REF	Σ
VE242007	1
VE242002	20
VE242008	100

Intended Use

Velo™ Multi-Drugs Rapid Test is a rapid, qualitative, competitive lateral flow immunoassay for the detection of DOA and/or their metabolites in human urine. The device allows the detection of multiple drugs, from 12 to 14 indicators, in one simple step. This kit is intended to be used by healthcare professionals and trained personnel in professional medical or forensic laboratories. It is a preliminary screening test and should be confirmed by other methods such as gas chromatography/mass spectrophotometry (GC/MS). This test is not intended to monitor drug levels, but only used to screen urine for the presence of the drugs as well as their metabolites in human urine at or above the following cut-off concentrations:

DOA Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	1000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Ketamine (KET)	Ketamine	1000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	D-Methamphetamine	1000
Opiates (OPI)	Morphine	300
Phencyclidine (PCP)	Phencyclidine	25
Tramadol (TRA)	Tramadol	200
Tricyclic Antidepressants (TCA)	Nortriptyline	1000

Summary

This kit employs highly sensitive antibodies to selectively detect and identify the following drugs of abuse and/or their metabolites in human urine specimens.

Amphetamines (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 urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Amphetamines in urine is great than or equal to 1000 ng/ml.

Barbiturates (Bar)

Barbiturates are central nervous system 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 400 mg/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 urine. 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. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Barbiturates (Secobarbital) in urine is great than or equal to 300 ng/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 urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Benzodiazepines (Oxazepam) is great than or equal to 300 ng/ml.

Buprenorphine (Bup)

Buprenorphine is a semisynthetic opioid analgesic derived from thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid- addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by US FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Buprenorphine in urine is great than or equal to 10 ng/ml.

Cocaine (Coc)

Cocaine is a potent central nervous system (CNS) 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 urine in a short time primarily as Benzoylecgonine.1.2 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. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Cocaine metabolites in urine is great than or equal to 300 ng/ml.

Ketamine (Ket)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Ketamine in urine is great than or equal to 1000 ng/ml.

Marijuana (Thc)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana 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 for3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- Δ^9- tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH). The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of 11-nor-Δ9-THC-9 COOH is great than or equal to the 50 ng/ml.

Mdma (Ecstasy)

Methylenedioxymethamphetamine (MDMA), also known as ecstasy, is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. 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 Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Methylenedioxymethamphetamine in urine is great than or equal to 500 ng/ml.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine 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 be prescribed 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 rollercoaster 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. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Methadone in urine is great than or equal to 300 ng/ml.

Methamphetamine (MET, mAMP)

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 ahigh potential for abuse and dependence. The drug can betaken 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 has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Methamphetamine is great than or equal to the 1000 ng/ml.

Opiates (MORPHINE, 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 central nervous system. 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 urine for several days after an opiate dose. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Morphine is great than or equal to the 300 ng/ml.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences moodswings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%). The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Phencyclidine in urine is great than or equal to 25 ng/ml.

Tramadol (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome. Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ(d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucuronidation or sulfation in the liver. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Tramadol in urine is great than or equal to 200 ng/ml.

Tricyclic Antidepressants (TCA)

TCA (Tricyclic Antidepressants) TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system 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 urine mostly in the form of metabolites for up to ten days. The Velo™ Multi-Drugs Rapid Test yields a positive result when the concentration of Tricyclic Antidepressants (Nortriptyline) in urine is great than or equal to 1000 ng/ml.

Principle

The Velo™ Multi-Drugs Rapid Test is a device composed of 12-14 chromatographic strips designed to detect 12-14 (as per the device format) individual drugs of abuse. Each strip consists of a sample pad containing antibody-dye colloidal gold conjugate and membrane contains immobilized drug conjugate and control reagent. Urine specimen initially reacts with the antibody-dye colloidal gold conjugate, and then flows onto the strip and migrates through the pads and membrane of the strip by capillary

action, to the test area. If sufficient drug is present in urine, it binds with the conjugate, preventing it from binding to the drug conjugate immobilized on the membrane in the test line region (T). Any unbound conjugate continues to migrate through the strip to the control line region (C) where it binds to the control reagent and generates a reddish purple line in the control line region (C). Presence of both a reddish purple quality control line (C) and areddish purple test line (T) on the strip indicate a negative test result, or the drug concentration is below limit of detection. Presence of only a reddish purple control line (C) on the strip indicates that specific drug has been detected and test result is positive.

Materials Supplied

- Test device(s) with desiccant in individual foil pouch or canister.
- Urine Cup (optional).
- Instructions for Use.

NOTE: Number(s) of kit contents can be found on kit box or label.

Materials Required But Not Provided

- Clock or Timer.
- Positive and negative controls available from commercial distributors.

Warnings & Precautions

- For in vitro diagnostic use only.
- These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results before performing the test.
- Do not reuse the test.
- Do not use the test beyond the expiration date printed on the outer package.
- Do not open foil pouch until urine is collected and ready to perform the test.
- Do not use the test if the pouch is damaged or the seal is broken.
- Do not mix components from different kit lots.
- Avoid cross contamination of urine specimens by using a new specimen collection device (urine cup) for each specimen.
- To avoid contamination or inaccurate test result, do not touch the reaction area of test strip when performing the test.
- Handle all specimens as potentially hazardous and handle in the same manner as an infectious agent.
- Use appropriate precautions in the collection, storage, handling and disposal of specimens and used kit contents.
- Dispose of containers and used contents according to local laws and regulations.

Storage & Stability

- Store as packaged at room temperature or refrigerated (2℃-30℃), away from direct sunlight.
- The test is stable through the expiration date printed on the sealed pouch and outer package (24 months from date of manufacture).
- DO NOT FREEZE or expose the kit to temperatures over 30℃.
- Perform the test immediately after taking out the test from the foil pouch or canister.

NOTE: For test strips in canister package, once the canister has been opened, the remaining test(s) are stable for 90 days only.

Specimen Collection & Preparation

Specimen Collection

Collect the urine specimen in the provided urine cup, or in a clean, dry glass or plastic container of similar size. Urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens maybe stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

Test Preparation

Open the package and equilibrate the test and specimens to room temperature. The most suitable temperature condition to perform the testis room temperature (15~30℃). If the test kit is stored at room temperature (15~30℃), it can be opened and used immediately.

Procedures

For direct Test Strip testing

1. Take out the test strip from the closed canister or sealed pouch. Use the test strip as soon as possible. NOTE: For canister packaging, immediately close the canister tightly after taking out the required number of the test strip(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test strip(s) are stable for 90 days only.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the specimen for at least 10-15 seconds until areddish color appears at the lower edge of the test membrane. NOTE: Ensure the specimens do not pass the maximum line marked on the test strip when immersing the strip. Please refer to the illustration below (Figure 1).
3. Withdraw the test strip and place on a non-absorbent clean and level surface, start the timer and wait for the colored line(s) to appear.
4. Interpret the result at 3-8 minutes, do not read the result after 8 minutes.

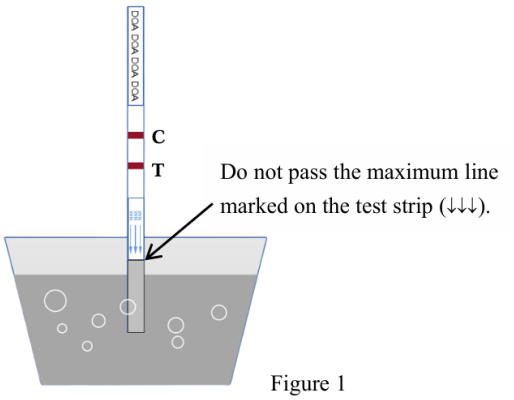

Figure 1

For Test Card

1. Take out the test card from the sealed pouch. Perform the test as soon as possible.
2. Remove the cap from the test card.
3. Hold the test card and immerse the bottom end of the test strip vertically in the specimen for at least 10-15 seconds until areddish color appears at the lower edge of the test membrane. NOTE: Keep the urine specimen below the lower edge of test card when immersing the strip. Please refer to the illustration below (Figure 2).
4. Withdraw the test strip from the urine specimen, cover the cap, place on anon-absorbent clean and level surface, start the timer and wait for the colored line(s) to appear.
5. Interpret the result at 3-8 minutes, do not read the result after 8 minutes.

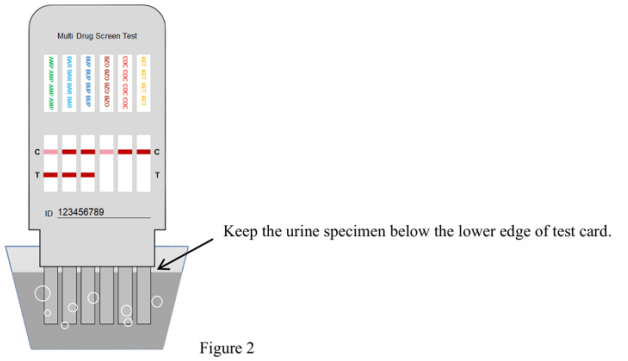

Figure 2

NOTE: This illustration is for One Step Multi-6 DOA Test.

For Test Strip assembled in plastic cup

1. Open the sealed pouch and take out the plastic cup. Perform the test as soon as possible.
2. Remove the lid in anticlockwise direction.
3. Identify test strips assembled inside the cup to ensure they are complete. Directly urinate into the test cup, or add the collected urine specimens along the insidewall where there is a scale line marked on the cup. NOTE: Ensure the specimens do not pass the maximum line marked on the test strip. Please refer to the illustration below (Figure 3).
4. Cover and tighten the lid on the cup in clockwise direction, place the cup on a level surface, start the timer and wait for the colored line(s) to appear.
5. Interpret the result at 3-8 minutes, do not read the result after 8 minutes.

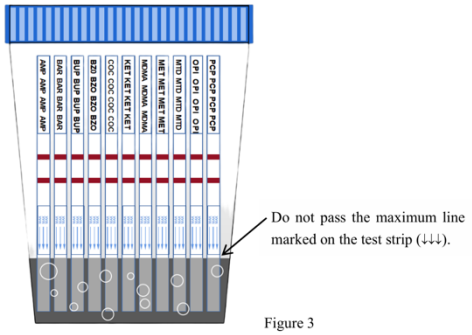

Figure 3

NOTE: This illustration is for One Step Multi-11 DOA Test.

Interpretatio of Test Results

- Negative: Presence of both a reddish purple quality control line (C) and a reddish purple test line (T) on the strip indicate a negative test result, or the drug concentration is below limit of detection.

NOTE: This test is a preliminary screening test. A negative result indicates the drug level is below the detection sensitivity. It is essential to understand that concentrations of the drug below the cut-off value may yield a faint “ghost line” to form in the test line region (T). This “ghost line” should be considered a negative test result.

- Positive: Presence of only a reddish purple control line (C) and no reddish purple line at the test line region (T) on the strip indicates that specific drug has been detected and test result is positive.

NOTE: The presence of the control line (C), no matter how faint, within the designated observation time, indicates a positive result.

- Invalid: There should always be a reddish purple line at the quality control line region (C) regardless of test result. If control line (C) is not presented, the testis considered invalid. Repeat the test using a new test device. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when results are positive. Positive results should be confirmed by an alternative method such as GC/MS.

Quality Control

1. An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the testis functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test.
2. The use of external controls is recommended to verify proper test kit performance. Quality Control samples should be tested with each new lot according to the quality control requirements of the testing facility. It is

also recommended to test the products in storage monthly. When testing quality control samples, follow the same testing procedure as for testing urine specimens.

Performance Characteristics

1. Accuracy

The accuracy of the Velo™ Multi-Drugs Rapid Test was evaluated in each individual test strip and in comparison to GC/MS method for 130 clinical urine specimens, including 110 positive specimens and 20 negative specimens. Each test was performed by three operators. The results of each test are listed below:

Specimen	AMP	BAR	BZO	BUP	COC
Sensitivity	98.1% 95% CI (93.6%-99.5%)	100% 95% CI (96.6%-99.5%)	97.2% 95% CI (92.2%-99.0%)	96.3% 95% CI (91.0%-98.5%)	99% 95% CI (95.0%-99.8%)
Specificity	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)
Accuracy	98.4% 95% CI (93.6%-99.5%)	100% 95% CI (97.1%-100%)	97.6% 95% CI (93.4%-99.2%)	96.9% 95% CI (92.3%-98.8%)	99.2% 95% CI (95.7%-99.8%)

Specimen	KET	THC	MDMA	MTD	MET
Sensitivity	98.1% 95% CI (93.6%-99.5%)	100% 95% CI (96.6%-99.5%)	97.2% 95% CI (92.2%-99.0%)	100% 95% CI (96.6%-99.5%)	99% 95% CI (95.0%-99.8%)
Specificity	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)
Accuracy	98.4% 95% CI (93.6%-99.5%)	100% 95% CI (97.1%-100%)	97.6% 95% CI (93.4%-99.2%)	100% 95% CI (97.1%-100%)	99.2% 95% CI (95.7%-99.8%)

Specimen	OPI	PCP	TRA	TCA
Sensitivity	98.1% 95% CI (93.6%-99.5%)	97.2% 95% CI (92.2%-99.0%)	96.3% 95% CI (91.0%-98.5%)	98.1% 95% CI (93.6%-99.5%)
Specificity	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)	100% 95% CI (83.8%-100%)
Accuracy	98.4% 95% CI (93.6%-99.5%)	97.6% 95% CI (93.4%-99.2%)	96.9% 95% CI (92.3%-98.8%)	98.4% 95% CI (93.6%-99.5%)

2. Precision

The precision of Velo™ Multi-Drugs Rapid Test was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 50 specimens each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between the three observers.

3. Analytical Sensitivity

The cut-off concentrations (sensitivity level) of each indicator of the Velo™ Multi-Drugs Rapid Test are determined to be: 1000ng/ml (AMP), 300 ng/ml (BAR), 300 ng/ml (BZO), 10ng/ml (BUP), 300ng/ml (COC), 1000ng/ml (KET), 50ng/ml (THC), 500ng/ml (MDMA), 300 ng/ml (MTD), 1000 ng/ml (MET), 300 ng/ml (OPI), 25 ng/ml (PCP), 200 ng/ml (TRA) and 1000 ng/ml (TCA).

4. Analytical Specificity

The specificity study for each of the indicator of the Velo™ Multi-Drugs Rapid Test was evaluated separately by adding structurally related compounds to normal human urine, and all of them produced positive results when tested at levels equal or greater than the concentrations listed below:

Tests	Compounds	Concentration
Amphetamine (AMP)	d-Amphetamine	1000 ng/ml
	l-Amphetamine	25 µg/ml
	d,l-Amphetamine	625 ng/ml
	(±)3,4-Methylenedioxyamphetamine	1 µg/ml
	(±)Phenylpropanolamine (PPA)	4 µg/ml
	Phentermine	1 µg/ml
Barbiturates (BAR)	Secobarbital	300 ng/ml
	Alphenol	150 ng/ml
	Aprobarbital	37.5 ng/ml
	Barbital	300 ng/ml
	Butabarbital	300 ng/ml
	Butalbital	75 ng/ml
	Phenobarbital	300 ng/ml
	Phentobarbital	300 ng/ml
	5,5'-diphenylhydantoin	300 ng/ml
Benzodiazepines (BZO)	Oxazepam	300 ng/ml
	α Hydroxyalprazolam	300 ng/ml
	α Hydroxyaltriazolam	300 ng/ml
	Alprazolam	100 ng/ml
	Bromazepam	400 ng/ml
	Clobazam	3000 ng/ml
	Clonazepam	1000 ng/ml
	Clorazepate	100 ng/ml
	Desmethyldiazepam	100 ng/ml
	Diazepam	100 ng/ml
	Flunitrazepam	400 ng/ml
	Flurazepam	150 ng/ml
	Lorazepam	300 ng/ml
	Lormetazepam	400 ng/ml
	Medazepam	1500 ng/ml
	Nitrazepam	400 ng/ml
	Nordiazepam	300 ng/ml
	Prazepam	150 ng/ml
	Temazepam	300 ng/ml
	Triazolam	750 ng/ml
Buprenorphine (BUP)	Buprenorphine	10 ng/ml
	Buprenorphine 3-D-Glucuronide	15 ng/ml
	Norbuprenorphine	20 ng/ml
	Norbuprenorphine	200 ng/ml
Cocaine (COC)	Benzoylecgonine	300 ng/ml
	Cocaine	15 µg/ml
	Ecgonine	100 µg/ml
	Tropacocaine	100 µg/ml

Ketamine (KET)	Ketamine	1000 ng/ml
Marijuana (THC)	11-nor-Δ-9-THC-9-COOH	50 ng/ml
	11-nor-Δ-8-THC-9-COOH	50 ng/ml
	Δ8-THC	1800 ng/ml
	Δ9-THC	2000 ng/ml
	Cannabinol	5000 ng/ml
	11-hydroxy-Δ9-THC	10 µg/ml
	11-hydroxy-Δ8-THC	10 µg/ml
Methylenedioxymethamphetamine (MDMA)	Methylenedioxyamppheta mine (MDA)	2000 ng/ml
	MethylenedioxyethylMDM A (MDEA)	1000 ng/ml
	L-MDMA	100 ng/ml
	d-MDMA	100 ng/ml
	L-methMDMA	100 ng/ml
	d-methMDMA	100 ng/ml
	HydroxymethMDMA (HAM)	100 ng/ml
	DihydroxymethMDMA (HMMA)	100 ng/ml
	N-methyl-1(1-3-benzodioxol-5-yl)-2-butanamine (MBDB)	100 ng/ml
Methadone (MTD)	(±) Methadone	300 ng/ml
Methamphetamine (MET)	(+) Methamphetamine	1000 ng/ml
	(±) Methamphetamine	1.0 µg/ml
	(±)3,4-Methylenedioxymethamphetamine	1.0 µg/ml
	(±)3,4-Methylenedioxyampheta mine	10 µg/ml
	d-amphetamine	5 µg/ml
	d, l-amphetamine	10 µg/ml
	Ephedrine	25 µg/ml
	Pseudoephedrine	10 µg/ml
	Phenylpropanolamine (PPA)	50 µg/ml
Opiates (OPI)	Morphine	300 ng/ml
	Morphine-3-d-glucuronide	300 ng/ml
	Hydromorphone	300 ng/ml
	Nalorphine	300 ng/ml
	Codeine	500 ng/ml
	Ethylmorphine	500 ng/ml
	Hydrocodone bitartrate	1000 ng/ml
	Norcodeine	2000 ng/ml
	Normorphine	3700 ng/ml
	Oxycodone	2500 ng/ml
	Heroin	4000 ng/ml
	Naloxone	6000 ng/ml
	Thebaine	5000 ng/ml
Phencyclidine (PCP)	Phencyclidine	25 ng/ml
	Naloxone	20 µg/ml
Tramadol (TRA)	n-Desmethyl-cis-tramadol	200 ng/ml
	o-Desmethyl-cis-tramadol	10,000 ng/ml
	Cis-tramadol	100 ng/ml
	Phencyclidine	100,000 g/ml
	Procyclidine	100,000 ng/ml
	d,l-O-Desmethyl venlafaxine	50,000 ng/ml
Tricyclic Antidepressants (TCA)	Tricyclic Antidepressants (TCA)	1000 ng/ml

5. Interferences

The following substances were tested and confirmed did not interfere with the Velo™ Multi-Drugs Rapid Test when tested at the listed concentrations.

Glucose	2000 mg/dl
Bilirubin	2 mg/dl
Human Albumin	2000 mg/dl
Hemoglobin	10 mg/dl
Uric Acid	10 mg/dl
Urea	4000 mg/dl

6. Cross-reactivity

The following compounds show no cross-reactivity with the Velo™ Multi-Drugs Rapid Test when tested at concentration up to 100 µg/ml (100,000 ng/ml) unless specified.

Acetaminophen, 4-Acetamidophenol, Acetylsalicylic acid, Amikacin, Arterenol, Aspartame, Ascorbic acid, Atrophine, Caffeine, Camphor, Chloroquine, Chlopheniramine, Cortisone, Deoxyephedrine, Dextromethorphan, Digitoxin, Digoxin, Diphenhydramine, Ecgonine, Ecgonine Methyl Ester, Ephedrine, Epinephrine, Gentisic acid, Guaiacol Glyceryl Ether, Histamine, Hydrochlorothiazide, Homatrophine, Ibuprofen, Isoproterenol, Lidocaine, Meperidine, Methaqualon, Methylphenidate, Neomycin, Niacinamide, Perphenazine, Penicillin G, Phenylethylamine, Phenylpropanolamine, Promethazine, Pseudoephedrine, Quinine antidine, Salicyclic acid, Tetracycline, Tetrahydrozoline, Theophyline, Thioridazine, Trifluoperazine, Tryptophan, Tyramine.

Limits

- The Velo™ Multi-Drugs Rapid Test is designed to be used for the detection of DOA and/or their metabolites with unadulterated human urine specimens only.
- There is a possibility that other substances and/or factors,e.g. technical or procedural errors, may interfere with the test and cause false results.
- Contaminated or tainted urine specimen may give false results.
- The test cannot determine the quantitative drug level or concentration in urine specimen.
- The test 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.

- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with a new test device and another new urine specimen.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

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Symbols

	Do not reuse	IVD	For in vitro diagnostic use only
	Temperature limit		Consult instruction for use
	Caution	LOT	Lot Number
	Keep away from sunlight	REF	Catalogue Number
	Use by	Σ	Contains sufficient for <n> tests
	Do not use if package is damaged		Keep dry
CE	CE Marking		Manufacturer
EC REP	EU Representative		Date of manufacture

Contact Information

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24-hour service hotline: +968-97058350

After-sale Service Center: Carbon Technologies LLC

CE
IVD

Release Date: ... ... Date of Manufacture: ... ...