BTNX INC.

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# Rapid™ Response

## Nitazene Test Strip

**(Liquid / Powder)**

REF NTZ-18S9-100

Product Insert

**For Forensic Use Only**
**Not an IVD**

**WARNING: THIS TEST DOES NOT EVALUATE DRUG SAFETY OR PURITY**

## Intended Use

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

| Parameter | Calibrator | Cut-off(ng/mL) |
|---|---|---|
| NTZ (Nitazene) | Isotonitazene | 500 |

## Materials

**Materials Provided**

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

**Materials Required but not Provided**

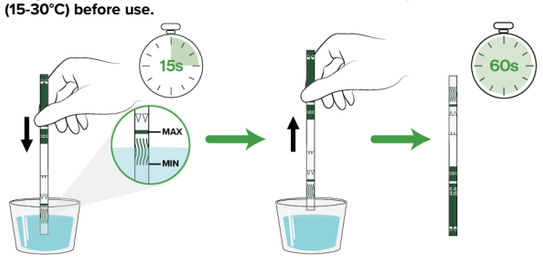
- Timer

## 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 being, 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™ Nitazene Test Strip Kit 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.**

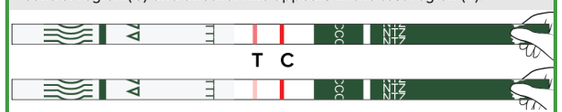



1. Dilute the drug to be tested in water. The Center for Forensic Science Research and Education (CFSRE) recommends adding one scoop (5-10mg) of drug sample to 5mL of water. Refer to the advice of your local health or harm reduction authority on how much water and drug sample you should use.
2. Remove 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 (NTZ) 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 positive result can be interpreted once the control line has appeared and the background has cleared to white, typically by 60 seconds. Do not read results after 10 minutes.

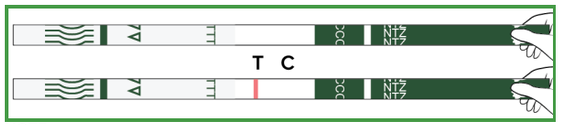
## Result Interpretation

**Positive - Nitazene Detected**
Only one colored line appears in the control region (C). No apparent colored line appears in the test region (T).


**Negative – Nitazene 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).




**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™ Nitazene Test Strip (Liquid / Powder) and cause false results.**
2. **A positive result indicates the presence of Nitazene only and does not indicate quantity.**
3. **A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.**
4. The Rapid Response™ Nitazene Test Strip (Liquid / Powder) test is for forensic use and should be only used for the qualitative detection of Nitazene.
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 Nitazene and other illicit substances.

## Performance Characteristics

**A. Reproducibility**

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

**B. Precision**

Test precision was determined by blind tests with control solutions. Controls with Nitazene concentrations at 50% of the cut-off yielded negative results, and controls with Nitazene concentrations at 200% of the cut-off yielded positive results.

**C. Specificity**

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

| Nitazene related compounds | Concentration (ng/ml) |
|---|---|
| Isotonitazene | 500 |
| Protonitazene | 3000 |
| *N*-Pyrrolidino Etonitazene | 500 |

**D. Non Cross-Reacting Compounds**

The following compounds demonstrated no false positive results when tested at a concentrations up to 100 µg/ml.

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

## 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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