PCP Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF DPC-402	English

A rapid test for the qualitative detection of Phencyclidine in human whole blood or serum or plasma.

For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the detection of Phencyclidine in whole blood or serum or plasma at a cut-off concentration of 20ng/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 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】

Phencyclidine, also known as PCP, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

【PRINCIPLE】

The PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) is an immunoassay based on the principle of competitive binding. Drugs that may be present in thewhole blood/serum/plasma specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a whole blood/serum/plasma specimen migrates upward by capillary action. Phencyclidine, if present in the whole blood/serum/plasma 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 Phencyclidine-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 Phencyclidine level exceeds the cut-off level because it will saturate all the binding sites of anti-Phencyclidineantibodies.

A drug-positive whole blood/serum/plasma specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative whole blood/serum/plasma 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-Phencyclidineantibody coupled particles and Phencyclidine-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch 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】

- The PCP Rapid Test Cassette can be performed using whole blood/serum/plasma (from venipuncture or fingerstick).
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test cassettes • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer 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 device from the sealed pouch and use it within one hour.
2. Place the device on a clean and level surface.

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40µL), then add **2 drops of buffer** (approximately 80µL) to the specimen well(S) of the device, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

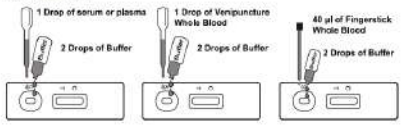
For Venipuncture Whole blood specimen:

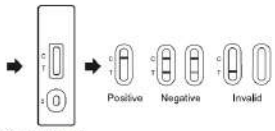
•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80µL), and start the timer. See illustration below.

For Fingerstick Whole blood specimen:

•To use a capillary tube: **Fill** the capillary tube and **transfer approximately 40µL of fingerstick whole blood specimen** to the specimen well(S) of test device, then add **2 drops of buffer** (approximately 80µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not interpret the result after 10 minutes.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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 Phencyclidine 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 Phencyclidine 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 region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) 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.[1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in thewhole blood or serum or plasma specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in whole blood or serum or plasma.
4. A negative result may not necessarily indicate drug-free whole blood. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the PCP Rapid Test Cassette and GC/MS at the cut-off of 20ng/mL. Testing was performed on 90 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
	Results	Positive	Negative	
PCP Rapid Test Cassette	Positive	21	1	22
	Negative	1	67	68
Total Results		22	68	90
% Agreement		95.5%	98.5%	97.8%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
	Results	Positive	Negative	
PCP Rapid Test Cassette	Positive	21	1	22
	Negative	1	67	68
Total Results		22	68	90
% Agreement		95.5%	98.5%	97.8%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Phencyclidine at the following concentrations of ±50% cutoff and 3x cutoff, the data are summarized below.

For whole blood:

PCP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

For serum or plasma:

PCP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
10	-50%	30	30	0
20	Cut-off	30	15	15
30	+50%	30	0	30
60	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) at 5 minutes.

Compound	Concentration (ng/mL)
4-Hydroxyphencyclidine	5,000
Phencyclidine	20

Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no PCP and 50% PCP above and below the 20ng/mL cut-off was provided to each site. The following results were tabulated:

PCP Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	8	2	9	1	9	1
30	10	1	9	1	9	2	8

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free whole blood/serum/plasma or determine positive whole blood. The following compounds show no cross-reactivity when tested with the PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Creatinine	Meperidine	Prednisolone
Acetophenetidin	Deoxycorticosterone	Meprobamate	Prednisone
N-Acetylprocainamide	Dextromethorphan	Methadone	Procaine
Acetylsalicylic acid	Diazepam	Methoxyphenamine	Promazine
Aminopyrine	Diclofenac	(+) 3,4-Methylenedioxy-	Promethazine
Amitryptyline	Diflunisal	Amphetamine	D,L-Propanolol
Amobarbital	Digoxin	(+) 3,4-Methylenedioxy-	D-Propoxyphene
Amoxicillin	Diphenhydramine	methamphetamine	D-Pseudoephedrine
Ampicillin	Doxylamine	Morphine-3-	Quinidine
L-Ascorbic acid	Ecgonine hydrochloride	β-D glucuronide	Quinine
D,L-Amphetamine	Ecgoninemethylester	Morphine Sulfate	Ranitidine
Apomorphine	(-)-ψ-Ephedrine	Nalidixic acid	Salicylic acid
Aspartame	Erythromycin	Naloxone	Secobarbital
Atropine	β-Estradiol	Naltrexone	Serotonin
Benzilic acid	Estrone-3-sulfate	Naproxen	(5-Hydroxytyramine)
Benzoic acid	Ethyl-p-aminobenzoate	Niacinamide	Sulfamethazine
Benzoylecgonine	Fenoprofen	Nifedipine	Sulindac
Benzphetamine	Furosemide	Norcodein	Temazepam
Bilirubin	Gentisic acid	Norethindrone	Tetracycline
(±) – Brompheniramine	Hemoglobin	D-Norpropoxyphene	Tetrahydrocortisone,
Caffeine	Hydralazine	Noscapine	3-Aacetate
Cannabidiol	Hydrochlorothiazide	D,L-Octopamine	Tetrahydrocortisone
Cannabinol	Hydrocodone	Oxalic acid	3-(β-D glucuronide)
Chloralhydrate	Hydrocortisone	Oxazepam	Tetrahydrozoline
Chloramphenicol	O-Hydroxyhippuric acid	Oxolinic acid	Thiamine
Chlordiazepoxide	p-Hydroxy-	Oxycodone	Thioridazine
Chlorothiazide	Methamphetamine	Oxymetazoline	D, L-Tyrosine
(±) Chlorpheniramine	3-Hydroxytyramine	Papaverine	Tolbutamide
Chlorpromazine	Ibuprofen	Penicillin-G	Triamterene
Chlorquine	Imipramine	Pentazocine hydrochloride	Trifluoperazine
Cholesterol	Iproniazid	Pentobarbital	Trimethoprim
Clomipramine	(±) - Isoproterenol	Perphenazine	Trimipramine
Clonidine	Isoxsuprine	Phenelzine	Tryptamine
Cocaine hydrochloride	Ketamine	Phenobarbital	D, L-Tryptophan
Codeine	Ketoprofen	Phentermine	Tyramine
Cortisone	Labetalol	L-Phenylephrine	Uric acid
(-) Cotinine	Loperamide	β-Phenylethylamine	Verapamil
	Maprotiline	Phenylpropanolamine	Zomepirac

Interfering Substances

The PCP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dL hemoglobin; up to 100 mg/dL bilirubin and up to 200 mg/dL human serum albumin.

【BIBLIOGRAPHY】

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

Index of Symbols

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30 °C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
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Number: 145713001
Revision date: 2023-12-20

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Date: 2026.01.21 09:10:13 EET
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