

ALL TEST™

α-PVP Rapid Test Cassette (Urine)

Package Insert
REF DAP-102 English

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

INTENDED USE

The α-PVP Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the detection of alpha-Pyrrolidinovaleorpherone (α-PVP) in human urine at a cut-off concentration of 1,000 ng/mL.

This assay provides only a qualitative, preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

alpha-Pyrrolidinovaleorpherone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes. α-PVP may be quantified in blood, plasma or urine to confirm a diagnosis of poisoning in hospitalized patients or to provide evidence in a medicolegal death investigation. It generally comes in the form of either a crystalline powder or crystallized shards which users can ingest to produce powerful but short-lived euphoric stimulant effects which are comparable to those of methamphetamine and cocaine when inhaled or vaporized. α-PVP has been reported to be the cause, or a significant contributory cause of death in suicides and overdoses caused by combinations of drugs. It has also been linked to at least one death where it was combined with pentetone and caused heart failure.

The α-PVP Rapid Test Cassette (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of alpha-Pyrrolidinovaleorpherone in urine. The α-PVP Rapid Test Cassette (Urine) yields a positive result when alpha-Pyrrolidinovaleorpherone in urine exceeds 1,000ng/mL.

PRINCIPLE

The α-PVP Rapid Test Cassette (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. alpha-Pyrrolidinovaleorpherone, if present in the urine specimen below 1,000ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody-coated particles will then be captured by immobilized alpha-Pyrrolidinovaleorpherone 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 alpha-Pyrrolidinovaleorpherone level exceeds 1,000ng/mL, because it will saturate all the binding sites of anti-alpha-Pyrrolidinovaleorpherone 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 lower 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal alpha-Pyrrolidinovaleorpherone antibody-coated particles and alpha-Pyrrolidinovaleorpherone-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.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

Specimen Collection

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

MATERIALS

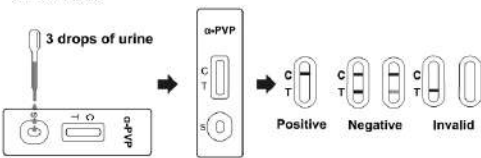
Materials Provided

- Test Cassettes
- Package Insert
- Droppers
- 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 cassette from the sealed pouch and use it within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: Two colored lines appear. One colored line should be in the control line region (C), and another colored line should be in the test line region (T). This negative result indicates that the alpha-Pyrrolidinovaleorpherone concentrations are below the detectable level (1,000ng/mL).

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test line region (T). This positive result indicates that the alpha-Pyrrolidinovaleorpherone concentration exceeds the detectable level (1,000ng/mL).

INVALID: Control line (C) 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 using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

A procedural control is included in the test. A colored line appearing in the control 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 practice to confirm the test procedure and to verify proper test performance.

QUALITY CONTROL

- The α-PVP Rapid Test Cassette (Urine) 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.
- 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the α-PVP Rapid Test Cassette and GC/MS at the cut-off of 1,000 ng/mL. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC/MS		Total Results
	Results		
α-PVP Rapid Test Cassette	Positive	35	37
	Negative	3	63
Total Results		38	100
% Agreement		92.1%	96.8%

Analytical Sensitivity

A drug-free urine pool was spiked with alpha-Pyrrolidinovaleorpherone at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL, 1,500 ng/mL, and 3,000 ng/mL. The result demonstrated >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

alpha-Pyrrolidinovaleorpherone Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
500	-50%	30	30	0
750	-25%	30	26	4
1,000	Cut-off	30	15	15
1,250	+25%	30	3	27
1,500	+50%	30	0	30
3,000	3X	30	0	30

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the α-PVP Rapid Test Cassette (Urine) at 5 minutes.

Test Cassette (Urine) at 5 minutes:	Concentration (ng/mL)			
Compound	1,000			
alpha-Pyrrolidinovaleorpherone	Precision			
A study was conducted at 3 hospitals using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no alpha-Pyrrolidinovaleorpherone, 25% alpha-Pyrrolidinovaleorpherone above and below the cutoff and 50% alpha-Pyrrolidinovaleorpherone above and below the 1000 ng/mL cutoff were provided to each site. The following results were tabulated:				
alpha-Pyrrolidinovaleorpherone Concentration (ng/mL)	n per Site	Site A	Site B	Site C
0	10	10	0	10
500	10	10	0	10
750	10	8	2	9
1,250	10	2	8	3
1,500	10	0	10	0

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.035 were spiked with alpha-Pyrrolidinovaleorpherone to the concentrations of 500 ng/mL and 1,500 ng/mL. The α-PVP Rapid Test Cassette (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 the 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 alpha-Pyrrolidinovaleorpherone to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the α-PVP Rapid Test Cassette (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 alpha-Pyrrolidinovaleorpherone positive urine. The following compounds show no cross-reactivity when tested with the α-PVP Rapid Test Cassette (Urine) at a concentration of 100 ng/mL.

Non Cross-Reacting Compounds

Acetophenetidin	amphetamin	Nimesulide	Metronidazole
N-Acetylprocainamide	Nalidixic acid	Bupropion	Venocur
Acetylsalicylic acid	Naloxone	5,5-Diphenylhydantoin	Spiroglactone
Aminopyrine	Nascanamide	1-Thymine	Emetine
Amtripyline	Nifedipine	EDDP	Paroxetine
Amobarbital	Noethindrone	Cydozepam	Diacylmorphine
Amoxicillin	Novethisterone	Lidocaine	St-2-Cathinone
Atropine	Norpropoxyphene	Guafenesin	R(+)-Methcathinone
Aspartame	Noscapine	Amoxapine	5-Methcathinone
Asp-Phenethylster	d-1-Opadamine	(+)-Chlorpheniramine	Barbital
Benzoic acid	Oxazepam	Quinacrine Glycyl-	Carbamazepine
Bilirubin	Oxymetazoline	Ether carbamate	Lansoprazole
Papaverine	Chlorophthene	Chlorophthene	Diphenoxylate
Penicillin	R(+)-Deprenyl	R(+)-Deprenyl	7-Amino-clonazepam
Phenothiazine	Phenothiazine	Phenothiazine	4-Acetaminophenyl-β-D-glucuronide
Hydrochloride	Perphenazine	Riboflavin	Clonazepam
Chloroquine	Phenazone	α-Naphthaleneacetic Acid	Terbutaline hemisulfate salt
Cholesterol	Phenobarbital	(+)-Ephedrine	Zolpidine hemitartrate
Clomprazine	Phenobarbital	Phenobarbital	Valproic acid
Clonidine Hydrochloride	β-Phenylethylamine	Albunin	Isotiazole
Cocaine	Prednisolone	Albumin	7-Aminoflunitrazepam
Codine	Prednisone	d-(-) Glucose	3,4-Methylenediphenylamine
Cortisone	l-Phenylephrine -	Sodium chloride	Hydrobromide
(-)-Cotinine	(R)-(-)-Phenylephrine	Pemoline	Alprazolam
Creastine	Procaine	Cimetidine	Hydrobromide
Deoxy corticosterone	Quinine	Disopyramide	Alprazolam
Diazepam	Quinine	Hexachlorocyclopentadiene	Hydrobromide
Diflunisal	5-Hydroxytryptamine	Etodolac	Estazolam
Dipoxin	Sulfamethazine	Metoprolol	Bromazepam
Doxylamine	Temazepam	Amantadine	Ethylmorphine
Erythromycin	Tetracycline	Chlorpropamide	Clonazepam dipotassium
β-Estradiol Estradiol	Tetralyzoline	Clazepam	Norchlorazepoxide
Diphenhydramine	Thebaine	Baclofen	Methoxetone
Hydrochloride	Thiamine	Amikacin	Nortriptyline
Estrore	Thioctazine	Droperidol	Dosepin
Ethyl-p-aminobenzoate	Tobutamide	Gentamicin	Desipramine
Fenopropfen	Triamterene	Indomethacin	Nordopren
Furosemide	Trimethoprim	Sulfamethoxazole	Desoxyflunitrazepam
Gentamicin	Trimethoprim	Sulfazoxazole	Ciprofloxacin Hydrochloride
Hydralazine	Triptamine	Nimesulide	Paritaprazole
Hydrochlorothiazide	d-1-Tyrosine	Bupropion	Pseudoephedrine -
O-Hydroxytyrosine	L-Tyrosine	5,5-Diphenylhydantoin	Hydrochloride
3-Hydroxytyrosine	d-1-Tryptophan	1-Thymine	PEG 400
Ibuprofen	Uric acid	Cymophore	Amidolipine Besylate
p-Hydroxy-methamphetamine	Verapamil	Cydozepam	(S)-(+)-Methoxy-α-Methyl-2-naphthaleneacetic acid
Imipramine	Zomepirac	Lidocaine	Valparan capsules
	Ampicillin	Guafenesin	

(-) Isoproterenol	Caffeine	Amoxapine	Sildenafil Citate
Ketoprofen	(+/-)-Chlorpheniramine	Guafacol Glyceryl-Ether carbamate	Tizandine HCL
Maprotiline	Ranitidine	(+)-Chlorpheniramine	Paritaprazole Sodium
Meperidine	Quinacrine	Gabapentin	Enticel-Coated
Methoxyphenamine	Trazodone	(+)-Nopseudoephedrine	Pyridoxine HCL
Atomoxetine	Trans-2-Phenyl-1-cyclopropylamine	Pregabalin	Dihydrocodine
		(1R, 2S) - (-)-Ephedrine	

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Index of Symbols

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