

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k043305

B. Purpose for Submission:

New Device

C. Measurand:

Phencyclidine

D. Type of Test:

Qualitative and Semi-quantitative

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

ONLINE DAT Phencyclidine Plus

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3100 - Amphetamine test system.

2. Classification:

Class II

3. Product code:

LCM - Enzyme Immunoassay, Phencyclidine

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

The Phencyclidine Plus is an in vitro diagnostic test for the qualitative and semi-quantitative detection of phencyclidine and its metabolites in human urine on automated clinical chemistry analyzers at a cutoff of 25 ng/ml. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

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. Gas chromatography/mass spectrometry (GS/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.

2. Indication(s) for use:

The Phencyclidine Plus is an in vitro diagnostic test for the qualitative and semi-quantitative detection of phencyclidine and its metabolites in human urine on automated clinical chemistry analyzers at a cutoff of 25 ng/ml. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

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. Gas chromatography/mass spectrometry (GS/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.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Roche Hitachi 911/912/917 analyzers and the MODULAR P and DAT analyzers (Qualitative assay)

Roche Hitachi 911/912/917/ analyzers and the MODULAR P and DAT analyzers (for Semiquantitative assay)

This assay is not for use on the MODULAR D modules.

I. Device Description:

The ONLINE DAT Phencyclidine Plus assay consists of 2 bottles (antibody and diluent) that are combined to make reagent 1. Reagent 2 consists of one bottle. Reagent one is the antibody working solution that contains phencyclidine antibody (mouse monoclonal) in buffer with bovine serum albumin and sodium azide. Reagent

2 is the microparticle working solution that contains conjugated phencyclidine derivative microparticles in buffer and sodium azide. Four different volumes of reagent 1 and 2 are supplied. Barcode labels are provided for the Hitachi 912, 917, Modular P and Modular DAT and are not available for the Hitachi 911.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Abuscreen OnLine Phencyclidine

2. Predicate 510(k) number(s):

k983704

3. Comparison with predicate:

Both the current device and the predicate device are similar in that the same analyte is measured (phencyclidine), in the same matrix (urine), available for use on the same instruments, methodology, reagents and cutoff (25 ng/mL) and limit of detection (2 ng/mL). There are no detectable differences.

K. Standard/Guidance Document Referenced (if applicable):

None Referenced

L. Test Principle:

ONLINE DAT Phencyclidine Plus automated assays are based on the kinetic interaction of microparticles in a solution (KIMS) 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The imprecision of the ONLINE DAT Phencyclidine Plus Assay was determined by running a series of calibrators and controls in replicates of 20 per day for five days on a Hitachi 917 analyzer. The acceptance criteria for within-run imprecision was <8% CV. The acceptance criteria for run-to-run imprecision was <10%. The following results were obtained for the 25 ng/mL cutoff.

Within-run Imprecision (N=20)

Calibrators/Controls (ng/mL)	Semi-Quantitative		Qualitative	
	Mean (ng/mL)	CV %	Mean (mAbs)	CV %
.50X (12.5)	11.9	4.9	508.4	2.4
.75X (18.8)	19.4	2.5	409.3	2.2
Cutoff (25)	25.3	2.1	330.3	2.0
1.25X (31.3)	32.8	2.0	274.2	1.7
1.5X (37.5)	39.4	1.5	219.9	2.0

Day-to-day Imprecision (N=100)

Calibrators/Controls (ng/mL)	Semi-Quantitative		Qualitative	
	Mean (ng/mL)	CV %	Mean (mAbs)	CV %
.50X (12.5)	12.9	6.1	512.8	2.6
.75X (18.8)	19.2	4.2	411.1	2.6
Cutoff (25)	25.8	3.1	332.9	2.0
1.25X (31.3)	32.4	2.7	271.8	2.0
1.5X (37.5)	40.0	2.0	218.8	2.1

Near Cut-off Imprecision

Controls (ng/mL)	Number Tested	Correct Results	Confidence Level
.75X (18.8)	100	100	>95% Negative reading
1.25X (31.3)	100	100	>95% Positive reading

b. *Linearity/assay reportable range:*

Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

This method has been standardized against GC/MS.

d. *Detection limit:*

The limit of detection of the ONLINE DAT Phencyclidine Plus is 2 ng/mL. This value represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above the mean (n=21) of the lowest standard.

e. *Analytical specificity:*

The specificity of ONLINE DAT Phencyclidine Plus for some structurally similar compounds was determined by a linear regression. The spiked cross-reactant responses closely above and below the response by the phencyclidine 25 ng/mL cutoff was estimated. The percent cross-reactivity was calculated by dividing the phencyclidine 25 ng/mL cutoff concentration by the cross-reactant concentration, multiplied by 100.

COMPOUND	Concentrations Tested (ng/mL)	Roche/Hitachi 917 (ng/mL)	Approx. Cross Reactivity	ng/mL Equivalent to 25 ng/mL Phencyclidine
Dextromethorphan	100000	13.6	0.01%	>100,000 ng/mL
Thienylcyclohexylpiperadine (TCP)	30	14.8	51.14%	49
	60	31.0	51.14%	49
Ketamine	100000	4.8	0.00%	>100,000 ng/mL

Cross-reactivity with unrelated drugs was also evaluated. Ninety-two (92) compounds were prepared in aliquots of pooled normal urine to yield a final concentration of 100,000 ng/mL. Excluding amitriptyline, desipramine and imipramine, values for the assay were not greater than 0.018%. Amitriptyline, desipramine and imipramine produced results that were either close to or above the cutoff were 0.031%, 0.022% and 0.37% respectively. This is written in the package insert and all 3 compounds were removed from the common list and labeled separately.

f. Assay cut-off:

See Detection Limit Section Above

2. Comparison studies:

a. *Method comparison with predicate device:*

Accuracy of the ONLINE DAT Phencyclidine Plus assay at a 25 ng/mL cutoff was evaluated in method comparison studies between the Phencyclidine Plus assay and GC/MS results.

One-Hundred (100) urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with ONLINE DAT Phencyclidine Plus. Ten of these samples were also confirmed negative by GC/MS. Of the 100 samples evaluated, 100 were negative relative to the 25 ng/mL cutoff.

Sixty-Five (65) urine samples were obtained from a clinical laboratory where they were screen positive for phencyclidine by a commercially available immunoassay and subsequently confirmed positive by GC/MS for Phencyclidine. These samples were evaluated with the ONLINE DAT Phencyclidine Plus. Semiquantitatively, 64 of the 65 were positive relative to the 25 ng/mL cutoff. Qualitatively, 63 of the 65 were positive relative to the 25 ng/mL cutoff.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Twenty non-diluted samples of the study samples are evenly distributed between 75% and 125% of the cutoff. Data from the accuracy studies described above that fell within the near cutoff value ranges were combined with data generated from the positive urine samples. The following results were obtained with the ONLINE DAT Phencyclidine Plus assay on the Roche/Hitachi 917 relative to the GC/MS values.

ONLINE DAT Phencyclidine Plus Cutoff =25 ng/mL		Negative Samples	GC/MS Values (ng/mL)		
			Near Cutoff Values		34->1000 ng/mL
			12-23 ng/mL	25-32 ng/mL	
Roche/ Hitachi 917	+	0	4	10	54
	-	100	5	1	0

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Qualitative Assay

Results of this assay distinguish positive (greater than or equal to 25 ng/mL) from negative samples only. The amount of drug detected in a positive sample cannot be estimated.

Semiquantitative Assay

Results of this assay yield only approximate cumulative concentrations of the drug and its metabolites.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.