Multi-Drug Rapid Test Cassette (Whole Blood/Serum/Plasma) English

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Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/MET/MDMA/MOP/OPI/TCA/MDPV/LSD/MEP/α-PVP/6-MAM

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human whole blood or serum or plasma, For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

INTENDED USE

The Multi-Drug Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in whole blood or serum or plasma at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	80
Barbiturates (BAR)	Secobarbital	100
Benzodiazepines (BZO)	Oxazepam	100
Cocaine (COC)	Benzoylecgonine	50
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	35
Methadone (MTD)	Methadone	40
Methamphetamine (MET)	d-Methamphetamine	70
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Morphine (MOP/OPI)	Morphine	40
Tricyclic Antidepressants (TCA)	Nortriptyline	300
3,4-methylenedioxypyrovalerone(MDPV)	3,4-methylenedioxypyrovalerone	300
Lysergic acid diethylamide (LSD)	Lysergic Acid Diethylamide	20
Mephedrone(MEP)	Mephedrone	100
alpha-Pyrrolidinovalerophenone (α -PVP)	alpha-Pyrrolidinovalerophenone	300
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	30

Configurations of the Multi-Drug Rapid Test Cassette come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (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 indicated.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional in vitro diagnostic use only. The Multi-Drug Rapid Test Cassette (Whole Blood/Serum/Plasma) should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

SUMMARY

The Multi-Drug Rapid Test Cassette is a rapid test in whole blood or serum or plasma screening test that can be performed without the use of an instrument.[1] The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in whole blood or serum or plasma.

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines 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 Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the whole blood or serum or plasma in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of amphetamines in whole blood/serum/plasma exceeds 80ng/mL.

Barbiturates (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the whole blood or serum or plasma.

The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4,5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[2]

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of barbiturates in whole blood/serum/plasma exceeds 100ng/mL.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g. daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the whole blood or serum or plasma; most of the concentration in whole blood/serum/plasma is conjugated drug. The detection period for benzodiazepines in whole blood/serum/plasma is 3-7 days.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of benzodiazepines in whole blood/serum/plasma exceeds 100ng/mL.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the whole blood/serum/plasma in a short time primarily as benzoylecgonine.[3,4] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[5]

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of benzoylecgonine in whole blood/serum/plasma exceeds 50 ng/mL.

Marijuana (THC)

THC (Δ9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the whole blood/ serum/ plasma is 11-nor-Δ9-tetrahydrocannabinol-9- carboxylic acid

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of THC-COOH in whole blood/serum/plasma exceeds 35ng/mL.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to beprescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[5]

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of methadone in whole blood/serum/plasma exceeds 40ng/mL.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. 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 Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the whole blood/serum/plasma primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the whole blood/serum/plasma indicates Methamphetamine use. Methamphetamine is generally detectable in the whole blood/serum/plasma for 3-5 days, depending on whole blood/serum/plasma pH level.

The Multi-Drug Rapid Test Cassette yields a positive result when the Methamphetamine in whole blood/serum/plasma exceeds 70ng/mL.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[6] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of Methylenedioxymethamphetamine in whole blood/serum/plasma exceeds 50ng/mL.

Morphine (MOP/OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the whole blood/serum/plasma for several days after an opiate dose.[7]

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of morphine in whole blood/serum/plasma exceeds 40ng/mL.

Tricyclic Antidepressants (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in whole blood/serum/plasma mostly in the form of metabolites for up to ten days.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of tricyclic antidepressants in whole blood/serum/plasma exceeds 100ng/mL.

3,4-methylenedioxypyrovalerone (MDPV)

3, 4-methylenedioxypyrovalerone (MDPV) is a psychoactive recreational drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). It was first developed in the 1960s by a team at Boehringer Ingelheim. MDPV remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing MDPV were previously sold as recreational drugs in gas stations and convenience stores in the United States, similar to the marketing for Spice and K2 as incense.

MDPV is the 3,4-methylenedioxy ring-substituted analog of the compound pyrovalerone, developed in the 1960s, which has been used for the treatment of chronic fatigue and as an anorectic, but caused problems of abuse and dependence. However, despite its structural similarity, the effects of MDPV bear little resemblance to other methylenedioxy phenylalkylamine derivatives such as 3,4-methylenedioxy-N-methylamphetamine (MDMA), instead producing primarily stimulant effects with only mild entactogenic qualities.

MDPV undergoes CYP450 2D6, 2C19, 1A2, and COMT phase 1 metabolism (liver) into methylcatechol and pyrrolidine, which in turn are glucuronated (uridine 5'-diphospho-glucuronosyl-transferase) allowing it to be excreted by the kidneys, with only a small fraction of the metabolites being excreted into the stools. No free pyrrolidine will be detected in the whole blood/serum/plasma.

The MDPV Rapid Test Cassette is a rapid blood screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of 3,4-methylenedioxypyrovalerone in whole blood or serum or plasma. The MDPV Rapid Test Cassette yields a positive result when 3,4-methylenedioxypyrovalerone in whole blood/serum/plasma fexceeds 300ng/mL.

Lysergic acid diethylamide (LSD)

Lysergic acid diethylamide (LSD) is a white powder or a clear, colorless liquid. LSD is manufactured from lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a Schedule I controlled substance, available in liquid, powder, tablet (microdots), and capsule form. LSD is recreationally used as a hallucinogen for its ability to alter human perception and mood. LSD is primarily used by oral administration, but can be inhaled, injected, and transdermally applied. LSD is a non-selective 5-HT agonist, may exert its hallucinogenic effect by interacting with 5-HT 2 Areceptors as a partial agonist and modulating the NMDA receptor-mediated sensory, perceptual, affective and cognitive processes. LSD mimics 5-HT at 5-HT 1A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD has a plasma half-life of 2.5-4 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD, and 2-oxo-3-hydroxy-LSD .These metabolites are all inactive.

The LSD Rapid Test Cassette (whole blood/serum/plasma) is a rapid whole blood/serum/plasma screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Lysergic Acid Diethylamide in whole blood/serum/plasma. The LSD Rapid Test Cassette (whole blood/serum/plasma)yields a positive result when Lysergic Acid Diethylamide in whole blood/serum/plasma exceeds 20 ng/mL.

Mephedrone(MEP)

Mephedrone, also known as 4-methylmethcathinone (4-MMC) or 4-methylephedrone is a synthetic stimulant drug of the amphetamine and cathinone classes. Slang names include drone,[8] M-CAT,[9] White Magic[10] and meow meow.[11] It is chemically similar to the cathinone compounds found in the khat plant of eastern Africa.

Mephedrone comes in the form of tablets or a powder, which users can swallow, snort or inject, producing similar effects to MDMA, amphetamines and cocaine. In addition to its stimulant effects, mephedrone produces side effects, of which teeth grinding are the most common. A number of metabolites are possible, however the n-demethyl metabolite of Mephedrone will be 4-Methylcathinone. This metabolite appears to be nearly inactive as a Monoamine Oxydase Inhibitor. On further metabolism of this metabolite one of the possible metabolites is 4-Methylnorephedrine, caused by the reduction of the Keto. A dose of 150mg-250mg is the average, giving a duration of around 2 hours. The duration will lengthen in larger 250mg+ dosages .

alpha-Pyrrolidinovalerophenone (α -PVP)

alpha-Pyrrolidinovalerophenone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes. α-PVP may be quantified in blood, plasma or urine to confirm a diagnosis of poisoning in hospitalized patients or to provide evidence in a medicolegal death investigation.[12] It generally comes in the form of either a crystalline powder or crystallized shards which users can ingest to produce powerful but short-lived euphoric stimulant effects which are comparable to those of methamphetamine and cocaine when insufflated or vaporized. α-PVP has been reported to be the cause, or a significant contributory cause of death in suicides and overdoses caused by combinations of drugs.[13] It has also been linked to at least one death where it was combined with pentedrone and caused heart failure.

6-Monoacetylmorphine (6-MAM)

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the whole blood or serum/plasma. 6-MAM remains in the whole blood or serum/plasma for no more than 24 hours. So a whole blood or serum/plasma specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain,[1] but in such small quantities that detection of this compound in whole blood or serum/plasma virtually guarantees that heroin has recently been consumed.

PRINCIPLE

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. A drug, if present in the whole blood/serum/plasma specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug cassette. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the specific test region of the cassette because of drug competition, while a drug-negative whole blood/serum/plasma specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line system contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 ℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Multi-Drug Rapid Test Cassette can be performed using whole blood or serum or plasma (from venipuncture or fingerstick).
- To collect **Fingerstick Whole blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2-8 ℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

• Test cassettes
• Droppers
• Buffer
• Package insert

Materials Required But Not Provided

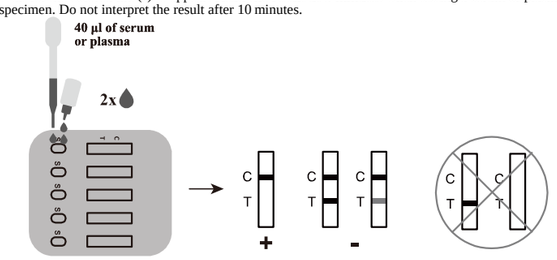
• Specimen collection containers
• Centrifuge
• Lancets (for fingerstick whole blood only)
• Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 ℃) prior to testing.

For serum or plasma specimen:

1. Bring the pouch to room temperature (15-30℃) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 1 full drop of serum or plasma (approximately 40μL), then add 2 drops of buffer (approximately 80 μL) to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result at 5 minutes** when testing a serum or plasma specimen. Do not interpret the result after 10 minutes.



For whole blood specimen:

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
   For Venipuncture Whole blood specimen:
   Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40 μL) to the specimen well, then add **2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.
   For Fingerstick Whole blood specimen:
   To use a capillary tube: Fill the capillary tube and transfer approximately **40μL of fingerstick whole blood** specimen to the specimen area of test cassette, then add **2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes

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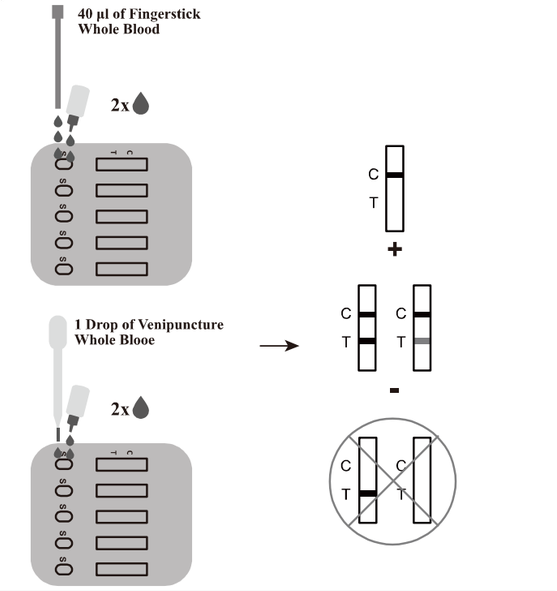

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appears in the Test region (T). This negative result means that the concentrations in the whole blood/serum/plasma sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the whole blood/serum/plasma is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control 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

1. The Multi-Drug Rapid Test Cassette (whole blood/serum/plasma) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method[13,14]
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood or serum or plasma specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
4. A negative result may not necessarily indicate drug-free whole blood/serum/plasma. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Cassette and commercially available drug rapid tests. Testing was performed on approximately 90 specimens per drug type previously collected from subjects presenting for Drug Screen Testing, Except TML who was 97 specimens, Presumptive positive results were confirmed by GC/MS.

Clinic Result of Whole Blood

Method		GC/MS		
Multi-Drug Rapid Test Cassette		Positive	Negative	% agreement with GC/MS
AMP	Positive	20	1	95.2%
	Negative	1	68	98.6%
BAR	Positive	20	2	90.9%
	Negative	2	66	97.1%
BZO	Positive	19	2	90.5%
	Negative	2	67	97.1%
COC	Positive	25	1	96.2%
	Negative	1	63	98.4%
THC	Positive	24	1	92.3%
	Negative	2	63	98.4%
MTD	Positive	19	2	95.0%
	Negative	1	68	97.1%
MET	Positive	25	2	92.6%
	Negative	2	61	96.8%
MDMA	Positive	20	2	90.9%
	Negative	2	66	97.1%
MOP/OPI	Positive	23	2	92.0%
	Negative	2	63	96.9%
TCA	Positive	23	2	92.0%
	Negative	2	63	96.9%

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Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Cassette		Positive	Negative	
MDPV	Positive	18	3	90.0%
	Negative	2	67	95.7%
LSD	Positive	20	1	95.2%
	Negative	1	69	98.6%
MEP	Positive	19	2	90.5%
	Negative	2	64	97.0%
α-PVP	Positive	35	2	92.1%
	Negative	3	60	96.8%
6-MAM	Positive	24	1	96.0%
	Negative	1	65	98.5%

Clinic Result of Serum or Plasma

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Cassette		Positive	Negative	
AMP	Positive	20	1	95.2%
	Negative	1	68	98.6%
BAR	Positive	20	2	90.9%
	Negative	2	66	97.1%
BZO	Positive	19	2	90.5%
	Negative	2	67	97.1%
COC	Positive	25	1	96.2%
	Negative	1	63	98.4%
THC	Positive	24	1	92.3%
	Negative	2	63	98.4%
MTD	Positive	19	2	95.0%
	Negative	1	68	97.1%
MET	Positive	25	2	92.6%
	Negative	2	61	96.8%
MDMA	Positive	20	2	90.9%
	Negative	2	66	97.1%
MOP/OPI	Positive	23	2	92.0%
	Negative	2	63	96.9%
TCA	Positive	23	2	92.0%
	Negative	2	63	96.9%
MDPV	Positive	18	3	90.0%
	Negative	2	67	95.7%
LSD	Positive	20	1	95.2%
	Negative	1	69	98.6%
MEP	Positive	19	2	90.5%
	Negative	2	64	97.0%
α-PVP	Positive	35	2	92.1%
	Negative	3	60	96.8%
6-MAM	Positive	24	1	96.0%
	Negative	1	65	98.5%

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP)

Amphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
40	10	8	2	9	1	9	1
120	10	1	9	1	9	2	8

BARBITURATES (BAR)

Secobarbital Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	8	2	9	1	9	1
150	10	1	9	1	9	2	8

BENZODIAZEPINES (BZO)

Benzodiazepines Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	8	2	9	1	9	1
150	10	1	9	1	9	2	8

COCAINE (COC)

Benzoylecgonine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	8	2	9	1	9	1
75	10	1	9	1	9	2	8

MARIJUANA (THC)

Marijuana Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
17.5	10	8	2	9	1	9	1
52.5	10	1	9	1	9	2	8

METHADONE (MTD)

Methadone Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
20	10	8	2	9	1	9	1
60	10	1	9	1	9	2	8

METHAMPHETAMINE (MET)

Methamphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
35	10	8	2	9	1	9	1
105	10	1	9	1	9	2	8

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy

MDMA Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	8	2	9	1	9	1
75	10	1	9	1	9	2	8

MORPHINE/Opiate (MOP/OPI)

Morphine/Opiate Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
20	10	8	2	9	1	9	1
60	10	1	9	1	9	2	8

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	8	2	9	1	9	1
450	10	1	9	1	9	2	8

3,4-METHYLENEDIOXYPYROVALERONE (MDPV)

MDPV Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	8	2	9	1	9	1
450	10	1	9	1	9	2	8

LYSERGIC ACID DIETHYLAMIDE (LSD)

LSD Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	8	2	9	1	9	1
30	10	1	9	1	9	2	8

Mephedrone(MEP)

MEP Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
50	10	10	0	10	0	10	0
150	10	0	10	0	10	0	10

alpha-Pyrrolidinovalerophenone (α -PVP)

α -PVP Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
450	10	0	10	0	10	0	10

6-MONOACETYLMORPHINE (6-MAM)

6-MAM Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
15	10	8	2	9	1	9	1
45	10	1	9	1	9	2	8

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with drugs at the listed concentrations. The results are summarized below.

For whole blood:

Drug Concentration	AMP		BAR		BZO		BUP		COC		THC		MTD	
Cut-off Range	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	16	14	15	15	14	16	13	17	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration	MET		MDMA		MOP/OPI		TCA		MDPV	
Cut-off Range	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
Cut-off	14	16	15	15	15	15	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30

Drug Concentration	LSD		MDA		MEP		α -PVP		6-MAM	
Cut-off Range	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	15	15	17	13	18	12	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30

For serum or plasma:

Drug Concentration	AMP		BAR		BZO		BUP		COC		THC		MTD	
Cut-off Range	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	16	14	15	15	14	16	13	17	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration	MET		MDMA		MOP/OPI		TCA		MDPV	
Cut-off Range	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
Cut-off	14	16	15	15	15	15	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30

Drug Concentration	LSD		MDA		MEP		α -PVP		6-MAM	
Cut-off Range	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	15	15	17	13	18	12	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in whole blood or serum or plasma by the Multi-Drug Rapid Test Cassette at 5 minutes.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
AMPHETAMINE (AMP)			
D,L-Amphetamine sulfate	20	Phentermine	150
L-Amphetamine	3,000	Maprotiline	6,000
(±) 3,4-Methylenedioxy amphetamine	40	Methoxyphenamine	1,500
		D-Amphetamine	80
BARBITURATES (BAR)			
Amobarbital	1,500	Alphenol	200
5,5-Diphenylhydantoin	2,500	Aprobarbital	150
Allobarbital	200	Butabarbital	80
Barbital	2,500	Butalbital	2,500
Talbutal	80	Butethal	150
Cyclopentobarbital	10,000	Secobarbital	100
Pentobarbital	2,500		

BENZODIAZEPINES (BZO)			
Alprazolam	40	Bromazepam	300
a-hydroxyalprazolam	500	Chlordiazepoxide	300
Clobazam	60	Nitrazepam	60
Clonazepam	150	Norchlordiazepoxide	40
Clorazepate dipotassium	150	Nordiazepam	300
Delorazepam	300	Oxazepam	100
Desalkylflurazepam	60	Temazepam	40
Flunitrazepam	60	Diazepam	100
(±) Lorazepam	1,000	Estazolam	2,000
RS-Lorazepam glucuronide	60	Triazolam	1,000
Midazolam	2,000	Alprazolam	40
COCAINE (COC)			
Benzoylecgonine	50	Cocaethylene	5,000
Cocaine HCl	60	Ecgonine	7,500
MARIJUANA (THC)			
Cannabinol	25,000	Δ^8-THC	12,000
11-nor-Δ^9-THC-9 COOH	25	Δ^9-THC	12,000
11-nor-Δ^9-THC-9 COOH	35		
METHADONE (MTD)			
Methadone	40	Doxylamine	13,000
METHAMPHETAMINE (MET)			
o-Hydroxymethamphetamine	1,800	(±)-3,4-Methylenedioxy-methamphetamine	900
D-Methamphetamine	70		
L-Methamphetamine	1,500	Mephentermine	3,500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA) Ecstasy			
(±)3,4-Methylenedioxymetha-mpheta mine HCl	50	3,4-Methylenedioxyethyl-amphetamine	40
(±) 3,4-Methylenedioxyamphetamine HCl	300		
MORPHINE/OPIATE (MOP/OPI)			
Codeine	50	Norcodeine	500
Levorphanol	200	Normorphone	5,000
Morphine-3-β-D-Glucuronide	120	Oxycodone	4,000
Ethylmorphine	500	Oxymorphone	500
Hydrocodone	5,000	Procaine	1,500
Hydromorphone	300	Thebaine	500
6-Monoacethylmorphine	100	Morphine	40
TRICYCLIC ANTIDEPRESSANTS (TCA)			
Nortriptyline	300	Imipramine	140
Nordoxepine	150	Clomipramine	18,000
Trimipramine	1,300	Doxepine	600
Amitriptyline	600	Maprotiline	600
Promazine	1,300	Promethazine	18,000
Desipramine	80	Perphenazine	18,000
Cyclobenzaprine	600		
3,4-METHYLENEDIOXYPYROVALERONE (MDPV)			
3,4-methylenedioxypyrovalerone	300		
LYSERGIC ACID DIETHYLAMIDE (LSD)			
Lysergic Acid Diethylamide	20		
Mephedrone(MEP)			
Mephedrone HCl	100	R(+)-Methcathinone HCl	1,500
S(-)-Methcathinone HCl	500	3-Fluoromethcathinone HCl	1,500
4-Fluoromethcathinone HCl	300	Methoxyphenamine	100,000
alpha-Pyrrolidinovalerophenone (α -PVP)			
alpha-Pyrrolidinovalerophenone	200		
6-MONOACETYLMORPHINE (6-MAM 30)			
6-Monoacethylmorphine	30	Morphine	300,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or drug positive whole blood/serum/plasma containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Propoxyphene, Tricyclic Antidepressants, Cotinine, EDDP ,KETand TML. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Cassette at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
l-Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Bilirubin
d,l-Brompheniramine
Caffeine
Cannabidiol
Chloral hydrate
Chloramphenicol
Chlorothiazide
d,l-Chlorpheniramine
Chlorpromazine
Cholesterol
Clonidine
Zomepirac
Ketoprofen
Labetalol
Loperamide
Meprobamate
Methoxyphenamine
Methylphenidate
Nalidixic acid
Naproxen
Niacinamide
Nifedipine
Norethindrone
Cortisone
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ethyl-p-aminobenzoate
β-Estradiol
Estrone-3-sulfate
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
3-Hydroxytyramine
d,l-Isoproterenol
Isoxsuprine
d-Pseudoephedrine
Quinidine
Quinine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone,
3-acetate
Tetrahydrocortisone
Tetrahydrozoline
Noscapine
d,l-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Perphenazine
Phenelzine
Prednisone
d,l-Propanolol
Thiamine
Thioridazine
d,l-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
d,l-Tryptophan
Uric acid
Verapamil

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INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device
2°C 30°C	Temperature limit
	Do not use if package is damaged and consult instructions for use
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
EU REP	Authorized representative in the European Community

Number: CT
Rev
Date:

Digitally signed by Dolgopol Iulian
Date: 2026.02.23 14:22:21 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ