510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K203647

B Applicant

Immunalysis Corporation

C Proprietary and Established Names

SEFRIA™ Methamphetamine Oral Fluid Enzyme Immunoassay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LAF	Class II	21 CFR 862.3610 - Methamphetamine Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

methamphetamine

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 Methamphetamine Oral Fluid Enzyme Immunoassay is an enzyme immunoassay with a cutoff of 50 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 methamphetamine in human oral fluid with clinical analyzers. This assay is calibrated against d-methamphetamine.

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 Methamphetamine 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™ Methamphetamine 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 methamphetamine, which does not interfere with the formation of active β-galactosidase. However, antibodies to methamphetamine bind to the ED- methamphetamine conjugate, and block complementation. The assay is based on the competition of methamphetamine in an oral fluid sample with the ED-methamphetamine conjugate for the fixed amount of antibody binding sites. In the absence of the free drug in the sample, the antibody binds the ED-methamphetamine conjugate, resulting in inhibition of enzyme formation. As the methamphetamine concentration in the sample increases, ED-methamphetamine becomes available for complementation, creating a dose response relationship between methamphetamine 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):
LZI Oral Fluid Methamphetamine Enzyme Immunoassay

B Predicate 510(k) Number(s):
K131652

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203647	K131652
Device Trade Name	SEFRIA Methamphetamine Oral Fluid Enzyme Immunoassay	LZI Oral Fluid Methamphetamine Enzyme Immunoassay
General Device Characteristic Similarities		
Intended Use/Indications for Use	Qualitative and semi-quantitative analysis of methamphetamine in human oral fluid	Same
Test Principle	Homogeneous enzyme immunoassay	Same
Calibrated Against	d-methamphetamine	Same

Device & Predicate Device(s):	K203647	K131652
Assay Materials	antibody reagent, drug conjugate reagent	Same
Cutoff Level	50 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
Mass Spectrometry Confirmation	Required for preliminary positive analytical results	Same
General Device Characteristic Differences		
Sample Collection Device	Oral fluid is collected with the Quantisal or Quantisal II Oral Fluid Collection Device.	Oral fluid is collected with the LZI Oral Fluid Collector.

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.

Summary of 15-Day Precision – Qualitative results

Concentration (ng/mL)	% of cutoff	# of determinations	Result
Quantisal			
0	-100%	60	60 Negative
12.5	-75%	60	60 Negative
25	-50%	60	60 Negative
37.5	-25%	60	60 Negative
50	Cutoff	60	26 Neg / 34 Pos
62.5	25%	60	60 Positive
75	50%	60	60 Positive
87.5	75%	60	60 Positive
100	100%	60	60 Positive
Quantisal II Pad A			
0	-100%	60	60 Negative
12.5	-75%	60	60 Negative
25	-50%	60	60 Negative
37.5	-25%	60	60 Negative
50	Cutoff	60	34 Neg / 26 Pos
62.5	25%	60	60 Positive
75	50%	60	60 Positive
87.5	75%	60	60 Positive
100	100%	60	60 Positive
Quantisal II Pad B			
0	-100%	60	60 Negative
12.5	-75%	60	60 Negative
25	-50%	60	60 Negative
37.5	-25%	60	60 Negative
50	Cutoff	60	31 Neg / 29 Pos
62.5	25%	60	60 Positive
75	50%	60	60 Positive
87.5	75%	60	60 Positive
100	100%	60	60 Positive

Summary of 15-Day Precision - Semi-Quantitative Results

Concentration (ng/mL)	% of cutoff	# of determinations	Mean Conc. (ng/mL)	Result
Quantisal				
0	-100%	60	1.1	60 Negative

Concentration (ng/mL)	% of cutoff	# of determinations	Mean Conc. (ng/mL)	Result
12.5	-75%	60	14.2	60 Negative
25	-50%	60	25.3	60 Negative
37.5	-25%	60	39.3	60 Negative
50	Cutoff	60	50.2	37 Neg / 23 Pos
62.5	25%	60	68.9	60 Positive
75	50%	60	78.9	60 Positive
87.5	75%	60	93.8	60 Positive
100	100%	60	112.2	60 Positive
Quantisal II Pad A				
0	-100%	60	2.4	60 Negative
12.5	-75%	60	14.7	60 Negative
25	-50%	60	25.1	60 Negative
37.5	-25%	60	38.4	60 Negative
50	Cutoff	60	48.6	44 Neg / 16 Pos
62.5	25%	60	63.8	60 Positive
75	50%	60	74.9	60 Positive
87.5	75%	60	86.8	60 Positive
100	100%	60	109.3	60 Positive
Quantisal II Pad B				
0	-100%	60	3.8	60 Negative
12.5	-75%	60	14.7	60 Negative
25	-50%	60	24.9	60 Negative
37.5	-25%	60	40.4	60 Negative
50	Cutoff	60	49.0	42 Neg / 18 Pos
62.5	25%	60	65.8	60 Positive
75	50%	60	78.3	60 Positive
87.5	75%	60	89.0	60 Positive
100	100%	60	111.9	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 methamphetamine. Additional pools were made by serially diluting the high concentration specimen with drug free oral fluid to achieve concentrations ranging from 20 ng/mL to 220 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 tables below.

Linearity/Recovery – Quantisal

Expected Concentration (ng/mL)	**Mean Concentration (ng/mL)**	**Recovery (%)**
0	1.0	N/A
20	20.7	103.3
40	43.1	107.8
50	51.9	103.8
60	64.8	107.9
80	81.2	101.5
100	96.8	96.8
120	127.7	106.4
140	141.4	101.0
160	150.3	93.9
180	184.6	102.6
200	194.8	97.4
220	225.3	102.4

Linearity/Recovery – Quantisal II " Pad A"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	-1.4	N/A
20	20.5	102.5
40	41.6	103.9
50	48.4	96.8
60	59.3	98.9
80	78.2	97.8
100	97.3	97.3
120	123.2	102.6
140	145.6	104.0
160	159.0	99.4
180	180.0	100.0
200	201.0	100.5
220	219.9	100.0

Linearity/Recovery – Quantisal II "Pad B"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	0.5	N/A
20	21.8	109.2
40	42.9	107.3
50	49.1	98.3
60	60.9	101.5
80	78.2	97.8
100	94.8	94.8
120	119.3	99.4
140	140.7	100.5
160	163.6	102.2
180	176.3	98.0
200	192.4	96.2
220	214.5	97.5

The study demonstrated that the SEFRIA™ Methamphetamine Oral Fluid Enzyme Immunoassay has good correlation to the expected concentration in the range from 20 ng/mL to 200 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 methamphetamine assay to related drugs and drug metabolites, in both the qualitative and semi-quantitative modes. Cross-reactivity test results in qualitative and semi-qualitative mode are presented in the tables below.

Cross-Reactivity – Qualitative

Compound	Compound Conc. (ng/mL)	Methamphetamine Equivalent Conc. (ng/mL)	Result	Cross-Reactivity (%)
l-Methamphetamine	7500	50	POS	0.7
d,l-Methamphetamine	110	50	POS	45.5
d-Amphetamine	8,000	50	POS	0.6
l-Amphetamine	40,000	<50	NEG	<0.1
Diphenhydramine	40,000	<50	NEG	<0.1
Doxylamine	40,000	<50	NEG	<0.1
d-Ephedrine	40,000	<50	NEG	<0.1
l-Ephedrine	4,250	50	POS	1.2
Fenfluramine	5,000	50	POS	1.0
Methylenedioxymethamphetamine (MDMA)	55	50	POS	90.9
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	110	50	POS	45.5
Methylenedioxyamphetamine (MDA)	6,000	50	POS	0.8
Methylone	27,500	50	POS	0.2
4-Methoxyamphetamine (PMA)	3,250	50	POS	1.5
Para-Methoxy-N-Methylamphetamine (PMMA)	27.75	50	POS	180.2
Phenethylamine	40,000	<50	NEG	<0.1
Phenylephrine	40,000	<50	POS	<0.1
Phentermine	40,000	<50	POS	<0.1
Phenylpropanolamine (PPA)	40,000	<50	POS	<0.1
d-Pseudoephedrine	15,000	50	POS	0.3
l-Pseudoephedrine	40,000	50	NEG	0.1*
Tyramine	40,000	<50	NEG	<0.1

*As the Semi-Quantitative result is positive, the % cross reactivity is calculated based on Semi-Quantitative result.

Cross-Reactivity – Semi-Quantitative

Compound	Compound Conc. (ng/mL)	Methamphetamine Equivalent Conc. (ng/mL)	Mean Value (ng/mL)	Result	Cross-Reactivity (%)
l-Methamphetamine	7,500	50	54.4	POS	0.7
d,l-Methamphetamine	110	50	54.1	POS	45.5
d-Amphetamine	8,000	50	51.2	POS	0.6
l-Amphetamine	40,000	<50	28.9	NEG	<0.1
Diphenhydramine	40,000	<50	2.8	NEG	<0.1
Doxylamine	40,000	<50	2.3	NEG	<0.1
d-Ephedrine	40,000	<50	22.9	NEG	<0.1
l-Ephedrine	4,250	50	50.0	POS	1.2
Fenfluramine	5,000	50	54.3	POS	1.0
Methylenedioxymethamphetamine (MDMA)	55	50	51.3	POS	90.9
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	110	50	50.0	POS	45.5
Methylenedioxyamphetamine (MDA)	6,000	50	53.7	POS	0.8
Methylone	27,500	50	52.2	POS	0.2
Methoxyamphetamine (PMA)	3,250	50	53.6	POS	1.5
Para-Methoxy-N-Methylamphetamine (PMMA)	27.75	50	51.5	POS	180.2
Phenethylamine	40,000	<50	14.1	NEG	<0.1
Phenylephrine	40,000	<50	14.8	POS	<0.1
Phentermine	40,000	<50	35.2	POS	<0.1
Phenylpropanolamine (PPA)	40,000	<50	15.9	POS	<0.1
d-Pseudoephedrine	15,000	50	52.5	POS	0.3
l-Pseudoephedrine	40,000	50	50.0	POS	0.1
Tyramine	40,000	<50	15.4	NEG	<0.1

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 methamphetamine 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 are presented below.

Non-Interfering Structurally Unrelated Compounds

Compound	Conc. Tested (ng/mL)
4-Bromo-2,5,Dimethoxyphenethylamine	40,000
Acetaminophen	40,000
6-Acetylcodeine	40,000
6-Acetylmorphine	40,000
Alprazolam	40,000
7-Aminoclonazepam	40,000
7-Aminoflunitrazepam	40,000
7-Aminonitrazepam	40,000
Amitriptyline	40,000
Amobarbital	40,000
Benzylpiperazine	5,000
Bromazepam	40,000
Buprenorphine	40,000
Bupropion	40,000
Butabarbital	40,000
Butalbital	40,000
Cannabidiol	40,000
Cannabinol	40,000
Carbamazepine	40,000
Carisoprodol	40,000
Chlordiazepoxide	40,000
Chlorpromazine	40,000
cis-Tramadol	40,000
Clobazam	40,000
Clomipramine	40,000
Clonazepam	40,000
Cocaine	40,000
Clozapine	40,000
Codeine	40,000
Cotinine	40,000
Cyclobenzaprine	40,000
Demoxepam	40,000
Desakylflurazepam	40,000
Desipramine	15,000
Desomorphine	40,000
Dextromethorphan	40,000
Dihydrocodeine	40,000
Diazepam	40,000
Digoxin	40,000

Compound	Conc. Tested (ng/mL)
Dehydronorketamine	40,000
Delta-9-THC	40,000
Doxepin	35,000
Ecgonine	40,000
Ecgonine Methyl Ester	40,000
EDDP	40,000
EMDP	40,000
Ethyl-β-D-Glucuronide	40,000
Ethylmorphine	40,000
Fentanyl	40,000
Flunitrazepam	40,000
Fluoxetine	15,000
Flurazepam	40,000
Haloperidol	40,000
Heroin	40,000
Hydrocodone	40,000
Hydromorphone	40,000
11-hydroxy-delta-9-THC	40,000
Imipramine	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
Meperidine	40,000
Meprobamate	40,000
Methadone	40,000
Methaqualone	40,000
Methoxetamine	40,000
Methylphenidate	40,000
Midazolam	40,000
Morphine	40,000
Morphine-3-Glucuronide	40,000
Morphine-6-Glucuronide	40,000
N-desmethyl tapentadol	40,000
N-desmethyl tramadol	40,000
N-desmethyl venlafaxine	40,000

Compound	Conc. Tested (ng/mL)
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	40,000
Norpseudoephedrine	40,000
Nortriptyline	20,000
O-desmethyl tramadol	40,000
O-desmethyl venlafaxine	40,000
Oxycodone	40,000
Oxymorphone	40,000
Oxycodone-3-β-Glucuronide	40,000
Olanzapine	40,000
Oxazepam	40,000
PCP	40,000
Pentazocine	40,000
Pentobarbital	40,000
Phenobarbital	40,000
Phenytoin	40,000
Prazepam	40,000
Propranolol	40,000
Propoxyphene	40,000
Protriptyline	20,000
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
Thioridazine	40,000

Compound	Conc. Tested (ng/mL)
Trazadone	40,000
Triazolam	40,000
3-Trifluoromethylphenyl-piperazine	20,000
Trimipramine	20,000
Venlafaxine	40,000
Verapamil	30,000
Zolpidem	40,000

Interference – Endogenous Compounds and Exogenous Compounds

Endogenous compounds and exogenous compounds were evaluated in qualitative and semi-quantit modes by spiking the potential interferent into drug free oral fluid containing methamphetamine at ±25% of the cutoff. Additional orally used products were tested by collecting oral fluid using Qua and Quantisal II Oral Fluid Collection Devices from subjects after use of the substances. At the l tested, there was no interference observed with endogenous compounds, exogenous compounds an orally used compounds. Endogenous compounds and exogenous compounds, along with orally used compounds tested are presented in the tables below.

Non-interfering Endogenous Compounds

Compound	Concentration Tested
Ascorbic Acid	2 mg/mL
Bilirubin	0.15 mg/mL
Cholesterol	0.45 mg/mL
γ-Globulin	0.8 mg/mL
Hemoglobin	2 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
Acetylsalicylic Acid	0.01 mg/mL
Baking Soda	0.6% v/v
Denture Adhesive	0.6% w/v
Ibuprofen	0.01 mg/mL
Alcohol (Ethanol)	6% v/v
Caffeine	0.01 mg/mL
Coffee	6% v/v
Cranberry Juice	6% v/v
Milk	1% v/v
Mouthwash	6% v/v
Naproxen	0.01 mg/mL
Orange Juice	2% v/v
Soft Drink (Pepsi)	6% v/v
Sodium Chloride	18 mg/mL
Sugar	10 mg/mL
Tea	6% v/v
Toothpaste	6% w/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
Milk	100 mL
Orange Juice	100 mL
Ibuprofen	200 mg
Acetaminophen	1000 mg

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 reportable range for the semi-quantitative mode is 20 ng/mL to 200 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.

   Methamphetamine Stability in Oral Fluid

   Drug free negative oral fluid spiked with methamphetamine at +50% of the 50 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 methamphetamine 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 methamphetamine in neat oral fluid is 50 ng/mL.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Eighty (80) deidentified, unaltered clinical oral fluid samples collected by using the Quantisal and Quantisal II Oral Fluid Collection Devices were obtained from clinical research facilities, analyzed for methamphetamine at assay cutoff with the SEFRIA Methamphetamine 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 below.

Method Comparison – Quantisal

	Immunoassay Result	LC-MS/MS Methamphetamine Concentration				Agreement (%)
		< 25 ng/mL (less than -50% cutoff)	25 – 49 ng/mL (betwen -50% cutoff and cutoff)	50 – 75 ng/mL (between cutoff and +50% cutoff)	> 75 ng/mL (greater than +50% cutoff)	
Qual.	Positive	0	0	4	36	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**
Semi-Quant.	Positive	0	0	4	36	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**

Method Comparison – Quantisal II "Pad A"

Immunoassay Result		LC-MS/MS Methamphetamine Concentration				Agreement (%)
		< 25 ng/mL (less than -50% cutoff)	25 – 49 ng/mL (between -50% cutoff and cutoff)	50 – 75 ng/mL (between cutoff and +50% cutoff)	> 75 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 – Quantisal II "Pad B"

Immunoassay Result		LC-MS/MS Methamphetamine Concentration				Agreement (%)
		< 25 ng/mL (less than -50% cutoff)	25 – 49 ng/mL (between -50% cutoff and cutoff)	50 – 75 ng/mL (between cutoff and +50% cutoff)	> 75 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.

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.