Qualitative determination of 6 Drugs of abuse (DOA), namely Cocaine, Opiates, Barbiturates, Benzodiazepines, Amphetamine, and Tetrahydrocannabinol in urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

Pack Size	REF
20 Tests	BBPMDT 20

CLINICAL SIGNIFICANCE

Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, and Opiate is a controlled substance available by prescription and is also available on the illicit market. Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The **Multiple Rapid Drugs (6 in 1) (Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate**) **Screening Test Kit** is a rapid test that qualitatively detects the presence of Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate in human urine specimen at the cut off value of 300 ng/mL, 1000 ng/mL, 300 ng/mL, 300 ng/mL, 50 ng/mL and 300 ng/mL respectively. The test utilizes a combination of monoclonal antibodies and BSA conjugated COC, AMP, BAR, BZO, THC and OPI to detect Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate in human urine sample.

The test is most often used to screen for drug use. It's often required by the court system and some workplaces.

PRINCIPLE

Rapid Multi Drugs (6 in 1) Screening Test kit is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. Each conjugate pad of the specific drug parameter is impregnated with two components - Agglutinating sera for specific drug conjugated to colloidal gold and mouse globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for specific drug- colloidal gold conjugate complexes with the specific drug present in the test specimen and travels on the membrane due to capillary action along with the mouse globulin colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by specific drug conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result. In absence of specific drug in the test specimen, the Agglutinating sera for specific drug- colloidal gold conjugate and along with mouse IgG colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by drug conjugated to BSA coated on the membrane, forming band indicating a negative result. The mouse IgG-colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Goat anti Mouse IgG coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

KIT COMPONENTS

• Test Cassettes • Droppers • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

- Rapid Multi Drugs (6 in 1) Screening Test kit is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Perform testing immediately after specimen collection.
- Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

DIRECTIONS FOR USE

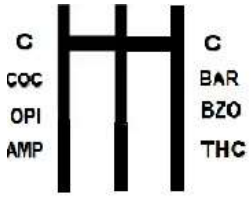
Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the kit components of Rapid Multi Drugs (6 in 1) Screening Test kit device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".

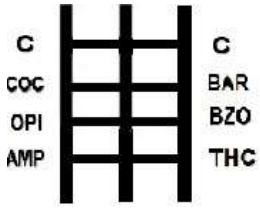
3. Remove the testing device and the sample applicator and the desiccant pouch.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard he test device and use another device. Once opened, the device must be used immediately.
5. Label the device with patient identity and place the testing device on a flat horizontal surface.
6. Dispense 3 drops urine sample into the each sample well (S) of the device using sample dropper. Avoid trapping air bubbles in the sample well, while dispensing the sample. Alternatively, carefully dispense 50µl urine in each sample well using pipette.
7. The drugs device results should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes but positive results must be reported at 5 minutes only.
   Note: Do not interpret the drug device results after 10 minutes after the addition of sample.

INTERPRETATION OF RESULTS

Positive Result



Negative Result



1) Positive

One bands appear at the control region (C). No band appears at specific test region, this indicates presence of the specific drug in the specimen.

2) Negative

Four bands appear at the control region (C) and drug test regions. This indicates absence of the specific drug in the specimen.

3) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The **Multiple Rapid Drugs (6 in 1) Screening Test Kit** is for professional in vitro diagnostic use, and should be only used for the qualitative detection of **Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate**.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results

Performance characteristics

Cut off Value

The **Multiple Rapid Drugs (6 in 1) (Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate**) **Screening Test Kit** is a rapid test that qualitatively detects the presence of Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate in human urine specimen at the cut off value of 300 ng/mL, 1000 ng/mL, 300 ng/mL, 300 ng/mL, 50 ng/mL and 300 ng/mL respectively.

Diagnostic Performance

A total of 140 normal human urine specimens were collected from human subjects and 2 positive composite control samples tested by The **Multiple Rapid Drugs (6 in 1) (Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate**) **Screening Test Kit**. These specimens were confirmed by commercially available kit. Comparison for all subjects is showed in the following table.

Commercial Multi Drug Rapid Test Results	MDT Test		Total
	Positive	Negative	
Positive	2	0	2
Negative	2	138	140
Total	4	138	142

Relative Sensitivity: 100%, Relative Specificity: 98.57%, Overall Agreement: 98.59%

Precision

Between-run precision has been determined by 3 independent assays on the same 2 specimens: Three different lots of the Rapid Drugs (Amphetamine) Screening Test Kit have been tested over a 3-days period using negative and positive specimens. The specimens were correctly identified >99% of the time

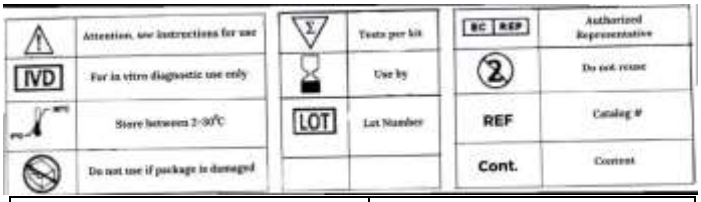
Specificity and cross-reactivity

The following substances were tested and confirmed did not interfere with Multiple Rapid Drugs (6 in 1) (Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Screening Test Kit. at the listed concentrations.

Substances	Concentration
Glucose	2000 mg/dl
Human Albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/d

To evaluate the analog cross-reactivity of the devices, the target drug, drug metabolites and the same class compounds that may cross-react with the target drugs are tested by Multi Rapid drugs screening test Kit.

All the compounds are added to drug-free urine at three different concentration levels. The final results are as following table. It displays the limits of detection for the specified drugs or their analog. Below these levels, the analog drugs show no cross-reactivity to target drugs.



Drugs derivative	Concentration (ng/ml)
d-Amphetamines	1,000
d.1-Amphetamines	3,000
1-Amphetamines	50,000
(+/-) 3,4 methylenedioxy Amphetamines	5,000
Benzoylecgonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Morphine	2,000
11-hydroxy-D9-Tetrahydrocannabinol	2,500
D8- Tetrahydrocannabinol	7,500
D9- Tetrahydrocannabinol	10,000
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butathal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Oxazepam	300
Alprazolam	200
-Hydroxyalprazolam	1,500
Bromazepam	1,500

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(1). www.drug detection .net/drug.html**.(2).**Klabunde R.E, Cardiovascular Pharmacology Concepts, Beta Adenoceptor Antagonists (Beta Blockers)Symphathomimetics, pgs 200, 2007**.(3).**Wu. AH, Onigbhinde TA, Wong SS, Johnson KG, Evaluation of full scanning GC/ion trap MS of NIDAdrugs of abuse urine testing in urine. J. Anal. Toxicol. 19992, May, Jun; 16(3) pgs 202-206. **(4).** Drugs and Human Performance, FACT SHEETS Cannabis, Amphetamines. **(5)**. Kreek M.J. and Hartmann N. Chronic use of opiods and anti psychotic drugs, side effects , effects of endogenous opiods and toxicity; Annals New York academy of Science pgs 151-172. **(6).** Drugs of Abuse, Drug Enforcement Administration (DEA) Barbiturates pg 52, Benzodiazepines pg 53, Cocaine, pg 45**. (7).** Volkow N.D, Prescription of drug abuse and addiction, National institute on Drug Abuse (NIDA) research report series, 2005

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

CE

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