510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K203564

B Applicant

Immunalysis Corporation

C Proprietary and Established Names

SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Oxycodone

C Type of Test:

Qualitative and Semi-quantitative Homogeneous Enzyme Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

For In Vitro Diagnostic Use.

The Immunalysis SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid collected by Quantisal or Quantisal II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of oxycodone in human oral fluid with clinical analyzers. This assay is calibrated against oxycodone.

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 Oxycodone 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

The SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay was validated using the Beckman Coulter AU480 chemistry analyzer. Confirmatory tests were run in the Agilent 6430 Liquid Chromatography-Tandem Mass Spectrometry.

IV Device/System Characteristics:

A Device Description:

The SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay consists of ready to use reagents for use on automated clinical chemistry analyzers. The SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is provided in two kit sizes by volume: 100 mL (621OF-0100K) and 500 mL (621OF-0500K). Each kit box contains the following reagents:

- 1 X Enzyme Acceptor/Antibody Reagent (EA) - This contains EA protein and recombinant antibodies to oxycodone, in PIPES buffer with sodium azide as a preservative.

- 1 X Enzyme Donor/Substrate Reagent (ED) - This contains ED peptide labeled with oxycodone and CPRG substrate in malic acid buffer with sodium azide as a preservative.

B Principle of Operation:

The SEFRIA technology is based on artificial fragments of the E. coli enzyme β-galactosidase. A mutant enzyme, termed Enzyme Acceptor (EA), is created by deletion of a short sequence in the amino-terminal region of the sequence. EA is inactive, but can combine with peptides, termed Enzyme Donors (ED's), containing the deleted sequence, to form active β-galactosidase. This process is termed complementation, and the active enzyme formed as a result can be measured by hydrolysis of a chromogenic substrate such as chlorophenol red β-D-galactopyranoside (CPRG). The ED peptides can be modified by attachment of a derivative of oxycodone, which does not interfere with the formation of active β-galactosidase. However, antibodies to oxycodone bind to the ED-oxycodone conjugate, and block complementation. The assay is based on the competition of oxycodone in an oral fluid sample with the ED-oxycodone conjugate for the fixed amount of antibody binding sites. In the absence of the free drug in the sample, the antibody binds the ED-oxycodone conjugate, resulting in inhibition of enzyme formation. As the oxycodone concentration in the sample increases, ED-oxycodone becomes available for complementation, creating a dose response relationship between oxycodone 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Thermo Scientific CEDIA Opiate OFT Assay

B Predicate 510(k) Number(s):
K101754

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203564	K101754
Device Trade Name	SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay	Thermo Scientific CEDIA Opiate OFT Assay
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative determination of opiates in human oral fluid	Same
Test Principle	Homogeneous enzyme immunoassay	Same
Assay Materials	Antibody reagent, drug conjugate reagent	Same

Device & Predicate Device(s):	K203564	K101754
Cutoff Level	30 ng/mL in Neat Oral Fluid	Same
User Environment	For use in laboratories	Same
Sample Matrix	Human oral fluid	Same
Reagent Storage	2-8◦C until expiration date	Same
Mass Spectrometry Confirmation	Required for prelimary positive analytical results	Same
General Device Characteristic Differences		
Calibrated Against	Oxycodone	Morphine
Sample Collection Device	Oral fluid collected with the Quantisal and Quantisal II Oral Fluid Collection Devices.	Oral fluid is collected with the Oral Eze™ Saliva Collection System.

VI Standards/Guidance Documents Referenced:

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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision study was performed over 15 days, 2 runs per day with 2 collection devices per run (N=60), one replicate per collection device on 1 lot of reagent and 1 lot of Quantisal and 1 lot of Quantisal II oral fluid collection devices. Drug free negative oral fluid was spiked to concentrations of assay cutoff and ±25%, ±50%, ±75%, ±100% of the cutoff and was collected using the collection devices. The spiked concentrations were confirmed by liquid chromatography tandem mass spectrometry (LC-MS/MS) before collection. The study established the repeatability of the testing system, including assay and oral fluid collection device. Test results in qualitative and semi-quantitative modes are presented in the following tables.

Precision – Qualitative results from samples collected using Quantisal

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	31 Neg/29 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Precision - Semi-Quantitative results from samples collected using Quantisal

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	-0.2	60 Negative
7.5	-75%	60	8.4	60 Negative
15	-50%	60	16.7	60 Negative
22.5	-25%	60	24.3	60 Negative
30	Cutoff	60	32.3	16 Neg/44 Pos
37.5	+25%	60	42.1	60 Positive
45	+50%	60	53.3	60 Positive
52.5	+75%	60	64.3	60 Positive
60	+100%	60	76.3	60 Positive

Precision – Qualitative results from samples collected using Quantisal II Pad A

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	31 Neg/29 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Precision - Semi-Quantitative results from samples collected using Quantisal II Pad A

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	36 Neg/24 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Precision – Qualitative results from samples collected using Quantisal II Pad B

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	28 Neg/32 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Precision - Semi-Quantitative results from samples collected using Quantisal II Pad B

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	28 Neg/32 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

An additional 20-day study was performed on 3 lots of assay reagent to demonstrate the repeatability across multiple reagent lots. All sample concentrations ranging from -100% to -25% of the cutoff were negative and all sample concentrations ranging from +25% to +100% of cutoff were positive for both qualitative and semi-quantitative interpretations.

2. Linearity:

Assay linearity was evaluated in the semi-quantitative mode by spiking a drug free oral fluid pool with a high concentration of oxycodone. Additional pools were made by serially diluting the high concentration specimen with drug free oral fluid to achieve concentrations ranging from 10 ng/mL to 110 ng/mL. The 0 ng/mL specimen was made from drug free oral fluid. Each pool was collected by Quantisal and Quantisal II oral fluid collection devices and tested in triplicate to calculate the mean concentration values that were used to calculate drug recovery. The results in semi-quantitative mode are presented in the following tables.

Linearity/Recovery – Quantisal

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	1.8	N/A
10	9.6	95.7
20	21.0	104.8
30	33.2	110.6
40	40.7	101.8
50	55.8	111.6
60	60.5	100.8
70	75.8	108.2
80	80.9	101.2
90	95.6	106.2
100	106.7	106.7
110	112.4	102.2

Linearity/Recovery – Quantisal II "Pad A"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	-1.5	N/A
10	10.2	102.0
20	20.4	102.2
30	29.8	99.2
40	42.0	104.9
50	50.2	100.3
60	57.1	95.2
70	69.4	99.1
80	81.9	102.3
90	87.9	97.7
100	107.7	107.7
110	109.7	99.7

Linearity/Recovery – Quantisal II "Pad B"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	-1.2	N/A
10	10.9	108.7
20	19.4	97.0
30	27.2	90.6
40	43.0	107.5
50	46.7	93.5
60	59.9	99.8
70	74.3	106.2
80	85.4	106.8
90	90.8	100.9
100	105.4	105.4
110	117.7	107.0

The study demonstrated that the SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay has good correlation to the expected concentration in the range from10 to 100 ng/mL.

3. Analytical Specificity/Interference:

Structurally and functionally similar compounds were spiked into drug free pooled oral fluid at levels that will yield a result that is equivalent to the cutoff, if cross reacting. The study assessed the cross reactivity of the oxycodone assay to related drugs and drug metabolites, in both the qualitative and semiquantitative modes. Cross-reactivity test results in qualitative and semi-quantitative modes are presented in the tables below.

Cross-Reactivity – Qualitative

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Result	Cross-Reactivity (%)
6-acetylcodeine	40,000	<30	NEG	<0.08
6-acetylmorphine	40,000	<30	NEG	<0.08
Buprenorphine	40,000	<30	NEG	<0.08
Codeine	40,000	<30	NEG	<0.08
Desomorphine	40,000	<30	NEG	<0.08
Dihydrocodeine	40,000	<30	NEG	<0.08
Ethylmorphine	40,000	<30	NEG	<0.08
Fentanyl	40,000	<30	NEG	<0.08
Heroin	40,000	<30	NEG	<0.08
Hydrocodone	40,000	<30	NEG	<0.08
Hydromorphone	40,000	<30	NEG	<0.08
Levorphanol	40,000	<30	NEG	<0.08
Meperidine	40,000	<30	NEG	<0.08
Morphine	40,000	<30	NEG	<0.08
Morphine-3-β-D-glucuronide	40,000	<30	NEG	<0.08
Morphine-6-β-D-glucuronide	40,000	<30	NEG	<0.08
Naloxone	6,000	30	POS	0.5
Naltrexone	40,000	<30	NEG	<0.08
Norbuprenorphine	40,000	<30	NEG	<0.08
Norcodeine	40,000	<30	NEG	<0.08
Normorphine	40,000	<30	NEG	<0.08
Noroxycodone	4,750	30	POS	0.6
Noroxymorphone	12,500	30	POS	0.2
Oxymorphone	35	30	POS	85.7
Oxymorphone-3-β-D-glucuronide	550	30	POS	5.5
Tapentadol	40,000	<30	NEG	<0.08
Tramadol	40,000	<30	NEG	<0.08

Cross-Reactivity – Semi-Quantitative

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Mean Value (ng/mL)	Result	Cross-Reactivity (%)
6-acetylcodeine	40,000	<30	3.1	NEG	<0.08
6-acetylmorphine	40,000	<30	2.1	NEG	<0.08
Buprenorphine	40,000	<30	1.4	NEG	<0.08
Codeine	40,000	<30	3.1	NEG	<0.08
Desomorphine	40,000	<30	3.2	NEG	<0.08
Dihydrocodeine	40,000	<30	4.0	NEG	<0.08
Ethylmorphine	40,000	<30	4.9	NEG	<0.08
Fentanyl	40,000	<30	2.1	NEG	<0.08

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Mean Value (ng/mL)	Result	Cross-Reactivity (%)
Heroin	40,000	<30	1.9	NEG	<0.08
Hydrocodone	40,000	<30	4.7	NEG	<0.08
Hydromorphone	40,000	<30	4.1	NEG	<0.08
Levorphanol	40,000	<30	2.9	NEG	<0.08
Meperidine	40,000	<30	1.8	NEG	<0.08
Morphine	40,000	<30	4.0	NEG	<0.08
Morphine-3-β-D-glucuronide	40,000	<30	1.3	NEG	<0.08
Morphine-6-β-D-glucuronide	40,000	<30	1.2	NEG	<0.08
Naloxone	6,000	30	32.5	POS	0.5
Naltrexone	40,000	<30	19.8	NEG	<0.08
Norbuprenorphine	40,000	<30	1.3	NEG	<0.08
Norcodeine	40,000	<30	1.4	NEG	<0.08
Normorphine	40,000	<30	1.4	NEG	<0.08
Noroxycodone	4,750	30	32.6	POS	0.6
Noroxymorphone	12,500	30	33.0	POS	0.2
Oxymorphone	35	30	31.0	POS	85.7
Oxymorphone-3-β-D-glucuronide	550	30	30.3	POS	5.5
Tapentadol	40,000	<30	1.6	NEG	<0.08
Tramadol	40,000	<30	1.8	NEG	<0.08

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 oxycodone at ±25% of the cutoff. No interference was observed at the concentrations tested with structurally unrelated compounds. The concentration levels of structurally unrelated compounds tested was 40,000 ng/mL.

Non-Interfering Structurally Unrelated Compounds
4-Bromo-2,5,Dimethoxyphenethylamine
Alprazolam
7-Aminoclonazepam
7-Aminoflunitrazepam
7-Aminonitrazepam
Amitriptyline
S-(+) Amphetamine
Benzylpiperazine
Bromazepam
Bupropion

Non-Interfering Structurally Unrelated Compounds
Butabarbital
Butalbital
Cannabidiol
Cannabinol
Carbamazepine
Carisoprodol
Chlordiazepoxide
Chlorpromazine
Clobazam
Clomipramine
Clonazepam
Clozapine
Cocaine
Cotinine
Cyclobenzaprine
Demoxepam
Desalkylflurazepam
Desipramine
Diazepam
Digoxin
Dehydronorketamine
Delta-9-THC
Diphenhydramine
Dextromethorphan
Doxepin
Ecgonine
Ecgonine Methyl Ester
EDDP
EMDP
1R,2S(-)-Ephedrine
1S,2R(+)-Ephedrine
Ethyl-β-D-Glucuronide
Fenfluramine
Flunitrazepam
Fluoxetine
Flurazepam
Haloperidol
11-hydroxy-delta-9-THC
Imipramine
Ketamine

Non-Interfering Structurally Unrelated Compounds
Lamotrigine
Lidocaine
Lorazepam
Lorazepam Glucuronide
Lormetazepam
LSD
Maprotiline
MDA
MDEA
MDMA
Meprobamate
S(+)-Methamphetamine
Methadone
Methaqualone
Methoxetamine
Methylone
Methylphenidate
Midazolam
N-desmethyltapentadol
N-desmethyl tramadol
N-desmethyl venlafaxine
Nalorphine
Nitrazepam
11-nor-9 carboxy THC
Nordiazepam
Norketamine
Norpropoxyphene
Norpseudoephedrine
Nortriptyline
O-desmethyl tramadol
O-desmethyl venlafaxine
Olanzapine
Oxazepam
Pentazocine
Pentobarbital
Phencyclidine
Phenobarbital
Phentermine
Phenylephrine
Phenytoin

Non-Interfering Structurally Unrelated Compounds
Phenylpropanolamine
PMA
Prazepam
Propranolol
Propoxyphene
Protriptyline
R,R(-)-Pseudoephedrine
S,S(+)-Pseudoephedrine
Ritalinic Acid
Salicylic Acid
Secobarbital
Sertraline
Sufentanil
Temazepam
Theophylline
Thioridazine
Trazadone
Triazolam
Trifluoromethylphenyl-piperazine
Trimipramine
Venlafaxine
Verapamil
Zolpidem Tartrate

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 oxycodone at ±25% of the cutoff. Additional orally used products were tested by collecting oral fluid using Quantisal and Quantisal II Oral Fluid Collection Devices from subjects after use of the substances. At the levels tested, there was no interference observed with endogenous compounds, exogenous compounds and orally used compounds. Endogenous compounds and exogenous compounds are presented in the first and second tables below. Orally used compounds are presented in the 3rd table below.

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

Non-interfering Exogenous Compounds

Compound	Concentration Tested
Acetaminophen	0.1 mg/mL
Acetylsalicylic Acid	0.1 mg/mL
Baking Soda	0.6% v/v
Denture Adhesive	0.6% w/v
Ibuprofen	0.1 mg/mL
Alcohol (Ethanol)	6% v/v
Caffeine	0.1 mg/mL
Cough Syrup	6% v/v
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	50 mg/mL
Tea	6% v/v
Toothpaste	6% v/v

Non-interfering Orally Used Exogenous Products

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

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 oxycodone at ±25% of the cutoff. At the pH levels tested, there was no interference observed for each test mode.

4. Assay Reportable Range:

   The assay reportable range for the semi-quantitative mode is 10 ng/mL to 100 ng/mL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability
   The assay is traceable to a commercially available, certified, standard material with the concentration verified by GC-MS or LC-MS/MS.

   Oxycodone Stability in Oral Fluid
   Drug free negative oral fluid spiked with oxycodone at +50% of the 30 ng/mL cutoff were collected and stored in Quantisal and Quantisal II Oral Fluid Collection Devices at 2°C - 8°C, tested by LC-MS/MS at each time point and compared to the baseline concentration result. The test results indicate that oral fluid samples containing oxycodone are stable for up to 12 months stored in Quantisal or Quantisal II Oral Fluid Collection Device at 2°C - 8°C.

   Data to support 10-day storage in Quantisal or Quantisal II Oral Fluid Collection Device at ambient temperature 8°C - 25°C were reported in K183048 and K200801.

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   The assay cut-off cutoff for the qualitative and semi-quantitative analysis of oxycodone in neat oral fluid is 30 ng/mL.

8. Carry-Over:

Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Eighty (80) deidentified, unaltered clinical oral fluid samples collected using the Quantisal and Quantisal II Oral Fluid Collection Devices were obtained from clinical research facilities, analyzed for oxycodone at assay cutoff with the SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay in both qualitative and semi-quantitative modes and compared to Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) results (using the Agilent 6430 Liquid Chromatography-Tandem Mass Spectrometry). Method comparison test results in qualitative and semi-quantitative modes are presented in the tables below.

Method Comparison –samples collected using Quantisal

Immunoassay Result		**LC-MS/MS Oxycodone Concentration**				**Agreement (%)**
		< 15 ng/mL (less than -50% cutoff)	**15 – 29 ng/mL (between -50% cutoff and cutoff)**	**30 – 45 ng/mL (between cutoff and +50% cutoff)**	**> 45 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)**

Method Comparison – samples collected using Quantisal II "Pad A"

Immunoassay Result		LC-MS/MS Oxycodone Concentration				Agreement (%)
		< 15 ng/mL (less than -50% cutoff)	15 – 29 ng/mL (between -50% cutoff and cutoff)	30 – 45 ng/mL (between cutoff and +50% cutoff)	> 45 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)**

Method Comparison – samples collected using Quantisal II "Pad B"

Immunoassay Result		LC-MS/MS Oxycodone Concentration				Agreement (%)
		< 15 ng/mL (less than -50% cutoff)	15 – 29 ng/mL (between -50% cutoff and cutoff)	30 – 45 ng/mL (between cutoff and +50% cutoff)	> 45 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)**

2. Matrix Comparison:

Not applicable. The assay is intended for use only with oral fluid samples.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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