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-Pyrrolidinovalerophenone (α-PVP) in human urine at a cut-off concentration of 1000 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) or 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-Pyrrolidinovalerophenone (also known as α-PVP, A-PVP, alpha-PVP, and Flakka) is a synthetic stimulant substance of the cathinone and pyrrolidine chemical classes.[1] 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.[2] 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 insufflated 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.[3, 4] It has also been linked to at least one death where it was combined with pentedrone 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-Pyrrolidinovalerophenone in urine. The α-PVP Rapid Test Cassette (Urine) yields a positive result when alpha-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone, 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-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone level exceeds 1,000ng/mL because it will saturate all the binding sites of anti-alpha-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone antibody-coupled particles and alpha-Pyrrolidinovalerophenone-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 the 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

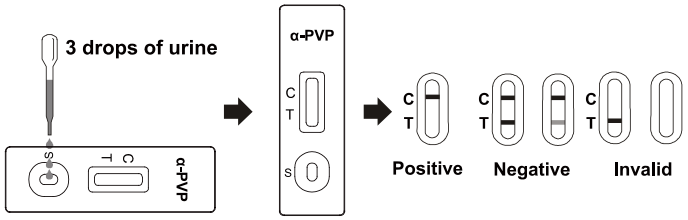
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. 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.
3. 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-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone 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.

【QUALITY CONTROL】

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.

【LIMITATIONS】

1. 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.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicates level of intoxication, administration route or concentration in urine.
5. 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.
6. 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
α-PVP Rapid Test Cassette	Results	Positive	Negative	
	Positive	35	2	37
	Negative	3	60	63
Total Results		38	62	100
% Agreement		92.1%	96.8%	95.0%

Analytical Sensitivity

A drug-free urine pool was spiked with alpha-Pyrrolidinovalerophenone 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 demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

alpha-Pyrrolidinovalerophenone 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.

Compound	Concentration (ng/mL)
alpha-Pyrrolidinovalerophenone	1,000

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-Pyrrolidinovalerophenone, 25% alpha-Pyrrolidinovalerophenone above and below the cutoff and 50% alpha-Pyrrolidinovalerophenone above and below the 1000 ng/mL cutoff were provided to each site. The following results were tabulated:

alpha-Pyrrolidinovalerophenone Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	8	2	9	1	9	1
1,250	10	2	8	3	7	1	9
1,500	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine samples with specific gravities ranging from 1.004 to 1.035 were spiked with alpha-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone 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-Pyrrolidinovalerophenone positive urine. The following compounds show no cross-reactivity when tested with the α-PVP Rapid Test Cassette (Urine) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	(±) 3,4-Methylendioxy amphetamine	Nimesulide	Metronidazole
N-Acetylprocainamide	Nalidixic acid	Buspirone	Vancomycin
Acetylsalicylic acid	Naloxone	5,5-Diphenylhydantoin	Spironolactone
Aminopyrine	Niacinamide	l-Thyroxine	Emetine
Amitriptyline	Nifedipine	EDDP	Paroxetine
Amobarbital	Norethindrone -	Oxymorphone	Diacetylmorphine
Amoxcillin	Norethisterone	Cyclobenzaprine	S(-)-Cathinone
Atropine	d-Norpropoxyphene	Lidocaine	R(+)-Methcathinone
Aspartame -	Noscapine	Guaifenesin	S(-)-Methcathinone
Asp-Phemethylester	d,l- Octopamine	Amoxapine	Barbital
Benzilic acid	Oxazepam	(+)- Chlorpheniramine	Carbamazepine
Benzoic acid	Oxymetazoline	Guaiacol Glyceryl - Ether carbamate	Lansoprazole
Bilirubin	Papaverine	Chlorprothixene	Diphenoxylate
Chloramphenicol	Penicillin	R (-)Deprenyl	7-Amino-clonazepam
Chlorothiazide	Promethazine	Pheniramine	p-Acetamidophenyl-β-D-glucuronide
Chlorpromazine	Hydrochioride	4-Dimethylaminoantipyrine	Clonazepam
Chloroquine	Perphenazine	Riboflavin	Terbutaline hemisulfate salt
Cholesterol	Phenelzine	α -Naphthaleneacetic Acid	Zolpiden hemitartrate
Clomipramine	Phenobarbital	(+/-) Epinephrine	Valproic acid
Clonidine Hydrochloride	β-Phenylethylamine	Phenothiazine	Isoniazid
Cocaine	Prednisolone	Albumin	7-Aminoflunitrazepam
Codeine	Prednisone	d (+) Glucose	DL-Homatropine – Hydrobromide
Cortisone	l-Phenylephrine - (R)-(-)-Phenylephrine	Sodium chloride	Alprazolam
(-)Cotinine	Procaine	Pemoline	3,4-Methylenedioxy-ethylamphetamine
Creatinine	Quinidine	Cimetidine	Estazolam
Deoxycorticosterone	Quinine	Disopyramide	Bromazepam
Diazepam	5-Hydroxytryptamine	Hexachlorocyclohexane	Ethylmorphine
Diflunisal	Sulfamethazine	Etodolac	Clorazepam dipotassium
Digoxin	Temazepam	Metoprolol	Norchlordiazepoxide
Doxylamine	Tetracycline	Amantadine	Methotrexate
Erythromycin	Tetrahydrozoline	Chlorpropamide	Nortriptyline
β-Estradiol Estradiol	Thebaine	Clozapine	Doxepin
Diphenhydramine -Hydrochloride	Thiamine	Baclofen	Desipramine
Estrone	Thioridazine	Amikacin	Nordoxepin
Ethyl-p-aminobenzoate	Tolbutamide	Droperidol	Desalkylflurazepam
Fenoprofen	Triamterene	Gentamicin	Ciprofloxacin Hydrochloride
Furosemide	Trimethoprim	Indomethacin	pantoprazole
Gentisic acid	Trimipramine	Sulfamethoxazole	Pseudoephedrine - Hydrochloride
Hydralazine	Tryptamine	Sulfisoxazole	PEG-400
Hydrochlorothiazide	d,l-Tyrosine -	Nimesulide	Amlodipine Besylate
O-Hydroxyhippuric acid	L-Tyrosine	Buspirone	(S)-(+)-Methoxy-α-Methyl -2-napthaleneacetic acid
3-Hydroxytyramine	d,l-Tryptophan	5,6-Diphenylhydantoin	Valsartan capsules
Ibuprofen	Uric acid	l-Thyroxine	
p-Hydroxy - methamphetamine	Verapamil	Oxymorphone	
Imipramine	Zomepirac	Cyclobenzaprine	
	Ampicillin	Lidocaine	
		Guaifenesin	

(-) Isoproterenol	Caffeine	Amoxapine	Sildenafil Citate
Ketoprofen	(+/-)-Chlorpheniramine	Guaiacol Glyceryl - Ether carbamate	Tizanidine HCL
Maprotiline	Ranitidine	(+)- Chlorpheniramine	Pantoprazole Sodium Enteric-Coated
Meprobamate	Quinacrine		
Meperidine	Dicyclomine	Gabapentin	Pyridoxine HCL
Methoxyphenamine	Trazodone	(+)-Nopseudoephedrine	Dihydrocodeine
Atomoxetine	Trans-2-Phenylcy-clopropylamine	Pregablin	
levetiracetam		(1R, 2S) - (-)-Ephedrine	

【BIBLIOGRAPHY】

1. "Drugs of Abuse Emerging Trends". National Institute on Drug Abuse. 6 April 2015.
2. Eiden, C.; Mathieu, O.; Catala, P. (2013). "Toxicity and death following recreational use of 2-pyrrolidino valerophenone.". Clinical Toxicology. 51: 899–903. PMID 24111554. doi:10.3109/15563650.2013.847187.
3. Marinetti, L. J.; Antonides, H. M. (2013). "Analysis of synthetic cathinones commonly found in bath salts in human performance and postmortem toxicology: Method development, drug distribution and interpretation of results". Journal of Analytical Toxicology. 37 (3): 135–46. PMID 23361867. doi:10.1093/jat/bks136.
4. Waugh; et al. (2013). "Deaths Involving the Recreational Use of α-PVP (α-pyrrolidinopentiophenone)" (PDF). AAFS Proceedings. Abstract K16.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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Number: 145722201
Revision date: 2023-10-10