

274 mm x 218mm



Rapid Competitive Immunochromatographic Assay for the detection of Benzodiazepines in human urine

D E V I C E

DEVICE

INTENDED USE

INSIGHT-BZO is a rapid, qualitative, immunochromatographic assay for the detection of benzodiazepines in human urine. This test is used to screen the benzodiazepines intoxication. For healthcare professional use only.

SUMMARY

Benzodiazepines such as Diazepam and Midazolam are psychoactive agents. Benzodiazepines are commonly administered either nasally, orally or intravenously. They are used extensively as anxiolytics, anti convulsants, hypnotics and muscle relaxants. Diazepam binds with a high affinity to the gamma amino butyric acid (GABA) α receptor in the brain thus reducing arousal and affecting emotions. Their use can result in drowsiness, confusion and insomnia. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine. The drug has a half - life of 40 to 100 hours.

INSIGHT-BZO detects the presence of benzodiazepines in human urine specimens, qualitatively, at concentrations as low as 300 ng/ml.

PRINCIPLE

INSIGHT-BZO is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for Benzodiazepine conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for Benzodiazepine - colloidal gold conjugate complexes with the Benzodiazepine present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by Benzodiazepine conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result.

In absence of Benzodiazepine in the test specimen, the Agglutinating sera for Benzodiazepine -colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the Benzodiazepine conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.

The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

- A. Each INSIGHT-BZO kit contains individual pouches each containing a
1. **DEVICE**: Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Benzodiazepine and rabbit globulin, Benzodiazepine conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions.
 2. **PIPETTE**: Sample applicator.
 3. Desiccant pouch.
- B. Package insert.

REF	10808010	10808050

OPTIONAL MATERIAL REQUIRED

Variable volume precision micropipettes, stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.

Insight

4. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-BZO uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-BZO device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 8 minutes.

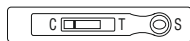
INTERPRETATION OF RESULTS

Negative Result:



Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of benzodiazepine in the specimen.

Positive Result:



One pink coloured band appears at the control region (C). This indicates that the specimen contains detectable amount of benzodiazepine.

Invalid Result:



The test result is invalid if no band appears either at the control region (C) or test region (T). In such cases, verify the test procedure and repeat the test with a INSIGHT-BZO device.

Important: A very faint line on the test region indicates that the benzodiazepine in the 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 positive determination is made.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT-BZO is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, some samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 8 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A preliminary positive result indicates only the presence of benzodiazepines and does not indicate or measure intoxication.
6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section that will produce positive results, or that do not interfere with the test performance.
7. If adulteration is suspected, the test should be repeated with a new sample.
8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time following drug use for which a positive result may occur is dependent upon several factors,

including the frequency and amount of drug, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.

10. **This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.**

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : INSIGHT-BZO detects benzodiazepines at concentrations equal to or greater than 300 ng/ml.
2. **Specificity** : Interference of substances that may be present in urine specimen, as well as effect of sample pH and specific gravity was also studied.
 - a. Cross-reactivity of non-benzodiazepine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
 - b. No cross-reactivity was detected with the substances listed in table I. Table II lists benzodiazepine related substances and concentrations that produced results approximately equivalent to the cut-off level for benzodiazepine.

Table I:

The following compounds were found not to cross-react when tested at concentrations up to 100 µg/ml.

Acetaminophen	Doxylamine
Acetone	(+/-) - Ephedrine
Albumin	(-) - Ephedrine
Amitriptyline	(+) - Epinephrine
Ampicillin	Erythromycin
Aspartame	Ethanol
Aspirin	Furosemide
Atropine	Glucose
Benzocaine	Guaiacol glyceryl ether
Benzoyllecgonine	Hemoglobin
Bilirubin	Hydromorphone
Caffeine	Hydroxytyramine
(+) - Chlorpheniramine	(+/-) - Chlorpheniramine
Imipramine	Chlorpromazine
(+/-) - Isoproterenol	Creatine
Lidocaine	Deoxyephedrine
Naloxone	Dexbrompheniramine
Naltrexone	Dextromethorphan
Naphthalene acetic acid	4 - Dimethylaminoantipyrine
(+) - Naproxen	Dopamine
(+/-) - Norephedrine	Quinidine
11 nor Δ 9 THC -9 carboxylic acid	Riboflavin
Oxalic acid	Secobarbital
Oxycodone	Sodium Chloride
Penicillin - G	Sulindac
Pentamine	Tenocyclidine
Pentobarbital	Thiordazine
Pheniramine	Trimethobenzamide
Phenobarbital	Trifluoperazine
Phenothiazine	Tyramine
L - Phenylephrine	Vitamin C
D - Propoxyphene	

Table II:

The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration (ng/ml)
Alprazolam	150
Bromazepam	800
Chlordiazepam	300
Clonazepam	1,000
Clobazam	200
Delorazepam	300
Clorazepam	100
Flunitrazepam	1,000
Diazepam	150
Lorazepam	1,500
Estazepam	150
Lormetazepam	1,000
Estazolam	2,500
Flurazepam	300
Medazepam	2,000
Nordiazepam	100
Nitrazepam	1,000
Oxazepam	300
Prazepam	1,000
Temazepam	150
Triazolam	1,500
















WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Drugs of Abuse. Drug Enforcement Administration (DEA); benzodiazepines pg 40 -41, 2005.
2. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS


 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 In vitro Diagnostic Medical Device	 This side up	 Production site
 Use by	 Catalogue Number	 Device	 Authorised Representative in the European Community
 Contains sufficient for <n> tests	 Batch Number / Lot Number	 Disposable Plastic Sample Applicator	

 **T TULIP DIAGNOSTICS (P) LTD.**



GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH,
ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202,
INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST.,
VERNA, GOA-403 722, INDIA.



CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

1017/VER-01

Insight