



## Mutli-Drugs (2-10 Strips) Rapid Test Cup

### Instructions For Use of any combination of the following drugs:

**Amphetamine (AMP), Barbiturates(BAR), Benzodiazepines(BZO), Buprenorphine (BUP), Cocaine(COC), Marijuana(THC), Methadone(MTD), Methamphetamine(MET), Ecstasy (MDMA) , Opiates/Morphine(MOP), Tricyclic Antidepressants(TCA), Oxycodone (OXY) , Phencyclidine (PCP) .**

#### PRODUCT NAME

Mutli-Drugs (2-10 Strips) Rapid Test Cup

#### PACKAGE SPECIFICATION

20 tests/kit

#### INTENDED USE

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

Test	Calibrator
Amphetamine (AMP)	D-Amphetamine
Barbiturates (BAR)	Secobarbital
Buprenorphine (BUP)	Buprenorphine
Benzodiazepines (BZO)	Oxazepam
Cocaine (COC)	Benzoylcegonine
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
Oxycodone (OXY)	Oxycodone
Phencyclidine (PCP)	Phencyclidine

#### SUMMARY AND PRINCIPLES OF THE PROCEDURE

FRENOVO Mutli-Drugs (2-10 Strips) Rapid Test Cup is an immunoassay test device based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

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

#### MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces Cups with multi-drug panels individually pouched.
2. Package insert: 1 piece attached.

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Disposable gloves and/or protective clothing

#### WARNINGS

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

#### PRECAUTIONS

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

#### Handling Precautions

1. Do not use if the cup box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the cup past the expiration date (this date is printed on the cup box).
5. Adequate lighting is required to read the test results.
6. The result should be read immediately after the end of the 5 minutes incubation time following the addition of specimen. Do not read results beyond 10 minutes.

#### STORAGE INSTRUCTIONS

1. FRENOVO Mutli-Drugs (2-10 Strips) Rapid Test Cup should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched cup is brought to room temperature before opening.
3. Do not freeze the cups.

#### SAMPLE COLLECTION AND PREPARATION

- FRENOVO Mutli-Drugs (2-10 Strips) Rapid Test Cup 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 cup; 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.

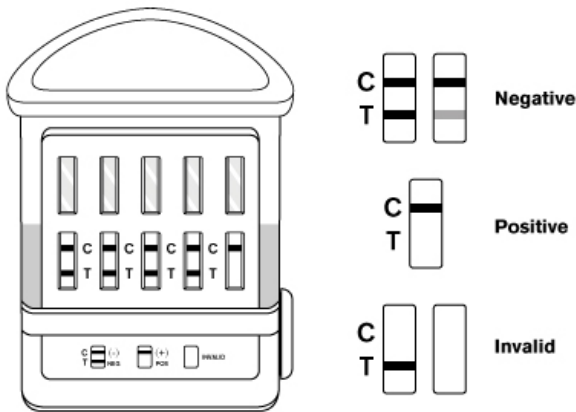
## TEST PROCEDURE

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

1. Remove the cup from its sealed pouch and use it as soon as possible.
2. Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
3. Operator checks the cap for tightness.
4. Remove the peel-off label.
5. Drug test results are indicated by the presence or absence of colored band(s) in the result area.

The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

6. Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.



## INTERPRETATION OF RESULTS

**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 cup. If the problem persists, discontinue using the lot immediately and contact your local distributor.

## LIMITATIONS

1. FrenoVO Multi-Drugs (2-10 Strips) Rapid Test Cup 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.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.
6. The test does not distinguish between drugs of abuse and certain medications.
7. 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 are set as following table stated.

Test	Cut-off
Amphetamine (AMP)	1,000 ng/mL
Barbiturates (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Buprenorphine (BUP)	10ng/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
Oxycodone (OXY)	100ng/mL
Phencyclidine (PCP)	25ng/mL

## Sensitivity and Specificity

### Accuracy

A clinical study was conducted using FrenoVO Multi-Drugs (2-10 Strips) Rapid Test Cup 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 FrenoVO Multi-Drugs (2-10 Strips) Rapid Test Cup has a high sensitivity and specificity as summarized below:

	Positive Agreement	Negative Agreement	Total Results
AMP	95%	>99%	98%
BAR	99%	>99%	100%
BUP	98%	>99%	>99%
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%
OXY	99%	98%	99%
PCP	>99%	96%	97%

## Analytical Sensitivity

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

Drug Conc. (Cut-off range)	AMP1000		BAR300	
	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
<b>Drug Conc.</b>	<b>BUP10</b>		<b>BZO300</b>	
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>	<b>POS/+</b>	<b>NEG/-</b>
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	5	25	4	26
Cut-off	10	20	18	12
+25% Cut-off	14	16	27	3
+50% Cut-off	30	0	30	0
<b>Drug Conc.</b>	<b>BZO300</b>		<b>THC50</b>	
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>	<b>POS/+</b>	<b>NEG/-</b>
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	9	21
+25% Cut-off	27	3	13	17
+50% Cut-off	30	0	30	0
<b>Drug Conc.</b>	<b>THC50</b>		<b>MET1000</b>	
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>	<b>POS/+</b>	<b>NEG/-</b>
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	0	30	6	24
Cut-off	9	21	12	18
+25% Cut-off	13	17	29	1
+50% Cut-off	30	0	30	0
<b>Drug Conc.</b>	<b>MET1000</b>		<b>MOP300</b>	
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>	<b>POS/+</b>	<b>NEG/-</b>
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	6	24	2	28
Cut-off	12	18	20	10
+25% Cut-off	29	1	27	3
+50% Cut-off	30	0	30	0
<b>Drug Conc.</b>	<b>MOP300</b>		<b>OXY100</b>	
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>	<b>POS/+</b>	<b>NEG/-</b>
0% Cut-off	0	30	0	30
-50% Cut-off	0	30	0	30
-25% Cut-off	2	28	0	30
Cut-off	20	10	12	18
+25% Cut-off	27	3	24	6
+50% Cut-off	30	0	30	0
<b>Drug Conc.</b>	<b>PCP25</b>			
<b>(Cut-off range)</b>	<b>POS/+</b>	<b>NEG/-</b>		
0% Cut-off	0	30		
-50% Cut-off	0	30		
-25% Cut-off	11	19		
Cut-off	14	16		
+25% Cut-off	24	6		
+50% Cut-off	30	0		

#### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by FRENOVO Multi-Drugs (2-10 Strips) Rapid Test Cup 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
Butobarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100

#### BUP

Compounds	Conc. ng/ml
Buprenorphine	10
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-glucuronide	200

#### 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
$\alpha$ -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

#### COC

Compounds	Conc. ng/ml
Benzoylcegonine	300
Cocaine	782
Cocaehtylene	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

#### MTD

Compounds	Conc. ng/ml
Méthadone	300
Doxylamine	50.000

#### MET

Compounds	Conc. ng/ml
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
l-Methamphetamine	8,000
d,l-3,4-Methylenedioxyamphetamine (MDMA)	2,000

#### MDMA

Compounds	Conc. ng/ml
d,l-3,4-Methylenedioxyamphetamine (MDMA)	500
d,l-3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300

#### 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

#### PCP

Compounds	Conc. ng/ml
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

#### OXY

Compounds	Conc. ng/ml
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Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Naloxone	37,500
Naltrexon	37,500
Oxymorphone	200

#### 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 FRENOVO Multi-Drugs (2-10 Strips) Rapid Test Cup 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	Guaiaicol Glyceryl Ether	Pheniramine
ApoAmphetamine	Hemoglobin	Phenothiazine
Ascorbic acid	Hydralazine	Prednisolone
Aspartame	Hydrochlorothiazide	Prednisone
Atropine	Hydrocortisone	d,l-Propranolol
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
$\beta$ -Estradiol	Noscapine	Zomepirac
Estrone-3-sulfate	d,l-Octopamine	-----

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**INDEX OF SYBOML**


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	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
	Temperature limit		Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	CE mark		Biological risks



**Hangzhou Frenovo Biotech Co., Ltd.**

**Address:** Room 401, Building 36, No.488-1, Donghu North Road, Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province, China.

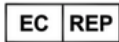
**Tel:** 86-0571-89170657

**Email:** business@frenovo.com

**Lotus NL B.V.**

**Address:** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

**Email:** peter@lotusnl.com




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**INSTRUCTION APPROVAL AND REVISION DATE**


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Approval Date:

Revision Date:

Date of Issue: