



Urine Drug Analysis Test No. 14-5671

Summary Report

This test was sent to 25 participants. Each sample set contained three testing events, each containing one specimen bottle of human urine. Participants were requested to examine these items and report their findings. Data were returned from 22 participants (88% response rate) and are compiled into the following tables:

	<u>Page</u>
<u>Manufacturer's Information</u>	<u>2</u>
<u>Summary Comments</u>	<u>3</u>
<u>Table 1: Item 1 Results</u>	<u>4</u>
<u>Table 2: Item 2 Results</u>	<u>12</u>
<u>Table 3: Item 3 Results</u>	<u>20</u>
<u>Table 4: Additional Test Comments</u>	<u>28</u>
<u>Appendix: Data Sheet</u>	<u>29</u>

This report contains the data received from the participants in this test. Since these participants are located in many countries around the world, and it is their option how the samples are to be used (e.g., training exercise, known or blind proficiency testing, research and development of new techniques, etc.), the results compiled in the Summary Report are not intended to be an overview of the quality of work performed in the profession and cannot be interpreted as such. The Summary Comments are included for the benefit of participants to assist with maintaining or enhancing the quality of their results. These comments are not intended to reflect the general state of the art within the profession.

Participant results are reported using a randomly assigned "WebCode". This code maintains participant's anonymity, provides linking of the various report sections, and will change with every report.

Manufacturer's Information

The sample sets contained urine samples from three cases, each with an individual case scenario. Each case sample consisted of one specimen bottle containing 50mL of human urine. Participants were requested to analyze the urine samples and report the presence of any drugs/metabolites, any quantitative data obtained (including uncertainty), methods used, and any additional comments.

SAMPLE PREPARATION-

The urine used in this test was from the same lot, which tested negative for a variety of common drugs and controlled substances prior to being obtained from a commercial supplier.

A stock solution of 1.0mg/mL of each drug in methanol was used to spike each item. These solutions were obtained in sealed ampoules and were not opened until needed for production. Items were prepared at separate times using the following procedure, and different glassware was used for each item.

ITEMS 1, 2, and 3 (PREPARATION): Sample preparation consisted of adding a predetermined amount of drug stock solution to a 500mL graduated cylinder containing human urine. The urine was then transferred to a beaker where the equivalent of 2% w/v sodium fluoride was added and then stirred with a magnetic stirrer for at least 20 minutes. 50mL of the mixture was then transferred into each of the pre-labeled specimen bottles. All bottles were stored in a refrigerator immediately after production until the sample sets were prepared.

SAMPLE SET ASSEMBLY: Each sample set contained Items 1, 2, and 3 and was placed into a Department of Transportation regulated shipping container. Each sample pack was labeled and returned to the refrigerator until shipment.

VERIFICATION-

Laboratories that conducted predistribution analysis of the samples reported consistent results that were comparable to the preparation drug concentrations.

<u>Item 1 Drug (Concentration)</u>	<u>Item 2 Drug (Concentration)</u>	<u>Item 3 Drug (Concentration)</u>
Morphine (1500ng/mL)	Methadone (1000ng/mL)	Amphetamine (400ng/mL)
6-acetylmorphine (250ng/mL)	11-Nor-9-carboxy-delta-9-THC (170ng/mL)	MDMA (2000ng/mL)
	EDDP Perchlorate (600ng/mL)	

Please note that the Preparation Value is the value used for calculations during the test preparation phase and may not necessarily represent the final concentration of the samples. It is advised to wait for the Grand Mean statistics available in the Summary and Individual Reports before evaluating performance.

Summary Comments

This test was designed to allow participants to assess their proficiency in the examination for the presence and concentration of drugs and/or metabolites in urine. Each participant was supplied with one specimen bottle containing 50mL of human urine spiked with differing drugs and/or metabolites for each of three case scenarios. Participants were asked to report the presence of any drugs/metabolites, any quantitative data obtained (including uncertainty), methods used, and any additional comments. (Refer to the Manufacturer's Information for preparation details.)

Of the 22 participants who reported results for Item 1, 17 (77.3%) reported the presence of morphine and 6-acetylmorphine. One participant reported only morphine and another only 6-monoacetylmorphine. The remaining three participants reported results that did not meet the consensus. Of the 22 participants who reported results for Item 2, 18 (81.8%) reported the presence of Methadone, 19 (86.4%) reported the presence of THC, and 9 (40.9%) reported the presence of EDDP. Two participants reported results that did not meet the consensus. Of the 22 participants who reported results for Item 3, 17 (77.3%) reported the presence of Amphetamine and 18 (81.8%) reported the presence of MDMA. Four participants reported results that did not meet the consensus.

Several of the participants had results that did not meet the consensus due to only performing screening tests. The inclusion of screening results is being examined for future Urine-Drug Analysis tests to better meet the needs of screening laboratories.

Due to the small sample number of participants who reported quantitative information, no grand mean statistics were calculated or determinations regarding "extreme" data made.

Reported Results - Item 1

TABLE 1A Item 1 Results

Item 1 Scenario:

A 31-year-old male was found dead in a trailer in a remote rural district several weeks after he had been reported missing. He appeared to have succumbed to respiratory depression. Empty beer bottles, a spoon, and a syringe were found near the body. A urine sample was the only sample collected for analysis.

Item Contents and Preparation Concentration: Morphine (1500 ng/mL)
6-acetylmorphine (250 ng/mL)

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
3PT284	Morphine		>1		µg/ml
	6-Acetylmorphine		0,27		µg/ml
4KYA4R	morphine		1591		ng/mL
	6-acetylmorphine		236		ng/mL
7X2HXF	Morphine	✓			
	6-monoacetylmorphine	✓			
AHF49D	Morphine	✓			
	6-monoacetylsic morphine (6 MAM)	✓			
AZCRCG	Morphine	✓			
	O6-monoacetylmorphine	✓			
B82WGM	MORPHINE		2324	152	ng/ml
	6-MAM		276	22	ng/ml
BT6MZN	Opiate Panel	✓			
	Oxycodone Panel	✓			
CBKDED	Opiates	✓			
ECQDND	Morphine	✓			
	6-Monoacetylmorphine	✓			

TABLE 1A Item 1 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
FVBTZP	Morphine	✓			
	6-acetylmorphine (MAM)	✓			
J9RVDD	Morphine	✓			
	6-Monoacetylmorphine	✓			
JGLVMK	Morphine	✓			
	6-Monoacetylmorphine	✓			
JRNYGA	Morphine	✓			
	O ⁶ -Monoacetylmorphine[sic]	✓			
LKH2L3	opiates (morphine)	✓			
N46CL7	6-Acetylmorphine	✓			
QCRCPA	Opiate Panel	✓			
	Oxycodone Panel	✓			
QUR27C	Morphine	✓			
	O ⁶ -monoacetylmorphine	✓			
UL836W	Morphine	✓			
	O-6-Monoacetylmorphine	✓			
V8HKKC	Morphine	✓			
	Monoacetyl morphine	✓			
YKD6GX	Morphine	✓			
	6-monoacetyl morphine	✓			

TABLE 1A Item 1 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
Z8K3EW	Morphine		1441	220	ng/mL
	6-monoacetylmorphine		247	40	ng/mL
ZBVD36	morphine		1326		
	6-mono-acetylmorphine		230		

Response Summary for Item 1		Participants: 22
Morphine:	18 (81.8%)	
6-acetylmorphine:	18 (81.8%)	
Other:	5 (22.7%)	

Raw Data - Item 1

List of raw data determinations in ng/mL.

TABLE 1B

Item 1 Raw Data - Morphine

Webcode	Raw Data (ng/mL)		Participant Mean
4KYA4R	1,604.00	1,578.30	1,591.2
Z8K3EW	1,441.00		1,441.0

Statistical Analysis for Item 1 - Morphine

Please note statistical analysis for this Item has not been provided due to the low number of raw data responses.

Item 1 Raw Data - 6-acetylmorphine

Webcode	Raw Data (ng/mL)		Participant Mean
4KYA4R	234.06	238.77	236.4
Z8K3EW	247.00		247.0

Statistical Analysis for Item 1 - 6-acetylmorphine

Please note statistical analysis for this Item has not been provided due to the low number of raw data responses.

Reporting Procedures - Item 1

If quantitative analysis was performed, the reported concentration procedure is:

TABLE 1C - Item 1

Webcode	Quantitative Reporting Procedures
3PT284	A single determination
4KYA4R	The mean of duplicate/several determinations
B82WGM	The mean of duplicate/several determinations
Z8K3EW	A single determination
ZBVD36	A single determination

Response Summary for Item 1	Participants: 5
A single determination:	3 (60.0%)
The mean of duplicate/several determinations:	2 (40.0%)
Other:	0 (0.0%)

Method of Analysis - Item 1

TABLE 1D
Method of Analysis

Webcode	Method	Screening	Confirmatory	Quantitation
3PT284	Immunoassay	✓		
	GC/MS		✓	✓
4KYA4R	Immunoassay	✓		
	GC/MS		✓	✓
	LC/MS/MS		✓	✓
7X2HXF	Immunoassay	✓		
	GC/MS		✓	
AHF49D	Immunoassay	✓		
	GC/MS		✓	
	LC/MS/MS		✓	
AZCRCG	Immunoassay	✓		
	GC/MS		✓	
B82WGM	Immunoassay	✓		
	GC/MS		✓	✓
BT6MZN	Immunoassay	✓		
CBKDED	Immunoassay	✓		
ECQDND	Immunoassay	✓		
	GC/MS		✓	
FVBTZP	Immunoassay	✓		
	GC/MS		✓	
J9RVDD	Immunoassay	✓		
	GC/MS		✓	
JGLVMK	Immunoassay	✓		
	GC/MS		✓	
JRNYGA	Immunoassay	✓		
	GC/MS	✓	✓	
LKH2L3	Immunoassay	✓		
N46CL7	LC/MS/MS	✓		
	Rapid Chromatographic Immunoassay	✓		
	GC/MS		✓	
QCRCPA	Immunoassay	✓		
QUR27C	Immunoassay	✓		
	LC/MS/MS		✓	

TABLE 1D
Method of Analysis

Webcode	Method	Screening	Confirmatory	Quantitation
UL836W	Immunoassay	✓		
	GC/MS		✓	
V8HKKC	Immunoassay	✓		
	GC/MS		✓	
YKD6GX	Immunoassay	✓		
	GC/MS	✓	✓	
Z8K3EW	Immunoassay	✓		
	GC/MS		✓	✓
ZBVD36	LC/MS/MS	✓		
	GC/MS	✓		✓

Additional Comments for Item 1

TABLE 1 E

Webcode	Item 1 - Comments
AZCRCG	Our facility does not normally analyze samples from deceased individuals, only living suspects/victims.
BT6MZN	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoylcegonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
CBKDED	Opiates cutoff is 300 ng/mL.
ECQDND	Phenyltoloxamine and heptabarbital are used as internal reference materials. This laboratory does not routinely analyze biological fluids from the deceased.
JGLVMK	Nalorphine was used as ISTD. LOD for 6-MAM was 50 ng/ml. LOD for morphine was 15 ng/ml.
JRNYGA	SPE - CSDAU (UCT). ISTD - phenyltoloxamine.
LKH2L3	Analysed Using Randox Evidence Investigator
N46CL7	Alere iCassette (THC) test device was used to screen for THC.
QCRCPA	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoylcegonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
UL836W	Phenyltoloxamine- basic Istd. Hexobarbital- acid Istd
V8HKKC	On receipt of Item 1, contents had leaked from specimen container into ziplock compartment. Recovery of the specimen was accomplished thru collection from ziplock container and from container. Approximately 10 mls of the specimen was recovered. Analysis was performed on the recovered specimen.
Z8K3EW	Internal Standards: Codeine -D6, Morphine-D6, 6-MAM-D6. Limits of detection: Codeine = 50ng/mL, Morphine = 50ng/mL, 6-MAM = 10 ng/mL. Morphine determined as unconjugated.
ZBVD36	for morphine quantitation : estimation (upper superior limit of quantitation)

Reported Results - Item 2

TABLE 2A Item 2 Results

Item 2 Scenario:

A 43-year-old female was pulled over for speeding and excessive tailgating. The driver admitted to being a previous heroin user. A Drug Recognition Expert was brought in and reported euphoria and red eyes but no horizontal or vertical nystagmus. A blood sample could not be collected so a urine sample was collected for analysis a few hours after the incident had occurred.

Item Contents and Preparation Concentration: Methadone (1000 ng/mL)
 11-Nor-9-carboxy-delta-9-THC (170ng/mL)
 EDDP Perchlorate (600 ng/mL)

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
3PT284	Methadone		0,92		µg/ml
	Tetrahydrocannabinol acid		0,15		µg/ml
	EDDP		0,58		µg/ml
4KYA4R	methadone	✓			
	Delta-9-tetrahydrocannabinol-9-carboxylic acid		141		ng/mL
7X2HXF	Methadone	✓			
	Delta9-THC-COOH	✓			
AHF49D	Methadone	✓			
	EDDP (methadone metabolite)	✓			
AZCRCG	Methadone	✓			
	THC-COOH (a marijuana metabolite)	✓			
B82WGM	METHADONE		953	15	ng/ml
	THC-COOH		120	10	ng/ml
	EDDP		584	10	ng/ml
BT6MZN	Cannabinoids Panel	✓			
CBKDED	THC/Marijuana	✓			

TABLE 2A Item 2 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
ECQDND	Methadone	✓			
	THC-COOH	✓			
FVBTZP	Methadone	✓			
	Delta-9-THC-COOH (Carboxy-THC)	✓			
J9RVDD	Methadone	✓			
	11-nor delta9 THC 9 carboxylic acid	✓			
JGLVMK	Methadone	✓			
	Delta9-Carboxy THC	✓			
JRNYGA	Methadone	✓			
	THCC	✓			
LKH2L3	Cannabis	✓			
N46CL7	Methadone	✓			
	11-nor-9-carboxy-delta9-THC	✓			
	EDDP	✓			
QCRCPA	Cannabinoids Panel	✓			
QUR27C	Methadone	✓			
	11-nor-9-carboxy-delta9-THC	✓			
	EDDP (methadone metabolite)	✓			
UL836W	Methadone	✓			
	THC- COOH	✓			
V8HKKC	Methadone	✓			

TABLE 2A Item 2 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
V8HKKC	THC Acid (cannabinoids)	✓			
	Methadone metbs (EDDP and EMDP)	✓			
YKD6GX	Methadone	✓			
	11-nor-9-carboxy-delta9-tetrahydrocannabinol (THCA)	✓			
	EDDP	✓			
Z8K3EW	Methadone	✓			
	11-nor-9-carboxy-delta-9-tetrahydrocannabinol EDDP (Methadone metabolite)	✓	130	36	ng/mL
ZBVD36	methadone		951		
	THCCOOH		97.6		
	EDDP	✓			

Response Summary for Item 2		Participants: 22
Methadone:	18 (81.8%)	
THC:	19 (86.4%)	
EDDP:	9 (40.9%)	
Other:	2 (9.1%)	

Raw Data - Item 2

List of raw data determinations in ng/mL.

TABLE 2B

Item 2 Raw Data - 11-Nor-9-carboxy-delta-9-THC

Webcode	Raw Data (ng/mL)	Participant Mean
4KYA4R	141.22 140.00	140.6
Z8K3EW	130.00	130.0

Statistical Analysis for Item 2- 11-Nor-9-carboxy-delta-9-THC

Please note statistical analysis for this Item has not been provided due to the low number of raw data responses.

Reporting Procedures - Item 2

If quantitative analysis was performed, the reported concentration procedure is:

TABLE 2C - Item 2

Webcode	Quantitative Reporting Procedures
3PT284	A single determination
4KYA4R	The mean of duplicate/several determinations
B82WGM	The mean of duplicate/several determinations
Z8K3EW	A single determination
ZBVD36	A single determination

Response Summary for Item 2		Participants: 5
A single determination:	3 (60.0%)	
The mean of duplicate/several determinations:	2 (40.0%)	
Other:	0 (0.0%)	

Method of Analysis - Item 2

TABLE 2D

Method of Analysis

Webcode	Method	Screening	Confirmatory	Quantitation
3PT284	Immunoassay	✓		
	LC/MS/MS		✓	✓
4KYA4R	Immunoassay	✓		
	GC/MS		✓	✓
7X2HXF	Immunoassay	✓		
	GC/MS		✓	
AHF49D	Immunoassay	✓		
	GC/MS		✓	
AZCRCG	Immunoassay	✓		
	GC/MS		✓	
B82WGM	Immunoassay	✓		
	GC/MS		✓	✓
	LC/MS/MS		✓	✓
BT6MZN	Immunoassay	✓		
CBKDED	Immunoassay	✓		
ECQDND	Immunoassay	✓		
	GC/MS		✓	
FVBTZP	Immunoassay	✓		
	GC/MS		✓	
J9RVDD	Immunoassay	✓		
	GC/MS		✓	
JGLVMK	Immunoassay	✓		
	GC/MS	✓	✓	
JRNYGA	Immunoassay	✓		
	GC/MS	✓	✓	
LKH2L3	Immunoassay	✓		
N46CL7	LC/MS/MS	✓		
	Rapid Chromatographic Immunoassay	✓		
	GC/MS		✓	
QCRCPA	Immunoassay	✓		

TABLE 2D
Method of Analysis

Webcode	Method	Screening	Confirmatory	Quantitation
QUR27C	Immunoassay	✓		
	LC/MS/MS	✓	✓	
UL836W	Immunoassay	✓		
	GC/MS		✓	
V8HKKC	Immunoassay	✓		
	GC/MS		✓	
YKD6GX	Immunoassay	✓		
	GC/MS	✓	✓	
Z8K3EW	Immunoassay	✓		
	GC/MS		✓	✓
ZBVD36	LC/MS/MS	✓		
	GC/MS	✓		✓

Additional Comments for Item 2

TABLE 2E

Webcode	Item 2 - Comments
BT6MZN	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoyllecgonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
CBKDED	THC/Marijuana cutoff is 50 ng/mL.
ECQDND	Phenyltoloxamine, heptabarbital and 11-hydroxy-THC are used as internal reference materials.
J9RVDD	The Cyclic Metabolite of Methadone was also detected but not confirmed with reference material.
JGLVMK	PCP-d5 was used as ISTD for Methadone. Delta9-Carboxy THC-d9 was used as ISTD for delta9-Carboxy THC. LOD of Methadone = 10 ng/ml. LOD of THCA = 5 ng/ml. EDDP was detected in this specimen. However, EDDP is not normally reported for our regular DUI cases, therefore, it is not reported for this proficiency case.
JRNYGA	SPE - CSDAU (UCT). SPE - CSTHC (UCT) - base hyd/deriv sydon BFT
LKH2L3	Analysed using the Randox Evidence Investigator
N46CL7	Alere iCassette (THC) test device was used to screen for THC.
QCRCPA	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoyllecgonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
UL836W	Phenyltoloxamine- basic lstd. Hexobarbital- acid lstd. 11-OH-THC - THC lstd
Z8K3EW	Internal Standards: THC-COOH -D9, Limit of Detection: 5ng/mL, Methadone - Limit of Detection: 300ng/mL
ZBVD36	for methadone quantitation : estimation (upper superior limit of quantitation)

Reported Results - Item 3

TABLE 3A Item 3 Results

Item 3 Scenario:

A 19-year-old female arrived at the police station the morning after a party during which she suspects she was the victim of a drug-facilitated sexual assault. She did not suffer from amnesia and recalls thinking that her drink tasted slightly bitter. She reported experiencing excessive sweating, agitation, jaw tension and recalls being physically unable to resist the assault. A urine sample was collected for analysis approximately 12 hours after the suspected incident.

Item Contents and Preparation Concentration: Amphetamine (400 ng/mL)
MDMA (2000 ng/mL)

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
3PT284	Amphetamine		0,34		µg/ml
	MDMA		1,61		µg/ml
4KYA4R	amphetamine		411		ng/mL
	methylenedioxyamphetamine		1934		ng/mL
7X2HXF	Amphetamine	✓			
	MDMA	✓			
AHF49D	Gamma-hydroxybutyric acid	✓			
AZCRCG	3,4-methylenedioxy methamphetamine (MDMA)	✓			
B82WGM	AMPHETAMINE		380	9	ng/ml
	MDMA		1966	105	ng/ml
BT6MZN	Amphetamine Panel	✓			
	Methamphetamine Panel	✓			
CBKDED	Amphetamines	✓			
ECQDND	Amphetamine	✓			
	MDMA	✓			
FVBTZP	Amphetamine	✓			
	Methylenedioxyamphetamine (MDMA)	✓			

TABLE 3A Item 3 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
J9RVDD	Amphetamine	✓			
	Methylenedioxymethamphetamine (MDMA)	✓			
JGLVMK	Amphetamine	✓			
	MDMA	✓			
JRNYGA	Amphetamine	✓			
	MDMA	✓			
LKH2L3	Methylenedioxymethamphetamine (MDMA)	✓			
	Methylamphetamine	✓			
N46CL7	Amphetamine	✓			
	Methylenedioxymethamphetamine (MDMA)	✓			
QCRCPA	Amphetamine Panel	✓			
	Methamphetamine Panel	✓			
QUR27C	Amphetamine	✓			
	MDMA (methylenedioxymethamphetamine)	✓			
UL836W	Amphetamine	✓			
	3,4-Methylenedioxy methamphetamine	✓			
V8HKKC	Amphetamine	✓			
	MDMA	✓			
YKD6GX	Amphetamine	✓			
	3,4-methylenedioxy methamphetamine (MDMA)	✓			
Z8K3EW	Amphetamine		371	49	ng/mL
	MDMA	✓			

TABLE 3A Item 3 Results

Webcode	Analyte Reported	Qualitative Only	Reported Concentration	Uncertainty	Units
ZBVD36	amphetamine		298.5		
	MDMA		1416		

Response Summary for Item 3		Participants: 22
Amphetamine:	17 (77.3%)	
MDMA:	18 (81.8%)	
Other:	6 (27.3%)	

Raw Data - Item 3

List of raw data determinations in ng/mL.

TABLE 3B

Item 3 Raw Data - Amphetamine

Webcode	Raw Data (ng/mL)		Participant Mean
4KYA4R	411.07	410.01	410.5
Z8K3EW	371.00		371.0

Statistical Analysis for Item 3 - Amphetamine

Please note statistical analysis for this Item has not been provided due to the low number of raw data responses.

Item 3 Raw Data - MDMA

Webcode	Raw Data (ng/mL)		Participant Mean
4KYA4R	1,926.81	1,940.50	1,933.7

Statistical Analysis for Item 3 - MDMA

Please note statistical analysis for this Item has not been provided due to the low number of raw data responses.

Reporting Procedures - Item 3

If quantitative analysis was performed, the reported concentration procedure is:

TABLE 3C - Item 3

WebCode	Quantitative Reporting Procedures
3PT284	A single determination
4KYA4R	The mean of duplicate/several determinations
B82WGM	The mean of duplicate/several determinations
Z8K3EW	A single determination
ZBVD36	A single determination

Response Summary for Item 3	Participants: 5
A single determination:	3 (60.0%)
The mean of duplicate/several determinations:	2 (40.0%)
Other:	0 (0.0%)

Method of Analysis - Item 3

TABLE 3D
Method of Analysis

WebCode	Method	Screening	Confirmatory	Quantitation
3PT284	Immunoassay LC/MS/MS	✓	✓	✓
4KYA4R	Immunoassay GC/MS	✓	✓	✓
7X2HXF	Immunoassay LC/MS/MS	✓	✓	
AHF49D	GC/MS		✓	
AZCRCG	Immunoassay GC/MS	✓	✓	
B82WGM	Immunoassay GC/MS	✓	✓	✓
BT6MZN	Immunoassay	✓		
CBKDED	Immunoassay	✓		
ECQDND	Immunoassay GC/MS	✓	✓	
FVBTZP	Immunoassay GC/MS	✓	✓	
J9RVDD	Immunoassay GC/MS	✓	✓	
JGLVMK	GC/MS	✓	✓	
JRNYGA	Immunoassay GC/MS	✓ ✓	✓	
LKH2L3	Immunoassay	✓		
N46CL7	LC/MS/MS Rapid Chromatographic Immunoassay GC/MS	✓ ✓	✓	
QCRCPA	Immunoassay	✓		

TABLE 3D
Method of Analysis

WebCode	Method	Screening	Confirmatory	Quantitation
QUR27C	Immunoassay	✓		
	LC/MS/MS	✓	✓	
UL836W	Immunoassay	✓		
	GC/MS		✓	
V8HKKC	Immunoassay	✓		
	GC/MS		✓	
YKD6GX	Immunoassay	✓		
	GC/MS	✓	✓	
Z8K3EW	Immunoassay	✓		
	GC/MS		✓	✓
ZBVD36	LC/MS/MS	✓		
	GC/MS	✓		✓

Additional Comments for Item 3

TABLE 3E

WebCode	Item 3 - Comments
7X2HXF	During the confirmation analysis for amphetamines, a peak was detected for MDA. The area of this peak was less than the area for our limit of detection. The limit of detection for MDA is 25ng/mL. It was determined that the result for MDA was none detected, per laboratory policy.
AZCRCG	Our facility does not perform DFSA analyses. Such cases are sent to our Central Laboratory.
BT6MZN	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoyllecgonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
CBKDED	Amphetamines cutoff is 500 ng/mL.
ECQDND	Phenyltoloxamine and heptabarbital are used as internal reference materials. This laboratory does not routinely analyze biological fluids from drug facilitated sexual assaults.
JGLVMK	PCP-d5 was used as ISTD for both Amphetamine & MDMA. LOD of Amphetamine = 50 ng/ml. LOD of MDMA = 25 ng/ml.
JRNYGA	SPE - CSDAU (UCT)
LKH2L3	Analysed Using Randox Evidence Investigator
N46CL7	Alere iCassette (THC) test device was used to screen for THC.
QCRCPA	We utilized ELISA, and use Immunalysis Kits. It is not our practice to report a specific analyte as a (+) or (-). We perform an ELISA screen that consists of 10 different panels, therefore an entire panel gets reported as positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoyllecgonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
QUR27C	Internal standards used: D5-MDMA & D5-Amphetamine.
UL836W	Phenyltoloxamine- basic lstd. Hexobarbital- acid lstd
Z8K3EW	Internal Standards: Amphetamine-D5, Methamphetamine-D5. Limit of Detection: Amphetamine = 150ng/mL, Methamphetamine = 150ng/mL, Phentermine = 150ng/mL, MDA = 150ng/mL, MDMA = 150ng/mL.
ZBVD36	for MDMA quantitation : estimation (upper superior limit of quantitation)

Additional Test Comments

TABLE 4

WebCode	Additional Comments
BT6MZN	Our method of analysis is ELISA and we use Immunalysis Kits. We do not report a specific analyte as positive (+) or negative (-). We perform an ELISA screen that consists of 10 different panels, thus an entire panel is reported as either positive or negative. ELISA Panels and Cutoffs (ng/ml)- Amphetamine 25, Benzodiazepines 25, Benzoylcegonine 10, Flunitrazepam 5, Ketamine 5, Methamphetamine 25, Opiates 10, Oxycodone 5, D9-THC 10, Zolpidem 5.
QCRCPA	Our ELISA panels test for a variety of analytes including both parent drugs and their metabolites. When a positive result is detected and reported, a single analyte (drug or metabolite) is not reported or confirmed, therefore, the result is reported out as a panel screening positive. Our presumptive results are not confirmed in-house. We send out for our confirmation tests upon request. These samples will be sent out for confirmation analysis. Your worksheet asks for a specific analyte in the results section. We are not able to provide such an answer. I provided our panel(s) that screened positive, which will absolutely not be the consensus result. Please take into consideration upon evaluation.
V8HKKC	On Item 3, I found in[sic] unusual to find MDMA and amphetamine w/o the presence of MDA or methamphetamine. On case submission of the type, I have seen MDA as a metabolite of MDMA as well as methamphetamine.

Appendix: Data Sheet

Collaborative Testing Services ~ Forensic Testing Program

Test No. 14-5671: Urine Drug Analysis

DATA MUST BE RECEIVED BY December 22, 2014 TO BE INCLUDED IN THE REPORT

Participant Code:

WebCode:

Accreditation Release Statement

CTS submits external proficiency test data directly to ASCLD/LAB and ANSI-ASQ NAB/FQS. Please select one of the following statements to ensure your data is handled appropriately.

- This participant's data is intended for submission to ASCLD/LAB and/or ANSI-ASQ NAB/FQS. (Accreditation Release section on the last page must be completed and submitted.)
- This participant's data is NOT intended for submission to ASCLD/LAB or ANSI-ASQ NAB/FQS.

Online Data Entry

Visit www.cts-portal.com to enter your proficiency test results online. If you have any questions please do not hesitate to contact CTS.

Scenario:

Investigators have submitted three urine specimens from three separate cases for your analysis. Using your laboratory's procedures, analyze each sample and report the presence of any drugs and/or metabolites.

Case 1: A 31-year-old male was found dead in a trailer in a remote rural district several weeks after he had been reported missing. He appeared to have succumbed to respiratory depression. Empty beer bottles, a spoon, and a syringe were found near the body. A urine sample was the only sample collected for analysis.

Case 2: A 43-year-old female was pulled over for speeding and excessive tailgating. The driver admitted to being a previous heroin user. A Drug Recognition Expert was brought in and reported euphoria and red eyes but no horizontal or vertical nystagmus. A blood sample could not be collected so a urine sample was collected for analysis a few hours after the incident had occurred.

Case 3: A 19-year-old female arrived at the police station the morning after a party during which she suspects she was the victim of a drug-facilitated sexual assault. She did not suffer from amnesia and recalls thinking that her drink tasted slightly bitter. She reported experiencing excessive sweating, agitation, jaw tension and recalls being physically unable to resist the assault. A urine sample was collected for analysis approximately 12 hours after the suspected incident.

Instructions:

- Please do not report the presence/concentration of drugs in concentrations less than 10ng/mL.
- The purpose of this test is the examination of drugs other than alcohol; please test accordingly. Samples may contain methanol and acetonitrile as artifacts from production.

Items Submitted (Sample Pack UDRG):

Items 1: Urine sample from Case 1

Items 2: Urine sample from Case 2

Items 3: Urine sample from Case 3

Please return all pages of this data sheet.

Page 1 of 9

Results for Item 1:**1-1.) Date Samples Received:** _____**1-2.) What drugs/metabolites were detected in Item 1? If quantitative determinations were performed, please record raw data in the provided spaces in ng/mL.**

The number of boxes shown does not indicate the number of analytes present. If additional space is needed, copy this page or attach your own form following this layout.

No drugs/metabolites detected

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Please return all pages of this data sheet.

Results for Item 1 (continued):

1-3) If quantitative analysis was performed, are the reported concentrations for Item 1:

A single determination? The mean of duplicate / several determinations?

Other? (Specify): _____

1-4.) Please check the methods used to analyze Item 1 by selecting whether each method used was for screening, confirmatory testing and/or quantitation.

<u>Method Used</u>	<u>Screening</u>	<u>Confirmatory</u>	<u>Quantitation</u>
Immunoassay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1-5.) Additional Comments for Item 1

Please include any relevant information such as internal standard(s) used, limits of detection, etc.

Results for Item 2:**2-1.) Date Samples Received:** _____**2-2.) What drugs/metabolites were detected in Item 2? If quantitative determinations were performed, please record raw data in the provided spaces in ng/mL.**

The number of boxes shown does not indicate the number of analytes present. If additional space is needed, copy this page or attach your own form following this layout.

No drugs/metabolites detected

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Results for Item 2 (continued):**2-3) If quantitative analysis was performed, are the reported concentrations for Item 2:**

A single determination? The mean of duplicate / several determinations?

Other? (Specify): _____

2-4.) Please check the methods used to analyze Item 2 by selecting whether each method used was for screening, confirmatory testing and/or quantitation.

<u>Method Used</u>	<u>Screening</u>	<u>Confirmatory</u>	<u>Quantitation</u>
Immunoassay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2-5.) Additional Comments for Item 2

Please include any relevant information such as internal standard(s) used, limits of detection, etc.

Results for Item 3:**3-1.) Date Samples Received:** _____**3-2.) What drugs/metabolites were detected in Item 3? If quantitative determinations were performed, please record raw data in the provided spaces in ng/mL.**

The number of boxes shown does not indicate the number of analytes present. If additional space is needed, copy this page or attach your own form following this layout.

 No drugs/metabolites detected

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Analyte	Qualitative Only?	Reported Concentration	Uncertainty	Units
_____	<input type="checkbox"/>	_____	_____	(_____)
Date(s) Quantitative Analysis Performed on Analyte: _____				
Raw Data (ng/mL):				
_____	_____	_____	_____	_____

Please return all pages of this data sheet.

Results for Item 3 (continued):**3-3) If quantitative analysis was performed, are the reported concentrations for Item 3:**

A single determination? The mean of duplicate / several determinations?

Other? (Specify): _____

3-4.) Please check the methods used to analyze Item 3 by selecting whether each method used was for screening, confirmatory testing and/or quantitation.

<u>Method Used</u>	<u>Screening</u>	<u>Confirmatory</u>	<u>Quantitation</u>
Immunoassay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LC/MS/MS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3-5.) Additional Comments for Item 3

Please include any relevant information such as internal standard(s) used, limits of detection, etc.

Participant Code:

WebCode:

Additional Comments on Test

Return Instructions: Data must be received via online data entry, fax (please include a cover sheet), or mail by *December 22, 2014* to be included in the report.

QUESTIONS?

TEL: +1-571-434-1925 (8 am - 4:30 pm EST)
EMAIL: forensics@cts-interlab.com
www.ctsforensics.com

Participant Code:

ONLINE DATA ENTRY: www.cts-portal.com
FAX: +1-571-434-1937
or Toll-Free: 1-866-FAX-2CTS (329-2287)

MAIL: Collaborative Testing Services, Inc.
P.O. Box 650820
Sterling, VA 20165-0820 USA

Please return all pages of this data sheet.

Page 8 of 9

RELEASE OF DATA TO ACCREDITATION BODIES

The following Accreditation Releases will apply only to:

Participant Code:

WebCode:

for Test No. **14-5671: Urine Drug Analysis**

This release page must be completed and received by **December 22, 2014** to have this participant's submitted data included in the reports forwarded to the respective Accreditation Bodies.

ASCLD/LAB RELEASE

If your lab has been accredited by ASCLD/LAB and you are submitting this data as part of their external proficiency test requirements, have the laboratory's designated individual complete the following.

The information below must be completed in its entirety for the results to be submitted to ASCLD/LAB.

ASCLD/LAB Legacy Certificate No. _____ ASCLD/LAB International Certificate No. _____

Signature _____ Date _____

Laboratory Name _____

Location (City/State) _____

ANSI-ASQ NAB/FQS RELEASE

If your laboratory maintains its accreditation through ANSI-ASQ NAB/FQS, please complete the following form in its entirety to have your results forwarded.

ANSI-ASQ NAB/FQS Certificate No. _____

Signature and Title _____ Date _____

Laboratory Name _____

Location (City/State) _____

Accreditation Release

Return Instructions

Please submit the completed Accreditation Release at the same time as your full data sheet. See Data Sheet Return Instructions on the previous page.

*Questions? Contact us 8 am-4:30 pm EST
Telephone: +1-571-434-1925
email: forensics@cts-interlab.com*

Please return all pages of this data sheet.

Page 9 of 9