BTNX INC.

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Rapid™ Response

Benzodiazepine Test Strip

(Liquid / Powder)

REF BZO-18S3-100, BZO-18S3-10 Product Insert

For Forensic Use Only

Not an IVD

WARNING: THIS TEST DOES NOT EVALUATE DRUG SAFETY OR PURITY

Intended Use

The Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of Benzodiazepine in suspicious substances at the cut-off concentration listed below:

Parameter	Calibrator	Cut-off(ng/mL)
BZO (Benzodiazepine)	Oxazepam	300

Materials

Materials Provided

- Individually packed test strips
- Results Interpretation Card
- Product insert

Materials Required but not Provided

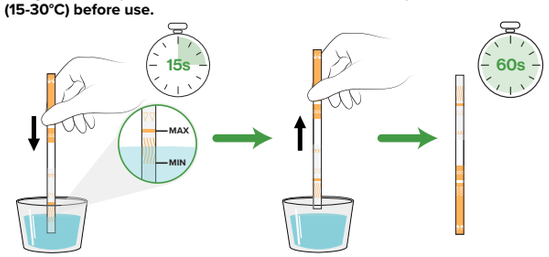
- Timer

Precautions

- **The test device is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.**
- **A positive or negative test result is NOT an indication that the substance being examined is safe to use.** Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility, and pH of the sample.
- **BTNX Inc. does not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The device is intended for harm reduction purposes.** Follow the advice of your local harm reduction or public health agency.
- There are no direct therapeutic or diagnostic claims being made for this product. These tests are not involved in diagnosing, treating, mitigating, or preventing a disease, disorder or symptom in human beings, nor do they restore, modify or correct a body structure, function of the human body.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the samples and kits are handled. It is recommended to wear protective clothing such as disposable gloves and eye protection when handling harmful substances.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.
- **The Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) has been tested for extreme shipping conditions and its performance has not been impacted.**
- The kit should be stored at 36-86˚F (2-30°C) until the expiry date printed on the sealed pouch.

Test Procedure

Bring tests, samples, buffer and/or controls to room temperature 59-86°F (15-30°C) before use.



1. Mix your drug sample thoroughly before testing. Dilute the drug to be tested in water. One scoop (5-10mg) of drug sample should be diluted in 5mL of water. Refer to the advice of your local health or harm reduction authority on how much water and drug sample you should use.
2. Remove the test strip from its sealed pouch and use it as soon as possible. For best results, the test should be performed within one hour.
3. Hold the strip by the end, where the product name (BZO) is printed. To avoid contamination, do not touch the strip membrane (the white section of the strip).
4. Holding the strip vertically, dip the test strip in the liquid for at least 10-15 seconds. Immerse the strip where the wavy lines are, but not above the solid (maximum) line on the test strip.
5. Remove the strip from the sample and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.
6. A negative result can be interpreted as soon as both the test (T) and control (C) lines appear. A result can be interpreted as positive when 60 seconds have passed since the control line has appeared and no line for that drug is present. Do not read results after 10 minutes.

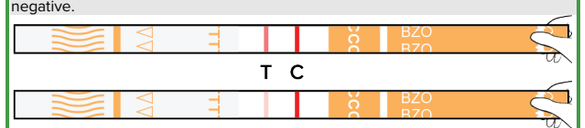
Result Interpretation

Positive - Benzodiazepine Detected

Only one colored line appears in the control region (C). No apparent colored line appears in the test region (T).

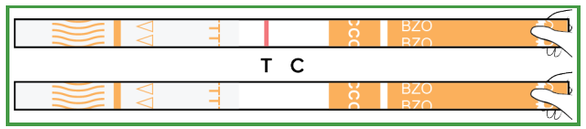
Negative – Benzodiazepine Could Not be Detected

Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T). Even faint lines are considered negative.



Invalid

Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Control

Internal Procedural Controls

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient sample volume and correct procedural technique.

Limitations of the Test

1. **There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) and cause false results.**
2. **A positive result indicates the presence of Benzodiazepine only and does not indicate quantity.**
3. **A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when the drug is present but below the cut-off level of the test**.
4. The Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) test is for forensic use and should be only used for the qualitative detection of Benzodiazepine.
5. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
6. This test may not distinguish between Benzodiazepine and other illicit substances.

Performance Characteristics

Accuracy

The accuracy of the Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests.

BZO300	Positive	Negative	Total
	95.30 %	92.90 %	93.90 %

Reproducibility

The reproducibility of the Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) was verified by blind tests performed at four different locations. Samples with Benzodiazepines concentrations at 50% of the cut-off were all determined to be negative, while samples with Benzodiazepines concentrations at 200% of the cut-off were all determined to be positive.

Precision

Test precision was determined by blind tests with control solutions. Controls with Benzodiazepines concentrations at 50% of the cut-off yielded negative results, and controls with Benzodiazepines concentrations at 150% of the cut-off yielded positive results.

Sensitivity

The sensitivity of the Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) was determined by testing GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc. (Cut-off Range)	n	BZO	
		-	+
Negative	50	50	0
-50% Cut-off	50	50	0
-25% Cut-off	50	50	0
Cut-off	50	17	33
+25% Cut-off	50	0	50
+50% Cut-off	50	0	50
+300% Cut-off	50	0	50

Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Rapid Response™ Benzodiazepine Test Strip (Liquid / Powder) identified positive results at 5 minutes.

Benzodiazepines 300 related compounds			
Oxazepam	300	Flurazepam	>100,000
Alprazolam	125	Lorazepam	1,250
Bromazepam	625	Lormetazepam	1,250
Chlordiazepoxide	2,500	Medazepam	>100,000
Clobazam	63	Midazolam	>100,000
Clonazepam	2,500	Nitrazepam	25,000
Clorazepate	3,330	Norchlordiazepoxide	250
Desalkflurazepam	250	Nordiazepam	500
Diazepam	250	Prazepam	>100,000
Estazolam	5,000	Temazepam	63
Fentanyl	>100,000	Triazolam	5,000
Flunitrazepam	375	Sulindac	100000

Non-Cross Reacting Compounds

The following compounds yielded negative results up to a concentration of 100 µg/mL:

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethylaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Imipramine	Trimeprazine
Bilirubin	(+/-)-Isoproterenol	Venlafaxine
b-Phenylethyl-amine	Methadone	Ibuprofen
Caffeine	Vitamin C (Ascorbic Acid)	Lidocaine
Chloroquine		

Glossary of Symbols

Consult instructions for use	Test per Kit	REF	Catalogue #
Store between 36-86˚F (2-30˚C)	Use by		Do Not Reuse
LOT Lot Number			

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