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

A. 510(k) Number:

k181135

B. Purpose for Submission:

New device

C. Measurand:

Phencyclidine (PCP)

D. Type of Test:

Qualitative, lateral flow immunochromatographic

E. Applicant:

Immunalysis Corporation

F. Proprietary and Established Names:

Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCM, Enzyme immunoassay, Phencyclidine	Class II	Unclassified	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use.

2. Indication(s) for use:

   The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 10 ng/mL in neat oral fluid collected with the

Quantisal II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of PCP in human oral fluid with clinical analyzers. This assay is calibrated against PCP. This in vitro diagnostic device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay 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 (GC-MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

3. Special conditions for use statement(s):

   For prescription use only.
   For use with the Quantisal II Oral Fluid Collection Device only.

4. Special instrument requirements:

   Beckman Coulter AU480 Clinical Chemistry Analyzer

I. Device Description:

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay consists of the following:

- The Enzyme Acceptor/Antibody Reagent (EA) is provided as a liquid, ready to use, and contains EA protein and recombinant antibodies to PCP, in PIPES buffer with Sodium Azide as a preservative.
- The Enzyme Donor/Substrate Reagent (ED) is provided as a liquid, ready to use, and contains ED peptide labeled with PCP and CPRG substrate in malic acid buffer with Sodium Azide as a preservative.
- The Quantisal II Oral Fluid Collection Device consists of two cellulose pads affixed to a polypropylene stem (for collecting saliva samples), and two transport tubes with snap caps, each containing three mL of preservative buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Biophor Diagnostics, Inc., RapidFRET Oral Fluid Assay for PCP

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

   k122703

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate (k122703)
Intended Use	Same	Detection of PCP in oral fluid
Cutoff concentration	Same	10 ng/mL
Intended user	Same	Prescription use only
Matrix	Same	Human oral fluid
Reagent composition	Same	PCP specific antibody reagent, PCP drug conjugate reagent
Reagent storage	Same	2 – 8° C until expiration date

Differences		
Item	Candidate Device	Predicate (k122703)
Collection device	Oral fluid is collected with the Quantisal II Oral Fluid Collection Device. Sample is stored in a plastic tube containing preservative buffer with snap cap. One mL of oral fluid is diluted with three mL of preservative resulting in a x4 dilution.	Neat oral fluid is collected with the RapidEASE Oral Fluid Collector via direct expectoration. No diluent is used and sample is stored in a glass sample tube with inert screw cap.

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

- CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition
- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
- EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

L. Test Principle:

The SEFRIA technology is based on artificial fragments of the E. coli enzyme β galactosidase: Enzyme Acceptor (EA), created by deletion of a short sequence in the amino-terminal region of the enzyme, and Enzyme Donor (ED), containing a fragment of the carboxy-terminal sequence of the enzyme. EA and ED are inactive, but when combined form active β-galactosidase. For the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay, ED peptides are modified by attachment of a derivative of PCP, which does not interfere with the formation of active β-galactosidase. However antibodies to PCP bind to the ED-PCP conjugate, and block complementation. The assay is based on the competition of free PCP in an oral fluid sample with the ED-PCP conjugate for the fixed amount of antibody binding sites. In the absence of the free drug in the sample, the antibody binds the ED-PCP conjugate, resulting in inhibition of enzyme formation. As the PCP concentration in the sample increases, ED-PCP becomes available for complementation, creating an inverse relationship between PCP concentration in the oral fluid and enzyme formation. The β-galactosidase activity is determined spectrophotometrically at 570 nm by the conversion of CPRG (orange) to chlorophenol red (red) and galactose.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A study was performed using three lots of the Quantisal II collection device, over 15 days, with two runs per day with two collection devices per run (N=60 per collection device lot) to evaluate precison of the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay. Oral fluid was collected using Quantisal II (including pad/tube "A" and pad/tube "B") by dipping each collection pad into the spiked PCP pooled neat human oral fluid near the cutoff concentration, until the volume adequacy indicator activated and turned blue. The pads were then placed into the corresponding transport tubes containing three mL of preservative buffer, incubated overnight at room temperature to simulate the transportation time via common carrier to the laboratory and tested. Results from one representative lot in qualitative and semi-quantitative mode are summarized below.

Qualitative mode using Quantisal II A collector

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	60	60 Negative
2.5	-75%	60	60 Negative
5	-50%	60	60 Negative
7.5	-25%	60	60 Negative
10	Cutoff	60	29 Neg / 31 Pos
12.5	25%	60	60 Positive

Concentration (ng/mL)	% of cutoff	# of determinations	Result
15	50%	60	60 Positive
17.5	75%	60	60 Positive
20	100%	60	60 Positive

Semiquantitative mode using Quantisal II A collector

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	60	60 Negative
2.5	-75%	60	60 Negative
5	-50%	60	60 Negative
7.5	-25%	60	60 Negative
10	Cutoff	60	28 Neg / 32 Pos
12.5	25%	60	60 Positive
15	50%	60	60 Positive
17.5	75%	60	60 Positive
20	100%	60	60 Positive

Qualitative mode using Quantisal II B collector

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	60	60 Negative
2.5	-75%	60	60 Negative
5	-50%	60	60 Negative
7.5	-25%	60	60 Negative
10	Cutoff	60	32 Neg / 28 Pos
12.5	25%	60	60 Positive
15	50%	60	60 Positive
17.5	75%	60	60 Positive
20	100%	60	60 Positive

Semiquantitative mode using Quantisal II B collector

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	60	60 Negative
2.5	-75%	60	60 Negative
5	-50%	60	60 Negative
7.5	-25%	60	60 Negative

Concentration (ng/mL)	% of cutoff	# of determinations	Result
10	Cutoff	60	29 Neg / 31 Pos
12.5	25%	60	60 Positive
15	50%	60	60 Positive
17.5	75%	60	60 Positive
20	100%	60	60 Positive

A second precision study was performed over 20 days and produced similar results.

Sample Volume:

The sponsor performed a study to validate the sample volume, and reproducibility of sample volume, collected using the Quantisal II Oral Fluid Collection Device. Oral fluid samples were collected using the Quantisal II Oral Fluid Collection Device from 125 individuals (50 non-drug abusers and 75 drug abusers). Prior to collection, each collector pad (A and B) was independently weighed. After the volume adequacy indicator turned blue on both A and B collector stems, each collector was weighed again. The difference in weight was noted, and the corresponding volume was calculated. The volumes collected from collector A ranged from 0.86 – 1.10 mL, and the volumes collected from collector B ranged from 0.90 – 1.09 mL.

Collection Time:

The sponsor performed a study designed to validate the sample collection time for the Quantisal II Oral Fluid Collection Device. 125 oral fluid samples were collected using Quantisal II Oral Fluid Collection Device (from 50 non-drug abusers and 75 known drug abusers). For each collection, a timer was started at the time the collector was placed into subject's mouth, and was stopped when the volume adequacy indicator turned blue on both A and B collector stems and the collector was taken out of the mouth. The sponsor reported that 124/125 subjects were able to provide sufficient sample (i.e. the collection device's volume adequacy indicator showed adequate collection) within the recommended collection timeframe of ten minutes. The mean time required for collection was three minutes and 42 seconds. The maximum time required for collection was reported as 11 minutes and 0 seconds.

The device labeling states that if the indicator has not turned blue within 15 minutes, the pad should be removed from the mouth and discarded, and that another collection should be attempted with a new collector.

b. Linearity/assay reportable range:

The sponsor performed a study to evaluate the recovery of PCP, using the semi-quantitative mode of the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay, across the claimed concentration range. Pooled drug-free oral fluid

was spiked with a high concentration of the drug analyte PCP (at 10% above the highest calibrator level) and was used as the high value specimen (44 ng/mL). Additional pools were made by serially diluting the high value specimen in human drug-free oral fluid in increments of approximately 10%. The 0 ng/mL sample was drug free oral fluid. Quantisal II oral fluid collection devices were dipped into aliquots from each pool until the adequacy indicator turned blue and were then placed into the associated transport tubes containing the preservative buffer per the package insert instructions. Each tube was analyzed in triplicate for drug recovery in semi-quantitative mode. The recovery at the claimed cutoff concentration of 10 ng/mL was 102.3% and the range of recoveries at concentrations from four to 44 ng/mL was 97.5 – 111.4 %.

Sample Recovery

The sponsor also performed a study to evaluate the recovery of PCP from the Quantisal II Oral Fluid Collection Device independent of the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay. Neat drug-free oral fluid was spiked with PCP at target concentrations of ±25% and +50% of the cutoff (7.5 ng/mL, 12.5 ng/mL and 15 ng/mL), and concentrations were verified by LC-MS/MS. Three Quantisal II collectors were introduced sequentially into each aliquot and removed after the volume adequacy indicator turned blue. The collectors were then placed into the transport tubes, sealed with snap caps and stored overnight at room temperature. The next day the liquids in the tubes were analyzed by LC-MS/MS in replicates of three for a total of nine replicates per concentration. Recoveries of PCP ranged from 86.2% – 105.7%.

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

Sample Storage Stability:
The sponsor performed a study to evaluate the stability of PCP in oral fluid samples at the recommended storage temperatures of 2 – 8° C and at room temperature (30° C was used). Drug-free oral fluid was spiked with PCP to a concentration approximately 50% above the cutoff. An aliquot was tested for its initial concentration by LC-MS/MS and another aliquot was processed through three independent Quantisal II Oral Fluid Collection Devices and stored at the above storage temperatures. Samples were analyzed for PCP at day five and day ten (for the 30° C storage condition), and at one, two, three and six months (for the 2 – 8° C storage condition). Recoveries at all test conditions and time points ranged from 91.0 – 105.7%

The results of the study support the sponsor's stability claims in labeling that PCP in oral fluid is stable for up to 10 days when stored in Quantisal II at ambient temperature up to 30°C and for up to two months when stored in Quantisal II at 2°C - 8°C.

Sample Transportation Stability

The sponsor performed a study to evaluate the stability of PCP in oral fluid samples after being transported under shipping conditions anticipated in the United States.

Drug free oral fluid was spiked with the drug analyte PCP at concentrations approximately ±50% of the cutoff (five ng/mL and 15 ng/mL). Three Quantisal II Oral Fluid Collection Devices were introduced sequentially into each aliquot and removed after the volume adequacy indicator turned blue. The collector was then placed into the transport tube, sealed with a snap cap and packed in standard boxes used by common freight carriers. During the simulated transportation study, the samples were stored in an oven and a freezer and cycled between temperatures ranging from -20°C to 40°C. Samples were also agitated during the shipping transportation study to simulate conditions of actual shipping. These temperatures were selected to include the extremes of temperature likely to occur during shipment of products. All conditions were evaluated for a minimum of 24 hours and a maximum of 63 hours. After the simulated shipping, LC-MS/MS testing was performed in replicates of two for each sample and compared to the reference sample. All samples at all shipping conditions recovered within ± 10% from the reference sample.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Cross-reactivity:

A study was performed to evaluate the cross-reactivity of the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay to compounds that are structurally similar to PCP. Structurally related compounds were spiked into drug-free oral fluid at high concentrations, and then if a given compound produced a positive result on the device, it was retested to identify the lowest concentration that yielded a result that is equivalent to the 10 ng/mL cutoff of PCP in neat oral fluid. Each compound sample was tested in replicates of five in qualitative and semi-quantitative modes; no differences in results were seen between the semi-quantitative and qualitative modes. Cross-reactivity was calculated as the cutoff divided by the lowest concentration of potential cross-reactant tested, and the results are summarized below.

Compound	**Concentration Equivalent to the cutoff (ng/mL)**	**Cross-Reactivity (%)**
Amitriptyline	22,000	0.05
Chlorpromazine	5,200	0.19

Compound	Concentration Equivalent to the cutoff (ng/mL)	Cross-Reactivity (%)
Clomipramine	22,000	0.05
Cyclobenzaprine	1,900	0.53
Desipramine	40,000	<0.03
Dextromethorphan	40,000	<0.03
Diphenhydramine	37,000	0.03
Doxepin	5,600	0.18
Doxylamine	40,000	<0.03
EDDP	40,000	<0.03
4-Hydroxyphencyclidine (PCHP)	85	11.76
Imipramine	13,400	0.07
Methoxetamine	34,000	0.03
Nortriptyline	40,000	<0.03
Protriptyline	40,000	<0.03
Thioridazine	8,600	0.12
Trimipramine	40,000	<0.03
Venlafaxine	40,000	<0.03

Interference from exogenous substances and pH:

Structurally unrelated compounds, endogenous compounds, exogenous compounds and effect of pH were evaluated for potential interference with the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay.

Test solutions for each compound were prepared by spiking the potential interfering compound into drug-free negative oral fluid containing a PCP concentration of 7.5 ng/mL and 12.5 ng/mL (±25% of the 10 ng/mL cutoff) and were one to four diluted using Quantisal preservative buffer. Each compound was an independent spike and no drug mixes were used. Each compound sample was tested in replicates of five in qualitative and semi-quantitative modes. None of the structurally unrelated compounds listed below caused positive or negative interference with the assay at the concentrations listed, and no differences were seen between the semi-quantitative and qualitative modes, at the concentrations tested below.

Compound	Concentration Tested (ng/mL)
4-Bromo-2,5,Dimethoxyphenethylamine	5,000
6-Acetylcodeine	40,000
6-Acetylmorphine	40,000
Alprazolam	40,000
7-Aminoclonazepam	40,000
7-Aminoflunitrazepam	40,000
7-Aminonitrazepam	40,000
S-(+) Amphetamine	40,000
Benzylpiperazine	40,000
Bromazepam	40,000
Buprenorphine	40,000
Bupropion	40,000
Butabarbital	40,000
Butalbital	40,000
Caffeine	40,000
Cannabidiol	40,000
Cannabinol	40,000
Carbamazepine	40,000
Carisoprodol	40,000
Chlordiazepoxide	40,000
cis-Tramadol	40,000
Clobazam	40,000
Clonazepam	40,000
Clozapine	40,000
Cocaine	40,000
Codeine	40,000
Cotinine	40,000
Demoxepam	40,000
Desalkylflurazepam	40,000
Dihydrocodeine	40,000
Diazepam	40,000
Digoxin	40,000
Dehydronorketamine	40,000
Delta-9-THC	40,000
Ecgonine	40,000
Ecgonine Methyl Ester	40,000

Compound	Concentration Tested (ng/mL)
EMDP	40,000
1R,2S(-)-Ephedrine	40,000
1S,2R(+)-Ephedrine	40,000
Ethyl-β-D-Glucuronide	40,000
Ethylmorphine	40,000
Fenfluramine	40,000
Fentanyl	20,000
Flunitrazepam	40,000
Fluoxetine	40,000
Flurazepam	40,000
Haloperidol	40,000
Heroin	40,000
Hexobarbital	40,000
Hydrocodone	40,000
Hydromorphone	40,000
11-hydroxy-delta-9-THC	40,000
Ibuprofen	40,000
Ketamine	40,000
Lamotrigine	40,000
Levorphanol	40,000
Lidocaine	40,000
Lorazepam	40,000
Lorazepam Glucuronide	40,000
Lormetazepam	40,000
LSD	40,000
Maprotiline	40,000
MDA	40,000
MDEA	40,000
MDMA	40,000
Meperidine	40,000
Meprobamate	40,000
S(+)-Methamphetamine	40,000
Methadone	40,000
Methaqualone	40,000
Methylone	40,000
Methylphenidate	40,000
Midazolam	40,000
Morphine	40,000
Morphine-3-Glucuronide	40,000
Morphine-6-Glucuronide	40,000

Compound	Concentration Tested (ng/mL)
N-desmethyltapentadol	40,000
N-desmethyl tramadol	40,000
N-desmethyl venlafaxine	40,000
Nalorphine	40,000
Naloxone	40,000
Naltrexone	40,000
Naproxen	40,000
Nitrazepam	40,000
11-nor-9 carboxy THC	40,000
Norbuprenorphine	40,000
Norcodeine	40,000
Nordiazepam	40,000
Norketamine	40,000
Normorphine	40,000
Noroxycodone	40,000
Noroxymorphone	40,000
Norpropoxyphene	20,000
Norpseudoephedrine	2,000
O-desmethyl tramadol	40,000
O-desmethyl venlafaxine	40,000
Oxycodone	40,000
Oxymorphone	40,000
Olanzapine	40,000
Oxazepam	40,000
Pentazocine	40,000
Pentobarbital	40,000
Phenobarbital	40,000
Phentermine	40,000
Phenylephrine	40,000
Phenytoin	40,000
Phenylpropanolamine	40,000
PMA	40,000
Prazepam	40,000
Propranolol	40,000
Propoxyphene	40,000
R,R(-)-Pseudoephedrine	40,000
S,S(+)-Pseudoephedrine	40,000
Ritalinic Acid	40,000
Salicylic Acid	40,000
Secobarbital	40,000
Sertraline	40,000

Compound	Concentration Tested (ng/mL)
Sufentanil	40,000
Tapentadol	40,000
Temazepam	40,000
Theophylline	40,000
Trazadone	40,000
Triazolam	40,000
Trifluoromethylphenyl-piperazine	40,000
Verapamil	40,000
Zolpidem Tartrate	40,000

Food and dental products:

Additional potential exogenous interferents, including common food and dental products, were evaluated by collecting oral fluid in Quantisal II oral fluid collectors from volunteers after use of the substances. Oral fluid of one volunteer was collected for each compound tested, spiked with PCP at the concentrations noted below, and tested with the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay. No negative or positive interference was observed in either the qualitative or semi-quantitative mode. Results are summarized as follows:

Compound	Compound Conc.	-25% Cutoff (7.5 ng/mL)		+25% Cutoff (12.5 ng/mL)	
		Result	Interference (Yes/No)?	Result	Interference (Yes/No)?
Acetaminophen	0.1 mg/mL	NEG	No	POS	No
Acetylsalicylic Acid	0.1 mg/mL	NEG	No	POS	No
Baking Soda	0.6% v/v	NEG	No	POS	No
Cotinine	0.03 mg/mL	NEG	No	POS	No
Denture Adhesive	0.6% w/v	NEG	No	POS	No
Ibuprofen	0.1 mg/mL	NEG	No	POS	No
Alcohol (Ethanol)	6% v/v	NEG	No	POS	No
Caffeine	0.1 mg/mL	NEG	No	POS	No
Coffee	6% v/v	NEG	No	POS	No
Cranberry Juice	6% v/v	NEG	No	POS	No
Hydrogen Peroxide (3% OTC)	0.5% v/v	NEG	No	POS	No
Milk	1% v/v	NEG	No	POS	No
Mouthwash	6% v/v	NEG	No	POS	No
Naproxen	0.1 mg/mL	NEG	No	POS	No

Compound	Compound Conc.	-25% Cutoff (7.5 ng/mL)		+25% Cutoff (12.5 ng/mL)	
		Result	Interference (Yes/No)?	Result	Interference (Yes/No)?
Orange Juice	6% v/v	NEG	No	POS	No
Soft Drink (Pepsi)	6% v/v	NEG	No	POS	No
Sodium Chloride	18 mg/mL	NEG	No	POS	No
Sugar	20 mg/mL	NEG	No	POS	No
Tea	6% v/v	NEG	No	POS	No
Toothpaste	6% v/v	NEG	No	POS	No
Teeth Whitener	2 strips	NEG	No	POS	No
Hydrogen Peroxide (3% OTC)	Neat (2 min mouth rinse)	NEG	No	POS	No
Cigarette	1 cigarette	NEG	No	POS	No
Hard Candy	1 piece	NEG	No	POS	No
Chewing Gum	1 piece	NEG	No	POS	No
Sugar	2 Teaspoons	NEG	No	POS	No
Cough Syrup	2 Teaspoons	NEG	No	POS	No

Endogenous substances:

The sponsor evaluated common endogenous substances that could be present in oral fluid to determine if these compounds had any effect on Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay results. The potential interferents were spiked at the concentrations below into oral fluid containing PCP at ± 25% of the cutoff. No negative or positive interference was observed in either the qualitative or semi-quantitative mode.

Compound	Compound Conc.	-25% Cutoff (7.5 ng/mL)		+25% Cutoff (12.5 ng/mL)	
		Result	Interference (Yes/No)?	Result	Interference (Yes/No)?
Ascorbic Acid	3 mg/mL	NEG	No	POS	No
Bilirubin	0.15 mg/mL	NEG	No	POS	No
Cholesterol	0.45 mg/mL	NEG	No	POS	No
γ-Globulin	0.8 mg/mL	NEG	No	POS	No
Hemoglobin	3 mg/mL	NEG	No	POS	No
Human Serum Albumin	15 mg/mL	NEG	No	POS	No

Compound	Compound Conc.	-25% Cutoff (7.5 ng/mL)		+25% Cutoff (12.5 ng/mL)	
		Result	Interference (Yes/No)?	Result	Interference (Yes/No)?
IgA	1 mg/mL	NEG	No	POS	No
IgG	1 mg/mL	NEG	No	POS	No
IgM	0.5 mg/mL	NEG	No	POS	No
Salivary-α-amylase	1000 U/mL	NEG	No	POS	No

Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay performance was tested for potential interference of oral fluid pH at pH levels of 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 11.0. All test samples used drug-free oral fluid spiked with PCP to concentrations of 7.5 ng/mL and 12.5 ng/mL (±25% of the 10 ng/mL cutoff). No positive or negative interference was seen in either the qualitative or semi-quantitative mode.

f. Assay cut-off:

See section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

80 unaltered, oral fluid samples collected by expectoration were analyzed by LC-MS/MS. A separate aliquot was processed through the Quantisal II Oral Fluid Collection Device and analyzed using the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay in qualitative and semi-quantitative modes, and collected specimens from each of the collection device's two collection pads (A and B) were compared to the LC-MS/MS-determined concentration. Results are summarized below:

Quantisal II "A" collection pad					
Immunalysis SEFRIA PCP Oral Fluid EIA Result		LC-MS/MS PCP Neat Oral Fluid Concentration			
		< 5 ng/mL (less than -50% cutoff)	5 – 9 ng/mL (between -50% cutoff and cutoff)	10 – 15 ng/mL (between cutoff and +50% cutoff)	> 15 ng/mL (greater than +50% cutoff)
Qualitative	Positive	0	0	5	35
	Negative	36	4	0	0
Semiquantitative	Positive	0	0	5	35
	Negative	36	4	0	0

Quantisal II "B" collection pad					
Immunalysis SEFRIA PCP Oral Fluid EIA Result		LC-MS/MS PCP Neat Oral Fluid Concentration			
		< 5 ng/mL (less than -50% cutoff)	5 – 9 ng/mL (between -50% cutoff and cutoff)	10 – 15 ng/mL (between cutoff and +50% cutoff)	> 15 ng/mL (greater than +50% cutoff)
Qualitative	Positive	0	0	5	35
	Negative	36	4	0	0
Semiquantitative	Positive	0	0	5	35
	Negative	36	4	0	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:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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