

One Step Benzodiazepines Urine Test

Catalog No. See Pouch Label

One Step Benzodiazepines Urine Test is a rapid one step test for the qualitative detection of Benzodiazepines and their metabolites in human urine at specified cut-off level.

For in vitro diagnostic use only. For professional use only.

INTENDED USE

One Step Benzodiazepines Urine Test is a lateral flow chromatographic immunoassay for the detection of Benzodiazepines in human urine at the cut-off concentration of 300 ng/ml. This assay provides only a qualitative, 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 used.

SUMMARY

Benzodiazepines are the most widely used anxiolytic drugs. They are used extensively as anti-anxiety agents, hypnotics, muscle relaxants and anti-convulsants. They are taken orally or sometimes by injection and have a wide range of half-life from 2 to 40 hours. They can generally be detected for 1 to 2 days after Benzodiazepines use. Benzodiazepines are metabolized in the liver. Some Benzodiazepines and their metabolites are excreted in the urine. Their use can result in drowsiness and/or confusion. Benzodiazepines potentiate alcohol and other CNS depressants. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period.

PRINCIPLE

One Step Benzodiazepines Urine Test is a competitive immunoassay that is used to screen for the presence of Benzodiazepines in urine. It is chromatographic absorbent device in which Benzodiazepines and their metabolites in a sample competitively combined to a limited number of anti-oxazepam monoclonal antibody (mouse) conjugate binding sites.

When add four drops of the urine specimen to the sample well, the urine is absorbed into the device by capillary action, mixes with the benzodiazepines monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-oxazepam monoclonal antibody (mouse) conjugate binds to the benzodiazepines-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the benzodiazepines monoclonal antibody conjugate preventing the benzodiazepines monoclonal antibody conjugate from binding to the benzodiazepines-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. 25 tests per kit., one test in one pouch.
2. One pouch containing a test and a desiccant. The only desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use.

STORAGE AND STABILITY

Store at 4 ~ 30 °C in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

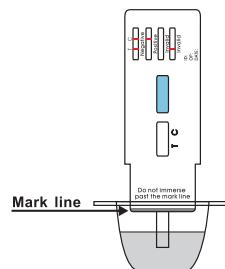
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18°C to 30°C)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**



INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

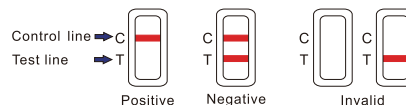
Negative (-)

A rose-pink band is visible in the control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning

the frequency of assaying external quality control materials.

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by One Step Benzodiazepines Test. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	2	17	20
Negative	20	18	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

Viewer B:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	1	20	20
Negative	20	19	0	0

% agreement among positives is 100%(95% Confidence Interval 84.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82% - 100%)

Viewer C:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	3	18	20
Negative	20	17	2	0

% agreement among positives is 95% (95% Confidence Interval 79.5% - 100%)

% agreement among negatives is 92.5% (95% Confidence Interval 77% - 100%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 95.8%
The average negative agreement is 95%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, and the cutoff + 50%. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
150	90	90/0
225	90	79/11
300	90	41/49
375	90	9/81
450	90	0/90

Lot 2

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
150	90	90/0
225	90	79/11
300	90	41/49
375	90	11/79
450	90	0/90

Lot 3

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
150	90	90/0
225	90	80/10
300	90	41/49
375	90	11/79
450	90	0/90

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test benzodiazepines, drug metabolites and other components of the same class that are likely to be present in urine, All the components were added to drug-free normal human urine.

These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
Oxazepam	300
Alprazolam	200
α-Hydroxyalprazolam	1,500
Bromazepam	1,500
Chlordiazepoxide	1,500
Clonazepam HCl	800
Clobazam	100
Clonazepam	800
Clorazepate dipotassium	200
Delorazepam	1,500
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
D,L-Lorazepam	1,500
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Temazepam	100
Trazolam	2,500

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with Benzodiazepines at 50% below and 50% above cutoff level. One step Benzodiazepines urine test was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Benzodiazepines at 50% below and 50% above cutoff levels. One step Benzodiazepines urine test was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a Benzodiazepines concentration 50% below the cutoff, and urine with a Benzodiazepines concentration 50% above the cutoff. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

4-Acetamidophenol	Labetalol
Acetophenetidin	Loperamide
N-Acetylprocainamide	Maprotiline
Acetvsalicylic acid	Meperidine
Aminopvrine	Meprobamate
Amityptvine	Methadone
Amorbarbital	Methoxyphenamine
Amoxicillin	(+) 3,4-Methylenedioxyamphetamine
Ampicillin	(+)-3,4-Methylenedioxy-methamphetamine
I-Ascorbic Acid	Nalidixic acid
D,L-Amphetamine	Nalorphine
Apomorphine	Naloxone
Aspartame	Naltrexone
Atropine	Naproxen
Benzillic acid	Niacinamide
Benzoic acid	Nifedipine
Benzoylecaonine	Norethindrone
Benzphetamine	D-Norpropoxyphene
Bilirubin	Noscapine
(±) Chlorpheniramine	D,L-Octopamine
Caffeine	Oxalic acid
Cannabidiol	Oxolinic acid
Chloralhvdrate	Pentobarbital
Chloramphenicol	Perphenazine
Chlorothiazide	Phencyclidine
(±)Chlorpheniramine	Phenelzine

Chlorpromazine	Phenobarbital
Chlorquine	Phentermine
Cholesterol	L-Phenylephrine
Clomipramine	β-Phenylethylamine
Clonidine	Phenylpropanotamine
Cocaine hydrochloride	Prednisone
Cortisone	D,L-Propanolol
(-)cotinine	D-Propoxyphene
Creatinine	D-Pseudoephedrine
Dextromethorphan	Quinine
Diclofrfenac	Ranitidine
Diffunisal	Salicylic acid
Diaoxin	Secobarbital
Diphenhydramine	Serotonin (5-Hydroxytyramine)
Doxylamine	Sulfamethazine
Ecaonine dydrochloride	Sulindac
Ecqonine methylester	Tetrahydrocortisone,3 Acetate
(-)-Ψ-Ephedrine	Tetrahydrocortisone,(β-D glucuronide)
Fenoprofen	Tetrahydrozoline
Furosemide	Thiamine
Gentisic acid	Thioridazine
Hemoglobin	D,L-Tyrosine
Hydrocortisone	Tolbutamide
O-Hydroxyhippuric acid	Triamterene
p-Hydroxy-methamphetamine	Trifluoperazine
3-Hydroxytyramine	Trimethoprim
Ibuprofen	Tryptamine
Imipramine	D,L-Tryptophan
Iproniazid	Yyramine
(±)Isoproterenol	Uric acid
Isosuprine	Verapamil
Ketamine	Zomepirac
Ketoprofen	

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Index of Symbols

	For <i>in vitro</i> diagnostic use only		Store between 4 ~ 30
	Do not reuse		Manufacturer
	Keep away from sunlight		Keep dry