January 24, 2019

Immunalysis Corporation
Michelle Bodien
Associate Director, Regulatory Affairs
829 Towne Center Drive
Pomona, CA 91767

Re: k181135
Trade/Device Name: Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay
Regulatory Class: Unclassified, 510(k) required
Product Code: LCM
Dated: December 13, 2018
Received: December 14, 2018

Dear Michelle Bodien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181135

Device Name
Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY **k181135**

A. GENERAL INFORMATION

Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767 Establishment # 2020952
Company Contact:	Michelle Bodien Assoc. Director, Regulatory Affairs Phone: (210)4058453 Email: michelle.bodien@alere.com
Date Prepared:	January 22, 2019

B. DEVICE IDENTIFICATION

Trade or Proprietary Names:	Immunalysis SEFRIA™ PCP Oral Fluid Enzyme Immunoassay
Common Name:	PCP Oral Fluid Enzyme Immunoassay

C. REGULATORY INFORMATION

Device Classification Name:	Enzyme Immunoassay, Phencyclidine
Product Codes:	LCM
Regulatory Class:	Class II
Classification Regulation:	Unclassified
Panel:	Toxicology (91)
Predicate Device:	RapidFRET Oral Fluid Assay for PCP, PCP Calibrator Set, PCP Control Set and RapidEase Oral Fluid Collector [K122703]

D. DEVICE DESCRIPTION

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is a sensitive *in vitro* diagnostic test to detect the presence of PCP in human oral fluid samples collected with the Quantisal II Oral Fluid Collection Device.

Quantisal II Oral Fluid Collection Device is a collection system comprised of a dual pad collector and transport vials. The dual pad collector is separated after collection of oral fluid from a subject's mouth enabling each specimen-saturated collection pad to be placed into its own transport vial. The split specimen (referred to as "A" and "B") allows for one sample to be tested in a screening assay and confirmed by a quantitative laboratory method (such as liquid chromatography tandem mass spectrometry [LC-MS/MS] and the second sample to be stored for secondary confirmation if needed.

PCP was first synthesized in 1926 and later tested after World War II as a surgical anesthetic. Because of its adverse side effects, such as hallucinations, mania, delirium, and disorientation, it was shelved until the 1950s. The drug is easily synthesized by anyone with a basic knowledge of chemistry and has become one of the drugs most frequently used by drug abusers. It has a variety of street names, including “angel dust,” “animal tranquilizer,” “PCP,” “peace pill,” “crystal joints,” and “peace weed,” with the name often reflecting the form in which it is taken. It can be smoked, “snorted” through the nose, ingested, or taken intravenously. Phencyclidine has also been shown to cause schizophrenia-like changes in Nacetylaspartate and N-acetylaspartylglutamate in the rat brain, which are detectable both in living rats and upon necropsy examination of brain tissue. It also induces symptoms in humans that mimic schizophrenia. Behavioral effects can vary by dosage. Low doses produce numbness in the extremities and intoxication, characterized by staggering, unsteady gait, slurred speech, bloodshot eyes, and loss of balance. Moderate doses (5–10 mg intranasal, or 0.01–0.02 mg/kg intramuscular or intravenous) will produce analgesia and anesthesia. High doses may lead to convulsions. Users frequently do not know how much of the drug they are taking due to the tendency of the drug to be made illegally in uncontrolled conditions.

E. INTENDED USE

Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay

The Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay is a homogenous 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.

F. COMPARISON WITH PREDICATE

Attribute	Predicate Device RapidFRET Oral Fluid Assay for PCP [k122703]	Candidate Device Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay
Similarities		
Test Principle	Homogeneous enzyme immunoassay	Same
Antibody	Antibodies to PCP	Same

Attribute	Predicate Device RapidFRET Oral Fluid Assay for PCP [k122703]	Candidate Device Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay
Materials	PCP specific antibody reagent, PCP drug conjugate reagent	Same
Cutoff Level	10 ng/mL	Same
User Environment	For use in laboratories	Same
Sample Matrix	Human oral fluid	Same
Reagent Storage	2-8°C until expiration date	Same
Differences		
Intended Use	Qualitative determination of phencyclidine in human oral fluid	Qualitative and semi-quantitative determination of phencyclidine in human oral fluid.
Sample Collection Device	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.	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.

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay and Quantisal II Oral Fluid Collection Devices to the predicate device. Assay performance was established using the Beckman Coulter AU480 chemistry analyzer.

1. Precision/ Cutoff Characterization

Precision/ Cutoff Characterization study was performed over 15 days, two collection device runs per day with two collections per run (N=60) on three lots of Quantisal II oral fluid collection devices. Drug free negative urine was spiked to concentrations of assay cutoff and ±25%, ±50%, ±75%, ±100% of the cutoff and transferred to the collection devices. The spiked concentrations were confirmed by mass spectrometry (LC-MS/MS). The study established the repeatability of the testing system, including assay and oral fluid collection device. Test results in qualitative and semi-quantitative modes for a representative lot are presented in **Tables 1 to 6**.

Table 1. Precision – Quantisal II "A" - Qualitative

Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	60	60 Negative

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

Table 2. Precision – Quantisal II "A" - Semi-Quantitative

Concentration (ng/mL)	% of cutoff	# of determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	0.5	60 Negative
2.5	-75%	60	2.7	60 Negative
5	-50%	60	5.5	60 Negative
7.5	-25%	60	7.8	60 Negative
10	Cutoff	60	10.1	28 Neg / 32 Pos
12.5	25%	60	12.5	60 Positive
15	50%	60	15.5	60 Positive
17.5	75%	60	17.4	60 Positive
20	100%	60	20.2	60 Positive

Table 3. Precision – Quantisal II "B" - Qualitative

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

Table 4. Precision – Quantisal II "B" - Semi-Quantitative

Concentration (ng/mL)	% of cutoff	# of determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	0.5	60 Negative
2.5	-75%	60	2.7	60 Negative
5	-50%	60	5.5	60 Negative

Concentration (ng/mL)	% of cutoff	# of determinations	Mean Conc. (ng/mL)	Result
7.5	-25%	60	8.0	60 Negative
10	Cutoff	60	10.1	29 Neg / 31 Pos
12.5	25%	60	12.7	60 Positive
15	50%	60	15.5	60 Positive
17.5	75%	60	17.5	60 Positive
20	100%	60	20.2	60 Positive

2. Specificity and Cross-Reactivity

Structurally and functionally similar compounds were spiked into drug free oral fluid at levels that will yield a result that is equivalent to the cutoff. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs, in both the qualitative and semi-quantitative modes. Cross-reactivity test results for qualitative and semi-quantitative modes are presented in **Table 7**.

Table 5. Cross-Reactivity – Qualitative

Compound	Compound Conc. (ng/mL)	PCP Equivalent Conc. (ng/mL)	Result	Cross-Reactivity (%)
Amitriptyline	22,000	10	POS	0.05
Chlorpromazine	5,200	10	POS	0.19
Clomipramine	22,000	10	POS	0.05
Cyclobenzaprine	1,900	10	POS	0.53
Desipramine	40,000	<10	NEG	<0.03
Dextromethorphan	40,000	<10	NEG	<0.03
Diphenhydramine	37,000	10	POS	0.03
Doxepin	5,600	10	POS	0.18
Doxylamine	40,000	<10	NEG	<0.03
EDDP	40,000	<10	NEG	<0.03
4-Hydroxyphencyclidine (PCHP)	85	10	POS	11.76
Imipramine	13,400	10	POS	0.07
Methoxetamine	34,000	10	POS	0.03
Nortriptyline	40,000	<10	NEG	<0.03
Protriptyline	40,000	<10	NEG	<0.03
Thioridazine	8,600	10	POS	0.12
Trimipramine	40,000	<10	NEG	<0.03
Venlafaxine	40,000	<10	NEG	<0.03

3. Interference – Structurally Unrelated Compounds

Structurally unrelated compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing PCP at ±25% of the cutoff. All potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds. The levels of structurally unrelated compounds that did not interfere in the assay are presented in **Table 8**.

Table 6. Non-Interfering Structurally Unrelated Compounds– Qualitative and Semi-quantitative

Compound	Conc. 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

Compound	Conc. Tested (ng/mL)
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
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

Compound	Conc. Tested (ng/mL)
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
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

Compound	Conc. Tested (ng/mL)
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
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

4. Interference – Endogenous Compounds and Exogenous Compounds

Endogenous compounds and exogenous compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing PCP at ±25% of the cutoff. Additional orally used products were tested by collecting oral fluid using

Quantisal II Oral Fluid Collection Devices from volunteers after use of the substances. Assay performance is unaffected by all of the substances tested. Endogenous compounds and exogenous compounds tested are presented in **Tables 9 and 10**. Orally used compounds tested are presented in **Table 11**.

Table 7. Non-interfering Endogenous Compounds

Compound	Concentration Tested
Ascorbic Acid	3 mg/mL
Bilirubin	0.15 mg/mL
Cholesterol	0.45 mg/mL
γ-Globulin	0.8 mg/mL
Hemoglobin	3 mg/mL
Human Serum Albumin	15 mg/mL
IgA	1 mg/mL
IgG	1 mg/mL
IgM	0.5 mg/mL
Salivary-α-amylase	1000 U/mL

Table 8. Non-interfering Exogenous Compounds

Compound	Concentration Tested
Acetaminophen	0.1 mg/mL
Acetylsalicylic Acid	0.1 mg/mL
Baking Soda	0.6% v/v
Cotinine	0.03 mg/mL
Denture Adhesive	0.6% w/v
Ibuprofen	0.1 mg/mL
Alcohol (Ethanol)	6% v/v
Caffeine	0.1 mg/mL
Coffee	6% v/v
Cranberry Juice	6% v/v
Hydrogen Peroxide (3% OTC)	0.5% v/v
Milk	1% v/v
Mouthwash	6% v/v
Naproxen	0.1 mg/mL
Orange Juice	6% v/v
Soft Drink (Pepsi)	6% v/v
Sodium Chloride	18 mg/mL
Sugar	20 mg/mL
Tea	6% v/v
Toothpaste	6% v/v

Table 9. Non-interfering Orally Used Exogenous Products

Compound	Concentration Tested
Teeth Whitener	2 strips
Hydrogen Peroxide (3% OTC)	Neat (2 min mouth rinse)
Cigarette	1 cigarette
Hard Candy	1 piece
Chewing Gum	1 piece
Cough Syrup	2 Teaspoons

5. Interference – pH

To evaluate potential interference from the effect of oral fluid pH, device performance in the qualitative and semi-quantitative modes was tested using a range of oral fluid pH values (3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 11.0). All test samples were prepared in drug free oral fluid containing PCP at ±25% of the cutoff. No positive or negative interference was observed at oral fluid pH values ranging from 3.0 to 11.0 for each test mode.

6. Linearity/Recovery

A linearity study in the semi-quantitative mode was conducted by spiking a drug free oral fluid pool with a high concentration of PCP above the highest calibrator. Additional pools were made by serially diluting the high concentration specimen with drug free oral fluid to achieve concentrations ranging from 4 ng/mL to 44 ng/mL. The 0 ng/mL specimen was made from drug free oral fluid. Each pool was collected using Quantisal II oral fluid collection devices and tested in triplicate to calculate the mean concentration values that were used to calculate drug recovery. Linearity test results in semi-quantitative mode are presented in **Tables 12 to 14**.

Table 10. Linearity/Recovery – Quantisal II "A"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	1.5	N/A
4	4.2	105.0
8	8.5	105.8
10	10.0	100.0
12	11.7	97.2
16	15.8	98.5
20	21.2	105.8
24	24.6	102.4
28	28.5	101.9
32	31.5	98.3
36	35.5	98.6
40	42.1	105.3
44	46.0	104.5

Table 11. Linearity/Recovery – Quantisal II "B"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	1.3	N/A
4	3.7	92.5
8	8.2	102.1
10	10.3	102.7
12	12.3	102.5
16	16.0	99.8
20	19.0	94.8
24	24.1	100.6
28	27.7	98.9
32	33.9	105.8
36	36.6	101.8
40	42.0	105.1
44	46.4	105.5

7. Calibration Duration

Drug free negative oral fluid spiked with PCP at ±25% of the cutoff were tested in qualitative mode at time points up to 14 days. At the initial time point, a two-point calibration curve was established. This calibration was used through the duration of this study. The test results met acceptance criteria at each time point. The recommended frequency of calibration is 14 days.

8. PCP Stability in Oral Fluid

Drug free negative oral fluid spiked with PCP at +50% of the cutoff were collected and stored in Quantisal II Oral Fluid Collection Device and tested by LC-MS/MS at each time point at 30°C and at 2°C - 8°C. Test results indicated that oral fluid samples containing PCP are stable for up to 10 days stored in Quantisal II transport tubes at ambient temperature up to 30°C and up to 2 months stored in Quantisal II transport tubes at 2°C - 8°C.

9. Sample Transportation Stability

Drug free negative oral fluid spiked with PCP at ±50% of the cutoff were collected and stored in Quantisal II Oral Fluid Collection Device and packed in standard boxes used by common carrier (FedEx). During the 4-day (96 hours) simulated transportation study, the samples were stored in oven/freezer at temperatures ranged from -20°C to 40°C to encompass the temperatures likely to occur during shipment of products. The device used as the reference (unstressed) condition was stored continuously at the recommended storage condition at 2°C - 8°C. LC-MS/MS testing was performed in replicates of two and compared to the reference sample. The studies demonstrated the PCP concentration of the sample collected by Quantisal II Oral Fluid Collection Device is within 20% of initial value during transportation.

10. Sample Recovery

Drug free negative oral fluid spiked with PCP at ±25%, +50% of the cutoff were collected and stored in Quantisal II Oral Fluid Collection Devices overnight at room temperature. LC-MS/MS testing was performed the next day to determine percentage recovery. The studies demonstrated

that the Quantisal II Collection Device recovers PCP at greater than 80% of the original concentration.

11. Quantisal II Sample Volume

Fifty oral fluid samples were collected using Quantisal II collectors (collection pad with plastic stem) from fifty volunteers. Prior to collection, each collector (A and B) was 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. Specific gravity of saliva was rounded to 1.000 to compute the volume collection. The results confirmed consistency of sample volume of 1 mL collected by each of Quantisal II collectors in this population.

Additional seventy-five oral fluid samples from known drug users were collected using Quantisal II collector. After the volume adequacy indicator turned blue on both A and B collector stems, each collector was weighed and compared to the average weight of collector before collection. The difference in weight was noted. Specific gravity of saliva was rounded to 1.000 to compute the volume collection. The results confirmed consistency of sample volume of 1 mL collected by each of Quantisal II collectors in this population.

12. Quantisal II Sample Collection Time

Fifty oral fluid samples from volunteers and seventy-five oral fluid samples from known drug users were collected using Quantisal II collector (collection pad with plastic stem). The collection time was documented. The results verified the sample collection time for Quantisal II Oral Fluid Collection Device is within the claimed time of 10 minutes in over 90% of subjects.

13. Method Comparison

Eighty deidentified, unaltered clinical oral fluid samples collected by Quantisal II Oral Fluid Collection Devices were obtained from drug treatment facilities, analyzed for PCP at assay cutoff with the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay in both qualitative and semi-quantitative modes and compared to Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) results with neat oral fluid collected by expectoration (spitting). The instruments used were the Beckman Coulter AU480 chemistry analyzer and an Agilent 6430 Liquid Chromatography-Tandem Mass Spectrometry. Method comparison test results in qualitative and semi-quantitative modes are presented from **Tables 15** to **17**.

Table 12. Method Comparison – Quantisal II "A"

Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay Result		**LC-MS/MS PCP Neat Oral Fluid Concentration**				**Agreement (%)**
		< 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)**	
Qual.	Positive	0	0	5	35	100% (40/40)
	Negative	36	4	0	0	100% (40/40)
Semi-Quant.	Positive	0	0	5	35	100% (40/40)
	Negative	36	4	0	0	100% (40/40)

Table 13. Method Comparison – Quantisal II "B"

Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay Result		LC-MS/MS PCP Neat Oral Fluid Concentration				Agreement (%)
		< 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)	
Qual.	Positive	0	0	5	35	100% (40/40)
	Negative	36	4	0	0	100% (40/40)
Semi-Quant.	Positive	0	0	5	35	100% (40/40)
	Negative	36	4	0	0	100% (40/40)

H. CONCLUSION

The information provided in this pre-market notification demonstrates that the Immunalysis SEFRIA PCP Oral Fluid Enzyme Immunoassay and Immunalysis Quantisal II Oral Fluid Collection Device are substantially equivalent to the legally marketed predicate device for their intended uses.