

DRUGS OF ABUSE ARRAY URINE

-evidence-MULTISTAT

INTENDED USE

The Evidence MultiSTAT DOA Urine Assays are tests for the qualitative determination of the parent molecule and metabolites of drugs in human urine. 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 Urine Assays provide only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas Chromatographylmass spectrometry (GC/MS) is the preferred confirmatory method. 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. EV4193

Containing the following components:

Ι.	Urine Test Cartridge	12 x 1 Cartridge
2.	Urine Cut Off	6 x I ml
3.	Urine 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:

I. MultiSTAT Tip Cartridge I2 x I 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. Urine drug testing can provide a tool for detecting users and for monitoring the compliance of subjects in recovery programs ²,

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.

LIMITATIONS

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 Urine Array is designed for use only with human urine samples.
- 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 qualitative test result.

SPECIMEN COLLECTION AND PREPARATION

- The Evidence MultiSTAT DOA Urine Array is designed for use with human urine samples. Randox has not tested all possible applications of this assay.
- Collection devices should be durable, leak-proof and constructed of non-absorbing plastics. The specimen should be free of faecal contamination and should not contain foreign materials – centrifuge if turbid.
- Samples should be at a room temperature of +15 to +25°C (+59 to +77°F) for testing.
- Fresh urine samples do not require any pre-treatment.
 Use of chemical preservatives is not recommended for urinalysis

SAMPLE STORAGE AND STABILITY

- Generally, it is accepted that the chemical composition of urine changes, and formed elements begin to deteriorate after it has been left standing 2 hours at room temperature.
- If the urine sample is not being analysed immediately it is recommended that it be stored at +2 to +8°C for up to 72 hours.
- There is no agreed length of time for refrigeration, however most drugs degrade in a urine specimen over time. This process is much slower in a refrigerated specimen and slower yet in a frozen specimen and thus, for prolonged storage, freezing of samples is recommended.
 - The specimen should be at room temperature before proceeding with the analysis

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

Contents

I. MULTISTAT DOA URINE ASSAY DILUENT

20 mM phosphate buffer, pH 7.2 containing protein, detergents and preservatives. This is contained within the cartridge.

2. MULTISTAT DOA URINE 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 URINE BIOCHIP

Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.

4. MULTISTAT DOA URINE 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

6. MULTISTAT DOA URINE CUT OFF

Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.

7. MULTISTAT DOA URINE 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

I. MULTISTAT DOA URINE 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. Once an individual test cartridge is open and out of its foil bag, it should be used for testing immediately.

2. MULTISTAT DOA URINE 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 Iml 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. MULTISTAT DOA URINE 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 Iml 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. 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 EV4193 a batch specific update will have to be completed from the USB provided:

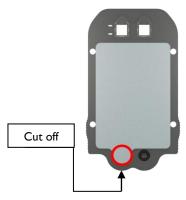
- Scan the cartridge barcode when scanned for the first time this will prompt the user to import the batch details from the provided USB.
- Insert the USB in to the USB port located on the bottom right hand side of the analyser below the power button.
- Once the USB has been connected select the import 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.

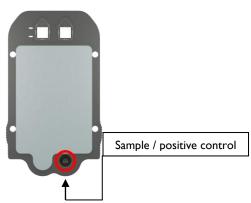


ASSAY PROTOCOL

 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 μ l of sample / positive control into the open sample well on the right as indicated below.



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.

MATERIALS PROVIDED

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١.	Urine Test Cartridge	12 x 1 Cartridge
2.	Urine Cut Off	6 x I ml
3.	Urine Positive Control	4 x l ml
4.	Reconstitution Buffer	2 x 10 ml
5.	Sample Droppers	24 x Dropper

MATERIALS REQUIRED BUT NOT PROVIDED

I. Pipette

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 Urine 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.

REFERENCES

- Vetulani J. (2001) Drug addiction. Part I. Psychoactive substances in the past and presence. Pol. J. Pharmacol. 53(3):201-214.
- Glass L R, Ingalls S T, Schilling C L and Hoppel C L, Atypical Urinary Opiate Excretion Pattern, Journal of Analytical Toxicology, October 1997; 21:509-514.

CUT OFF MATERIAL

In order to provide a qualitative result, the sample must be assayed against a cut off of known concentration. Table I indicates the cut off concentrations for each of the assays on the Evidence MultiSTAT DOA Urine Array. If the concentration of drug in the sample is greater than the cut off the result will be reported as POSITIVE. If the concentration of drug in the sample is less than the cut off the result will be reported as NEGATIVE.

CREATININE reporting: A normal sample will contain a concentration greater than the cut off and will report NEGATIVE for adulteration. An adulterated sample will have a concentration less than the cut off and will report POSITIVE for adulteration.

Table I. Cut Off Concentrations for the Evidence MultiSTAT DOA Urine Array.

Assay	Cut Off	
Fentanyl	2 ng/ml	
ETG	750 ng/ml	
Methamphetamine	200 ng/ml	
Barbiturates	200 ng/ml	
Benzodiazepines I	I50ng/ml	
Benzodiazepines II	I50ng/ml	
Methadone	300 ng/ml	
Opiate	200 ng/ml	
BZG/Cocaine	I50 ng/ml	
Oxycodone	50 ng/ml	
Tramadol	5 ng/ml	
TCA	I 50ng/ml	
Cannabinoids (THC)	20 ng/ml	
Amphetamine	200 ng/ml	
Buprenorphine	l ng/ml	
6-MAM	I0 ng/ml	
Synthetic Cannabinoids (JWH-018)	20 ng/ml	
alpha-PVP	5 ng/ml	
Synthetic Cannabinoids (UR-144)	I0 ng/ml	
AB PINACA	2.5ng/ml	
Creatinine	20mg/dl	



PERFORMANCE DATA

REPEATABILITY

The repeatability for all analytes on the Evidence MultiSTAT DOA Urine array was determined by assessing control material prepared at the cut off and at $\pm 50\%$ 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 % agreement is calculated for the number of samples that correctly reported negative and positive as shown in Table 2.

Table 2. Repeatability of Evidence MultiSTAT DOA Urine Array.

ASSAY		-50%	CUT	+50%	%
ASSA		3070	OFF	130/0	AGREE
FENT	+	0	13	20	100
	-	20	7	0	
ETG	+	0	8	19	97.5
	_	20	12	i	1
MAMP	+	0	12	20	100
	-	20	8	0	1
BARB	+	0	8	20	100
	-	20	12	0	
BENZ I	+	0	12	20	100
	-	20	8	0	1
BENZ II	+	0	H	20	100
	-	20	9	0	
MDONE	+	0	12	20	100
	-	20	8	0	1
OPIATE	+	0	12	20	100
	-	20	8	0	
BZG	+	0	12	20	100
	-	20	8	0	
OXYC	+	0	7	20	100
	-	20	13	0	
TRAM	+	0	12	20	100
	-	20	8	0	
TCA	+	0	11	20	100
	-	20	9	0	
THC	+	0	14	20	100
	-	20	6	0	
AMP	+	0	7	20	100
	-	20	13	0	
BUP	+	0	8	20	100
	-	20	12	0	1
6-MAM	+	0	14	20	100
	-	20	6	0	
JWH-	+	0	12	20	100
018	-	20	8	0	
APVP	+	0	10	20	100
	-	20	10	0	
UR-144	+	0	9	20	100
	-	20	- 11	0	
AB-PIN	+	0	8	19	97.5
	-	20	12	ı	
CREAT	+	20	10	0	100
	-	0	10	20	

Note: For the creatinine assay the -50% sample was spiked for 10 mg/dL and reported POSITIVE for adulteration. The +50% sample was spiked for 30 mg/dL and reported NEGATIVE for adulteration.

LIMIT OF DETECTION

The limit of detection for all analytes on the Evidence MultiSTAT DOA Urine Array was established by analysing 20 authentic negative, unadulterated urine samples. Each sample was 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 Urine Array.

ASSAY	REPORT	REPORT
	POSITIVE	NEGATIVE
FENT	0	20
ETG	0	20
MAMP	0	20
BARB	0	20
BENZ I	0	20
BENZ II	0	20
MDONE	0	20
OPIATE	0	20
BZG	0	20
OXYC	0	20
TRAM	0	20
TCA	0	20
THC	0	20
AMP	0	20
BUP	0	20
6-MAM	0	20
JWH-018	0	20
APVP	0	20
UR-144	0	20
AB-PIN	0	20
CREAT	0	20



ACCURACY

The accuracy for all analytes on the Evidence MultiSTAT DOA Urine 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 Urine Array.

ASSAY		SPIKE	SPIKE	%
		+	-	AGREE
FENT	+	50	0	100
	-	0	50	1
ETG	+	50	0	100
	-	0	50	
MAMP	+	50	0	100
	-	0	50	1
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	1
OPIATE	+	50	0	100
	-	0	50	
BZG	+	50	0	100
	-	0	50	
OXYC	+	50	0	100
	-	0	50	
TRAM	+	50	0	100
	-	0	50	
TCA	+	50	0	100
	-	0	50	
THC	+	44	0	94
	-	6	50	
AMP	+	50	0	100
	-	0	50	
BUP	+	46	0	96
	-	4	50	
6-MAM	+	50	0	100
	-	0	50	
JWH-	+	50	0	100
018	-	0	50	
APVP	+	50	0	100
	-	0	50	
UR-144	+	50	0	100
	-	0	50	
AB-PIN	+	50	0	100
	-	0	50	
CREAT	+	50	0	100
	-	0	100	

Note: Spike + Samples for Creatinine are POSITIVE for adulteration. Spike – Samples for Creatinine are NEGATIVE for adulteration.

INTERFERENCE

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

Method

- Two drug free urine samples were spiked, one at -50% of the cut off and one at +50% of the cut off
- The sample was divided and I portion was prepared containing the interferent
- 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.

Note: Creatinine interference is not applicable to the Creatinine assay.

Table 5. Interference assessed on the Evidence MultiSTAT DOA Urine Array.

Interference	Level Tested	
Acetaminophen	Img/ml	
Acetone	I 000mg/dl	
Acetylsalicylic acid	lmg/ml	
Ascorbic acid	I 500mg/dl	
Caffeine	Img/ml	
Creatinine	5mg/ml	
Ethanol	I 000mg/dl	
Galactose	I 0mg/dl	
Gamma globulin	500mg/dl	
Glucose	3000mg/dl	
Haemoglobin	300mg/dl	
Human serum	F00mg/dl	
albumin	500mg/dl	
Ibuprofen	Img/ml	
Oxalic acid	I00mg/dl	
Ranitidine	0.9 mg/ml	
Riboflavin	7.5mg/dl	
Sodium chloride	6000mg/dl	
Urea	3500mg/dl	
U		



SPECIFICITY

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

Fentanyl Assay				
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity		
Fentanyl	2	100		
para-fluorofentanyl	1.56	128.2		
Thiofentanyl HCL	1.82	110		
α-methylfentanyl	3	66.7		
Furanylethylfentanyl	3	66.7		
Butrylfentanyl	3.5	57		
Benzylfentanyl	6	33.5		
Methoxyacetyl fentanyl	8.4	23.8		
Ortho Fluro Fentanyl	8.4	23.8		
Acrylfentanyl	9	22.2		
Meta-hydroxy- acrylfentanyl	9.6	20.8		
Thienyl Fentanyl	12.6	15.9		
Isobutyrylfentanyl	14.5	13.8		
Furanylfentanyl	14.5	13.8		
Norfentanyl	19.2	10.42		
Valeryl Fentanyl	35	5.7		
Cyclopentylfentanyl	57.6	3.5		
Ocfentanil	60	3.3		
(±)-trans-3-methyl Fentanyl	60	3.3		
ω-hydroxyfentanyl	64.5	3.1		
Ohmefentanyl	70	2.9		
cis-Mefentanyl HCI Salt	80	2.5		
3-Methylthiofentanyl	85	2.4		
Norfuranylfentanyl	120	1.67		
Acetylfentanyl	200	<i< td=""></i<>		
4-				
Fluorobutyrfentanyl / Para Fluoroisobutrylfentanyl	400	<1		
Norocfentanyl	200	<i< td=""></i<>		
ω-Hydroxy norfentanyl	670	<1		
Remifentanyl	ND	ND		

Table 7. Specificity of the EthylGlucuronide Assay on Evidence MultiSTAT DOA Urine Array

EthylGlucuronide Assay			
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity	
Ethyl glucuronide	750	100	
Methylethyl glucuronide	1000	75	
Methyl- βD- glucuronide	14000	5.4	

Table 8. Specificity of the Methamphetamine Assay on Evidence MultiSTAT DOA Urine Array

Methamphetamine Assay				
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity		
S(+)- Methamphetamine	200	100		
PMMA HCI	100	200		
MDMA	300	66.7		
BDB	20000			
D-Amphetamine	ND	ND		
Fenfluramine	ND	ND		
(±) MDA	ND	ND		
Phenteramine	ND	ND		
PMA	ND	ND		
R(-) Methamphetamine	ND	ND		

Table 9. Specificity of the Barbiturates Assay on Evidence MultiSTAT DOA Urine Array

Barbiturates Assay				
Approximate				
	Concentration	Approximate %		
Compound	to Read	Cross		
	Positive	Reactivity		
	(ng/ml)	_		
Phenobarbital	200	100		
Secobarbital	130	153		
Pentobarbital	145	138		
Butabarbital	145	138		
Cyclopentobarbital	255	78		
Amobarbital	475	42.1		
Barbital	605	33.1		
Butalbital	750	26.7		



Table 10. Specificity of the Benzodiazepines I Assay on Evidence MultiSTAT DOA Urine Array

Benzodiazepines I Assay				
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity		
Oxazepam	150	100		
Alprazolam	3.125	4800		
Diazepam	6.24	2403.8		
alpha- hydroxyalprazolam	7.5	2000		
Estazolam	7.5	2000		
Prazepam	15	1000		
Nordiazepam	24.5	612.24		
Temazepam	28.8	520.8		
Midazolam	43.75	342.86		
Triazolam	49.2	304		
Clobazam	60	250		
2-OH Ethylflurazepam	60	250		
Flurazepam	100	150		
Nitrazepam	115	130		
Medazepam	220	68.18		
Lorazepam	300	50		
Chlordiazepoxide	575	26		
Bromazepam	850	17.6		
N- Desmethylflunitraz epam	885	16.9		
Clonazepam	2150	7		
7- Aminonitrazepam	3900	3.85		
Lorazepam Glucuronide	15000	<1		
7-NH Clonazepam	ND	ND		
Oxazepam Glucuronide	ND	ND		
Temazepam Glucuronide	ND	ND		

Table 11. Specificity of the Benzodiazepines II Assay on Evidence MultiSTAT DOA Urine Array

Benzodiazepines II Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Lorazepam	150	100
Oxazepam	300	50
Clonazepam	900	16.7
Lorazepam Glucuronide	1200	12.5
Nordiazepam	2750	5.45
N- Desmethylflunitraz epam	3750	4
Alprazolam	15000	<i< td=""></i<>
Oxazepam Glucuronide	18720	<i< td=""></i<>
Flurazepam	150000	<i< td=""></i<>
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
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 12. Specificity of the Methadone Assay on Evidence MultiSTAT DOA Urine Array

	Methadone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity	
Methadone	300	100	
EDDP Perchlorate	30000	<1	



Table 13. Specificity of the Opiates Assay on Evidence
MultiSTAT DOA Urine Array

Opiate Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Morphine	200	100
Heroin	15	1333.3
6-Acetylmorphine	20	1000
Codeine	325	61.5
6-Acetylcodeine	400	50
Morphine-3βD- Glucuronide	1500	13.3
Desomorphine	2000	10
Dihydrocodeine	3500	5.7
Hydrocodone	4200	4.8
Levorphanol	5000	4
Morphine-6βD- Glucuronide	6000	3.3
Thebaine	7000	2.9
Hydromorphone	10,000	2
Oxycodone	20,000	<i< td=""></i<>
Dextromethorphan	ND	ND
Meperidine	ND	ND
Norcodeine	ND	ND
Normorphine	ND	ND
Noroxycodone HCI	ND	ND
Noroxymorphone HCI	ND	ND

Table 14. Specificity of the BZG/Cocaine Assay on Evidence MultiSTAT DOA Urine Array

Evidence MultiSTAT DOA Offile Array		
BZG/Cocaine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Benzoylecgonine	150	100
Cocaine	100	150
m- hydroxybenzoylec gonine	210	71.4
Ecgonine HCI	ND	ND
Norcocaine HCI	ND	ND

Table 15. Specificity of the Oxycodone Assay on Evidence MultiSTAT DOA Urine Array

Oxycodone Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Noroxycodone	50	100
Hydrocodone	19.5	256.4
Oxycodone	34	147
6-Acetylcodeine	20,000	< I
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 HCI	ND	ND
Oxymorphone	ND	ND
Thebaine	ND	ND

Table 16. Specificity of the Tramadol Assay on Evidence MultiSTAT DOA Urine Array

Tramadol Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Tramadol	5	100
O- Desmethyltramadol HCl	32	15.6
(±) N- Desmethyltramadol HCl	390	1.3



Table 17. Specificity of the Tricyclic Antidepressants (TCA) Assay on Evidence MultiSTAT DOA Urine

Array Tricyclic Antidepressants (TCA) Assay **Approximate** Concentration **Approximate** to Read Compound % Cross **Positive** Reactivity (ng/ml) Nortriptyline 150 100 Imipramine N-15 1000 oxide **Imipramine** 50 300 Amitriptyline 52.5 285.8 238 Trimipramine 63 74.7 20 I Cyclobenzapine **Desipramine** 80 187.5 **Promazine** 85.5 175.4 **Opipramol** 89.8 167 Doxepin 105 142.8 **Maprotiline** 155 96.8 Dothiepin 200 **75 Protriptyline** 223.9 67 Cyproheptadine 230 65.2 Lofepramine 258.7 58 Clomipramine 270 55.5 **Norclomipramine** 560 26.8 **HCL** Nordoxepin 24 625 Chlorpromazine 625 24 769.2 19.5 hydroxyimipramine Perphenazine 867.I 17.3

Table 18. Specificity of the Cannabinoids Assay on Evidence MultiSTAT DOA Urine Array

Cannabinoids (THC) Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
(-)-II-nor-9- Carboxy-Δ ⁹ -THC	20	100
delta 9-THC	200	10
(±)-II-hydroxy- delta-9-THC	275	7.3
delta 8-THC	500	4
Cannabidiol	2000	< I

Table 19. Specificity of the Amphetamine Assay on Evidence MultiSTAT DOA Urine Array

Amphetamine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
S(+)-Amphetamine	200	100
(±) MDA	60	333
PMA HCI	85	235
BDB	180	111
D-Amphetamine	240	83.3
Phentermine	875	22.9
Fenfluramine	ND	ND
PMMA HCI	ND	ND
R(-) Methamphetamine	ND	ND

Table 20. Specificity of the Buprenorphine Assay on Evidence MultiSTAT DOA Urine Array

Buprenorphine Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
Norbuprenorphine	I	100
Buprenorphine HCL	8	12.5
Norbuprenorphine- 3βD-Glucuronide	8.6	11.7
Buprenorphine- 3βD-Glucuronide	65	1.6

Table 21. Specificity of the 6-MAM Assay on Evidence MultiSTAT DOA Urine Array

6-MAM Assay			
Approximate			
Compound	Concentration	Approximate	
	to Read	% Cross	
	Positive	Reactivity	
	(ng/ml)		
6-Acetylmorphine	10	100	
Heroin	200	5	
6-Acetylcodeine	3,000	<i< td=""></i<>	
Oxycodone	20,000	<i< td=""></i<>	
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-	ND	ND	
Glucuronide	ND	ND	
Morphine-6βD-	ND	ND	
Glucuronide	ND	ND	
Norcodeine	ND	ND	
Normorphine	ND	ND	
Noroxycodone HCI	ND	ND	
Noroxymorphone	ND	ND	
HCI	ND	IAD	
Oxymorphone	ND	ND	
Thebaine	ND	ND	



Table 22. Specificity of the Synthetic Cannabinoids (UR-144) Assay on Evidence MultiSTAT DOA Urine

Array		
Synthetic Cannabinoids (UR-144) Assay		
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity
UR-144 N-	10	100
Pentanoic Acid	10	100
UR-144 N-(5- hydroxypentyl) metabolite	6	167
(±)-UR-144 N-(4- hydroxypentyl) metabolite	8.5	118
UR-144 N-(5- hydroxypentyl)-βD- Glucuronide	9.5	105
A-834735	10	100
A-796260	11.5	87
XLR-11 N-(4- pentyl) analog	51	19.7
XLR-11	53	18.9
AB-005	56	17.9
UR-144 N-(5- chloropentyl) analog	58	17.2
URI44 Desalkyl	58.5	17
XLR-II N-(2- fluoropentyl) isomer	80	12.5
UR-144 N-(5- bromopentyl) analog	125	8
UR-144 N-(heptyl) analog	126	7.9
UR-144	130	7.7

Table 23. Specificity of the AB-PINACA Assay on Evidence MultiSTAT DOA Urine Array

AB-PINACA Assay			
Compound	Approximate Concentratio n to Read Positive (ng/ml)	Approxim ate % Cross Reactivity	
AB-PINACA N- Pentanoic acid	2.5	100	
5-Fluoro AB-PINACA	1.75	143	
5-Hydroxypentyl AB- PINACA	2.5	100	
AB-PINACA	3.5	71.4	
4-Hydroxypentyl AB- PINACA	5	50	
5-Fluoro AB-PINACA N-(4-hydroxypentyl) metabolite	6	41.7	
ADB-PINACA N-(5- hydroxypentyl) metabolite	8	31.3	
ADB-PINACA pentanoic acid metabolite	11	22.8	
AB-FUBINACA	89.7	2.8	

Table 24. Specificity of the Synthetic Cannabinoids (JWH-018) Assay on Evidence MultiSTAT DOA Urine Array

Array		
Synthetic Can	nabinoids (JWH-018)	Assay
	Approximate	Approximate
Compound	Concentration to	% Cross
Compound	Read Positive	Reactivity
	(ng/ml)	Reactivity
JWH 018 N-pentanoic	20	100
acid metabolite	20	100
AM2201 N-(4-	F	400
fluoropentyl) isomer	5	400
JWH 018 N-(5-		
hydroxypentyl)	5	400
metabolite		
JWH 073 N-(4-		
hydroxybutyl)	7	286
metabolite		
AM2201	7	285.8
JWH 073	7.2	277.8
(±)-JWH 018 n-(4-		
hydroxypentyl)	7.5	266.7
metabolite		
JWH-200	8.5	235
JWH 018 N-(5-		
hydroxypentyl) β-D-	9.6	208.3
glucuronide		
JWH 073 6-		
hydroxyindole	10	200
metabolite		
JWH-018	10	200
JWH 018 6-		
methoxyindole analog	П	181.9
ÁM1220	11.5	174
JWH 022	12	166.7
JWH 200 6-		
hydroxyindole	12.25	163.2
metabolite		
AM2201 N-(4-		
hydroxypentyl	14.5	138
metabolite)		
JWH 073 N-(2-	15	122.2
methylpropyl) isomer	15	133.3
JWH-073 N-Butanol	16	125
JWH 018 6-		
hydroxyindole	16	125
metabolite		
(I-(4-Carboxybutyl)-		·
l H-indol-3-yl)		
(naphthalene-I-yl)	17.8	112.3
methanone (N-	17.0	114.3
carboxybutyl) JWH-		
018		
JWH 073 5-		
hydroxyindole	18	111.1
metabolite		
AM2201 6-		
hydroxyindole	20	100
metabolite		
JWH 018 5-	20	100
hydroxyindole	20	100
metabolite		



Table 24. Specificity of the Synthetic Cannabinoids (JWH-018) Assay on Evidence MultiSTAT DOA Urine Array (Continued)

JWH018 N-(1,2-		
dimethylpropyl)	20	100
isomer		
JWH 019 N-(6-		100
hydroxyhexyl)	20	
metabolite		
JWH 073 7-	20.5	97.6
hydroxyindole		
metabolite		
JWH 018 7-		
hydroxyindole	22	90.9
metabolite		
JWH 018 N- (2-	22.5	88.9
methylbutyl) isomer	22.3	00.7
JWH 018 N- (1-	36	55.6
methylbutyl) isomer	30	33.0
JWH 018 N- (2,2-		
dimethylpropyl)	37.4	53.4
isomer		
JWH 073 N-(1-	40	50
methylpropyl) isomer	70	
JWH 019 5-		50
hydroxyindole	40	
metabolite		
JWH 200 5-		
hydroxyindole	50	40
metabolite		
JWH 398 N-(5-		
hydroxypentyl)	52	38.4
metabolite		
JWH 020	59	33.9
JWH 073 N-butanoic	83.5	24
acid metabolite	03.3	
JWH 122 N-(5-		
hydroxypentyl)	90	22.2
metabolite		
JWH-424	100	20
JWH-018 4-	120	16.7
hydroxyindole		
metabolite		

Table 25. Specificity of the alpha-PVP Assay on Evidence MultiSTAT DOA Urine Array

alpha-PVP Assay				
Compound	Approximate Concentration to Read Positive (ng/ml)	Approximate % Cross Reactivity		
α-				
Pyrrolidinovalerop	5	100		
henone				
Naphyrone HCI	3.5	143		
MDPV HCI	7	71.4		
Butylone HCI	ND	ND		
Methedrone HCI	ND	ND		
Methylone HCI	ND	ND		
MDPPP HCI	ND	ND		

Table 26. Specificity of the Creatinine Assay on Evidence MultiSTAT DOA Urine Array

Creatinine Assay		
Compound	Approximate Concentration to Read Positive (mg/dL)	Approximate % Cross Reactivity
Creatinine	20	100

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