Benzodiazepines (BZO) Rapid Test Kit

Instructions For Use

PRODUCT NAME

Benzodiazepines (BZO) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Benzodiazepines (BZO) Rapid Test is a lateral flow, qualitative immunoassay. It is intended for qualitative detection of Oxazepam, a Benzodiazepines metabolite with a minimum detection concentration of 300 ng/ml in human urine samples, and for the preliminary screening detection of Benzodiazepines.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

FRENOVO Benzodiazepines (BZO) Rapid Test uses the highly specific antibody & antigen reaction principle, as well as immunochromatography and colloidal gold labeling technology.

The test kit contains Oxazepam antibody labeled with colloidal gold, and Oxazepam antigen which is fixed in the test area (T) on the membrane. When the urine sample was dropped into the sample well, the urine sample was then chromatography upward under capillary effect. If the concentration of Oxazepam in urine is lower than 300ng/ml, the colloidal gold antibody can not be combined with all Oxazepam. In this way, the colloidal gold antibody binding will be bound by Oxazepam antigen fixed on the membrane during the chromatography, and a purple red band will appear in the test area (T). If the concentration of Oxazepam in urine is higher than 300ng/ml, the colloidal gold antibody is bound to Oxazepam, so that (T) in the test area (T) there is no purple red band because the competitive reaction does not bind to Oxazepam antigen. Whether Oxazepam is present in urine, a purple red strip will appear in the quality control area (c). The purple red band in the quality control area (c) is the standard to determine whether there is enough urine sample, whether the chromatography process is normal, and also as the internal control standard of tests.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Droppers: 20 pieces droppers of 25 ul
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

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

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 Benzodiazepines (BZO) Rapid Test is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Benzodiazepines (BZO) Rapid Test 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 kit 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 kit past the expiration date (this date is printed on the kit 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 and wash buffer solution. Do not read results beyond 10 minutes.

STORAGE INSTRUCTIONS

1. FRENOVO Benzodiazepines (BZO) Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. Urine 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 supernatant for testing. Urine specimens may be 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 well before testing.

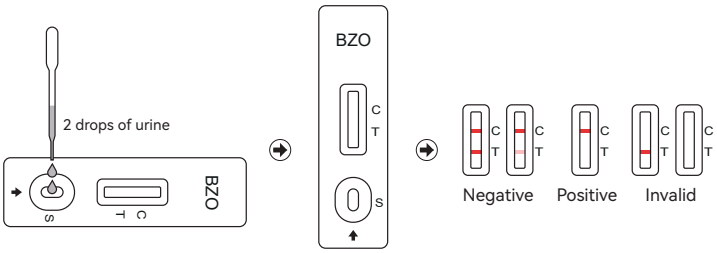
QUALITY CONTROL

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.

TEST PROCEDURE

Allow the test, 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 device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 full drops of urine (approx. 50 µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result 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.

LIMITATIONS

1. FRENOVO Benzodiazepines (BZO) Rapid 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.
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 Benzodiazepines in urine, the detection threshold of BZO is set at 300ng/ml.

Sensitivity and Specificity
Accuracy
A clinical study was conducted using FRENOVO Benzodiazepines (BZO) Rapid Testand 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 Benzodiazepines (BZO) Rapid Test-has a high sensitivity and specificity as summarized below:

clinical study		GC/MS		Total Results
FRENOVO Benzodiazepines (BZO) Rapid Test	Results	Positive	Negative	
	Positive	140	3	143
	Negative	10	147	157
Total Results		150	150	300

Accuracy Results:
Clinical sensitivity = 93.33 % (95%CI* 88.08 % to 96.76 %)
Clinical specificity =98.00 % (95%CI* 94.27 % to 99.59 %)
Accuracy= 95.67 % (95%CI* 92.70 % to 97.67 %)

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. (Cut-off range)	BZO300	
	POS/+	NEG/-
0% Cut-off	0	30
-50% Cut-off	0	30
-25% Cut-off	4	26
Cut-off	18	12
+25% Cut-off	27	3
+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 Benzodiazepines (BZO) Rapid Test at 5 minutes.

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

Cross-Reactivity
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Oxazepam positive urine. The following compounds show no cross-reactivity when tested with FRENOVO Benzodiazepines (BZO) Rapid Test 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
Apomorphine	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	/

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

EC REP
CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Emai: info@cmcmedicaldevices.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date: 2023.01.23
Approval Date: 2023.01.23
Date of Issue: 2023.01.23