RANDOX

DRUGS OF ABUSE ARRAY ORAL FLUID (DOA OF)

—evidence—
MULTISTAT

INTENDED USE

The Evidence MultiSTAT DOA Oral Fluid (DOA OF) 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 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. EV4117

Containing the following components:

1.	DOA OF Test Cartridge	12 x 1 Cartridge
2.	DOA OF Cut Off	6 x 1 ml
3.	DOA OF Positive Control	4 x 1 ml
4.	Reconstitution Buffer	2 x 10 ml
5.	Sample Pipettes	24 x Pipettes

Cat. No. EV4116

Containing the following components:

1. MultiSTAT Tip Cartridge	12 x 1 Tip Cartridge

LABELLING GUIDE

DOA OF	Drugs of Abuse Oral Fluid

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 Array is designed for use only with human oral fluid samples collected using the Intercept® i2™ Oral Fluid Collection Device (OraSure Technologies, Inc. 1001-0362).
- 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.
- Cross reactivity information is provided for each analyte, however there may be additional compounds which have not been tested that may cross react with some assays, giving a positive result. Additionally, compounds with low cross reactivity could cause a positive result if they are present in high concentrations.

SPECIMEN COLLECTION AND PREPARATION

- The Evidence MultiSTAT DOA Oral Fluid Array is designed for use with human oral fluid samples collected using the Intercept® i2™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.
- Toxicological results may be affected by the quality of the sample which may be influenced by how it is handled, the length of time it is stored and the storage conditions. Samples stability should be determined by the end user.

REAGENT COMPOSITION

1. **DOA OF ASSAY DILUENT**
   20 mM phosphate buffer, pH 7.2 containing protein, detergents and preservatives. This is contained within the cartridge.

2. **DOA OF 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. **DOA OF BIOCHIP**
   Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.

4. **DOA OF 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-EV934.

6. **DOA OF CUT OFF**
   Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.

7. **DOA OF POSITIVE CONTROL**
   Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.

8. **RECONSTITUTION BUFFER**
   A solution at a neutral pH containing preservatives.

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

STABILITY AND PREPARATION OF REAGENTS

1. **DOA OF 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. **DOA OF CUT OFF**
   Lyophilised cut offs are stable until the expiry date when stored unopened, at +2 to +8°C. Gently tap the vial on the bench to ensure all material is at the bottom of the vial. Open the vial by partially removing the rubber stopper, avoiding any loss of material. Reconstitute in 1ml of accurately measured reconstitution buffer. Replace the rubber stopper and close the vial. After 2 minutes, swirl the vial gently and complete 3 quick inversions to ensure that all the material is dissolved, then leave upright for 30 minutes out of bright light before use. Following reconstitution, ensure that the vial 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. **DOA OF POSITIVE CONTROL**
   Lyophilised positive controls are stable until the expiry date when stored unopened, at +2 to +8°C. Gently tap the vial on the bench to ensure all material is at the bottom of the vial. Open the vial by partially removing the rubber stopper, avoiding any loss of material. Reconstitute in 1ml of accurately measured reconstitution buffer. Replace the rubber stopper and close the vial. After 2 minutes, swirl the vial gently and complete 3 quick inversions to ensure that all the material is dissolved, then leave upright for 30 minutes out of bright light before use. Following reconstitution, ensure that the vial 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 and +2 to +8°C.

4. **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

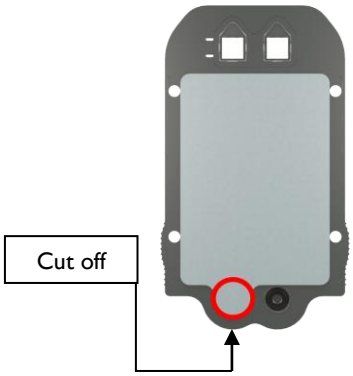
Upon receipt of a new batch of EV4117, a batch specific update will have to be completed from the USB provided:

- 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.
  NOTE: The Evidence MultiSTAT will request the reference material, for this the cut-off material should be used.

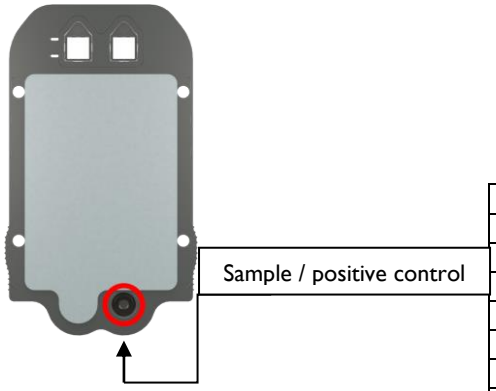
For further information please refer to the Evidence MultiSTAT Operators Manual.

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 3-fold dilution applied by the Intercept® i2™ 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 3-fold sample dilution has been applied as per the Intercept® i2™ Oral Fluid Collection Device.

MATERIALS PROVIDED

1.	DOA OF Test Cartridge	12 x 1 Cartridge
2.	DOA OF Cut Off	6 x 1 ml
3.	DOA OF Positive Control	4 x 1 ml
4.	Reconstitution Buffer	2 x 10 ml
5.	Sample Pipettes	24 x Pipettes

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipette
2. Intercept® i2™ Oral Fluid Collection Device

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 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 Array. The cut off material has been prepared to account for the 3-fold sample dilution applied by the Intercept® i2™ 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 Array.

Assay	Cut Off
Fentanyl	1 ng/ml
Ketamine	50 ng/ml
LSD	1 ng/ml
Methamphetamine	50 ng/ml
Barbiturates	50 ng/ml
Benzodiazepines I	10 ng/ml
Benzodiazepines II	10 ng/ml
Methadone	4 ng/ml
Opiate	10 ng/ml
PCP	5 ng/ml
BZG/Cocaine	20 ng/ml
Oxycodone	8 ng/ml
Tramadol	4 ng/ml
Cannabinoids (THC)	2 ng/ml
Amphetamine	50 ng/ml
Buprenorphine	1 ng/ml
6-MAM	2 ng/ml
Synthetic Cannabinoids (JWH-018)	5 ng/ml
alpha-PVP	2 ng/ml
Synthetic Cannabinoids (UR-144)	10 ng/ml

REPEATABILITY

The repeatability for all analytes on the Evidence MultiSTAT DOA Oral Fluid 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 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 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	98.75
	-	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 array was established by analysing 20 negative human oral fluid samples collected using the Intercept® i2™ 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 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 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 Array.

ASSAY		SPIKE +	SPIKE -	% AGREE
FENT	+	50	0	100
	-	0	50	
KET	+	50	1	99
	-	0	49	
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	+	50	0	100
	-	0	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	0	100
	-	0	50	
AMP	+	50	0	100
	-	0	50	
BUP	+	49	0	99
	-	1	50	
6-MAM	+	50	1	99
	-	0	49	
JWH-018	+	50	0	100
	-	0	50	
α-PVP	+	50	0	100
	-	0	50	
UR-144	+	50	0	100
	-	0	50	

INTERFERENCE

The Evidence MultiSTAT DOA Oral Fluid 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 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
Ephedrine HCl	100µg/ml
Haemoglobin	10mg/dl
Listerine	As consumed
Menthol	50ng/ml
Orange Juice	As consumed
(1S,2S)-(+)-Pseudoephedrine	100µg/ml*
Sodium Bicarbonate	50ng/ml
Sugar	As consumed
Toothpaste	As consumed
Vitamin C	50ng/ml
Water	As consumed

*Note: 100µg/ml of (1S,2S)-(+)-Pseudoephedrine did not interfere with any assay with the exception of Methamphetamine.

SPECIFICITY

The specificity for all analytes on the Evidence MultiSTAT DOA Oral Fluid Array was determined by identifying the concentration of a compound that would produce a positive response on the Evidence MultiSTAT DOA Oral Fluid 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 Array

Fentanyl Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Fentanyl	1	100
ρ-fentanyl	1.5	66
Benzylfentanyl	3	33
α-methylfentanyl	6	16.5
Norfentanyl Oxalate	6	16.5
Acetylfentanyl	105	<1
Remifentanyl	ND	ND

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

Ketamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Ketamine	50	100
(±) Norketamine	225	22
Dehydronorketamine	ND	ND

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

LSD Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
LSD	1	100
2-oxo-3-hydroxy LSD	3	33
Nor LSD	6	16.5

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

Methamphetamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Methamphetamine	50	100
PMMA HCl	24	208
MDMA	75	67
BDB	5100	1
(1S,2S)-(+)-Pseudoephedrine	100,000	<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 Array

Barbiturates Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Phenobarbital	50	100
Secobarbital	25.5	196
Pentobarbital	36	139
Butabarbital	36	139
Cyclopentobarbital	60	83
Amobarbital	120	42
Barbital	150	33

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

Benzodiazepines I Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Oxazepam	10	100
Diazepam	2.55	392
alpha-hydroxyalprazolam	3	333
Alprazolam	3	333
Estazolam	3	333
Nordiazepam	3.6	278
Clobazam	4.5	222
Temazepam	6	167
2-OH Ethylflurazepam	7.5	133
Prazepam	7.5	133
Nitrazepam	7.5	133
Triazolam	7.5	133
Flurazepam	15	67
Midazolam	15	67
Chlordiazepoxide	30	33
Lormetazepam	30	33
Bromazepam	51	20
N-Desmethylflunitrazepam	60	17
Clonazepam	135	7
Medazepam	180	6
7-Aminonitrazepam	840	1
Lorazepam Glucuronide	1050	<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 Array

Benzodiazepines II Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Lorazepam	10	100
Clonazepam	30	33
Lorazepam Glucuronide	45	22
N-Desmethylflunitrazepam	225	4
Oxazepam Glucuronide	450	2
Nordiazepam	450	2
Alprazolam	1050	<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 Array

Methadone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Methadone	4	100

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

Opiate Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Morphine	10	100
6-Acetylmorphine	2	500
Heroin	6	167
Codeine	52.5	19
Morphine-3βD-Glucuronide	165	6
Desomorphine	210	5
Dihydrocodeine	450	2
Hydrocodone	450	2
Levorphanol	450	2
Hydromorphone	750	1
Morphine-6βD-Glucuronide	750	1
Thebaine	750	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 Array

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

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

BZG/Cocaine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Benzoylecgonine	20	100
Cocaine	15	133
m-hydroxybenzoylecgonine	30	67
Ecgonine HCl	ND	ND
Norcocaine HCl	ND	ND

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

Oxycodone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Oxycodone	8	100
Hydrocodone	6	134
Noroxyodone HCl	21	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 Array

Tramadol Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Tramadol	4	100
O-Desmethyltramadol HCl	30	13
(±) N-Desmethyltramadol HCl	375	1
Venlafaxine HCl	100,000	<0.01

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

Cannabinoids (THC) Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
(-)-11-nor-9-Carboxy-Δ^9-THC	2	100
delta 9-THC	10	20
(±)-11-hydroxy-delta-9-THC	22.5	9
delta 8-THC	45	4
Cannabidiol	450	<1

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

Amphetamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Amphetamine	50	100
(±) MDA	15	333
PMA HCl	21	238
BDB	45	111
D-Amphetamine	60	83
Phentermine	210	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 Array

Buprenorphine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Buprenorphine	1	100
Norbuprenorphine	0.45	220
Norbuprenorphine-3βD-Glucuronide	0.75	132
Buprenorphine-3βD-Glucuronide	1.05	94

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

6-MAM Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
6-Acetylmorphine	2	100
Heroin	142.5	1.4
6-Acetylcodeine	150	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 Array

Synthetic Cannabinoids (JWH-018) Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
JWH-018	5	100
AM2201	12	42
JWH-073 5-hydroxyindole metabolite	22.5	22
JWH-022	30	17
JWH-073	30	17
JWH-073 4-hydroxyindole metabolite	30	17
JWH-018 N-(5-hydroxypentyl) metabolite	30	17
JWH-018 N-(3-methylbutyl) isomer	30	17
JWH-015	37.5	13
AM694	45	11
JWH-073 4-methylnapthyl analog	45	11
JWH-122	60	8
JWH-200	60	8
JWH-018 5-hydroxyindole	60	8
JWH-018 6-hydroxyindole	60	8
JWH-018 N-(1-methylbutyl) isomer	60	8
JWH-018 N-(2-methylbutyl) isomer	60	8
JWH-018 7-hydroxyindole metabolite	60	8
JWH-018 N-butanol	150	3

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

alpha-PVP Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
α-Pyrrolidinovalerophenone	2	100
MDPV HCl	3	67
Naphyrone HCl	4.5	45
Butylone HCl	ND	ND
Methedrone HCl	ND	ND
Methylone HCl	ND	ND
MDPPP HCl	ND	ND
Tramadol	100,000	<0.01
Venlafaxine HCl	1,000,000	<0.01

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

Synthetic Cannabinoids (UR-144) Assay		
Compound	**Approximate Concentration to Read Positive (ng/ml)**	**Approximate % Cross Reactivity**
UR-144	10	100
UR-144 N-Pentanoic Acid	1.35	740
A-796260	1.5	666
UR-144 N-(5-hydroxypentyl) metabolite	1.5	666
UR-144 N-(5-hydroxypentyl)-βD-Glucuronide	2.25	444
AB-005	4.5	222
XLR-11	9	111
XLR-11 N-(4-pentyl) analog	12	83
XLR-11 N-(2-fluoropentyl) isomer	24	42
UR-144 N-(5-bromopentyl) analog	30	33
UR-144 N-(5-chloropentyl) analog	37.5	27
UR-144 N-(heptyl) analog	61.5	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.
   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.

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