Alprazolam (ALP) - XANAX Presence Test Package Insert

INTENDED USE

The Alprazolam (ALP) Test Panel is a rapid chromatographic immunoassay for the detection of alprazolam in powder at a cut-off concentration of 100 ng/mL. With this surface test, you can test:

1. Solid substances such as tablets and powder.
2. Urine samples, which can be used to detect drug use.
3. Liquids from ampoules or other containers that may contain suspicious substances.

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

SUMMARY

Alprazolam, available under the trade name Xanax among others, is a short-acting anxiolytic of the benzodiazepine class. It is commonly used for the treatment of panic disorder, and anxiety disorders, such as generalized anxiety disorder {GAD) or social anxiety disorder (SAD). Alprazolam, like other benzodiazepines, binds to specific sites on the GABAA receptor. It possesses anxiolytic, sedative, hypnotic, skeletal muscle relaxant, anticonvulsant, and amnestic properties.

A mean half-life of alprazolam of 16.3 hours has been observed in healthy elderly subjects (range: 9.0-26.9 hours, n= 16) compared to 11.0 hours (range: 6.3-15.8 hours, n= 16) in healthy adult subjects.

Alprazolam and its metabolites are excreted primarily in the urine. The pharmacokinetics of alprazolam and two of its major active metabolites (4-hydroxyalprazolam and a-hydroxyalprazolam) are linear, and concentrations are proportional up to the recommended maximum daily dose of 10 mg given once daily. Peak concentrations in the plasma occur in one to two hours following administration. Plasma levels are proportionate to the dose given; over the dose range of 0.5 to 3.0 mg, peak levels of 8.0 to 37ng/ml were observed.

The Alprazolam (ALP) Surface Test Panel is a rapid powder screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of alprazolam in powder. The Alprazolam {ALP) Surface Test Panel yields a positive result when the alprazolam in powder exceed 100 ng/mL.

PRINCIPLE

The Alprazolam {ALP) Surface Test Panel is an immunoassay based on the principle of competitive binding. Drugs which may be present in the powder specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a powder specimen migrates upward by capillary action. alprazolam, if present in the powder specimen below 100 ng/mL, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized alprazolam-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the alprazolam level exceeds 100 ng/mL because it will saturate all the binding sites of anti-alprazolam antibody.

A drug-positive powder specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative powder specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal anti-alprazolam antibody coupled particles and alprazolam-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- Use only once. Do not use the test after expiration date.
- Do not touch the free endings of the strip to avoid contamination.
- Do not dip the panel above the maximum deepness level mark.
- Do not spill the samples into the reaction zone.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the test after damage of the packaging foil.
- Use test right after unwrapping.
- Please take the specificity and the cross reactivity into account for evaluation.
- Store and transport the test device always at 2-30° C.
- Strong acid, alkali, oxidation and corrosion liquid is not suitable for this test, thick, oily liquid is not suitable for this test.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

Materials provided

- Test device
- Package insert

Materials required but not provided

- Specimen collection containers
- Timer

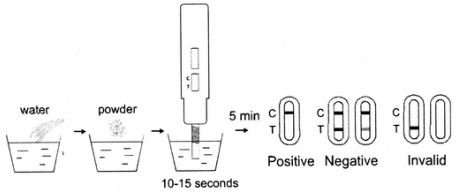
DIRECTIONS FOR USE

Allow the test and/or controls to reach room temperature (15-30° C) prior to testing.

Remove the test panel from the sealed pouch and use it as soon as possible.

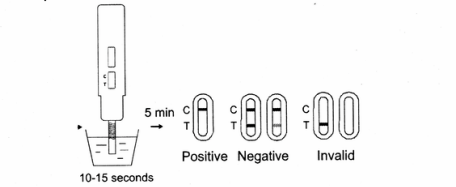
FOR SOLIDS:

1. Prepare specimen collection ,. containers and solid . sample.
2. Pour solid sample into the specimen collection containers.
3. At least 1mg solid diluted with 5ml water (1 mineral water bottle cap=5mL). Shake to mix well.
4. Remove the panel cap, with the arrow pointing toward the water immerse the test panel vertically in the diluted specimen for at least 10 to 15 seconds. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
5. Wait for the colored lines to appear, read the results at 5 minutes and do not interpret the result after 10 minutes.



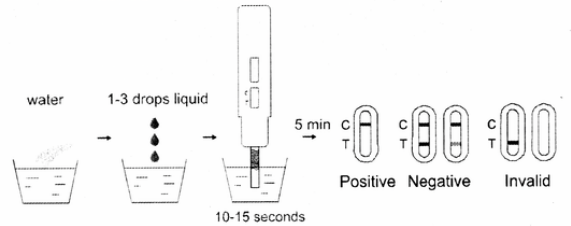
FOR URINE:

1. Collect urine in a clean and dry container.
2. Remove the panel cap, with the arrow pointing toward the specimen, immerse the test panel vertically in the specimen for at least 10 to 15 seconds. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, read the results at 5 minutes and do not interpret the result after 10 minutes.

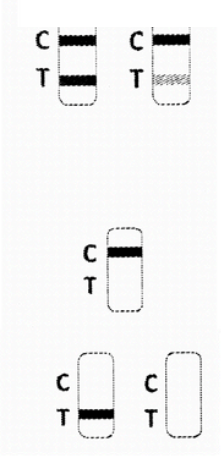


FOR LIQUIDS:

1. Prepare specimen collection containers and liquid sample.
2. Pour one to three drops of suspicious liquid into 5ml water (1 mineral water bottle cap = 5mL). Shake to mix well.
3. Remove the panel cap, with the arrow pointing toward the specimen; immerse the test panel vertically in the specimen for at least 10 to 15 seconds. Immerse the strip to at least the level of the wavy lines. but not above the arrow on the test panel.
4. Wait for the colored lines to appear. read the results at 5 minutes and do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS



(Please refer to the illustration)

NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

*NOTE: The shade of the colored lines(s) in the test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the control region (CJ and no colored line appears in the test region (T). The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume. adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however. it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Alprazolam (ALP) Surface Test Panel provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.
3. A negative result may not necessarily indicate drug-free. Negative results can be obtained when drug is present but below the cut-off level of the test.
4. Test does not distinguish between drugs of abuse and certain medications.