



# CLO Rapid Test Dipstick (Urine) Package Insert

REF DCL-101/111 English

A rapid test for the qualitative detection of Benzodiazepines in human urine. For medical and other professional in vitro diagnostic use only.

### INTENDED USE

The CLO Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of Clonazepam in urine at a cut-off concentration of 400ng/ml. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert. 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

Clonazepam is a benzodiazepine drug having anxiolytic, anticonvulsant, muscle relaxant, amnesic, sedative, and hypnotic properties. Clonazepam has an intermediate onset of action, with a peak blood level occurring one to four hours after oral administration. Long-term effects of benzodiazepines include tolerance, benzodiazepine dependence, and benzodiazepine withdrawal syndrome, which occurs in one third of patients treated with clonazepam for longer than four weeks. Benzodiazepines such as clonazepam have a fast onset of action, high effectiveness rate, and low toxicity in overdose; however, as with most medications, it may have drawbacks due to adverse or paradoxical effects. The detection period for the Benzodiazepines in the urine is 3-7 days. The CLO Rapid Test Dipstick (Urine) is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of Benzodiazepines in urine. The CLO Rapid Test Dipstick (Urine) yields a positive result when the Benzodiazepines in urine exceeds the cut-off level.

### PRINCIPLE

The CLO Rapid Test Dipstick (Urine) 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 antibody. During testing, a urine specimen migrates upward by capillary action. Benzodiazepines, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Benzodiazepines-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 Benzodiazepines level exceeds the cut-off level, because it will saturate all the binding sites of anti-Benzodiazepines antibody.

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-Benzodiazepines antibody coupled particles and Benzodiazepines-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 at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister 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 a clear specimen for testing.

#### Specimen Storage

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

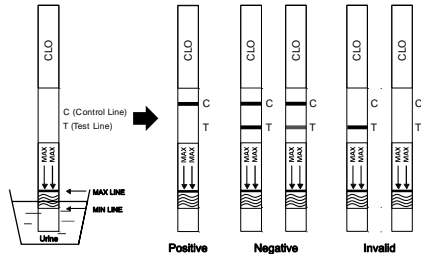
### MATERIALS

- Test Dipsticks
Materials Provided: Package insert
Materials Required But Not Provided: 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 colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Benzodiazepine concentration is below the detectable cut-off level.

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Benzodiazepine concentration exceeds the detectable cut-off 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. If the problem persists, discontinue using the test kit immediately and 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

- The CLO Rapid Test Dipstick (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
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

This negative result indicates that the Benzodiazepine concentration is below the detectable level of 400ng/ml. Positive result means the concentration of Benzodiazepine is above the level of 400ng/ml.

The CLO Rapid Test Dipstick has a sensitivity of 400ng/ml

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using The CLO Rapid Test Dipstick (Urine) and GC/MS at the cut-off of 400ng/ml. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results
	Results	Positive	
CLO Rapid Test Dipstick	Positive	101	102
	Negative	3	148
	Total Results	104	250
% Agreement	97.1%	99.3%	98.4%

#### Analytical Sensitivity

A drug-free urine pool was spiked with Clonazepam at the following concentrations: 0ng/ml, 200ng/ml, 300 ng/ml, 400ng/ml, 500ng/ml, 600ng/ml and 1200ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Clonazepam Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
200	-50%	30	30	0
300	-25%	30	26	4
400	Cut-off	30	14	16
500	+25%	30	5	25
600	+50%	30	0	30
1200	3X	30	0	30

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the CLO Rapid Test Dipstick (Urine) at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Clonazepam	400	Flunitrazepam	300
Alprazolam	200	(±) Lorazepam	1,250
a-hydroxyalprazolam	2,000	RS-Lorazepam glucuronide	250
Bromazepam	1,000	Midazolam	5,000
Chloridiazepoxide	1,000	Nitrazepam	200
Clobazam	250	Norcloridiazepoxide	200
Clorazepate	600	Nordiazepam	1,000
Deslorazepam	1,000	Oxazepam	350
Demoxylfurazepam	250	Temazepam	150
Diazepam	300	Triazolam	5,000
Estazolam	1,250		

#### Precision

A study was conducted at three hospitals by laypersons 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 Clonazepam, 25% Clonazepam above and below the cut-off and 50% Clonazepam above and below the 400ng/ml cut-off was provided to each site. The following results were tabulated:

Clonazepam Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
200	10	10	0	10	0	10	0
300	10	9	1	8	2	9	1
500	10	1	9	2	8	1	9
600	10	0	10	0	10	0	10

#### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 200ng/ml

and 600ng/ml of Clonazepam. The CLO Rapid Test Dipstick (Urine) 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 Clonazepam to 200ng/ml and 600ng/ml. The spiked, pH-adjusted urine was tested with The CLO Rapid Test Dipstick (Urine) 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 Clonazepam positive urine. The following compounds show no cross-reactivity when tested with The CLO Rapid Test Dipstick (Urine) at a concentration of 100 µg/ml.

#### Non Cross-Reacting Compounds

Acetaminophen	Deoxycorticosterone	MDE	β-Phenylethylamine
Acetophenetidin	Dextromethorphan	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diclofenac	Meprobamate	Prednisolone
Acetylsalicylic acid	Diffunilal	Methadone	Prednisone
Amnopirine	Digoxin	L-Methamphetamine	Procaine
Amityriptyline	Diphenhydramine	Methoxyphenamine	Promazine
Amobarbital	Doxylamine	(±) - 3,4-Methylenedioxy-amphetamine	Promethazine
Ecgonine	Ecgonine methyl ester	(±) - 3,4-Methylenedioxy-methamphetamine	D,L-Propranolol
Amoxicillin	Ecgonine	(±) - 3,4-Methylenedioxy-methamphetamine	D-Propoxyphene
Ampicillin	(-) - ψ-Ephedrine	Morphine-3-β-D glucuronide	D-Pseudoephedrine
L-Ascorbic acid	(-) - ψ-Ephedrine	(L) - Epinephrine	Quinacrine
D,L-Amphetamine sulfate	[R,2S] (-) Ephedrine	(L) - Epinephrine	Quinidine
Apomorphine	(L) - Epinephrine	Morphine Sulfate	Quinine
Aspartame	Erythromycin	Nalidixic acid	Quinine
Atropine	β-Estradiol	Naloxone	Ranitidine
Benzilic acid	Estrone-3-sulfate	Nalrexone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Benzoylcegonine	Fenoprofen	Niacinamide	Serotonin
Benzphetamine	Furosemide	Nifedipine	Sulfamethazine
Bilirubin	Genetic acid	Norcodeine	Sulindac
(±) - Brompheniramine	Hemoglobin	Norethidrone	Tetracycline
Caffeine	Hydralazine	D-Norpropoxyphene	Tetrahydrocortisone, 3-Acetate
Cannabidiol	Hydrochlorothiazide	Noscapine	Tetrahydrocortisone 3-(β-D-glucuronide)
Cannabinol	Hydrocodone	D,L-Oxycodamine	Tetrahydrozoline
Chloralhydrate	Hydrocortisone	Oxalic acid	Thiamine
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Thioridazine
Chlorothiazide	p-Hydroxyamphetamine	Oxycodone	D,L-Tyrosine
(±) - Chlorpheniramine	p-Hydroxy-methamphetamine	Oxymetazoline	Tolbutamide
Chlorpromazine	3-Hydroxytyramine	Papaverine	Triamterene
Chlorquine	3-Hydroxytyramine	Penicillin-G	Trifluoperazine
Cholesterol	Ibuprofen	Phenazone	Trimethoprim
Clonipramine	Imipramine	Phenylhydrazine	Trimipramine
Clonidine	Iproniazid	(±) - Isoproterenol	Triptamine
Coacethylen	(±) - Isoproterenol	Phenazine	Triptamine
Cocaine	Isoxsuprine	Phenobarbital	D,L-Tryptophan
Cocaine	Ketamine	Phentermine	Tyramine
Cortisone	Ketoprofen	Trans-2-phenylcyclopropylamine hydrochloride	Uric acid
(-) Cotinine	Labeltalol	L-Phenylephrine	Zomepirac
Crotamine	Loperamide		
	Maprotiline		

### BIBLIOGRAPHY

- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

### 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: 145026202 Effective date: 2015-09-14