



INTERCEPT[®] *i2he*™ PHENCYCLIDINE (PCP) ORAL FLUID ASSAY APPLICATION

SIEMENS ADVIA® 1800, 2400

Catalog No. 1001-0389

The Intercept *i2he* Phencyclidine (PCP) Oral Fluid Assay is intended for use in the qualitative determination of PCP in human oral fluid at a cutoff concentration of 3.0 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Intercept *i2he* Oral Fluid Collection Device. The assay is calibrated against PCP and performed on clinical chemistry analyzers. This device is not intended for use for clinical diagnostic applications.

For Forensic Use Only.

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen storage, quality control, and additional performance data.

Ordering Information

Item	Size	Catalog Number
Intercept i2he Phencyclidine Oral Fluid Assay	65 mL	1001-0389
Intercept i2he Multi-Drug Oral Fluid Negative Calibrator	20 mL	1001-0396
Intercept i2he Multi-Drug Oral Fluid Cutoff Calibrator	10 mL	1001-0395
Intercept i2he Multi-Drug Oral Fluid Control Set A	15 mL x 2	1001-0394

To place an order or for technical service contact:

OraSure Technologies, Inc. 220 East First Street Bethlehem, PA 18015 U.S. Toll free: (800) 673-7873 Outside the U.S.: (001) 610-882-1820

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Reagent Preparation and Storage	Refer to package insert for information on reagent preparation and storage.
Procedure for Analyzer	Refer to operator's manuals for information on analyzer operation. Dispense adequate amounts of R1 and R2 into appropriate containers. Make sure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.
Results and Data Interpretation	Refer to the package insert for information on results and data interpretation. Continued on the next page

Intercept *i2he* Phencyclidine (PCP) Oral Fluid Assay – Qualitative Siemens ADVIA 1800, 2400 System Parameters

Assay Name: i2he PCP

Analytical conditions	
R1 volume□	38.00
R2 volume □	38.00
R1 diluent vol	0.000
R2 diluent vol	0.000
Serum reac.s.vol	25
Serum dil.method	Special
Serum dil.s.vol	30
Serum dil.volume	30
Serum dil. posit	0
Urine reac.s.vol	25
Urine dil.method	Special
Urine dil.s.vol	30
Urine dil. volume	30
Urine dil. posit	0
Reaction time	10 min
Reagent 1 stir	Weak
Reagent 2 stir	Weak

Analy.Cond.no.	User-defined		
Sub-analy. conditions			
Name	i2he PCP		
M-wave.L.	571 nm		
S-wave.L	658 nm		
Analy. mthd	RRA		
Calc. mthd	STD		
Qualit.judg	User-defined		
Digits	User-defined		

Reanalysis conditions	
Serum reac.smp.vol (u)	0
Serum dil. method (u)	None
Serum dil. smp.vol (u)	0
Serum diluent vol. (u)	0
Serum diluent posi (u)	0
Serum reac.smp.vol (d)	0
Serum dil.method (d)	None
Serum dil. smp.vol (d)	0
Serum diluent vol. (d)	0
Serum diluent posi (d)	0

Reanalysis conditions (urine)			
Urine reac.smp.vol (u)	0		
Urine dil.method (u)	None		
Urine dil. smp.vol (u)	0		
Urine diluent vol. (u)	0		
Urine diluent posi (u)	0		
Urine reac.smp.vol (d)	0		
Urine dil.method (d)	None		
Urine dil. smp.vol (d)	0		
Urine diluent vol. (d)	0		
Urine diluent posi (d)	0		

Standard settings				
BLK H	9.99999	Abn. Ser H	999999	
BLK L	-9.99999	Abn. Ser L	-99999	
STD H	9.99999	Abn. Uri H	999999	
STD L	-9.99999	Abn. Uri L	-99999	
FV	100 or cal cutoff value			

Calculation Method setting			
M-DET.P.I	0	Reac. type	Inc
M-DET.P.m	†	*Reaction rate method	
M-DET.P.n	††	Cycle	2
Check D.P.I	0	Factor	2.2
S-DET.P.p.	0	E2 corre	Not do
S-DET.P.r.	0	Blank (u)	9.9999
Limit value	0.003	Blank (d)	-9.999
Variance	10	Sample (u)	9.9999
		Sample (d)	-9.999
Proz. form	none		
Proz. limit	9.999	*Endpoint method	
Proz. judge	Up limit	Re-abs. (u)	9.999
Judge limit	9.999	Re-abs. (d)	-9.99
M-DET.P.m	0	S-DET.P.p	0
M-DET.P.n	0	S-DET.P.r	0

R1 is EA Reagent and R2 is ED Reagent.

Use Intercept i2he Multi-Drug Oral Fluid Negative Calibrator for Blank, along with the Intercept i2he Cutoff Calibrator.

		<u>1800</u>	<u>2400</u>
†	S-DET.P.m.	86	36
++	S-DET.P.n.	96	40

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