INSTANT-VIEW® Multi-Drug of Abuse Urine Test

LAB - STIX DIAGNOSTICS (Pty) Ltd.

DOA 6 PANEL URINE TETS

(AMP / COC / MET / MOR/OPI / THC / XTC)

INSTRUCTIONS FOR USE

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

INTENDED USE

The Multi-Drug of Abuse Urine Test is a rapid, qualitative immunoassay for screening potential abuse of one or more drugs. This device detects any combination of up to twelve drugs or drug metabolites at or above the specified cut-off levels. This device is for health care professional use only.

Abbreviation	Parameter	Calibrator	Cutoff
AMP	Amphetamine	d-Amphetamine	1,000 ng/mL
AMP300*	Amphetamine	d-Amphetamine	300 ng/mL
COC	Cocaine	Benzoylecgonine	300 ng/mL
COC150	Cocaine	Benzoylecgonine	150 ng/mL
MET	Methamphetamine	d-Methamphetamine	1,000 ng/mL
MET500*	Methamphetamine	d-Methamphetamine	500 ng/mL
MET300*	Methamphetamine	d-Methamphetamine	300 ng/mL
MOR	Morphine	Morphine	2,000 ng/mL
MOR300*	Morphine	Morphine	300 ng/mL
THC	Marijuana/Hashish	11-nor-Δ^9-THC-9-COOH	50 ng/mL
XTC	MDMA (Ecstasy)	Methylenedioxy-methamphetamine	500 ng/mL

**Non-SAMHSA levels. **Combined concentration of buprenorphine and norbuprenorphine. ***SAMHSA has not recommended screening cutoff levels for positive specimens. ****BAR, BZD and TCA tests will yield preliminary positive results when BAR, BZD or TCA are ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturates, benzodiazepines or tricyclic antidepressants in urine. The Multi-Drug of Abuse Urine Test shows whether drug is present at the cutoff level.*

This device provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or high performance liquid chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY

Amphetamine (AMP, AMP300)

The detection of amphetamines in human urine has been widely used to assess abuse. Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and an 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 nervous system. Amphetamines appear in the urine within three hours after administration (any route), and remain present for approximately 24-48 hours after the last dose.

Cocaine (COC, COC150)

Cocaine is a nervous system stimulant that can be addictive. Cocaine may appear in urine for only a few hours after use, whereas benzoylecgonine, a hydrolytic degradation product of cocaine, may be detectable in urine for over 2 days after cocaine use. Therefore the detection of benzoylecgonine in human urine is widely used to evaluate cocaine usage.

Methamphetamine (MET, MET500, MET300)

Methamphetamine overdose causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions and coma. Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis. d-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine, utilized in the treatment of obesity. Methamphetamine is administered by oral or nasal insufflation, or by intravenous injection, with a duration of 2-4 hours. Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. In normal conditions, up to 43% of a dose is eliminated, with about 4-7% as amphetamine. In acidic 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 (mean value 142) have been observed in the urine of methamphetamine abusers.

Morphine (MOR, MOR300)

Morphine is a popular marketed drug for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (a semi-synthetic derivative of morphine)]. Opiates are administered 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 overdose.

The duration of effect of morphine is 3-6 hours. Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in the 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, with 10-15% of the dose demethylated to form morphine and norcodeine. It has been reported that unchanged morphine may remain detectable in urine for up to one week, which makes morphine a useful marker of opiates abuse.

Marijuana (THC)

Tetrahydrocannabinols (THC, Δ^9-THC, Δ^1-THC) are the most active principal constituents and major metabolites 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 nervous system. The detection of THC in human urine is widely used to evaluate the abuse of cannabinoids.

MDMA (XTC)

MDMA is an abbreviation of the chemical methylenedioxymethamphetamine. It is also known by street names such as Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. It is described as an empathogen since it releases mood-altering chemicals such as 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. Adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke.

MDMA belongs to a family of manmade drugs; its relatives are MDA (methylenedioxyamphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also known as EVE. Both exhibit 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. The clinical dose is 50-100 mg; the threshold toxic dose is 500 mg. The effects of MDMA begin 30 minutes after use. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine, and MDMA is detectable in urine for up to 3 days after use.

PRINCIPLE OF THE PROCEDURE

The Multi-Drug of Abuse Urine Test consists of any combination of between one (1) to twelve (12) individual test strip(s) for the drug(s) being tested. The assay is a one-step lateral flow chromatographic immunoassay based on the principle of competition for limited antibody binding sites between a drug or drug metabolite(s) in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During testing, urine migrates to the test area of the membrane by capillary action, mobilizing the colored antibody conjugates. The antibody conjugates then move along the membrane to the test area. In the absence of drug or if the drug concentration is below the cutoff limit in the sample, the colored conjugates attach to the respective drug antigen immobilized in the test line region, forming a colored band (T line). If drug is present in the sample, the drug or drug metabolite(s) compete for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the colored conjugates to the antigen in the test line area of the membrane. Therefore no colored line will form.

The control line (C line) serves as an internal quality control of the system. It should always appear as a colored band regardless of the presence of the drug.

REAGENTS AND MATERIALS SUPPLIED

- 25 Test devices, each sealed in a foil pouch with a desiccant and a dropper pipette (20 devices for 7-12 test panel)
- 1 Package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- External positive and negative controls

INSTANT-VIEW® Multi-Drug of Abuse Urine Test

PRECAUTIONS

- The instructions must be followed exactly to obtain accurate results.
- Do not open the sealed pouch until ready to conduct the assay.
- Do not use expired devices.
- Dispose of all specimens and used assay materials as potentially biohazardous.
- Do not use the device if you are colorblind.

STORAGE AND STABILITY

- Store the product 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.
- Do not freeze and/or expose this kit to temperatures over 30°C.

SPECIMEN COLLECTION

- Each urine specimen must be collected in a clean container. Do not combine specimens.
- Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or below for long term storage.

ASSAY PROCEDURE

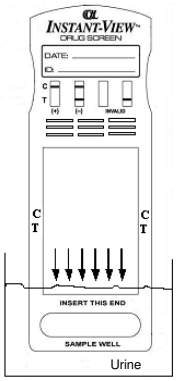
Important: Refrigerated specimens and other test materials, including devices, must be equilibrated to room temperature before testing.

1. Bring the pouch to room temperature before opening.
2. Remove the device from the sealed pouch and label it with specimen identification.
3. Remove the cap from the device and add the urine sample to the device using either the "Dip Method (I)" or the "Dropper Method (II)" as described below:

I. DIP METHOD

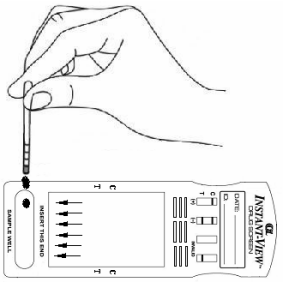
a) Dip the sample well end of the device into the specimen.
b) Start the timer.
c) Remove the device from the specimen after 10 seconds.
d) Replace the cap back onto the device. Set the device on a clean and level surface.
e) Read results between 4-7 minutes.

Note: Immerse the sample well completely in the urine sample. Make sure the tips of the arrows in the device window are above the surface of the urine sample.



II. DROPPER METHOD (Recommended for small sample volumes)

a) Set the device on a clean and level surface.
b) Use the provided dropper to pick up the urine sample and fill the dropper to the mark.
c) Transfer all of the urine sample in the dropper to the sample well of the device. Avoid trapping air bubbles in the sample well.
d) For a double-sided panel (7-12 drugs), turn the device over and add a full dropper of urine (up to the mark on the dropper) to the sample well on side 2.
e) Start the timer.
f) Read results between 4-7 minutes.



INTERPRETATION OF RESULTS

Each test strip is labeled with an abbreviation for its target drug. For example, "COC" indicates a cocaine test. A complete list of abbreviations can be found in the Intended Use section on Page 1.

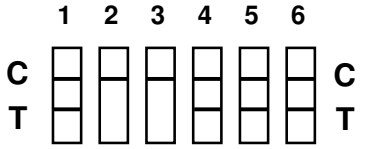
IMPORTANT:

- Read each test independently.
- Do not compare the color intensity of one test to anther.
- Do not compare the color intensity of the T line to the C line.
- Do not interpret results after 7 minutes.

Preliminary Positive:

If the C line appears and there is no T line, the result is a preliminary positive for that drug. More than one test may be preliminary positive.

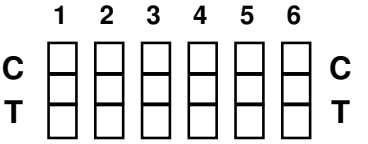
Note: Preliminary positive results should be confirmed with a more specific method. GC/MS or HPLC are the preferred confirmatory methods.



Preliminary positive for test 2 and test 3

Negative:

If both the C and T lines appear for a test, the result is negative for that drug. If both the C and T lines appear for all tests, the urine specimen is negative for all the drugs tested.

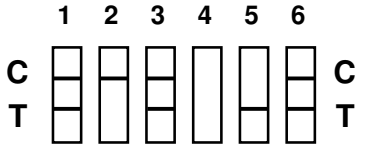


Negative for all 6 drugs tested

Note: Even a very faint T line is negative.

Invalid:

If no C line develops within 4 minutes on any test strip, the result is invalid. In this case, do not report test results. Repeat the assay with a new device. If the result is still invalid, stop using the device and contact the manufacturer.



Invalid for test 4 and test 5

QUALITY CONTROL

Built-in Control Features:

Each 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 result is invalid. Review the procedure and repeat with a new device.

External Quality Control:

Users should follow 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. This device provides only preliminary qualitative analytical test results. A more specific alternate method must be used 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 adulteration is suspected, collect a fresh specimen and repeat the procedure 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 device is capable of detecting specific drugs and/or drug metabolites in human urine at or above the cutoff concentrations in the Intended Use section on page 1.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study was performed at two physician's office laboratories (POL) and a reference laboratory. Samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site with the Multi-Drug of Abuse Urine Test and the results were compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (negative), above 125% cutoff (positive), between 75% cutoff and cutoff, between cutoff and 125% cutoff according to the analyte concentrations from GC/MS for all analytes except BUP and TCA, which were tested with HPLC/MS. Overall, this test exhibited more than 90% agreement with the selected analytical method for each analyte. The test results are tabulated below.

INSTANT-VIEW® Multi-Drug of Abuse Urine Test

Method			GC/MS					
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	Overall
Drug	Cutoff (ng/mL)							
AMP	1000	Positive	0	0	37	15	148	
		Negative	176	76	23	1	0	
		Total	176	76	60	16	148	476
		Agreement	100%	100%	38.3%	93.8%	100%	92%
AMP300	300	Positive	0	0	0	39	75	
		Negative	30	45	45	6	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	86.7%	100%	97.5%
COC	300	Positive	0	0	9	24	164	
		Negative	188	4	11	0	0	
		Total	188	4	20	24	164	400
		Agreement	100%	100%	55%	100%	100%	97.8%
COC150	150	Positive	0	0	2	42	75	
		Negative	30	45	43	3	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	95.6%	93.3%	100%	97.9%
MET	1000	Positive	0	0	12	24	136	
		Negative	200	16	12	0	0	
		Total	200	16	24	24	136	400
		Agreement	100%	100%	50%	100%	100%	97%
MET500	500	Positive	0	0	6	24	152	
		Negative	220	36	22	16	0	
		Total	220	36	28	40	152	476
		Agreement	100%	100%	78.6%	60%	100%	95.4%
MET300	300	Positive	0	0	0	38	75	
		Negative	30	45	45	7	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	84.4%	100%	97.1%
MOR300	300	Positive	0	0	13	24	136	
		Negative	180	12	11	0	0	
		Total	180	12	24	24	136	376
		Agreement	100%	100%	45.8%	100%	100%	96.5%
MOR	2000	Positive	0	0	2	28	144	
		Negative	132	64	30	0	0	
		Total	132	64	32	28	144	400
		Agreement	100%	100%	93.8%	100%	100%	99.5%
THC	50	Positive	0	0	11	17	156	
		Negative	160	36	13	3	0	
		Total	160	36	24	20	156	396
		Agreement	100%	100%	54.2%	85%	100%	96.5%
XTC (MDMA)	500	Positive	0	0	2	9	10	
		Negative	40	10	9	0	0	
		Total	40	10	11	9	10	80
		Agreement	100%	100%	82%	100%	100%	97.5%

Method			HPLC/MS					
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	Overall
Drug	Cutoff (ng/mL)							

Reproducibility

The reproducibility of each test was determined by replicate assays of three different production lots with four levels of samples: Drug-free, 75% cutoff, 125% cutoff and 300% cutoff. For the AMP, AMP300, BUP, COC, COC150, MET500, MET300, MOR300, OXY, OXY300, THC and XTC tests, the devices were run on three consecutive days, six replicates per day, for a total of eighteen tests for each control. For the BAR, BZD, MET, MOR, MTD, PCP, PPX and TCA tests, the devices were run on five consecutive days, five times per day, for a total of 25 assays for each control. The results indicate 100% precision for replicates within each lot and no appreciable inter-lot variation across three different lots of devices.

Cross Reactivity

The cross reactivity of the device was evaluated by spiking drug free samples with structurally related compounds. Compounds producing positive responses are listed below.

Drug	Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
AMP	l-Amphetamine	20,000	3,4-Methylenedioxy-amphetamine (MDA)	3,000
	d-l-Amphetamine	1,000		
AMP300	l-Amphetamine	20,000	3,4-Methylenedioxy-amphetamine (MDA)	3,000
	d-l-Amphetamine	300		
COC	Benzoylecgonine	300	Isoxsuprine	1,500
COC150	Benzoylecgonine	150	Isoxsuprine	1,500
MET	d-Amphetamine	50,000	3,4-Methylenedioxy-amphetamine (MDA)	50,000
	l-Amphetamine	10,000		
MET500	d-Amphetamine	50,000	3,4-Methylenedioxy-amphetamine (MDA)	50,000
	l-Amphetamine	10,000		
	l-Methamphetamine	25,000		
MET300	d-Amphetamine	50,000	3,4-Methylenedioxy-amphetamine (MDA)	50,000
	l-Amphetamine	10,000		
	l-Methamphetamine	25,000		
MOR	Codeine	2,000	Meperidine	30,000
	Ethyl morphine	2,000	Morphine-6-glucuronide	3,000
	Hydromorphone	2,500		
MOR300	Codeine	300	Meperidine	30,000
	Ethyl morphine	300	Morphine-6-glucuronide	500
	Hydromorphone	400	Oxycodone	1,000
THC	Cannabinol	50	11-nor-Δ^9-THC-9-COOH	10,000
	11-Hydroxy-Δ^9-THC	100	Δ^9-THC	10,000
XTC (MDMA)	Methylenedioxy-amphetamine (MDA)	2,000	Methylenedioxyethyl-amphetamine (MDEA)	1,000

Interference

To determine the interference of structurally unrelated substances, various substances were tested in both drug-free urine pools and urine pools spiked with the cutoff level of each analyte.

The common substances listed in this table were found not to interfere with test results at a concentration of 100 µg/mL			
Acetaminophen	Atropine	Ethanol	Phenylpropanolamine
Acetylsalicylic acid	Benzoic acid	Lidocaine	Ranitidine
Amikacin	Caffeine	Methanol	Salicylic acid
Ampicillin	(+)-Chlorpheniramine	Oxalic acid	Thioridazine
Arterenol	Cortisone	Penicillin-G	Trifluoperazine
Aspirin			

Analyte	Concentration	Analyte	Concentration
Albumin	200 µg/mL	Hemoglobin	100 µg/mL
Bilirubin	100 µg/mL	Uric acid	100 µg/mL
Creatine	100 µg/mL	Vitamin C (l-Ascorbic acid)	100 µg/mL
Glucose	200 µg/mL		

Drug-free and spiked urine pools were tested with the Multi-Drug of Abuse Urine Test at various pH levels and specific gravities. pH ranges from pH 5 to pH 9 and specific gravity ranges from 1.002 – 1.035 g/mL did not affect the expected results in the study.

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

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	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	Do not reuse		Caution, consult accompanying documents

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