



## ZOL Rapid Test Dipstick (Urine) Package Insert

REF DZO-101/111 English

A rapid test for the qualitative detection of Zolpidem in human urine. For professional *in vitro* diagnostic use only.

### INTENDED USE

The ZOL Rapid Test Dipstick is a rapid chromatographic immunoassay for the detection of Zolpidem in human urine at the cut-off concentration of 50ng/ml. Please refer to Analytical Specificity table in this package insert for details on reactivity.

This assay provides only a qualitative, preliminary, analytical 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. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

### SUMMARY

Zolpidem (brand names Ambien, Ambien CR, Intermezzo, Stilnox, Stilnoct, Sublinox, Hypnogen, Zonadin, Sanval and Zolsana) is a prescription medication used for the treatment of insomnia and some brain disorders.<sup>[1]</sup> It is a short-acting nonbenzodiazepine hypnotic of the imidazopyridine class<sup>[1]</sup> that potentiates GABA, an inhibitory neurotransmitter, by binding to GABAA receptors at the same location as benzodiazepines.<sup>[2]</sup> It works quickly, usually within 15 minutes, and has a short half-life of two to three hours.

Zolpidem may be detected in blood or plasma to confirm a diagnosis of poisoning in hospitalized patients, provide evidence in an impaired driving arrest, or to assist in a medico-legal death investigation. Blood or plasma Zolpidem concentrations are usually in a range of 30–300 µg/l in persons receiving the drug therapeutically, 100–700 µg/l in those arrested for impaired driving, and 1000–7000 µg/l in victims of acute overdosage. Analytical techniques, in general, involve gas or liquid chromatography.<sup>[3][4][5]</sup>

The ZOL Rapid Test Dipstick is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of Zolpidem in urine. The ZOL Rapid Test Dipstick yields a positive result when Zolpidem in urine reaches 50ng/ml.

### PRINCIPLE

The ZOL Rapid Test Dipstick is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibodies.

During testing, as urine specimen migrates upward by capillary action, Zolpidem, if present in the urine specimen below 50ng/ml, will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized Zolpidem 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 Zolpidem level is at or above 50ng/ml because it will saturate all the binding sites of anti-Zolpidem antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine 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-Zolpidem antibody-coupled particles and Zolpidem-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

### 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 until use. **DO NOT FREEZE.** Do not use beyond the expiration date. **NOTE:** Once the canister has been opened, the remaining test(s) are stable for 50 days only.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test Dipsticks
- Package insert

#### Materials Required But Not Provided

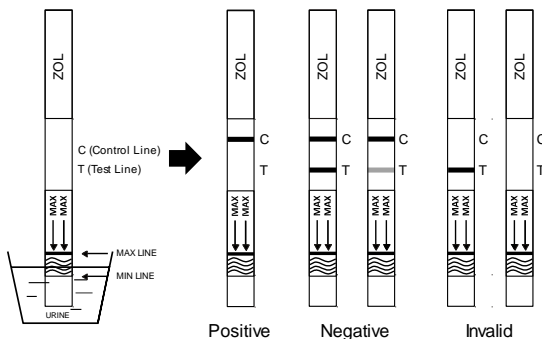
- Specimen collection container
- Timer

### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.
- With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.

- Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** Two lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Zolpidem concentration is below the detectable cutoff level.

**\*NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint color line.

**POSITIVE:** One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Zolpidem concentration is above the detectable cutoff level.

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Dipstick. If the problem persists, discontinue using the test Dipstick immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this test Dipstick; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The ZOL Rapid Test Dipstick provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.<sup>[6][7]</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

### EXPECTED VALUES

A negative result indicates that the Zolpidem concentration is below the detectable level of 50ng/ml. A positive result indicates the concentration of Zolpidem is above the level of 50ng/ml. The ZOL Rapid Test Dipstick has a sensitivity of 50ng/ml.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the ZOL Rapid Test Dipstick and GC/MS at the cut-off of 50ng/ml. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results
	Results		
ZOL Rapid Test Dipstick	Positive	20	22
	Negative	2	68
		66	90
<b>Total Results</b>		22	68
<b>% Agreement</b>		90.9%	97.1%

#### Analytical Sensitivity

A drug-free urine pool was spiked with Zolpidem at the following concentrations: 0ng/ml, 25ng/ml, 50ng/ml, 75ng/ml and 150ng/ml. The result demonstrates >96% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Zolpidem Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	29	1
50	Cut-off	30	15	15
75	+50%	30	1	29
150	3x	30	0	30

### Analytical Specificity

The following table lists compounds that are positively detected in urine by The ZOL Rapid Test Dipstick at 5 minutes.

Compound	Concentration (ng/ml)
Zolpidem	50

### Precision

A study was conducted with untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Zolpidem, 50% Zolpidem above and below the 50ng/ml cut-off was provided to each site. The results are given below:

Zolpidem Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	9	1	10	0	10	0
75	10	0	10	1	9	0	10

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 25ng/ml and 75ng/ml of Zolpidem. The ZOL Rapid Test Dipstick was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Zolpidem to 25ng/ml and 75ng/ml. The spiked, pH-adjusted urine was tested with the ZOL Rapid Test Dipstick in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Zolpidem positive urine. The following compounds show no cross-reactivity when tested with The ZOL Rapid Test Dipstick at a concentration of 100µg/ml.

#### Non Cross-Reacting Compounds

Acetaminophen	Dextromethorphan	Pheniramine
Acetone	4-Dimethylaminoantipyrine	Phenothiazine
Albumin	Dopamine	Phenylethylamine
Amitriptyline	Erythromycin	Procaine
Ampicillin	Ethanol	Quinidine
Aspartame	Furosemide	Ranitidine
Aspirin	Glucose	Riboflavin
Atropine	Guaiaacol Glyceryl Ether	Sodium Chloride
Benzocaine	Hemoglobin	Sulindac
Bilirubin	Imipramine	Thioridazine
Caffeine	Isoproterenol	Trifluoperazine
Chloroquine	Lidocaine	Trimethobenzamide
Chlorpheniramine	Naproxen	Tyramine
Creatine	Oxalic Acid	Vitamin C
Dexbrompheniramine	Pencillin-G	

### BIBLIOGRAPHY

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### Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged				

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Number: 145062902  
Effective date: 2016-06-23