PCP

cobas®

ONLINE DAT Phencyclidine Plus

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08058130190	08058130500	ONLINE DAT Phencyclidine Plus (**cobas c** pack 1), 850 tests	System-ID 2096 011	**cobas c** 303, **cobas c** 503, **cobas c** 703
		ONLINE DAT Phencyclidine Plus (**cobas c** pack 2), 850 tests	System-ID 2096 012	

Materials required (but not provided):

03304671190	Preciset DAT Plus I CAL 1-6 (6 x 5 mL)	Codes 20431-20436	
03304698190	C.f.a.s. DAT Qualitative Plus (6 x 5 mL)	Code 20698	
04590856190	C.f.a.s. DAT Qualitative Plus Clinical (3 x 5 mL)	Code 20699	
03312950190	Control Set DAT I PreciPos DAT Set I (2 x 10 mL) PreciNeg DAT Set I (2 x 10 mL)		
04500873190	Control Set DAT Clinical PreciPos DAT Clinical (2 x 10 mL) PreciNeg DAT Clinical (2 x 10 mL)		

English

System information

PC2QP: ACN 20960: for qualitative assay

PC2SP: ACN 20961: for semiquantitative assay

PC2QC: ACN 20962: for qualitative assay; using C.f.a.s. DAT Qualitative Plus Clinical

PC2-QP: ACN 20963: for qualitative assay; using C.f.a.s. DAT Qualitative Plus

Intended use

Phencyclidine Plus (PCP) is an in vitro diagnostic test for the qualitative and semiquantitative detection of phencyclidine and its metabolites in human urine on **cobas c** systems at a cutoff concentration of 25 ng/mL. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC-MS).

Phencyclidine Plus provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC-MS is the preferred confirmatory method.[1] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary

Detection of phencyclidine with this assay in human urine is used for presumptive testing of exposure to phencyclidine in individuals with suspected exposure and in individuals under pain management treatments.

Phencyclidine is an arylcyclohexylamine that was developed as a general anesthetic, but was discontinued because of the post-anesthetic adverse effects, including psychosis and dysphoria.[2,3] Although phencyclidine can induce bizarre psychotomimetic effects, it has become a drug of abuse for its mind-altering "out of body" experience.[2,4] Sold illegally on the street, it is known by various names such as "angel dust"; while names such as "supergrass" refer to phencyclidine combined with marijuana.[5]

The water-soluble powder of phencyclidine can be ingested, snorted, injected intravenously, or smoked.[5] The hallucinogenic, central nervous system (CNS)-stimulant, and CNS-depressant properties are dose-dependent and the clinical picture may wax and wane between extreme agitation and sedation.[6] Signs of intoxication include tachycardia, hypertension, violent behavior, nystagmus, anesthesia, and analgesia. Doses greater than 10 mg can cause symptoms that mimic schizophrenia and can culminate in convulsions and prolonged or fatal coma. Repeated use of phencyclidine can result in addiction and prolonged psychosis, with increased risk of developing true schizophrenia.[6]

The onset of phencyclidine effects is dependent upon the route of administration. Phencyclidine is highly brain penetrant and readily absorbed by adipose tissue, where it has been detected for up to 4 weeks. Significant variations in the elimination half-life have been found in humans, ranging from 7 to 57 hours. Phencyclidine is metabolized via ring-hydroxylation and oxidation by the cytochrome P450 enzymes and only 10 % is excreted unchanged in the urine.[7]

In pain management patients phencyclidine testing is recommended to identify its illicit use.[8] In the context of drug screening, samples that test negative on initial screening tests can be reported as negative and disposed of as planned. Otherwise, depending on the situation, presence of the drugs indicated by a positive screening result may need to be confirmed using a suitable confirmatory technique (e.g., GC-MS or LC-MS).[8,9,10,11]

Test principle

The assay is based on the kinetic interaction of microparticles in a solution (KIMS)[12] as measured by changes in light transmission. In the absence of sample drug, free antibody binds to drug-microparticle conjugates causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases.

When a urine sample contains the drug in question, this drug competes with the particle-bound drug derivative for free antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

Reagents - working solutions

R1 Buffer; 0.09 % sodium azide

R2 PCP antibody (mouse monoclonal); buffer; bovine serum albumin; 0.09 % sodium azide

R3 Conjugated PCP derivative microparticles; buffer; 0.09 % sodium azide

Cat. No. 08058130190 consists of 2 **cobas c** packs: 1 x R1 + R2 and 1 x R3. R1 is in position B and R2 is in position C of **cobas c** pack 1. R3 is in position C of **cobas c** pack 2.

Precautions and warnings

For in vitro diagnostic use for laboratory professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.
Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Carefully invert reagent container several times prior to use to ensure that the reagent components are mixed.

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label
On-board in use and refrigerated on the analyzer:	18 weeks

Do not freeze.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Urine: Collect urine samples in clean glass or plastic containers. Fresh urine specimens do not require any special handling or pretreatment, but an effort should be made to keep pipetted samples free of gross debris. Samples should be within the normal physiological pH range of 5-8. No additives or preservatives are required. It is recommended that urine specimens be stored at 2-8 °C and tested within 5 days of collection.[13]

For prolonged storage, freezing of samples is recommended.[13]

Freeze only once.

Centrifuge highly turbid specimens before testing.

See the limitations and interferences section for details about possible sample interferences.

Adulteration or dilution of the sample can cause erroneous results. If adulteration is suspected, another sample should be collected. Specimen validity testing is required for specimens collected under the *Mandatory Guidelines for Federal Workplace Drug Testing Programs*.[14]

CAUTION: Specimen dilutions should only be used to interpret results of Calc.? and Samp.? alarms, or when estimating concentration in preparation for GC-MS. Dilution results are not intended for patient values. Dilution procedures, when used, should be validated.

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

See “Order information” section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for urine

Test definition

	Semiquantitative		Qualitative
Reporting time	10 min		10 min
Wavelength (sub/main)	– /505 nm		– /505 nm
Reagent pipetting			Diluent
R1	26 µL		–
R2	26 µL		–
R3	24 µL		–
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent*
Normal	5 µL	–	–
Decreased	5 µL	–	–
Increased	5 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Semiquantitative application

Calibrators	S1-4: Preciset DAT Plus I, CAL 1-4 0, 12.5, 25, 50 ng/mL
Calibration mode	Non-linear
Calibration frequency	Full calibration - after reagent lot change - every 9 weeks on-board - as required following quality control procedures

Qualitative application

Calibrators	S1: C.f.a.s. DAT Qualitative Plus, C.f.a.s. DAT Qualitative Plus Clinical, or Preciset DAT Plus I, CAL 3 25 ng/mL
Cutoff calibrator	A value of "0" is encoded in the e-barcode in order to ensure flagging of positive samples with >Test and negative absorbance values for negative samples.
Calibration K factor	The K factor of -1000 is predefined in the application settings.
Calibration mode	Linear
Calibration frequency	Full calibration - after reagent lot change - every 9 weeks on-board - as required following quality control procedures

The drug concentrations of the calibrators have been verified by GC-MS.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against a primary reference method (GC-MS).

Quality control

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

Drug concentrations of Control Set DAT I and Clinical have been verified by GC-MS.

The control intervals and limits should be adapted to each laboratory’s individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 8 weeks.

Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Results

For the qualitative assay, the cutoff calibrator is used as a reference in distinguishing between preliminary positive and negative samples. Samples producing a positive or “0” absorbance value are considered preliminary positive. Preliminary positive samples are flagged with >Test . Samples producing a negative absorbance value are considered negative. Negative samples are preceded by a minus sign.

The semiquantitation of preliminary positive results should only be used by laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS. It also permits the laboratory to establish quality control procedures and assess control performance.

cobas c systems automatically calculate the drug or drug metabolite concentration of each sample in the unit ng/mL.

NOTE: If a result of Calc.? or Samp.? alarm is obtained, review the Reaction Monitor data for the sample and compare with the Reaction Monitor data for the highest calibrator. The most likely cause is a high concentration of the analyte in the sample, in which case the absorbance value for the sample will be less than that of the highest calibrator. Make an appropriate dilution of the sample using the 0 ng/mL calibrator and rerun the sample. A normal drug-free urine may be substituted for the 0 ng/mL calibrator if the urine and procedure have been validated by the laboratory. To ensure that the sample was not over-diluted, the diluted result, prior to multiplying by the dilution factor, must be at least half the analyte cutoff value. If the diluted result falls below half the analyte cutoff value, repeat the sample with a smaller dilution. A dilution that produces a result closest to the analyte cutoff is the most accurate estimation. To estimate the preliminary positive sample's concentration, multiply the result by the appropriate dilution factor. Dilutions should only be used to interpret results of Calc.? or Samp.? alarms, or when estimating concentration in preparation for GC-MS.

For the semiquantitative applications **cobas c** systems automatically calculate the drug or metabolite concentration of each sample in the unit ng/mL. Results equal to or greater than the respective cutoff value are considered preliminary positive. Concentration values below the respective cutoff indicate a negative result.

Use caution when reporting results as there are various factors that influence a urine test result, such as fluid intake and other biological factors.

As with any sensitive test for drugs of abuse on automated clinical chemistry analyzers, the possibility exists for analyte carry-over from a sample with an extremely high concentration to a normal (negative) sample which immediately follows it.

Preliminary positive results should be confirmed by another method.

Limitations - interference

See the "Specific performance data" section of this document for information on substances tested with this assay. There is the possibility that other substances and/or factors may interfere with the test and cause erroneous results (e.g., technical or procedural errors).

A preliminary positive result with this assay indicates the presence of PCP and/or its metabolites in urine. It does not measure the level of intoxication.

Interfering substances were added to drug free urine at the concentration listed below. These samples were then spiked to 25 ng/mL using a PCP stock solution. Samples were tested in triplicate (n = 3) on a **cobas c** 501 analyzer. The median % recoveries were calculated and are listed below.

Substance	Concentration tested	% Phencyclidine recovery
Acetone	1 %	98
Ascorbic acid	1.5 %	105
Bilirubin	0.25 mg/mL	98
Creatinine	5 mg/mL	113
Ethanol	1 %	100
Glucose	2 %	105
Hemoglobin	7.5 g/L	94
Human albumin	0.5 %	102
Oxalic acid	2 mg/mL	98
Sodium chloride	0.5 M	100
Sodium chloride	1 M	102
Urea	6 %	106

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[15]

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Expected values

Qualitative assay

Results of this assay distinguish preliminary positive (≥ 25 ng/mL) from negative samples only. The amount of drug detected in a preliminary positive sample cannot be estimated.

Semiquantitative assay

Results of this assay yield only approximate cumulative concentrations of the drug and its metabolites (see "Analytical specificity" section).

Specific performance data

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Semiquantitative precision

Repeatability	*Mean* ng/mL	*SD* ng/mL	*CV* %
Urine -50 %	11.0	0.432	3.9
DAT1N	19.8	0.498	2.5
DATCN	19.5	0.423	2.2
Cutoff urine	25.5	0.565	2.2
DAT1P	32.2	0.508	1.6
DATCP	31.7	0.653	2.1
Urine +50 %	38.2	0.524	1.4

Intermediate precision	*Mean* ng/mL	*SD* ng/mL	*CV* %
Urine -50 %	11.0	0.750	6.8
DAT1N	19.8	0.698	3.5
DATCN	19.5	0.760	3.9
Cutoff urine	25.5	0.920	3.6
DAT1P	32.2	0.702	2.2
DATCP	31.7	0.933	2.9
Urine +50 %	38.2	0.850	2.2

Qualitative precision

	Number tested	Correct results	Confidence level
Urine -50 %	84	84	> 95 % negative reading
DAT1N	84	84	> 95 % negative reading
Cutoff urine	84	n.a.*	n.a.*
DAT1P	84	84	> 95 % positive reading
Urine +50 %	84	84	> 95 % positive reading

*n.a. = not applicable

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

PCP

ONLINE DAT Phencyclidine Plus

Accuracy

100 urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Phencyclidine Plus assay. 100 % of these normal urines were negative relative to a 25 ng/mL cutoff. 65 samples obtained from a clinical laboratory, where they screened preliminary positive with a commercially available immunoassay and were subsequently confirmed by GC-MS, were evaluated with the Phencyclidine Plus assay. 99 % of these samples were positive relative to a 25 ng/mL cutoff. In addition, 9 samples with GC-MS values approximately 50-100 % of the cutoff were evaluated with the Phencyclidine Plus assay. Data from the accuracy studies described above were combined with data generated from these samples. The following results were obtained with the Phencyclidine Plus assay on the Roche/Hitachi 917 analyzer relative to the GC-MS values.

Phencyclidine Plus clinical correlation (cutoff = 25 ng/mL)

		Negative samples	GC-MS values (ng/mL)		
			Near cutoff		Positive samples
			12-23	25-32	34- > 1000
Roche/Hitachi 917 analyzer	+	0	4	10	54
	-	100	5	1	0

111 urine samples screened negative for phencyclidine on a **cobas c** 501 analyzer were evaluated with the Phencyclidine Plus assay on a **cobas c** 503 analyzer. 100 % of these normal urines were negative relative to a 25 ng/mL cutoff with the Phencyclidine Plus assay on a **cobas c** 503 analyzer. 58 urine samples screened positive for phencyclidine relative to the corresponding cutoff on a **cobas c** 501 analyzer and subsequently confirmed by GC-MS, were evaluated with the Phencyclidine Plus assay on a **cobas c** 503 analyzer. At the 25 ng/mL cutoff, 100 % of the samples were positive on both the **cobas c** 501 analyzer and the **cobas c** 503 analyzer.

Phencyclidine Plus correlation (cutoff = 25 ng/mL)

		cobas c 501 analyzer	
		+	-
cobas c 503 analyzer	+	58	0
	-	0	111

110 urine samples screened negative for phencyclidine on a **cobas c** 501 analyzer were evaluated with the Phencyclidine Plus assay on a **cobas c** 303 analyzer. 100 % of these normal urines were negative relative to a 25 ng/mL cutoff with the Phencyclidine Plus assay on a **cobas c** 303 analyzer. 51 urine samples screened positive for phencyclidine relative to the corresponding cutoff on a **cobas c** 501 analyzer and subsequently confirmed by GC-MS, were evaluated with the Phencyclidine Plus assay on a **cobas c** 303 analyzer. At the 25 ng/mL cutoff, 100 % of the samples were positive on both the **cobas c** 501 analyzer and the **cobas c** 303 analyzer.

Phencyclidine Plus correlation (cutoff = 25 ng/mL)

		cobas c 501 analyzer	
		+	-
cobas c 303 analyzer	+	51	0
	-	0	110

110 urine samples screened negative for phencyclidine on a **cobas c** 503 analyzer were evaluated with the Phencyclidine Plus assay on a **cobas c** 703 analyzer. 100 % of these normal urines were negative relative to a 25 ng/mL cutoff with the Phencyclidine Plus assay on a **cobas c** 703 analyzer. 61 urine samples screened positive for phencyclidine relative to the corresponding cutoff on a **cobas c** 503 analyzer and subsequently confirmed by GC-MS, were evaluated with the Phencyclidine Plus assay on a **cobas c** 703 analyzer. At the 25 ng/mL cutoff, 100 % of the samples were positive on both the **cobas c** 503 analyzer and the **cobas c** 703 analyzer.

Phencyclidine Plus correlation (cutoff = 25 ng/mL)

		cobas c 503 analyzer	
		+	-
cobas c 703 analyzer	+	61	0
	-	0	110

Analytical specificity

The specificity of this assay for structurally similar compounds was determined by generating inhibition curves for each of the compounds listed and determining the approximate quantity of each compound that is equivalent in assay reactivity to a 25 ng/mL phencyclidine assay cutoff. The following results were obtained on a Roche/Hitachi 917 analyzer.

Compound	**ng/mL Equivalent to 25 ng/mL phencyclidine**	**Approximate % cross-reactivity**
Thienylcyclo-hexylpiperidine (TCP)	49	51.14
Dextromethorphan	> 100000	0.01
Ketamine	> 100000	0.00

Drug interference

The following compounds were prepared in aliquots of pooled normal human urine to yield a final concentration of 100000 ng/mL. None of these compounds gave values in the assay that were greater than 0.018 % cross-reactivity.

Acetaminophen
Acetylsalicylic acid
Aminopyrine
Amobarbital
d-Amphetamine
l-Amphetamine
Ampicillin
Ascorbic acid
Aspartame
Atropine
Benzocaine
Benzoylecgonine
(cocaine metabolite)
Benzphetamine
Butabarbital
Caffeine
Calcium hypochlorite
Chlordiazepoxide
Chloroquine
Chlorpheniramine
Chlorpromazine
Cocaine
Codeine
Dextropropoxyphene
Diazepam
Diphenhydramine
Dopamine
Doxepin
Ecgonine
Ecgonine methyl ester
d-Ephedrine
Lidocaine
LSD
MDA
MDMA
Melanin
Meperidine
Methadone
d-Methamphetamine
l-Methamphetamine
Methaqualone
Methylphenidate
Methyprylon
Morphine
Naloxone
Naltrexone
Naproxen
Niacinamide
Norethindrone
l-Norpseudoephedrine
Nortriptyline
Oxazepam
Penicillin G
Pentobarbital
β-Phenethylamine
Phenobarbital
Phenothiazine
Phentermine
Phenylbutazone
d-Phenylpropanolamine
d,l-Phenylpropanolamine
Procaine

d,l-Ephedrine	Promethazine
l-Ephedrine	*d*-Pseudoephedrine
Epinephrine	*l*-Pseudoephedrine
Erythromycin	Quinidine
Estriol	Quinine
Fenoprofen	Secobarbital
Furosemide	Sulindac
Gentisic acid	Tetracycline
Glutethimide	Δ^9 THC-9-carboxylic acid
Guaiacol glycerol ether	Tetrahydrozoline
Hydrochlorothiazide	Trifluoperazine
p-Hydroxyamphetamine	Trimipramine
Ibuprofen	Tyramine
Isoproterenol	Verapamil
Lamotrigin	

The cross-reactivity for amitriptyline, desipramine, and imipramine was tested at a concentration of 100000 ng/mL with the Phencyclidine Plus assay. The results obtained were 0.031 %, 0.022 %, and 0.037 %, respectively.

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

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