Velo Multi-Drugs Rapid Test

REF	Σ
VE242002	20

Intended Use

Velo Multi-Drugs (2-10 Strips) Rapid Test Panel is a lateral flow chromatographic immunoassay test device for the qualitative detection of following drugs.

Test	Calibrator
Amphetamine (AMP)	D-Amphetamine
Barbiturates (BAR)	Secobarbital
Benzodiazepines (BZO)	Oxazepam
Cocaine (COC)	Benzoylecgonine
Marijuana (THC)	11-nor-D9-THC-9 COOH
Methadone (MTD)	Methadone
Methamphetamine (MET)	D-Methamphetamine
Methylenedioxymethamphetamine (MDMA)	D, L-Methylenedioxymethamphetamine
Opiates/Morphine (MOP)	Morphine
Tricyclic Antidepressants (TCA)	Nortriptyline

Summary & Principles of the Procedure

Velo Multi-Drug Rapid Test Panel (2-10 Strips) operates on the principle of competitive binding in immunoassay testing. Each test device is designed to detect the presence of specific drugs in urine specimens by competition between the drugs and their corresponding drug conjugates for binding sites on specific antibodies.

During the test, a urine specimen moves upwards through capillary action. If a drug is present in the urine specimen below its cut-off concentration, it will not fully occupy the binding sites of its specific antibody coated on particles. Consequently, the antibody-coated particles will bind to the immobilized drug conjugate, resulting in a visible colored line in the test line region of the respective drug strip. Conversely, if the drug concentration exceeds its cut-off level, the binding sites will be saturated, preventing the formation of a colored line in the test line region.

A drug-positive urine specimen will not produce a colored line in the specific test line region due to competition with the drug, whereas a drug-negative specimen or one containing a drug concentration below the cut-off will yield a line in the test line region. As a procedural control, a colored line will always appear at the control line region, indicating the proper volume of specimen addition and membrane wicking.

Kit Content

- Test Devices: 20 pieces test panel individually pouched.
- Package insert: 1 piece attached.

Additional Materials Needed (but Not Included in the Kit)

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing

Warnings

- Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
- Velo Multi-Drugs (2-10 Strips) Rapid Test Panel is for diagnostic use only.
- Perform test at room temperature.

Precautions

- Velo Multi-Drugs (2-10 Strips) Rapid Test Panel is for professional use only.
- The package insert instructions must be followed to ensure optimum test performance.
- The used test device should be discarded according to local regulations.

Handling Precautions

- Do not use if the kit box safety seal is absent, damaged or broken.
- Do not use any device if the pouches have been perforated.
- Each device is for single use only.
- Do not use the kit past the expiration date (this

date is printed on the kit box).

- Adequate lighting is required to read the test results.
- The result should be read immediately after the end of the 5 minutes incubation time following the addition of specimen and wash buffer solution. Results should not be read after 10 minutes.

Storage Instructions

- Velo Multi-Drugs (2-10 Strips) Rapid Test Panel should be stored between 2-30°C and the shelf life is 24 months.
- If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
- Do not freeze the kit.

Sample Collection and Preparation

- Velo Multi-Drugs (2-10 Strips) Rapid Test Panel (Urine is intended for use with human urine specimens only).
- Urine collected at any time of the day may be used.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- 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.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Quality Control

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

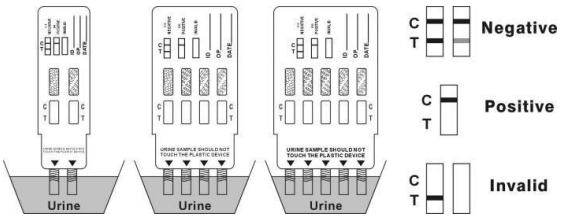
Procedure

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

1- Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it as soon as possible.

2- Take off the cap outside of the test end. With arrows pointing toward the urine specimen, immerse the test panel vertically into the urine specimen for at least 15-20 seconds. Immerse the test panel to at least the level of the wavy lines on the strip(s), do not pass the arrows on the test panel when immersing the panel. Then close it. see the illustration below.

3- Place the test panel on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The results should be read at 5 minutes. Do not interpret results after 10 minutes.



Interpretation of Results

(Please refer to the illustration above)

NEGATIVE: * Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of color in the test line region (T) will vary, but it should always be considered as negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the drug

concentration exceeds the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Limits

- Velo Multi-Drugs (2-10 Strips) Rapid Test Panel 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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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 another 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 may be obtained from certain foods or food supplements.

Performance Characteristics

Positive cutoff reference range

According to the requirements of American drug abuse and mental health service administration (SAMHSA) for the cutoff value of drugs of abuse in urine, the detection threshold is set as following table stated.

Test	Cut-off
Amphetamine (AMP)	1,000 ng/mL
Barbiturates (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
Marijuana (THC)	50 ng/mL
Methadone (MTD)	300 ng/mL
Methamphetamine (MET)	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Opiates/Morphine (MOP)	300 ng/mL
Tricyclic Antidepressants (TCA)	1,000 ng/mL

Sensitivity and Specificity Accuracy

A clinical study was conducted using Velo Multi-Drugs (2-10 Strips) Rapid Test Panel and GC/MS. Testing was performed on 150 pieces positive urine specimens and 150 pieces negative urine specimens previously collected and confirmed by GC/MS. The results indicated that Velo Multi-Drugs (2-10 Strips) Rapid Test Panel has a high sensitivity and specificity as summarized below:

Items	Positive Agreement	Negative Agreement	Total Results
AMP	95%	>99%	98%
BAR	99%	>99%	100%
BZO	93%	98%	95%
COC	96%	>99%	98%
THC	>99%	>99%	>99%
MTD	>99%	>99%	>99%
MET	>99%	>99%	>99%
MDMA	>99%	99%	100%
OPI/MOP	99%	100%	99%
TCA	97%	>99%	98%

Analytical Sensitivity

A piece of drug-free urine was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. Each titer was repeated 30 pieces of test. The results are summarized below.

Drug Conc.	AMP1000		BAR300	
(Cut-off range)	POS/+	NEG/-	POS/+	NEG/-
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	7	23	10	20
Cut-off	21	9	17	13
+25% Cut-off	29	1	22	8
+50% Cut-off	30	0	30	0
Drug Conc.	**BZO300**		**COC300**	
(Cut-off range)	POS/+	NEG/-	POS/+	NEG/-
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	4	26	0	30
Cut-off	18	12	21	9
+25% Cut-off	27	3	23	7
+50% Cut-off	30	0	30	0
Drug Conc.	**THC50**		**MTD300**	
(Cut-off range)	POS/+	NEG/-	POS/+	NEG/-
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	0	30	4	26
Cut-off	9	21	14	16
+25% Cut-off	13	17	26	4
+50% Cut-off	30	0	30	0
Drug Conc.	**MET1000**		**MDMA500**	
(Cut-off range)	POS/+	NEG/-	POS/+	NEG/-
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	6	24	7	23
Cut-off	12	18	15	15
+25% Cut-off	29	1	24	6
+50% Cut-off	30	0	30	0
Drug Conc.	**MOP300**		**TCA1000**	
(Cut-off range)	POS/+	NEG/-	POS/+	NEG/-
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	2	28	4	26
Cut-off	20	10	16	14
+25% Cut-off	27	3	26	4
+50% Cut-off	30	0	30	0

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by Velo Multi-Drugs (2-10 Strips) Rapid Test Panel at 5 minutes.

AMP-Compounds	**Conc. ng/ml**
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
d,l-3,4-Methylenedioxyamphetamine (MDA)	2,000
BAR-Compounds	**Conc. ng/ml**
Secobarbital	300
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
COC-Compounds	**Conc. ng/ml**
Benzoylecgonine	300
Cocaine	782
Cocaethylene	12500
Ecgonine	3200
THC -Compounds	**Conc. ng/ml**
11-nor-9-THC-9 COOH	50
Cannabinol	20,000
11-nor-8-THC-9 COOH	30
□8-THC	15,000
□9-THC	15,000
MET-Compounds	**Conc. ng/ml**
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
l-Methamphetamine	8,000
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	2,000

BZO-Compounds	Conc. ng/ml
Oxazepam	300
Alprazolam	196
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
α-Hydroxyalprazolam	1,262
d,l-Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
MDMA -Compounds	**Conc. ng/ml**
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	500
d,l-3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
MTD-Compounds	**Conc. ng/ml**
Méthadone	300
Doxylamine	50.000

MOP-Compounds	Conc. ng/ml
Morphine	300
Codeine	300
Ethylmorphine	6250
Hydrocodone	50000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-b-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	150,000
Thebaine	6,250
TCA-Compounds	Conc. ng/ml
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepin	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepin	1,000
Promazine	1,500
Promethazine	25,000
Trimipramine	3,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or positive urine. The following compounds show no cross-reactivity when tested with Velo Multi-Drugs (2-10 Strips) Rapid Test Panel at a concentration of 100 µg/mL.

Non-Cross-Reacting Compounds		
4-Acetamidophenol	Ethyl alcohol	Orphenadrine
Acetone	Ethyl-p-aminobenzoate	Oxalic acid
Acetophenetidin	Etodolac	Oxolinic acid
Acetylsalicylic acid	Famprofazone	Oxymetazoline
Albumin	Fenoprofen	Papaverine
alpha-Naphthaleneacetic Acid	Fluoxetine	Pemoline
Aminopyrine	Furosemide	Penicillin
Amoxapine	Gentisic acid	Pentazocine
Amoxicillin	d-Glucose	Phenelzine
Ampicillin	Guaiacol Glyceryl Ether	Pheniramine
ApoAmphetamine	Hemoglobin	Phenothiazine
Ascorbic acid	Hydralazine	Prednisolone
Aspartame	Hydrochlorothiazide	Prednisone
Atropine	Hydrocortisone	d,l-Propanolol
Benzilic acid	o-Hydroxyhippuric acid	Quinacrine
Benzoic acid	3-Hydroxytyramine	Quinidine
Benzydamine	Ibuprofen	Quinine
Brompheniramine	Iproniazid	R(-) Deprenyl
Caffeine	Isoproterenol	Riboflavin
Cannabidiol	Isoxsuprine	Salicylic acid
Chloral Hydrate	Kanamycin	Serotonin
Chloramphenicol	Ketoprofen	Seroquel
Chloroquine	Labetalol	Sertraline
Chlorothiazide	Lidocaine	Sodium Chloride
Chlorpromazine	Lindane	Sulfamethazine
Chlorprothixene	Lithium	Sulindac
Cholesterol	Loperamide	Tetracycline
Cimetidine	l-Thyroxine	Tetrahydrocortison-3-acetate
Clonidine	Meperidine	Tetrahydrozoline
Cortisone	Meprobamate	Theophylline
Creatinine	Methaqualone	Thiamine
Deoxycorticosterone	Methoxyphenamine	Thioridazine
Dextromethorphan	Methylphenidate	Tolbutamide
Diclofenac	Metoprolol	Trans-2-phenylcyclopropylamine
Dicyclomine	N-Acetylprocainamide	Trazodone
Diflunisal	Nalidixic acid	Triamterene
Digoxin	Nalorphine	Trifluoperazine
4-Dimethylaminoantipyrine	Naproxen	Trimethoprim
Diphenhydramine	Niacinamide	d,l-Tryptophan
5,5-Diphenylhydantoin	Nifedipine	d,l-Tyrosine
EMDP	Nimesulide	Uric acid
Erythromycin	Norethindrone	Verapamil
β-Estradiol	Noscapine	Zomepirac
Estrone-3-sulfate	d,l-Octopamine	-----

Symbols


Manufacturer


Date of manufacture


Use-by date


Contains sufficient for <n> tests


Consult instructions for use


Biological risks


Temperature limit


CE Marking

EC REP EU Representative

IVD In Vitro diagnostic medical device

REF Catalogue Number

LOT Lot Number


Cautions


Avoid overexposure to the sun


single-use, please don't reuse it


Keep Dry


Don’t use the product when the package is damaged

Contact Information

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Barcelona, SPAIN.


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After-sale Service Center: Carbon Technologies LLC

CE

IVD

Release Date: … … … Date of Manufacture: … … …