: Please store MultiSTAT cartridges with label facing upwards.

- If this is not adhered to the integrity of the cartridge may be compromised and could impact on test results.
- Visually check the cartridge foil for evidence of moisture or damage to the foil seal.
- If there is any concern that the integrity of the cartridge has been compromised, do not use and contact Randox Toxicology Support.
- The Evidence MultiSTAT DOA Oral Fluid II Array is designed for use only with human oral fluid samples collected using the Neosal Oral Fluid Collection Device (Neogen).
- There is a possibility that other substances and/or factors may interfere with the assays and cause erroneous results (e.g. technical or procedural errors).
- These assays have been designed to reduce HAMA and other heterophilic antibodies interference. However, HAMA and other heterophilic antibodies can react with the immunoglobulins included in the assay components. Clinical consideration and professional judgement should be applied to any drugs of abuse oral fluid qualitative test result.

SPECIMEN COLLECTION AND PREPARATION

- The Evidence MultiSTAT DOA Oral Fluid II Array is designed for use with human oral fluid samples collected using the Neosal Oral Fluid Collection Device.
- Sample preparation should be carried out in accordance with the collection tube manufacturer's recommendations.

SAMPLE STORAGE AND STABILITY

- If specimens are not to be analysed immediately, they should be frozen in small aliquots at –20°C. Repeat freeze/thaw cycles should be avoided.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* human forensic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Wash buffer and Reconstitution buffer contain preservative. Avoid ingestion or contact with skin or mucous membranes.

Human samples should be handled and treated as if they are potentially infectious.

Please dispose of all biological and chemical materials according to local guidelines.

Health and Safety data sheets are available on request.

On opening the cartridge foil bag, visually check the cartridge for evidence of moisture and the cartridge foil for signs of tearing. If there is any concern that the integrity of the cartridge has been affected, do not use and contact Randox Toxicology Support.

REAGENT COMPOSITION

1. **MultiSTAT DOA ORAL FLUID ASSAY DILUENT**
   20 mM phosphate buffer, pH 7.2 containing protein, detergents and preservatives. This is contained within the cartridge.
2. **MultiSTAT DOA ORAL FLUID CONJUGATE**
   20 mM Tris based buffer, pH 7.0 containing protein, preservatives and horseradish peroxidase - labelled drug derivatives. This is contained within the cartridge.
3. **MultiSTAT DOA ORAL FLUID BIOCHIP**
   Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.
4. **MultiSTAT DOA ORAL FLUID WASH BUFFER**
   20 mM Tris buffered saline, pH 7.4, containing surfactant and preservatives. This is contained within the cartridge.
5. **LUM-EV934/PX**
   Luminol-EV934 and Peroxide are contained within the cartridge and are mixed in a ratio of 1:1 by the analyser to give the working signal reagent-EV919.
6. **MultiSTAT DOA ORAL FLUID CUT OFF**
   Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.
7. **MultiSTAT DOA ORAL FLUID POSITIVE CONTROL**
   Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.
8. **MultiSTAT RECONSTITUTION BUFFER**
   A solution at a neutral pH containing preservatives.

STABILITY AND PREPARATION OF REAGENTS

1. **MultiSTAT DOA ORAL FLUID II TEST CARTRIDGE**
   The test cartridge is ready for use and is stable up to the expiry date when stored at +2°C to +8°C, protected from light. Test cartridges must be brought to room temperature for at least 30 minutes before opening.
2. **MultiSTAT DOA ORAL FLUID CUT OFF**
   Lyophilised cut offs are stable until the expiry date when stored unopened, at +2 to +8°C. Open the vial very carefully, avoiding any loss of material. Reconstitute in 1ml of accurately measured reconstitution buffer. Replace the rubber stopper, close vial and leave upright for 30 minutes out of bright light before use. Ensure that contents are completely dissolved by swirling gently. Following reconstitution ensure that the cut off is stored upright and does not come in contact with the bung or plastics. Once reconstituted the cut off material is stable for 14 days when stored at +2 to +8°C.
3. **MultiSTAT DOA ORAL FLUID POSITIVE CONTROL**
   Lyophilised positive controls are stable until the expiry date when stored unopened, at +2 to +8°C. Open the vial very carefully, avoiding any loss of material. Reconstitute in 1ml of accurately measured reconstitution buffer. Replace the rubber stopper, close vial and leave upright for 30 minutes out of bright light before use. Ensure that contents are completely dissolved by swirling gently. Following reconstitution ensure that the positive control is stored upright and does not come in contact with the bung or plastics. Once reconstituted the cut off material is stable for 14 days when stored at +2 to +8°C.
4. **MultiSTAT RECONSTITUTION BUFFER**
   Reconstitution Buffer is ready for use and is stable up to the expiry date when stored at +2 to +8°C protected from light.

PROCEDURE

BATCH UPDATE FROM USB

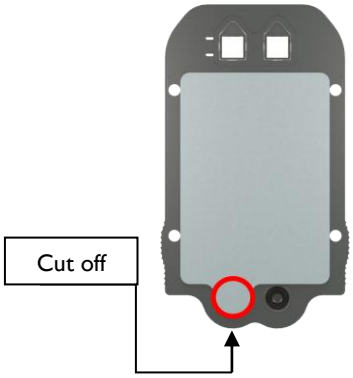
Upon receipt of a new batch of EV4279, a batch specific update will have to be completed from the USB provided:

- Scan the cartridge barcode – when scanned for the first time this will prompt the user to import the batch details from the provided USB.
- Insert the USB in to the USB port located on the bottom right hand side of the analyser below the power button.
- Once the USB has been connected select the import data button on screen.
- Select the batch update and select OK.
- A loading screen will appear briefly and the batch update will now be complete.
- For each batch, an initial 'Batch QC' must be run on the analyser, this will consist of running the provided cut off and positive control material as indicated in the assay protocol section.

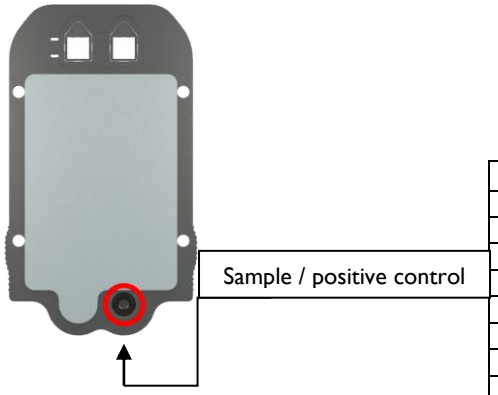
For further information please refer to the Evidence MultiSTAT Operators Manual.

ASSAY PROTOCOL

1. Pierce the foil and pipette a minimum of 200 µl of cut off into the left foil covered well as indicated below.



2. Pipette a minimum of 200 µl of sample / positive control into the open sample well on the right as indicated below.



3. The cartridge is now ready to be inserted carefully into the Evidence MultiSTAT analyser along with a new tip cartridge (Catalogue Number EV4116) ready for analysis.

CARTRIDGE ANALYSIS

Please refer to the Operators Manual for general operating procedure.

RESULTS PROCESSING

Results are processed automatically using the dedicated software. The 4-fold dilution applied by the Neosal Oral Fluid Collection Device has been accounted for in the cut off material provided.

NOTE: Cut-off concentrations are for the neat sample assuming that a 4-fold sample dilution has been applied as per the Neosal Oral Fluid Collection Device.

MATERIALS PROVIDED

1.	Oral Fluid Test Cartridge	12 x 1 Cartridge
2.	Oral Fluid Cut Off	6 x 1 ml
3.	Oral Fluid Positive Control	4 x 1 ml
4.	Reconstitution Buffer	2 x 10 ml
5.	Sample Droppers	24 x Dropper

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipette
2. Neosal Oral Fluid Collection Device (NEOGEN Cat No: 128101-25)

QUALITATIVE ANALYSIS

Each test sample is assayed against the provided cut off material of known concentration which is used to determine the classification of the samples. (Refer to Evidence MultiSTAT Operators Manual for additional information.)

QUALITY CONTROL

Evidence MultiSTAT® DOA Oral Fluid II Positive Control Material is provided with the kit and is required to run the initial batch QC upon receipt of the kit, following this the Batch QC should be repeated at 30-day intervals. The positive control material can be assayed more frequently at the discretion of the user. Control results should be acceptable, otherwise corrective action should be taken as established by laboratory guidelines.

INSTRUMENT SETTINGS

Instrument settings are included in the batch update.

CUT OFF MATERIAL

In order to provide a qualitative result for a sample it must be assayed against a cut off of known concentration. Table 1 indicates the cut off concentrations for each of the assays on the Evidence MultiSTAT DOA Oral Fluid II Array. The cut off material has been prepared to account for the 4-fold sample dilution applied by the Neosal Oral Fluid Collection Device. The values shown below equate to the cut off in a neat sample.

Table 1. Cut Off Concentrations for the Evidence MultiSTAT DOA Oral Fluid II Array.

Assay	Cut Off
Fentanyl	1.5ng/ml
Ketamine	65ng/ml
LSD	1.5ng/ml
Methamphetamine	70ng/ml
Barbiturates	60ng/ml
Benzodiazepines I	15ng/ml
Benzodiazepines II	15ng/ml
Methadone	5ng/ml
Opiate	15ng/ml
PCP	7ng/ml
BZG/Cocaine	30ng/ml
Oxycodone	10ng/ml
Tramadol	5ng/ml
Cannabinoids (THC)	5ng/ml
Amphetamine	60ng/ml
Buprenorphine	1.5ng/ml
6-MAM	3ng/ml
Synthetic Cannabinoids (JWH-018)	20ng/ml
alpha-PVP	2.5ng/ml
Synthetic Cannabinoids (UR-144)	25ng/ml

REPEATABILITY

The repeatability for all analytes on the Evidence MultiSTAT DOA Oral Fluid II array 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 on 2 different analysers across 2 batches of reagents resulting in n=80 results for each sample. The % agreement is calculated for the number of samples that reported negative and positive correctly as shown in Table 2.

Table2. Repeatability of Evidence MultiSTAT DOA Oral Fluid II Array.

ASSAY		-50%	CUT OFF	+50%	% AGREE
FENT	+	0	69	80	100
	-	80	11	0	
KET	+	0	58	79	99.4
	-	80	22	1	
LSD	+	0	37	80	100
	-	80	43	0	
MAMP	+	0	59	80	100
	-	80	21	0	
BARB	+	0	45	80	100
	-	80	35	0	
BENZ I	+	0	42	80	100
	-	80	38	0	
BENZ II	+	0	30	80	100
	-	80	50	0	
MDONE	+	0	74	80	100
	-	80	6	0	
OPI	+	0	60	80	100
	-	80	20	0	
PCP	+	0	37	79	99.4
	-	80	43	1	
BZG	+	0	38	80	100
	-	80	42	0	
OXY	+	1	15	80	99.4
	-	79	65	0	
TRM	+	0	73	80	100
	-	80	7	0	
THC	+	0	53	80	100
	-	80	27	0	
AMP	+	0	36	80	100
	-	80	44	0	
BUP	+	0	37	79	99.4
	-	80	43	1	
6-MAM	+	1	61	79	98.6
	-	79	9	1	
JWH-018	+	0	47	80	100
	-	80	33	0	
α-PVP	+	0	34	79	99.4
	-	80	46	1	
UR-144	+	0	12	80	100
	-	80	68	0	

LIMIT OF DETECTION

The limit of detection for all analytes on the Evidence MultiSTAT DOA Oral Fluid II array was established by analysing 20 negative human oral fluid samples collected using the Neosal Oral Fluid Collection Device. Each sample was prepared following the manufactures instruction and assessed against the cut off material to determine a positive or negative result as shown in Table 3.

Table 3. Limit of Detection of the Evidence MultiSTAT DOA Oral Fluid II Array.

ASSAY	REPORT POSITIVE	REPORT NEGATIVE
FENT	0	20
KET	0	20
LSD	0	20
MAMP	0	20
BARB	0	20
BENZ I	0	20
BENZ II	0	20
MDONE	0	20
OPI	0	20
PCP	0	20
BZG	0	20
OXY	0	20
TRM	0	20
THC	0	20
AMP	0	20
BUP	0	20
6-MAM	0	20
JWH-018	0	20
α-PVP	0	20
UR-144	0	20

ACCURACY

The accuracy for all analytes on the Evidence MultiSTAT DOA Oral Fluid II Array 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 % agreement was calculated as the % of correct reports out of the total number of samples (n=100) analysed, as shown in Table 4.

Table 4. Accuracy of the Evidence MultiSTAT DOA Oral Fluid II Array.

ASSAY		SPIKE +	SPIKE -	% AGREE
FENT	+	50	0	100
	-	0	50	
KET	+	45	0	95
	-	5	50	
LSD	+	50	0	100
	-	0	50	
MAMP	+	50	0	100
	-	0	50	
BARB	+	50	0	100
	-	0	50	
BENZ I	+	50	0	100
	-	0	50	
BENZ II	+	49	0	99
	-	1	50	
MDONE	+	50	0	100
	-	0	50	
OPI	+	50	0	100
	-	0	50	
PCP	+	49	0	99
	-	1	50	
BZG	+	49	0	99
	-	1	50	
OXY	+	49	0	99
	-	1	50	
TRM	+	50	0	100
	-	0	50	
THC	+	50	2	98
	-	0	48	
AMP	+	50	0	100
	-	0	50	
BUP	+	49	0	99
	-	1	50	
6-MAM	+	50	1	99
	-	0	49	
JWH-018	+	50	10	90
	-	0	40	
α-PVP	+	50	0	100
	-	0	50	
UR-144	+	50	0	100
	-	0	50	

INTERFERENCE

The Evidence MultiSTAT DOA Oral Fluid II Array was assessed for interference with the compounds listed in Table 5.

Two methods were used to assess interference:

Method 1 – At a Specific Concentration

- A negative oral fluid sample was provided
- The sample was divided and 1 portion was prepared containing the interferent.
- These samples were then spiked with antigen at ±50% of the cut off. These samples were then analysed on the Evidence MultiSTAT analyser against the cut off material to generate a positive or negative result.

Method 2 – As Consumed

- Participant provides an initial oral fluid sample
- Participant consumes the interferent
- Participant provides another oral fluid sample.
- The initial sample and the sample provided after consumption of the interferent are spiked with antigen at ±50% of the cut off. These samples were then analysed on the Evidence MultiSTAT analyser against the cut off material to generate a positive or negative result.

No interference was observed from the compounds shown in Table 5.

Table 5. Interference assessed on the Evidence MultiSTAT DOA Oral Fluid II Array.

Interference	Level Tested
Antacid	As consumed
Antiseptic Mouthwash	As consumed
Caffeine	50ng/ml
Cigarette (menthol)	5 smoked in 20 minutes
Coca Cola	As consumed
Cough Syrup	As consumed
Cranberry Juice	As consumed
DL Phenylalanine	50ng/ml
Haemoglobin	10mg/dl
Listerine	As consumed
Menthol	50ng/ml
Orange Juice	As consumed
Sodium Bicarbonate	50ng/ml
Sugar	As consumed
Toothpaste	As consumed
Vitamin C	50ng/ml
Water	As consumed

SPECIFICITY

The specificity for all analytes on the Evidence MultiSTAT DOA Oral Fluid II Array was determined by identifying the concentration of a compound that would produce a positive response on the Evidence MultiSTAT DOA Oral Fluid II Assays where analysed against the cut off material.

The specificity of each of the assays are shown in Tables 6 – 25 (**NOTE**: ND indicates no detection).

Table 6. Specificity of the Fentanyl Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Fentanyl Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Fentanyl	1.5	100
ρ-fentanyl	2.3	66
Benzylfentanyl	4.5	33
α-methylfentanyl	9	16.5
Norfentanyl Oxalate	27.3	5.5
Acetylfentanyl	158	<1
Remifentanyl	ND	ND

Table 7. Specificity of the Ketamine Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Ketamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Ketamine	65	100
(±) Norketamine	295.5	22
Dehydronorketamine	ND	ND

Table 8. Specificity of the LSD Assay on Evidence MultiSTAT DOA Oral Fluid II Array

LSD Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
LSD	1.5	100
2-oxo-3-hydroxy LSD	4.5	33
Nor LSD	9	16.5

Table 9. Specificity of the Methamphetamine Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Methamphetamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	70	100
PMMA HCl	33.5	208
MDMA	104.5	67
BDB	7000	1
D-Amphetamine	ND	ND
Fenfluramine	ND	ND
(±) MDA	ND	ND
Phentermine	ND	ND
PMA	ND	ND
R(-) Methamphetamine	ND	ND

Table 10. Specificity of the Barbiturates Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Barbiturates Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Phenobarbital	60	100
Secobarbital	30.5	196
Pentobarbital	43	139
Butabarbital	43	139
Cyclopentobarbital	72.5	83
Amobarbital	143	42
Barbital	182	33

Table 11. Specificity of the Benzodiazepines I Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Benzodiazepines I Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Oxazepam	15	100
Diazepam	4	392
alpha-hydroxyalprazolam	4.5	333
Alprazolam	4.5	333
Estazolam	4.5	333
Nordiazepam	5.5	278
Clobazam	7	222
Temazepam	9	167
2-OH Ethylflurazepam	11.5	133
Prazepam	11.5	133
Nitrazepam	11.5	133
Triazolam	11.5	133
Flurazepam	22.5	67
Midazolam	22.5	67
Chlordiazepoxide	45.5	33
Lormetazepam	45.5	33
Bromazepam	75	20
N-Desmethylflunitrazepam	88.5	17
Clonazepam	214.5	7
Medazepam	250	6
7-Aminonitrazepam	1500	1
Lorazepam Glucuronide	1579	<1
7-NH Clonazepam	ND	ND
Oxazepam Glucuronide	ND	ND
Temazepam Glucuronide	ND	ND

Table 12. Specificity of the Benzodiazepines II Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Benzodiazepines II Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Lorazepam	15	100
Clonazepam	45.5	33
Lorazepam Glucuronide	68	22
N-Desmethylflunitrazepam	375	4
Oxazepam Glucuronide	750	2
Nordiazepam	750	2
Alprazolam	1579	<1
7-Aminonitrazepam	ND	ND
Bromazepam	ND	ND
Chlordiazepoxide	ND	ND
Clobazam	ND	ND
7-NH Clonazepam	ND	ND
Diazepam	ND	ND
Estazolam	ND	ND
2-OH Ethylflurazepam	ND	ND
Flurazepam	ND	ND
alpha-hydroxyalprazolam	ND	ND
Lormetazepam	ND	ND
Medazepam	ND	ND
Midazolam	ND	ND
Nitrazepam	ND	ND
Prazepam	ND	ND
Temazepam	ND	ND
Temazepam Glucuronide	ND	ND
Triazolam	ND	ND

Table 13. Specificity of the Methadone Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Methadone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Methadone	5	100

Table 14. Specificity of the Opiates Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Opiate Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Morphine	15	100
6-Acetylmorphine	3	500
Heroin	9	167
Codeine	79	19
Morphine-3βD-Glucuronide	250	6
Desomorphine	300	5
Dihydrocodeine	750	2
Hydrocodone	750	2
Levorphanol	750	2
Hydromorphone	1500	1
Morphine-6βD-Glucuronide	1500	1
Thebaine	1500	1
Dextromethorphan	ND	ND
Meperidine	ND	ND
Norcodeine	ND	ND
Normorphine	ND	ND
Noroxycodone HCl	ND	ND
Noroxymorphone HCl	ND	ND
Oxymorphone	ND	ND

Table 15. Specificity of the PCP Assay on Evidence MultiSTAT DOA Oral Fluid II Array

PCP Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Phencyclidine	7	100

Table 16. Specificity of the BZG/Cocaine Assay on Evidence MultiSTAT DOA Oral Fluid II Array

BZG/Cocaine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Benzoylecgonine	30	100
Cocaine	22.5	133
m-hydroxybenzoylecgonine	45	67
Ecgonine HCl	ND	ND
Norcocaine HCl	ND	ND

Table 17. Specificity of the Oxycodone Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Oxycodone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Oxycodone	10	100
Hydrocodone	7.5	134
Noroxyodone HCl	26.5	38
Codeine	ND	ND
Desomorphine	ND	ND
Dextromethorphan	ND	ND
Dihydrocodeine	ND	ND
Heroin	ND	ND
Hydromorphone	ND	ND
Levorphanol	ND	ND
Meperidine	ND	ND
Morphine-3βD-Glucuronide	ND	ND
Morphine-6βD-Glucuronide	ND	ND
Norcodeine	ND	ND
Normorphine	ND	ND
Noroxymorphone HCl	ND	ND
Oxymorphone	ND	ND
Thebaine	ND	ND

Table 18. Specificity of the Tramadol Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Tramadol Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Tramadol	5	100
O-Desmethyltramadol HCl	38.5	13
(±) N-Desmethyltramadol HCl	500	1

Table 19. Specificity of the Cannabinoids Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Cannabinoids (THC) Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
(-)-11-nor-9-Carboxy-Δ^9-THC	5	100
delta 9-THC	25	20
(±)-11-hydroxy-delta-9-THC	55.5	9
delta 8-THC	125	4
Cannabidiol	1250	<1

Table 20. Specificity of the Amphetamine Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Amphetamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Amphetamine	60	100
(±) MDA	18	333
PMA HCl	25	238
BDB	54	111
D-Amphetamine	72.5	83
Phentermine	250	24
Fenfluramine	ND	ND
PMMA HCl	ND	ND
R(-) Methamphetamine	ND	ND

Table 21. Specificity of the Buprenorphine Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Buprenorphine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Buprenorphine	1.5	100
Norbuprenorphine	0.68	220
Norbuprenorphine-3βD-Glucuronide	1.14	132
Buprenorphine-3βD-Glucuronide	1.6	94

Table 22. Specificity of the 6-MAM Assay on Evidence MultiSTAT DOA Oral Fluid II Array

6-MAM Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
6-Acetylmorphine	3	100
Heroin	214.5	1.4
6-Acetylcodeine	231	1.3
Codeine	ND	ND
Desomorphine	ND	ND
Dextromethorphan	ND	ND
Dihydrocodeine	ND	ND
Hydrocodone	ND	ND
Hydromorphone	ND	ND
Levorphanol	ND	ND
Meperidine	ND	ND
Morphine	ND	ND
Morphine-3βD-Glucuronide	ND	ND
Morphine-6βD-Glucuronide	ND	ND
Norcodeine	ND	ND
Normorphine	ND	ND
Noroxycodone HCl	ND	ND
Noroxymorphone HCl	ND	ND
Oxymorphone	ND	ND
Thebaine	ND	ND

Table 23. Specificity of the Synthetic Cannabinoids (JWH-018) Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Synthetic Cannabinoids (JWH-018) Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
JWH-018	20	100
AM2201	47.5	42
JWH-073 5-hydroxyindole metabolite	90	22
JWH-022	117.5	17
JWH-073	117.5	17
JWH-073 4-hydroxyindole metabolite	117.5	17
JWH-018 N-(5-hydroxypentyl) metabolite	117.5	17
JWH-018 N-(3-methylbutyl) isomer	117.5	17
JWH-015	154	13
AM694	182	11
JWH-073 4-methylnapthyl analog	182	11
JWH-122	250	8
JWH-200	250	8
JWH-018 5-hydroxyindole	250	8
JWH-018 6-hydroxyindole	250	8
JWH-018 N-(1-methylbutyl) isomer	250	8
JWH-018 N-(2-methylbutyl) isomer	250	8
JWH-018 7-hydroxyindole metabolite	250	8
JWH-018 N-butanol	667	3

Table 24. Specificity of the alpha-PVP Assay on Evidence MultiSTAT DOA Oral Fluid II Array

alpha-PVP Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
α-Pyrrolidinovalerophenone	2.5	100
MDPV HCl	4	67
Naphyrone HCl	5.5	45
Butylone HCl	ND	ND
Methedrone HCl	ND	ND
Methylone HCl	ND	ND
MDPPP HCl	ND	ND

Table 25. Specificity of the Synthetic Cannabinoids (UR-144) Assay on Evidence MultiSTAT DOA Oral Fluid II Array

Synthetic Cannabinoids (UR-144) Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
UR-144	25	100
UR-144 N-Pentanoic Acid	3.4	740
A-796260	4	666
UR-144 N-(5-hydroxypentyl) metabolite	4	666
UR-144 N-(5-hydroxypentyl)-βD-Glucuronide	5.5	444
AB-005	11.5	222
XLR-11	22.5	111
XLR-11 N-(4-pentyl) analog	30	83
XLR-11 N-(2-fluoropentyl) isomer	59.5	42
UR-144 N-(5-bromopentyl) analog	76	33
UR-144 N-(5-chloropentyl) analog	92.5	27
UR-144 N-(heptyl) analog	156.5	16

REFERENCES

1. Vetulani J. (2001) Drug addiction. Part I. Psychoactive substances in the past and presence. *Pol. J. Pharmacol.* 53(3):201-214.
2. Drummer O.H. (2006) Drug testing in oral fluid. *Clin. Biochem. Rev.* **27(3):**147-159.
3. Schepers R.J., Oyler J.M., Joseph R.E. Jr, Cone E.J., Moolchan E.T. and Huestis M.A. (2003) Methamphetamine and amphetamine pharmacokinetics in oral fluid and plasma after controlled oral methamphetamine administration to human volunteers. *Clin. Chem.* **49(1):**121-132.

21 Dec 18 pq