INSTANT-VIEW® Multi-Drug Screen Urine Test

INSTRUCTIONS FOR USE

One Step Assay
Rapid Visual Results
For Professional, Qualitative In Vitro Diagnostic Use

INTENDED USE AND SUMMARY OF TESTS

The *INSTANT-VIEW® Multi-Drug Screen Urine Test* is a qualitative immunoassay intended to be used to detect the presence of drugs and/or drug metabolites in human urine at, their specified cutoff levels, in a single assay. It is intended for health care professional use only.

The INSTANT-VIEW® Multi-Drug Screen Urine Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrophotometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.[1]

Immunoassay urine-based testing for drugs of abuse has become one of the most accepted methods of preliminary screening. These assays allow laboratories to eliminate a large number of negative specimens and focus on the smaller number of initially positive samples.

PRINCIPLE OF THE PROCEDURE

The *INSTANT-VIEW®* assay is a one-step lateral flow chromatographic immunoassay with test strips which include 1) a burgundy-colored conjugate pad containing colloidal gold conjugated to anti-drug antibodies and 2) a nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with the drug antigen; and the C line is coated with goat anti-mouse IgG antibody.

This test is a competitive binding immunoassay. The drug or drug metabolite in the urine specimen competes with the antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine migrates by capillary action through the test strips. If the drug level in the specimen is below the cutoff level, the burgundy-colored gold-antibody conjugate will bind to the antigens coated on the nitrocellulose membrane, and form a burgundy T line, indicating a negative result.

If the drug in the urine specimen is at a test strip's cutoff level or higher, it will bind to conjugated antibodies, so that no T line develops, indicating a positive result.

The colored gold-antibody conjugate should bind to the C line and form a burgundy-colored band regardless of the presence of the drug.

REAGENTS & MATERIALS SUPPLIED

- 25 test devices each sealed in a foil pouch with a desiccant and a dropper pipette (20 devices, if 7-12 test panel)
- 1 Instructions for Use

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen Collection Containers
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch containing desiccant.

Do not expose the kit to temperatures over 30°C (86°F).

SPECIMEN COLLECTION AND STORAGE

Each urine specimen must be collected in a clean container. Do not combine specimens.

Specimens may be kept at room temperature for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

Urine samples exhibiting visible precipitates should be filtered or centrifuged and allowed to settle. Use only clear aliquots for testing.

PRECAUTION

1. Instructions must be followed to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Remove the test device from the pouch and label it with specimen identification.
3. Perform assay:

DIP METHOD

a) Remove the cap and dip the device into the specimen for **at least 10 seconds.**
The surface of the sample must be above the sample well and below the level of the arrowheads in the window.
b) Remove the device from the specimen after 10 seconds.

OPTIONAL PROCEDURE: (Recommended for small sample volumes.)

a) Remove the cap. Take the pipette from the pouch.
b) Press bulb to fill the pipette with the sample specimen up to the line on the barrel. Add all the specimen into the sample well. For 2-sided panels (7-12 test), repeat sample addition by pipette on side 2.

4. Put the cap back on the device and place it on a flat dry surface.
5. Read the test result between four (4) to seven (7) minutes after adding the specimen.

IMPORTANT: Do not read test results after seven (7) minutes.

INTERPRETATION OF RESULTS

Positive:

If the C line appears and there is no T line, the test indicates a positive result for that particular drug.

Samples with positive results should be confirmed with a more specific method before a positive determination is made.

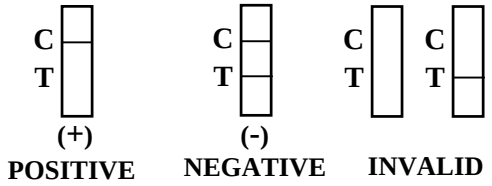
Negative:

If the C line and the T line both appear, the test indicates that the level for the corresponding drug or its metabolites is below the cutoff level.

Note: A very faint T line should be considered negative.

Invalid:

If no C line develops within 5 minutes on any test strip, the assay is invalid. In this case repeat the assay with a new test device.



QUALITY CONTROL

- **Built-in Control Features**

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the testing with a new device.

- **External Quality Control**

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS

1. This kit is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative analytical test result. A more specific alternate method must be used in order to obtain a confirmed analytical result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results if added in the device. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES

This test is capable of detecting each drug and/or drug metabolite specified in human urine at or above its specified cutoff level.

PERFORMANCE CHARACTERISTICS

INSTANT-VIEW® Multi-Drug Screen Urine Test devices are qualitative immunoassays intended for use by health care professionals to screen for potential abuse of one or more drugs in a single assay. Different devices are made to screen for different numbers and combinations of drugs. Performance attributes of the individual tests that may be in a given *INSTANT-VIEW®* device panel are summarized herein.

SENSITIVITY (CUTOFF):

Each assay is developed to detect the presence of a drug of abuse or metabolite(s)* thereof at or above a specified cutoff level. For all assays, tests of patient's samples should consistently indicate negative results for specimens below concentration of 75% of the cutoff and positive results above 125% of the cutoff. The drugs and their cutoff levels are listed below:

AMP	- Amphetamine……	1000 ng/ml	**MOR**	- Morphine……	2000 ng/ml
BAR	- Barbiturates……	200 ng/ml	**MTD**	- Methadone……	300 ng/ml
BZD	- Benzodiazepines…	300 ng/ml	**PCP**	- Phencyclidine……	25 ng/ml
COC	- Cocaine……	300 ng/ml	**PPX**	- Propoxyphene…	300 ng/ml
MET	- Methamphetamine**	500 ng/ml	**TCA**	- Tricyclics……	1000 ng/ml
MET	- Methamphetamine…	1000 ng/ml	**THC**	- Marijuana/Hashish	50 ng/ml
MOR	- Morphine**……	300 ng/ml	**XTC**	- MDMA or Ecstasy	500 ng/ml

**Metabolites detected in the above tests are listed in the sections below:*
***Available but not SAMHSA levels.*

INTERFERING SUBSTANCES:

Interfering Substances: To determine the interference of structurally unrelated analytes, each test analyte was evaluated, using the analyte specific *INSTANT-VIEW® Urine Test* device, in both drug free urine pools and urine pools spiked with the cutoff level of each analyte listed in the following table...

Common substances listed in this table were found not to interfere with the test results at the concentration of 100 µg/ml

Acetaminophen	*Oxalic Acid*	*Ethanol*
Acetylsalicylic Acid	*Caffeine*	*Lidocaine*
Amikacin	*(+)-Chlorpheniramine*	*Penicillin-G*
Amitriptyline	*Cocaine*	*Phenylpropanalamine*
Ampicillin	*Codeine*	*Ranitidine*
Arterenal	*Cortisone*	*Salicyclic Acid*
Aspirin	*Methadone*	*Thioridazine*
Atropine	*Methanol*	*Trifluoperazine*
Benzoic Acid		

Biological Analytes	Concentration	Biological Analytes	Concentration
Albumin	*200 µg/ml*	*pH*	*5.0 – 9.0*
Bilirubin	*100 µg/ml*	*Specific Gravity*	*1.002 – 1.035 g/ml*
Creatine	*100 µg/ml*	*Uric Acid*	*100 µg/ml*
Glucose	*200 µg/ml*	*Vitamin C*	*100 µg/ml*
Hemoglobin	*100 µg/ml*	*(L-Ascorbic Acid)*	

There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.(e.g., technical or procedural errors)

A. Amphetamine (AMP)

1. Summary and Explanation of the Test

The detection of amphetamines in human urine has been widely used to assess the abuse of amphetamines. Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and overall feeling of well-being. Overdose and extended usage of amphetamines may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours after administration (any type), and may be present for about 24-48 hours after the last dose.[2,3,4]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred nineteen (119) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Amphetamine Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Amphetamine Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above 125% of the cutoff (positive). Thirty eight (38) discrepancies were observed on the specimens at the level between 75% and 125% of the cutoff.

The overall agreement was 92.0%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	176	176	100%
	<75% (0~750)	0	76	76	100%
	75%~Cutoff (750~1000)	37	23	60	38.3%
	Cutoff~125% (1000~1250)	15	1	16	93.8%
	Positive (>1250)	148	0	148	100%
Total		200	276	476	92.0%

3. Reproducibility

Reproducibility was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty-pooled drug-free human urine specimens were spiked with amphetamine at different levels. All specimens were blind labeled and tested. The results are as follows:

Amp. Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
750	8	4	4	0	8	2	6
1000	8	8	0	8	0	8	0
1250	8	8	0	8	0	8	0
2000	8	8	0	8	0	8	0

The results indicate a 95.0% concordance with the expected results.

4. Cross-Reactivity

A study was conducted using amphetamine-related compounds to determine the cross-reactivity of the test.

Amphetamine related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level.

Compounds	Concentration (ng/ml)	Compounds	Concentration (ng/ml)
d-Amphetamine	*1000*	*3,4-methylenedioxyamphetamine (MDA)*	*3000*
l-Amphetamine	*20,000*		
d-,l-Amphetamine	*1000*		

B. Barbiturates (BAR)

1. Summary and Explanation of the Test

Barbiturates are central nervous system depressants and used as hypnotic sedatives. Overdose and extended usage of barbiturates may lead to severe and/or permanent damage to the human nervous system.[2] Barbiturates are classified as (1) ultra-short, (2) short-intermediate, and (3) long-acting. The duration range of the ultra short-acting compounds, secobarbital, pentobarbital etc. is from fifteen (15) minutes to six (6) hours. The duration range of the intermediate acting compounds, amobarbital, etc. is from three (3) to twenty-four (24) hours. The duration range of the long-acting compounds, phenobarbital etc. is from fifteen (15) to forty-eight (48) hours.[3,5]

The most commonly abused barbiturates are short- and intermediate-acting agents. The long-acting agents are rarely subject to abuse. Barbiturate derivatives are excreted into urine in varying amounts of unchanged drug and metabolites.[5] Long-acting barbiturates are excreted with a higher percentage of unchanged drug in the urine, while shorter-acting barbiturates, secobarbital and amobarbital, are extensively metabolized and excreted in the urine with a smaller percentage of unchanged drugs.[2,3]

The *INSTANT-VIEW® Barbiturate Urine Test* is designated to detect unchanged secobarbital in the urine; however, as with some other analytical methods such as EMIT and RIA, this assay can also detect other commonly encountered barbiturates, depending on the concentration of drug present in the sample. Phenobarbital positives have been noted in chronic users up to several weeks after cessation of use. With standard single doses of secobarbital, pentobarbital, or amobarbital, positive results may be identified from 30 hours to 76 hours.[2]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Barbiturate Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Barbiturate Urine Test* agreed 100% with the GC/MS data of specimens at levels below the cutoff (negative) and above 125% of the cutoff (positive). One (1) discrepancies was observed on the specimens at the level between the cutoff and 125% of the cutoff.

The overall agreement was 99.8%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	200	200	100%
	<75% (0~150)	0	12	12	100%
	75%~Cutoff (150~200)	0	20	20	100%
	Cutoff~125% (200~250)	27	1	28	96.4%
	Positive (>250)	140	0	140	100%
Total		167	233	400	99.8%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Barbiturate Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Amobarbital	*250*	*Phenobarbital*	*200*
Barbital	*250*	*Pentobarbital*	*250*
Butabarbital	*300*	*Secobarbital*	*200*
Butalbital	*200*		

C. Benzodiazepines (BZD)

1. Summary and Explanation of the Test

Benzodiazepines, including Alprazolam, Diazepam, Lorazepam, Triazolam, Chlordiazepoxide, Flurazepam and Temazepam are sedative, hypnotic and anti-anxiety drugs commonly being used as oral tranquilizers. Most benzodiazepine are extensively metabolized in the liver and excreted in the urine as metabolites.[3] Benzodiazepines have a low potential for physical or psychological dependence. However, the same as other central nervous system stimulating drugs, they may induce drowsiness and muscle relaxation. Chronic abuse of benzodiazepine may result in intoxication, similar to drunken behavior. Overdose and extended usage of benzodiazepine may lead to coma and possibly

death. Benzodiazepines may remain effective for 4-8 hours.[3, 5] The members of the Benzodiazepine family are absorbed at different rates and their effects may vary with the absorption rate. They are excreted in the urine primarily as their parent compounds or an inactive metabolite, oxazepam glucuronide, that are only detectable for one (1) to two (2) days. Oxazepam, a common metabolite of many benzodiazepines, is also a marketed drug (Serax); it may remain detectable in urine for up to one week.[3] That makes oxazepam a useful marker of benzodiazepine abuse.

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Benzodiazepine Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Benzodiazepine Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Seven (7) discrepancies were observed on the specimens at the level between 75% of the cutoff and the cutoff.

The overall agreement was 98.3%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	168	168	100%
	<75% (0~225)	0	24	24	100%
	75%~Cutoff (225~300)	7	25	32	78%
	Cutoff~125% (300~375)	32	0	32	100%
	Positive (>375)	144	0	144	100%
Total		183	217	400	98.3%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The device was tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100 % precision for the replicate within each lot and no appreciable interlot variation across the three (3) different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Benzodiazepine Urine Test*.

Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Alprazolam	*300*	*Lormetazepam*	*300*
Bromazepam	*500*	*Medazepam*	*300*
Clobazem	*1500*	*Nitrazepam*	*250*
Chlonazepam	*500*	*Nordiazepam*	*400*
Diazepam	*200*	*Prazepam*	*250*
Desmethyldiazepam	*300*	*Triazolam*	*300*
Flurazapam	*300*	*Oxazepam*	*300*
Lorazepam	*450*		

D. Cocaine (COC)

1. Summary and Explanation of the Test

Cocaine is one of the nervous system's stimulating drugs with pharmacological properties, such as a local anesthetic. It has addictive effects leading to substance abuse. Cocaine may appear in urine for only few hours after use, whereas the benzoylecgonine, a hydrolytic degradation product of cocaine, may be detectable in urine over 2 days after taking cocaine. Therefore the detection of benzoylecgonine in human urine has been widely used to evaluate cocaine usage.[2,3, 4]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Cocaine (Benzoylecgonine) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Cocaine (Benzoylecgonine) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Nine (9) discrepancies were observed on the specimens at the level between 75% of the cutoff and the cutoff.

The overall agreement was 97.8%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	188	188	100%
	<75% (0~225)	0	4	4	100%
	75%~Cutoff (225~300)	9	11	20	55%
	Cutoff~125% (300~375)	24	0	24	100%
	Positive (>375)	164	0	164	100%
Total		197	203	400	97.8%

3. Reproducibility

Reproducibility was determined at the three different POL locations by persons with diverse educational backgrounds and work experiences. Forty-pooled drug-free human urine specimens were spiked with benzoylecgonine at different levels. All specimens were blind labeled and tested. The result is as follows:

Benz Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
225	8	5	3	2	6	0	8
300	8	8	0	8	0	8	0
375	8	8	0	8	0	8	0
600	8	8	0	8	0	8	0

Results indicate an average concordance of 94.2 % with the expected results.

4. Cross-Reactivity

A study was conducted using cocaine-related compounds to determine the cross-reactivity of the test.

Cocaine and its structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Cocaine	*300*	*Isoxsuprine*	*1500*
Benzoylecgonine	*300*		

E. Methamphetamine (MET500)

1. Summary and Explanation of Test

Methamphetamine in overdosage causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions, and coma.[3] Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis.[1] D-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine. It is utilized in the treatment of obesity. Methamphetamine is administered by oral, nasal insufflation, or intravenous injection with duration of 2-4 hours.[3, 5]

Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. During normal conditions up to 43% of a dose is eliminated unchanged in the 24-hour urine, with about 4-7% as amphetamine. In acid urine, up to 76% is found as unchanged drug and 7% as amphetamine in 24 hours, whereas in alkaline urine the corresponding values are 2% and less than 0.1%. Methamphetamine urine concentrations of 0.5-4.0 mg/L are commonly observed during the first 24 hours after ingestion of 10 mg. Methamphetamine concentrations of 24-333 mg/L (average, 142) were observed in the urine of methamphetamine abusers.[5]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred nineteen (119) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Methamphetamine Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Methamphetamine(500) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above 125% of the cutoff (positive). Twenty two (22) discrepancies were observed on the specimens at level between 75% and 125% of the cutoff.

The overall agreement was 95.4%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	220	220	100%
	<75% (0~375)	0	36	36	100%
	75%~Cutoff (375~500)	6	22	28	78.6%
	Cutoff~125% (500~625)	24	16	40	60%
	Positive (>625)	152	0	152	100%
Total		182	294	476	95.4%

3. Reproducibility

Reproducibility was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty-pooled drug-free human urine specimens were spiked with methamphetamine at different levels. All specimens were blind labeled and tested. The result is as follows:

Methamp. Conc (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
375	8	0	8	0	8	1	7
500	8	8	0	8	0	8	0
625	8	8	0	8	0	8	0
1000	8	8	0	8	0	8	0

The results indicate a 99.2% concordance with the expected results.

4. Cross-Reactivity

A study was conducted using methamphetamine-related compounds to determine the cross-reactivity of the test.

Methamphetamine related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level.

Description	Concentration (ng/ml)
d-Methamphetamine	*500*
l-Methamphetamine	*25,000*
d-Amphetamine	*50,000*
l-Amphetamine	*10,000*
3,4-methylenedioxyamphetamine (MDA)	*50,000*

F. Methamphetamine (MET1000)

1. Summary and Explanation of Test

Methamphetamine in overdosage causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions, and coma.[3] Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis.[1] D-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine. It is utilized in the treatment of obesity. Methamphetamine is administered by oral, nasal insufflation, or intravenous injection with duration of 2-4 hours.[3, 5]

Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. During normal conditions up to 43% of a dose is eliminated unchanged in the 24-hour urine, with about 4-7% as amphetamine. In acid urine, up to 76% is found as unchanged drug and 7% as amphetamine in 24 hours, whereas in alkaline urine the corresponding values are 2% and less than 0.1%. Methamphetamine urine concentrations of 0.5-4.0 mg/L are commonly observed during the first 24 hours after ingestion of 10 mg.

Methamphetamine concentrations of 24-333 mg/L (average, 142) were observed in the urine of methamphetamine abusers.[5]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Methamphetamine (1000) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Methamphetamine(1000) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Twelve (12) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 97%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	200	200	100%
	<75% (0~750)	0	16	16	100%
	75%~Cutoff (750~1000)	12	12	24	50%
	Cutoff~125% (1000~1250)	24	0	24	100%
	Positive (>1250)	136	0	136	100%
Total		172	228	400	97%

3. Reproducibility

Reproducibility was determined by replicate assays on four different concentrations (GC/MS) of methamphetamine in urine samples: 0ng/ml, 870ng/ml (within 25% below the cutoff), 1200ng/ml (within 25% above the cutoff), and 2000ng/ml (positive) with three different production lots. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Methamphetamine Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)
d-Amphetamine	*50,000*
l-Amphetamine	*10,000*
3,4-methylenedioxyamphetamine (MDA)	*50,000*

G. Morphine (MOR300)

1. Summary and Explanation of Test

Morphine is a popular marketed drug (e.g. Serax) for treatment of moderate to severe pain.[3] It is also a common metabolite of Opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered either by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include pupillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma, and pulmonary edema. Death may occur following an overdosage.[3,4]

The duration of effect of morphine is 3-6 hours.[3] Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in urine. Heroin is rapidly metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized, 10-15% of the dose is demethylated to form morphine and norcodeine. It has been reported that the unchanged morphine may remain detectable in urine for up to one week,[3] which make morphine a marker of opiates abuse.

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. Ninety four (94) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Morphine (300) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Morphine (300) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Thirteen (13) discrepancies were observed on the specimens at the level between 75% of the cutoff and the cutoff.

The overall agreement was 96.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	180	180	100%
	<75%(0~225)	0	12	12	100%
	75%~Cutoff(225~300)	13	11	24	45.8%
	Cutoff~125%(300~375)	24	0	24	100%
	Positive(>375)	136	0	136	100%
Total		173	203	376	96.5%

3. Reproducibility

Reproducibility was determined at three different POL locations, by persons with diverse educational backgrounds and work experiences. Forty-pooled drug-free human urine specimens were spiked with morphine at different levels. All specimens were blind labeled and tested. The results are as follows:

Morphine Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
225	8	3	5	3	5	1	7
300	8	7	1	8	0	7	1
375	8	8	0	8	0	8	0
600	8	8	0	8	0	8	0

The results indicate a 92.5% concordance with the expected results.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Morphine Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Morphine structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Morphine	*300*	*Morphine-glucuronide*	*500*
Codeine	*300*	*Meperidine*	*30000*
Ethyl Morphine	*300*	*Oxycodone*	*1000*
Hydromorphine	*400*		

H. Morphine (MOR2000)

1. Summary and Explanation of Test

Morphine is a popular marketed drug (e.g. Serax) for treatment of moderate to severe pain.[3] It is also a common metabolite of Opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered either by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include pupillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma, and pulmonary edema. Death may occur following an overdosage.[3,4]

The duration of effect of morphine is 3-6 hours.[3] Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in urine. Heroin is rapidly metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized, 10-15% of the dose is demethylated to form morphine and norcodeine. It has been reported that the unchanged morphine may remain detectable in urine for up to one week,[3] which make morphine a marker of opiates abuse.

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Morphine (2000) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Morphine (2000) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Two (2) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 99.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	132	132	100%
	<75% (0~1500)	0	64	64	100%
	75%~Cutoff (1500~2000)	2	30	32	93.8%
	Cutoff~125% (2000~2500)	28	0	28	100%
	Positive (>2500)	144	0	144	100%
Total		174	226	400	99.5%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The device was tested for five consecutive days for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot, and no appreciable inter-lot variation across the three (3) different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Morphine Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Codeine	*2000*	*Morphine- glucuronide*	*3000*
Ethyl Morphine	*2000*	*Meperidine*	*30,000*
Hydro morphine	*2500*		

I. Methadone (MTD)

1. Summary and Explanation of the Test

Methadone, also called Dolophine, Methadose and Amidone, possesses many of the pharmacological properties of morphine and is approximately equipotent as an analgesic when administered parenterally. Unlike morphine, however, methadone produces marked sedative effects with repeated administration as a result of drug accumulation. Methadone has been used as a major substitute for opiates, such as heroin, morphine, and codeine in drug maintenance treatment clinics. It is administered either orally or by intravenous or intra-muscular injection.[3] The duration of effect of methadone is 12-24 hours.[5] Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3, 3-diphenylpyrrolidine). The percentage of methadone excreted unchanged in urine is 5-50%, much higher than EDDP and EMDP, of the dose in 24 hours. Large individual variations in the percentage of unchanged methadone excreted in urine have been observed due to urine pH, urine volume, dose and rate of metabolism, etc. Methadone has been found remaining in urine for higher than 1,000 ng/ml 24 hours after overdose.[5] Therefore the concentration of methadone in human urine has been used as a marker of methadone abuse.

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested.

Each sample was tested at each site, with *INSTANT-VIEW® Methadone (MTD) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Methadone Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Ten (10) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 97.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	<75% (0~225)	0	192	192	100%
	75%~Cutoff (225~300)	10	18	28	64.3%
	Cutoff~125% (300~375)	36	0	36	100%
	Positive (>375)	144	0	144	100%
Total		190	210	400	97.5%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The device was tested for five consecutive days, five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable interlot variation across the three (3) different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Methadone Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)
(-)-α-Methadol	*800*
(-)-α-Acetylmethadol (LAAM)	*1000*

J. Phencyclidine (PCP)

1. Summary and Explanation of the Test

Phencyclidine (PCP), also named as Angel Dust, Hog, and Killer Weed, is a popular drug of abuse as well as a legitimate veterinary tranquilizer. It is self-administered either by smoking, nasal insufflation, intravenous injection or oral ingestion.[3] Its duration of effect is 2-4 hours, and psychosis may last for weeks. PCP has three major metabolites; however, the percentage of an intravenous dose excreted unchanged in urine is 30-50% in the 72 hours. Only 2% of a dose is excreted in feces. An average of 77% of an intravenous dose is excreted in urine and feces in 10 days.[3, 5] Therefore, the PCP in human urine has been used as a marker of PCP abuse.[4] Concentrations of unchanged drug in the urine of ambulatory users of PCP are most frequently between 0.04 and 3.4mg/L.[3]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. One hundred (100) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Phencyclidine (PCP) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Phencyclidine Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Eight (8) discrepancies were observed on the specimens at level between 75% of the cutoff and the cutoff.

The overall agreement was 98%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	<75% (0~18.75)	0	184	184	100%
	75%~Cutoff (18.75~25)	8	16	24	66.7%
	Cutoff~125% (25~31.25)	32	0	32	100%
	Positive (>31.25)	160	0	160	100%
Total		200	200	400	98%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The device was tested for five consecutive days for a total of 25 assays for each control.

The results indicate 100% precision for the replicate within each lot and no appreciable interlot variation across the three (3) different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® Phencyclidine(PCP) Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Methylphenidate	*25,000*	*Tenocyclidine*	2,000
Pheniramine	*25,000*		

K. Propoxyphene (PPX)

1. Summary and Explanation of the Test

Propoxyphene is a prescription drug for the relief of pain. Propoxyphene hydrochloride (Darvon, Dolene, and others) is available in 32mg and 65mg capsules; propoxyphene napsylate (Darvon-N) is available in 100mg tablets or as a suspension. It is structurally related to methadone. Overdose of the drug can affect the brain region and cause euphoria as many opioids do. The progressive symptomatology of propoxyphene includes analgesia, stupor, respiratory depression, and coma, etc. The half-life of propoxyphene is 8-24 hours. Following oral administration, propoxyphene reaches its peak in 1 to 2 hours. There is great variability between subjects in the rate of clearance. The percentage of excreted unchanged propoxyphene in urine is less than 1%. The major metabolite of propoxyphene is norpropoxyphene. Therefore, the detection of norpropoxyphene is widely used for the testing of propoxyphene abuse. The half-life of norpropoxyphene is about 30 hours, and its accumulation with repeated doses may be responsible for some of the toxicity observed.[5, 6]

2. Accuracy

The accuracy of this device was determined by a comparison study between the *INSTANT-VIEW® Propoxyphene (PPX) Urine Test* and the GC/MS. This study was conducted in house, using one hundred (100) blind labeled clinical urine specimens. The detailed data is listed in this section.

The results from the *INSTANT-VIEW® Propoxyphene (PPX) Urine Test* agreed 100% with the GC/MS data of specimens at levels below the cutoff (negative) and above 125% of the cutoff (positive). Two (2) discrepancies were observed on the specimens at the level between the cutoff and 125% of the cutoff.

The overall agreement was 98%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	40	40	100%
	<75% (0~225)	0	10	10	100%
	75%~Cutoff (225~300)	0	10	10	100%
	Cutoff~125% (300~375)	8	2	10	80%
	Positive (>375)	30	0	30	100%
Total		38	62	100	98%

3. Reproducibility

Reproducibility of the device was determined by replicate assays with three different lots. Specimens used in this study were the same as used in the accuracy study. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control. The results obtained indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

4. Cross-Reactivity

Cross-reactivity of the propoxyphene structurally related compounds were evaluated with this device. The following compounds were spiked into known drug-free urine pools and then tested with the *INSTANT-VIEW® Propoxyphene (PPX) Urine Test*.

Propoxyphene and its major metabolite, norpropoxyphene, have a similar positive response at the concentration of 300 ng/ml. Other compounds tested produced positive responses at a very high concentration: methadone at 1,350,000 ng/ml and the metabolite of methadone (EDDP) at 200,000ng/ml.

Drugs or compounds	Concentration
Propoxyphene	*300 ng/ml*
Norpropoxyphene	*300 ng/ml*
Methadone	*1,350,000 ng/ml*
2-ethyl-1,5-dimethyl-3,3-diphenylpyrroline (EDDP, Methadone Metabolite)	*200,000 ng/ml*

L. Tricyclics (TCA)

1. Summary and Explanation of the Test

Tricyclics (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure.[7] TCA can be taken orally or by intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to a few days. The commonly used tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting the metabolites of TCA in human urine has been used for screening the abuse of TCA.[3, 5] This test is able to detect amitriptyline, desipramine, Imipramine and nortriptyline at a cutoff level of 1,000 ng/ml.

2. Accuracy

The accuracy was determined by comparing the results from the *INSTANT-VIEW® TCA Urine Test* with the GC/MS data. This study was carried out in house, using eight (80) blind labeled clinical urine specimens. The detailed data is shown in the table in this section.

The results from the *INSTANT-VIEW® TCA Urine Test* agreed 100% with the TCA GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Two (2) discrepancies were observed on the specimens with the GC/MS data between 75% of the cutoff and the cutoff. The overall agreement was 97.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	40	40	100%
	<75% (0~750)	0	10	10	100%
	75%~Cutoff (750~1000)	2	8	10	80%
	Cutoff~125% (1000~1250)	8	0	8	100%
	Positive (>1250)	12	0	12	100%
Total		22	58	80	97.5%

3. Reproducibility

Reproducibility was determined by replicate assays of four different levels of samples with three different production lots. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control.

The results indicate 100% precision for the replicates within each lot and no appreciable inter-lot variation across the three different lots of devices.

4. Cross-Reactivity

To determine the cross-reactivity of the structurally related compounds with the device, the following compounds were spiked into known drug-free urine pools and tested with the *INSTANT-VIEW® TCA Urine Test*. Those compounds showed a positive response at the concentration indicated in the following table:

Description	Concentration (ng/ml)	Description	Concentration (ng/ml)
Nortriptyline	*1,000*	*Clomipramine*	*5,000*
Amitriptyline	*1,000*	*Doxepin*	*3,000*
Imipramine	*800*	*Protriptyline*	*2,000*
Desipramine	*800*	*Perphenazine*	*75,000*
Nordoxepine	*1,000*	*Promazine*	*15,000*
Cycolbenzaprine	*1,500*	*Trimipramine*	*2,000*

M. Marijuana (THC)

1. Summary and Explanation of the Test

Tetrahydrocannabinol (THC, Δ-9-THC, Δ-1-THC), is the most active of the principal constituents, as well as the major metabolite of cannabinoids, such as marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage of cannabinoids may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. The detection of THC in human urine has been widely used to assess the abuse of cannabinoids. [2,3, 4]

2. Accuracy

A study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. Ninety nine (99) clinical samples were blind labeled and tested. Each sample was tested at each site, with *INSTANT-VIEW® Marijuana (THC) Urine Test*, and compared with GC/MS results.

The results from the *INSTANT-VIEW® Marijuana (THC) Urine Test* agreed 100% with the GC/MS data of specimens at levels below 75% of the cutoff (negative) and above 125% of the cutoff (positive). Fourteen (14) discrepancies were observed on the specimens at the level between 75% and 125% of the cutoff.

The overall agreement was 96.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	160	160	100%
	<75% (0~37.5)	0	36	36	100%
	75%~Cutoff (37.5~50)	11	13	24	54.2%
	Cutoff~125% (50~62.5)	17	3	20	85%
	Positive (>62.5)	156	0	156	100%
Total		184	212	396	96.5%

3. Reproducibility

Reproducibility was determined at three different POL locations, by persons with diverse educational backgrounds and work experiences. Forty-pooled drug-free human urine specimens were spiked with THC at different levels. All specimens were blind labeled and tested. The results are as follows:

THC Conc. (ng/ml)	No of Samples	POL 1		POL 2		POL 3	
		+	–	+	–	+	–
0	8	0	8	0	8	0	8
37.5	8	0	8	1	7	0	8
50	8	8	0	8	0	8	0
62.5	8	8	0	8	0	8	0
100	8	8	0	8	0	8	0

The results indicate a 99.2 % concordance with the expected results.

4. Cross-Reactivity

A study was conducted using THC-related compounds to determine the cross-reactivity of the test.

THC structurally related compounds showing the lowest concentration of the drug producing a positive response equivalent to the cutoff level:

Description	Concentration (ng/ml)
11-nor-Δ-8-THC-9-COOH	*50*
11-nor-Δ-9-THC-9-COOH	*50*
11-hydroxy-Δ-9-THC	*100*
9-Tetrahydrocannabinol	*10,000*
Cannabonol	*10,000*

N. MDMA (Ecstasy, XTC)

1. Summary and Explanation of the Test

MDMA is an abbreviation for the chemical methylenedioxymethamphetamine. It has many street names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks. It is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdose of MDMA can be fatal, often resulting in heart failure or heat stroke.[5, 8]

MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxyamphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also know as EVE. They all share the amphetamine-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg; the threshold toxic dose is 500mg. The effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine: it is detectible in the urine for up to 3 days after use.[5,8]

2. Accuracy

The accuracy was determined by comparing the results from the *INSTANT-VIEW® MDMA Urine Test* with the GC/MS data. This study was carried out in house, using eighty (80) blind labeled clinical urine specimens. The detailed data is shown in the table in this sections.

The results from the *INSTANT-VIEW® MDMA (Ecstasy, XTC) Urine Test* agreed 100% with the MDMA GC/MS data of specimens at levels below 75% of the cutoff (negative) and above the cutoff (positive). Two (2) discrepancies were observed on the specimens with the GC/MS data between 75% of the cutoff and the cutoff.

The overall agreement was 97.5%.

		INSTANT-VIEW® Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	40	40	100%
	<75% (0~375)	0	10	10	100%
	75%~Cutoff (375~500)	2	9	11	82%
	Cutoff~125% (500~625)	9	0	9	100%
	Positive (>625)	10	0	10	100%
Total		21	59	80	97.5%

3. Reproducibility

The reproducibility study on this test was performed outside of Alfa facility, at three (3) Physician's Office Laboratories (POL) and a clinical reference laboratory by personnel with diverse educational backgrounds and working experiences. One hundred and ten (110) MDMA-spiked urine samples containing six different levels of MDMA: 0, 257, 378, 615, 709, and 1417 ng/ml (determined by GC/MS), were used for this study. The results are summarized in the following table.

Samples		Test Site I	Test Site II	Test Site III	Test Site IV	Total
0 ng/ml	Number	15	15	15	15	60
	Result	15-	15-	15-	15-	60-
257 ng/ml	Number	15	15	15	15	60
	Result	15-	15-	15-	15-	60-
378 ng/ml	Number	25	25	25	25	100
	Result	25-	25-	25-	25-	100-
615 ng/ml	Number	25	25	25	25	100
	Result	23+, 2-	23+, 2-	22+, 3-	24+, 1-	92+, 8-
709 ng/ml	Number	15	15	15	15	60
	Result	15+	14+, 1-	15+	15+	59+, 1-
1417 ng/ml	Number	15	15	15	15	60
	Result	15+	15+	15+	15+	60+

At the four evaluation sites, two hundred and twenty (220) devices tested with samples containing less than 378 ng/ml MDMA (75% of the cutoff) were negative (100% agreement). Among the one hundred (100) devices tested with samples containing 615 ng/ml MDMA (125% of the cutoff), ninety two (92) were positive and eight (8) were negative (92% agreement). For the sixty (60) devices tested with samples containing 709 ng/ml MDMA (150% of the cutoff), fifty nine (59) were positive and one (1) was negative (98.3% agreement). The sixty (60) devices tested with samples containing 1417 ng/ml MDMA were all positive. No significant within-day, between-day, or between-assay discrepancy was observed. The results obtained from the four evaluation sites agreed 97.5% with each other, indicating a high reproducibility of the device.

4. Cross-Reactivity

The cross-reactivity of the structurally related compounds with the device was studied. The following compounds were spiked into known drug-free urine pools and tested with the MDMA Urine Test.

Compounds produced positive results at a concentration below 10μg/ml are indicated in the following table:

Description	Concentration (ng/ml)
methylenedioxyampphetamine (MDA)	*2000*
Methylenedioxyethylamphetamine(MDEA)	*1000*

Compounds that did not produce positive responses at a concentration of 100μg/ml are indicated in the following table:

Description	Concentration (μg/ml)
L-amphetamine	*100*
d-amphetamine	*100*
L-methamphetamine	*100*
d-methamphetamine	*100*
Hydroxymethamphetamine (HAM)	*100*
Dihydroxymethamphetamine (HMMA)	*100*
N-methyl-1-(1-3-benzodioxol-5-yl)-2-butanamine(MBDB)	*100*

REFERENCES

1. FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21.
2. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
3. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p713-715, 1995.
4. Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. (69): 11970 (1988).
5. Wilson, John, Abused Drugs II, a Laboratory Pocket Guide., AACC Press. Washington, DC; 1994.
6. Gilman AG, Rall TW, Nies AS, Taylor P eds., Goodman and Gilman's the Pharmacological Basis of Therapeutics, 8th ed., New York, Pergamon Press, 1990.
7. Dorland's Illustrated Medical Dictionary, 26th Edition, W.B. Saunders Company, Philadelphia, PA, pp89, 1981. 4Urine Testing for Drugs of Abuse, National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
8. S-J. Peroutka ed. Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA. Kluwer Academic Publishers, 1990.

Manufactured by:
ALFA SCIENTIFIC DESIGNS INC.

POWAY, CA 92064 - USA
MADE IN USA

European Authorized Representative

Obelis s.a.
Avenue de Tervueren, 34, Bte 44
B-1040 Brussels
Tel.: +32.2.732.59.54 Fax: +32.2.732.60.03
Email: mail@obelis.net