

HEALTH-CHEM DIAGNOSTICS, LLC

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ONE STEP DRUGS OF ABUSE TEST STRIP - BENZODIAZEPINE™

NAME AND INTENDED USE

The HCD's **One Step Drugs of Abuse Test Strip - Benzodiazepine™** is a rapid, qualitative, competitive binding immunoassay for the determination of Benzodiazepines and their metabolites in human urine in a convenient one step strip test format. The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** is not intended to monitor drug levels, but only to screen urines for the presence of Benzodiazepines and their metabolites. Both the testing and the results are intended to be used by medical and legal professionals only. The test should not be used without appropriate supervision. The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** assay is not intended for Over The Counter (OTC) sale to lay persons.

The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** is for the rapid determination of Benzodiazepines and their metabolites in human urine. The test is used to obtain a visual, qualitative result and is intended for professional (Medical/Legal) use. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectroscopy (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

EXPLANATION OF THE TEST

Benzodiazepines are therapeutically used for anxiolytic, hypnotic, anticonvulsant, and muscle relaxant effects. Acute higher doses lead to drowsiness, muscle relaxation, lethargy and even coma. Many of the Benzodiazepines share a common metabolic route, and are excreted as oxazepam and its Glucuronide in urine. Thus, the presence of the Oxazepam in the urine indicates parent Benzodiazepines use.

The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids. The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** test is an easy, fast, visually read competitive binding immunoassay method for the screening which does not require instrumentation to arrive at a determination.

PRINCIPLE OF THE PROCEDURE

The **One Step Drugs of Abuse Test Strip - Benzodiazepine™** test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 300 ng/ml. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band,

demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area.

A **POSITIVE** specimen produces only one color band in the control area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or Timer.
3. 13 x 100mm Test Tube.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional medical and legal use only.
3. Avoid cross contamination of urine samples by using a new urine specimen cup and dropper for each sample.
4. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine specimens may be infectious. Upon completion of all testing dispose of residual urine in a medically approved manner.
6. Properly handle and dispose of all used reaction devices in an approved biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C)(35°-46°F) (**DO NOT FREEZE**) or at room temperature (18°-30°C)(64°-86°F) and will be stable for 12 months.

SAMPLE COLLECTION AND PREPARATION

Urine (1.0 ml) - the sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) (35°-46°F) and stored up to 48 hours, or frozen (-20°C or colder)(-4°F or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Remove **One Step Drugs of Abuse Test Strip - Benzodiazepine™** test from its protective foil wrapper by tearing along the notch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place it into the urine and simultaneously start timing. Make sure that only the end with the arrow pointing down is placed in the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip.

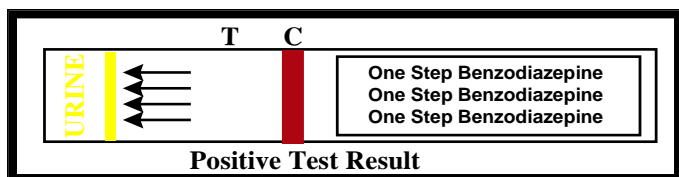
- Read the results after 3 minutes. Test results should not be interpreted after 5 minutes.

NOTES:

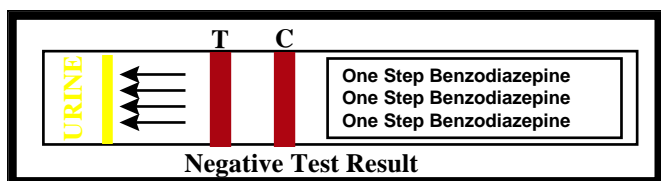
- Refrigerated strips should be allowed to come to room temperature before opening the pouch.

READING THE TEST RESULTS

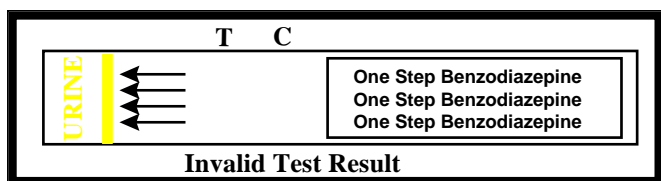
- POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Benzodiazepine level is above the detection sensitivity level of 300 ng/ml.



- NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Benzodiazepine level is below the detection sensitivity level 300 ng/ml.



- INVALID:** If there is no distinct color bands in both the upper and lower portions of the read area, (lower portion of the strip), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.



QUALITY CONTROL

Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the strip, the strip may have been placed into the tube incorrectly or the test device may have deteriorated. The assay will have to be repeated using a new **One Step Drugs of Abuse Test Strip - Benzodiazepine™** test strip. Re-read the instructions carefully or call for assistance (800 482-2907).

Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Uro-Qual Abutrol, Utak and Alltech are available for validation of the device functionality. NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte at levels at least 20% above the NIDA cut off values.

AFTER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard

container. Residual urine should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

Sensitivity:

One Step Drugs of Abuse Test Strip - Benzodiazepine™ test has been designed for the detection of Benzodiazepines in urine at the detection sensitivity of 300 ng/ml which is suggested for the immunoassay method.

Specificity:

Table 1 - Compounds which produce a positive result at a concentration of 300 ng/ml in urine.

Oxazepam
Diazepam
Desmethyldiazepam
Clorazepate HCl
Estazolam
Flurazepam
Nitrazepam
Alprazolam
Medazepam
Temazepam

Table 2 - Compounds which do not produce a positive result at a concentration of 300 ng/ml in urine.

Acetaminophen	11-nor-d-9 carboxy THC
Acetylsalicylic Acid	Meperidine
Ampicillin	Morphine Glucuronide
Benzoic Acid	Morphine Sulfate
Benzoylcegonine HCl	Methylphenidate
Caffeine	Methadone
Chlorpheniramine	Methaqualone
Chlorpromazine	Oxycodone
Cimetidine	Propranolol
Codeine	d-Propoxyphene
Dextromethorphan	Hydrochlorothiazide
Diethylpropion	Phencyclidine
Diphenylhydantoin	Phenylpropanolamine
Doxylamine	Pendimethazine
Ecgonine HCl	Pentobarbital
Ecgonine Methyl Ester	Phenobarbital
Hydrocodone	Phentermine
Hydromorphone	Penicillin G
Indomethacin	L-Phenylephrine
Ketoprofen	Quinine
Levorphanol	Ranitidine
Sodium Salicylate	Tryptophan
d-9-THC	

LIMITATIONS OF THE TEST

- This product is designed to be used for the detection of Benzodiazepines in human urine only.
- Although **One Step Benzodiazepines Test Strip™** test is very accurate in detecting the urine Benzodiazepines level, there is a possibility of false results due to the presence of interfering substances in the urine.
- Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.
- A test result read after 8 minutes may not be consistent with the original reading obtained within the 8 minute test period.
- The test is a qualitative screening assay and is not suggested for determining the quantitative Benzodiazepines level of urine.

BIBLIOGRAPHY

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6. FDA Guidance for labeling Urine Drugs of Abuse Screening Testing, Kshitij Mohan, 7/21/1987.

Manufactured in the USA by:

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