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“See Now” Benzodiazepine Strip/Cassette Test Urine

For in vitro Diagnosis Use
Product Code: SN 7.3



INTRODUCTION

The “See Now” Benzodiazepine (BZO) Test is a rapid and convenient immunochromatographic in vitro assay. It is intended for the qualitative detection of the presence of BZO and its metabolites in urine at or above the cutoff level of 300 ng/ml. The device is designed for professional use. This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed.

SUMMARY OF THE TEST

BZO are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. BZO have a lower order of acute and chronic toxicity when used in a medically supervised manner. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. More than a dozen BZOs are in clinical use today. The best know BZO drugs are Valium (Diazepam) and Librium (Chlordiazepoxide). Many of the new BZOs are metabolites and derivatives of the old drugs. For example, oxazepam is a common urinary metabolites of many BZOs and is also a marketed drug (Serax). Most BZOs are extensively metabolized in the liver and excreted in the urine as metabolites. The duration of action and elimination of half-lives of the different BZOs vary widely. The half-lives for major BZOss are: Chlordiazepoxide, 5-10 hours, diazepam, 30-60 hours, oxazepam, 5-10 hours, flurazepam, 2-3 hours for the parent drug and 50-100 hours for active metabolites. The major pathways of elimination are the kidneys (urine) and the liver, where it is conjugated to glucuronic acid. Large doses of BZO could develop tolerances and physiological dependency and lead to its abuse.

The “See Now” BZO Test device contains mouse monoclonal anti- BZO antibody colloidal gold conjugate predried on a pad. BZO-BSA conjugates antigen (on test region) and goat anti mouse IgG (on control region) are coated and immobilized on a reaction membrane.

The principle of the “See Now” BZO Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in urine, for limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action toward the test window where the test reaction occurs. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone; A positive specimen produces only one color band in the control zone.

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

SPECIMEN COLLECTION AND STORAGE

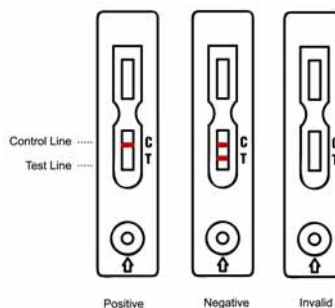
- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at -20°C for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.

- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well.
- For strip test, immerse the strip into the urine cup and take out the strip after 10 sec. Lay the strip on a flat, clean, dry, non-absorbent surface
- Read the results at 10 minutes. Ensure that the background of the test area is white before interpreting the result

INTERPRETATION OF RESULTS



Positive

Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

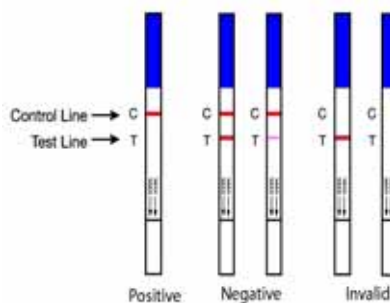
Negative

Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

Invalid

No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

Note: A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.



STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- **FOR IN VITRO DIAGNOSTIC USE ONLY.**
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

Sensitivity

The “See Now” Benzodiazepine Urinary Test detects Benzodiazepine and its metabolites in urine at concentrations equal to or greater than 300 ng/ml.

Specificity

A study was conducted with the “See Now” Amphetamine Urinary Rapid Test to determine the cross-reactivity of amphetamine-related compounds with the test device (Table I).

Table-I Concentration of Benzodiazepine-related compounds showing a positive response approximately equivalent to the Benzodiazepine cut off set for the test

Structurally related compounds	ng/ml	Structurally related compounds	ng/ml
Alprazolam	1000	Lorazepam	5000
Clobazam	600	Nitrazepam	1000
Clonazepam	100000	Nordiazepam	300
Diazepam	300	Oxazepam	300
Estazolam	150	Praxepam	100000
Flunitrazepam	100000	Temazepam	300
Flurazepam	100000	Trazolam	5000

A separate study was conducted to determine the cross-reactivity of non-Benzodiazepine related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table II.

Table- II Compounds tested and found not to cross-react with the test at a 1000 µg/ml concentration in urine

Amobarbital	Methadone	Maprotiline
Butobarbital	Diohenhdromine	Nortriptyline
Hexobarbital	Dextromethorphan	Promazine
Pentobarbital	Doxylamine	Promethazine
Phenobarbital	Morphine	Protriptyline
secobarbital	Morphine-3-β-D-Glucuro	Trimipramine
d-Amphetamine	Codeine	Acetaminophen
3,4-Methylenedioxyamphetamine (MDA)	6-monoacetylmorphine	Acetylsalicylic Acid
d,l-Amphetamine	Ethylmorphine	Amikacin
Phentermine	Nalorphine	Ascorbic acid
d-methamphetamine	Hydrocodone	Aspartame
Ephedrine	Hydromorphone	Atropine Sulfate
Pseudoephedrine	Heroin	Benzoic Acid
3,4-Methylenedioxyethylamphetamine (MDEA)	Oxycodone	Caffeine
d,l-3,4-Methylenedioxyamphetamine	Levorphanol	Deoxyephedrine
l-methamphetamine	Naloxone	Dextromethorphan
l-amphetamine	Thebaine	Gentamic acid
Benzylecgonine	Norcodeine	Histamine
Cocaine HCl	Phencyclidine	Methacalone
Cocaethylene	Phencyclidine	Pendimethazine
Ecgonine	4hydroxyphencyclidine	Penicillin G
Δ ⁸ -Tetrahydrocannabinol	Amitriptyline	Quinine
Δ ⁹ -Tetrahydrocannabinol	Clomipramine	Ranitidine
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	Cyclobenzaprine	Sodium Salicylate
11-Nor-Δ ⁸ -Tetrahydrocannabinol carboxylic acid	Desipramine	Tryptophan
11-Nor-Δ ⁹ -Tetrahydrocannabinol carboxylic acid	Doxepin	Tetracycline
Cannabinol	Imipramine	Tetrahydrozoline
Cannabidiol		

• Interference Testing

The following conditions were found not to interfere with the test.

Ethanol	1%
Methanol	1%
EDTA	80 mg/dl
Albumin	2,000 mg/dl

Glucose	2,000 mg/dl
Bilirubin	1,000 µg/dl
Hemoglobin	1,000 µg/dl
Urinary Test pH:	pH 3 –pH 9
Specific Gravity:	1.003 – 1.040

• Accuracy

Accuracy of the "See Now" Benzodiazepine Urinary Test Device has been evaluated. A total of 82 clinic samples tested (42 negative and 40 positive), The two assays gave an overall of 95.1%.

Conc. of Sample (ng/ml)	No. of test	Results (# Neg/ #Pos)			
		Lot 1	Lot 2	Lot 3	Total
< 150	35	35 / 0	35 / 0	35 / 0	105 / 0
150 - 299	7	5 / 2	5 / 2	5 / 2	15 / 6
300 - 450	9	2 / 7	2 / 7	2 / 7	6 / 21
> 450	31	0 / 31	0 / 31	0 / 31	0 / 93
% of Negative				95.2%	
% of Positive				95%	
% of overall				95.1%	

• Reproducibility

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.