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

A. 510(k) Number:
k102210

B. Purpose for Submission:
New device

C. Measurand:
Amphetamine, Methamphetamine

D. Type of Test:
Qualitative and Semi-Quantitative Enzyme linked Immunoassay (ELISA)

E. Applicant:
Lin-Zhi International, Inc.

F. Proprietary and Established Names:
LZI Amphetamines 500 Homogeneous Enzyme Immunoassay
LZI Amphetamines 500 Drugs of Abuse Calibrators
LZI Amphetamines 500 Drugs of Abuse Controls

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKZ, enzyme immunoassay, amphetamine	Class II	21 CFR § 862.3100, Amphetamine test system	Toxicology (91)
DJC, thin layer chromatography, methamphetamine	Class II	21 CFR § 862.3610, Methamphetamine test system	Toxicology (91)
DLJ, calibrators, drug specific	Class II	21 CFR § 862.3200, Clinical toxicology calibrator.	Toxicology (91)
LAS, drug specific control materials	Class I	21 CFR § 862.3280, Clinical toxicology control material.	Toxicology (91)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   The LZI Amphetamines 500 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL when calibrated with d-methamphetamine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Amphetamines Enzyme Immunoassay.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Amphetamines 500 Enzyme Immunoassay.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

3. Special conditions for use statement(s):
   For prescription use only.

4. Special instrument requirements:
   Performance data was provided for Hitachi 717 analyzer. The assay can be used on a clinical chemistry analyzer capable of measuring absorbance at 340 nanometers.

I. Device Description:

The LZI Amphetamines 500 Homogeneous Enzyme Immunoassay consists of two separately packaged reagents (R1 and R2):

Reagent	Description
R1	Contains two mouse monoclonal anti-amphetamines antibodies, glucose-6-phosphate (G6P), nicotinamide adenine dinucleotide (NAD), stabilizers and sodium azide as a preservative.
R2	Contains amphetamines-labeled glucose-6-phosphate dehydrogenase (G6PDH) in buffer with sodium azide as a preservative.

Each LZI Amphetamines 500 Drugs of Abuse Calibrator kit contains five calibrators comprised of a human urine matrix containing buffers, stabilizers and less than 0.1% of sodium azide. The controls are prepared by spiking known concentrations of d-methamphetamine into the drug-free matrix. The calibrators cover the calibration range of the assay (0 to 2,000 ng/mL) and are at the following concentrations:

Calibrator	Target Concentration (ng/mL)
Negative Calibrator	0
250 ng/mL Calibrator	250
500 ng/mL Calibrator	500
1000 ng/mL Calibrator	1,000
2000 ng/mL Calibrator	2,000

Each LZI Amphetamines 500 Drugs of Abuse Control Kit contains two levels comprised of a human urine matrix containing buffers, stabilizers and less than 0.1% of sodium azide. The controls are prepared by spiking known concentrations of d-methamphetamine into the drug-free matrix. The controls are available at the following concentrations:

Control	**Target Concentration (ng/mL)**
375 ng/mL Control	375
625 ng/mL Control	625

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
LZI Amphetamines Enzyme Immunoassay	k020395

Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate (k020395)
Indications for Use	The LZI Amphetamines 500 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL when calibrated with d-methamphetamine. The assay is designed for professional use with a number of automated clinical chemistry analyzers. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.	The LZI Amphetamines Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of Amphetamines in human urine, at a cutoff value of 1000 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Analyte	d-amphetamine and d-methamphetamine	Amphetamines
Assay Type	Same	Qualitative and Semi-Quantitative
Cutoff value	500 ng/mL	1000 ng/ml
Sample	Same	Urine
Methodology	Same	Enzyme linked Immunoassay (ELISA)
Test Principle	Same	The assay is an Enzyme linked Immunoassay (ELISA) based on competition between drug (amphetamine and methamphetamine) in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, buprenorphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound amphetamine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.
Analyzer	Same	Clinical chemistry analyzer capable of measuring absorbance at 340 nanometers.
Detection Wavelength	Same	340 nanometers
Calibrators	Five Levels (0, 250, 500, 1000 and 2000 ng/mL)	Five Levels (0, 500, 1000, 1500, 2000 ng/mL)
Controls	Two Levels (375 and 625 ng/mL)	Two Levels (750 and 1250 ng/mL)

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

EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices

L. Test Principle:

The assay is an Enzyme linked Immunoassay (ELISA) based on competition between drug (amphetamine and methamphetamine) in the sample and drug labeled with the

enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, buprenorphine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound amphetamine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor conducted two separate precision studies on the Hitachi 717 analyzer using samples containing d-methamphetamine or d-amphetamine. The precision studies were performed according to CLSI EP5-A2. Samples were prepared by spiking a negative human urine pool with either d-methamphetamine or d-amphetamine at the following concentrations: zero drug (-100%), -75%, -50%, and -25% below the cutoff, cutoff, and +25%, +50%, +75%, and +100% above the cutoff. Samples were tested in 2 replicates per run, 2 runs per day for 22 days, total n=88. Results of the studies are presented below:

Semi-Quantitative Precision Data for d-amphetamine

500 ng/mL Cutoff Result		Within Run		Total Precision	
Sample Concentration (ng/mL)	% of Cutoff	Number of Determinations	Immunoassay Result	Number of Determinations	Immunoassay Result
0	-100%	22	22 Negative	88	88 Negative
125	-75%	22	22 Negative	88	88 Negative
250	-50%	22	22 Negative	88	88 Negative
375	-25%	22	22 Negative	88	88 Negative
500	0	22	22 Positive	88	83 Positive 5 Negative
625	+25%	22	22 Positive	88	88 Positive
750	+50%	22	22 Positive	88	88 Positive
875	+75%	22	22 Positive	88	88 Positive
1000	+100%	22	22 Positive	88	88 Positive

Qualitative Precision Data for d-amphetamine

500 ng/mL Cutoff Result		Within Run		Total Precision	
Sample Concentration (ng/mL)	% of Cutoff	Number of Determinations	Immunoassay Result	Number of Determinations	Immunoassay Result
0	-100%	22	22 Negative	88	88 Negative
125	-75%	22	22 Negative	88	88 Negative
250	-50%	22	22 Negative	88	88 Negative
375	-25%	22	22 Negative	88	88 Negative
500	0	22	15 Positive	88	48 Positive

			7 Negative		40 Negative
625	+25%	22	22 Positive	88	88 Positive
750	+50%	22	22 Positive	88	88 Positive
875	+75%	22	22 Positive	88	88 Positive
1000	+100%	22	22 Positive	88	88 Positive

Semi-Quantitative Precision Data for d-methamphetamine

500 ng/mL Cutoff Result		Within Run		Total Precision	
Sample Concentration (ng/mL)	% of Cutoff	Number of Determinations	Immunoassay Result	Number of Determinations	Immunoassay Result
0	-100%	22	22 Negative	88	88 Negative
125	-75%	22	22 Negative	88	88 Negative
250	-50%	22	22 Negative	88	88 Negative
375	-25%	22	22 Negative	88	88 Negative
500	0	22	3 Positive 19 Negative	88	18 Positive 70 Negative
625	+25%	22	22 Positive	88	88 Positive
750	+50%	22	22 Positive	88	88 Positive
875	+75%	22	22 Positive	88	88 Positive
1000	+100%	22	22 Positive	88	88 Positive

Qualitative Precision Data for d-methamphetamine

500 ng/mL Cutoff Result		Within Run		Total Precision	
Sample Concentration (ng/mL)	% of Cutoff	Number of Determinations	Immunoassay Result	Number of Determinations	Immunoassay Result
0	-100%	22	22 Negative	88	88 Negative
125	-75%	22	22 Negative	88	88 Negative
250	-50%	22	22 Negative	88	88 Negative
375	-25%	22	22 Negative	88	88 Negative
500	0	22	13 Positive 9 Negative	88	54 Positive 34 Negative
625	+25%	22	22 Positive	88	88 Positive
750	+50%	22	22 Positive	88	88 Positive
875	+75%	22	22 Positive	88	88 Positive
1000	+100%	22	22 Positive	88	88 Positive

b. Linearity/assay reportable range:

Linearity across the range was confirmed in two separate studies by serially diluting a spiked urine pool containing d-methamphetamine or d-amphetamine in desired levels listed in the table below. Each sample was assayed in 10 replicates on Hitachi 717 analyzer in the semi-quantitative mode. The results were averaged and compared to the expected result and the percent recovery was calculated. Results are presented below:

Linearity Data for d-amphetamine			Linearity Data for d-methamphetamine		
Expected	Observed	% Recovery	Expected	Observed	% Recovery

Value (ng/mL)	Value (ng/mL)		Value (ng/mL)	Value (ng/mL)	
0	4.1		0	5.7	
25	30.1	120%	25	36.0	144%
150	193.7	129%	50	56.2	112%
300	346.6	116%	200	205.8	103%
400	438.9	110%	300	293.6	97.9%
500	485.5	97.1%	400	380.7	95.2%
600	562.2	93.7%	500	489.4	97.9%
750	734.9	98.0%	600	564.8	94.1%
1000	926.9	92.7%	750	732.3	97.6%
1400	1340.8	95.8%	1000	974.9	97.5%
2000	1934.6	96.7%	1500	1552.3	103%
			2000	1894.9	94.7%

Linear regression analysis of the results yielded the following:
Amphetamine: $y = 0.9447x + 24.34$, $r^2 = 0.9978$.
Methamphetamine: $y = 0.9717x + 5.734$, $r^2 = 0.9971$.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
A stock solution of 1000 µg/mL d-methamphetamine purchased from a commercial source is spiked into the calibrator and controls to the desired concentration. The concentration of the calibrator and controls are confirmed by GC/MS. The sponsor claimed an open vial stability of 18 months at 2 to 8°C for the calibrator and control bottles. After the calibrator and control bottles are initially opened, the screw-on caps can be resealed.

d. *Detection limit:*
Performance at low drug concentrations in the semi-quantitative assay was characterized by determination of recovery (see section M1b above).

e. *Analytical specificity:*
The sponsor prepared urine-free samples spiked with d-amphetamine or d-methamphetamine at control levels (±25% of the 500 ng/mL cutoff concentration) and evaluated the possible interference from endogenous compounds on the Hitachi 717 analyzer. No positive or negative interference due to endogenous compounds tested was observed. The results are listed below.

Endogenous Compounds Interference Data for d-amphetamine

Compound	Concentration (mg/dL)	-25% d-amphetamine (375 ng/mL)	+25% d-amphetamine (625 ng/mL)
Acetone	1000	Negative	Positive
Ascorbic Acid	1500	Negative	Positive
Creatinine	500	Negative	Positive
Ethanol	1000	Negative	Positive
Galactose	10	Negative	Positive
γ-Globulin	500	Negative	Positive
Glucose	1500	Negative	Positive
Hemoglobin	300	Negative	Positive

Compound	Concentration (mg/dL)	-25% d-amphetamine (375 ng/mL)	+25% d-amphetamine (625 ng/mL)
Human Serum Albumin	500	Negative	Positive
Oxalic Acid	100	Negative	Positive
Riboflavin	2.5	Negative	Positive
Sodium Chloride	6000	Negative	Positive
Urea	2000	Negative	Positive

Endogenous Compounds Interference Data for d-methamphetamine

Compound	Concentration (mg/dL)	-25% d-methamphetamine (375 ng/mL)	+25% d-methamphetamine (625 ng/mL)
Acetone	1000	Negative	Positive
Ascorbic Acid	1500	Negative	Positive
Creatinine	500	Negative	Positive
Ethanol	1000	Negative	Positive
Galactose	10	Negative	Positive
γ-Globulin	500	Negative	Positive
Glucose	1500	Negative	Positive
Hemoglobin	300	Negative	Positive
Human Serum Albumin	500	Negative	Positive
Oxalic Acid	100	Negative	Positive
Riboflavin	2.5	Negative	Positive
Sodium Chloride	6000	Negative	Positive
Urea	2000	Negative	Positive

To test for possible positive and/or negative interference from specific gravity, the sponsor prepared samples containing d-amphetamine or d-methamphetamine at control levels (±25% of the 500 ng/mL cutoff concentration) with specific gravities ranging from 1.002 to 1.030. No positive or negative interference due to specific gravity was observed.

To test for potential positive or negative interference from pH the sponsor prepared samples containing d-amphetamine or d-methamphetamine at control levels (±25% of the 500 ng/mL cutoff concentration) with pH values of 3, 4.5, 5, 6, 7, 8 and 11. No negative interference due to pH was observed.

Cross reactivity of various potential interfering drugs were tested by spiking a final concentration of up to 500,000 ng/mL of each substance into drug free urine, and then evaluated with the assay's calibrated dose-response curve. The following table summarizes the approximate quantity of each compound that is equivalent in assay reactivity to the 500 ng/mL d-Methamphetamine cutoff. The sponsor claimed cross-reactivity with four compounds: PMA, MDA, MDMA, and Fenfluramine. The results are presented below.

Structurally Related Compounds Interference Data

Compound	Concentration (ng/dL)	Response equivalent to cutoff (ng/mL)	% Cross-reactivity

d-amphetamine	500	480.7	96.13%
d-methamphetamine	500	489.4	97.87%
l-Amphetamine	12,000	271.6	2.26%
Atomoxetine	500,000	75.2	0.02%
Benzphetamine	500,000	121.4	0.02%
d-Ephedrine	150,000	400.7	0.27%
l-Ephedrine	200,000	409.1	0.20%
Fenfluramine	4,000	433.3	10.83%
3-Hydroxy-Tyramine	500,000	300.5	0.06%
Isoxsuprine	500,000	83.9	0.02%
Mephentermine	25,000	57.4	0.23%
l-Methamphetamine	5,000	386.1	7.72%
para-Methoxyamphetamine (PMA)	400	433.8	108.44%
Methylenedioxyamphetamine (MDA)	1,400	306.0	21.85%
Methylenedioxyethylamphetamine (MDEA)	10,000	441.9	4.42%
Methylenedioxymethamphetamine (MDMA)	1,250	427.1	34.17%
Phendimetrazine	150,000	213.5	0.14%
Phenethylamine	25,000	411.4	1.65%
Phenmetrazine	40,000	313.2	0.78%
Phentermine	20,000	416.3	2.08%
Phenylephrine	400,000	453.4	0.11%
d,l-Phenylpropanolamine	150,000	403.9	0.27%
d-Pseudoephedrine	150,000	422.3	0.28%
l-Pseudoephedrine	200,000	106.9	0.05%
Tranylcypromine	50,000	399.1	0.80%
Tyramine	400,000	423.5	0.11%

Structurally Unrelated Compounds Interference Data

Compound	Concentration (ng/dL)	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Acetaminophen	500,000	108.6	0.02 %
Acetylsalicylic acid	500,000	97.8	0.02 %
Amobarbital	500,000	100.1	0.02 %
Benzoylecgonine	500,000	103.1	0.02 %
Bromopheniramine	500,000	125.0	0.02 %
Bupropion	500,000	194.0	0.04 %
Buspiron	500,000	170.0	0.03 %
Caffeine	500,000	105.1	0.02 %
Chlorpheniramine	500,000	129.7	0.03 %
Chlorpromazine	500,000	159.7	0.03 %
Codeine	500,000	109.4	0.02 %
Dextromethorphan	500,000	107.2	0.02 %
Doxepine	500,000	240.4	0.05 %
Meperidine	500,000	30.8	0.01 %
Methadone	500,000	121.2	0.02 %
Methapyrilene	500,000	191.5	0.04 %
Methaqualone	500,000	101.6	0.02 %
Morphine	500,000	62.9	0.01 %
Oxazepam	500,000	101.2	0.02 %
Phencyclidine	500,000	29.3	0.01 %
Phenobarbital	500,000	99.7	0.02 %
Phenothiazine	500,000	65.0	0.01 %

Procainamide	500,000	412.4	0.08 %
Promethazine	500,000	122.0	0.02 %
Propoxyphene	500,000	92.2	0.02 %
Propranolol	500,000	102.3	0.02 %
Ranitidine	80,000	799.8	1.00 %
Scopolamine	500,000	105.6	0.02 %
Secobarbital	500,000	92.3	0.02 %
Sertraline	500,000	194.1	0.04 %
Thioridazine	500,000	103.6	0.02 %
Trazodone	500,000	251.6	0.05 %
Trifluoperazine	500,000	123.0	0.02 %
Trifluopromazine	500,000	127.8	0.03 %
Valproic Acid	500,000	88.3	0.02 %

f. Assay cut-off:
There is a 500 ng/mL cutoff concentration claimed for both d-amphetamine and methamphetamine.

2. Comparison studies:

a. Method comparison with predicate device:
The sponsor conducted two separate method comparison studies to evaluate the performance of the device for detection of d-methamphetamine or d-amphetamine. For method comparison study for the detection of amphetamine, one hundred and eleven unaltered samples (55 negative and 56 positive samples) were tested with LZI Amphetamines 500 Enzyme Immunoassay on the Hitachi 717 analyzer and compared against the results (d-amphetamine and d-methamphetamine concentration) obtained with GC/MS or LC/MS. The results of the studies are presented below:

Semi-Quantitative Method Comparison Data for Amphetamine 500 ng/mL Cutoff					
Candidate Device Results	Negative	**<50 % of the cutoff** concentration (1-250 ng/mL)	**Near Negative Cutoff** (250-500 ng/mL)	**Near Positive Cutoff** (500-750 ng/mL)	**High Positive** (>750 ng/mL)
Positive (56 samples)	0	0	0	10	45
Negative (55 samples)	12	22	21	1	0

Summary of Discordant Results (Semi-Quantitative)

Assay	Cutoff Value (ng/mL)	Candidate Device Result	GC/MS or LC/MS result
Amphetamine	500	Negative	531 ng/mL amphetamine 0 ng/mL methamphetamine

Qualitative Method Comparison Data for Amphetamine 500 ng/mL Cutoff					
Candidate Device Results	Negative	**<50 % of the cutoff** concentration (1-250 ng/mL)	**Near Negative Cutoff** (250-500 ng/mL)	**Near Positive Cutoff** (500-750 ng/mL)	**High Positive** (>750 ng/mL)
Positive (56 samples)	0	0	0	9	45
Negative (55 samples)	12	22	21	2	0

Summary of Discordant Results (Qualitative)

Assay	Cutoff Value (ng/mL)	Candidate Device Result	GC/MS or LC/MS result
Amphetamine	500	Negative	510 ng/mL amphetamine 0 ng/mL methamphetamine
Amphetamine	500	Negative	531 ng/mL amphetamine 0 ng/mL methamphetamine

For method comparison study for the detection of methamphetamine, eighty-six unaltered samples (43 negative and 43 positive samples) were tested with LZI Amphetamines 500 Enzyme Immunoassay on the Hitachi 717 analyzer and compared against the results (d-amphetamine and d-methamphetamine concentration) obtained with GC/MS or LC/MS. The results of the studies are presented below:

Semi-Quantitative Method Comparison Data for Methamphetamine 500 ng/mL Cutoff					
Candidate Device Results	Negative	**<50 % of the cutoff** concentration (1-250 ng/mL)	**Near Negative Cutoff** (250-500 ng/mL)	**Near Positive Cutoff** (500-750 ng/mL)	**High Positive** (>750 ng/mL)
Positive (43 samples)	0	4	10	9	34
Negative (43 samples)	4	20	5	0	0

Summary of Discordant Results (Semi-Quantitative)

Assay	Cutoff Value (ng/mL)	Candidate Device Result	GC/MS or LC/MS result
Methamphetamine	500	Positive	16 ng/mL methamphetamine 584 ng/mL amphetamine
Methamphetamine	500	Positive	114 ng/mL methamphetamine 621 ng/mL amphetamine
Methamphetamine	500	Positive	133 ng/mL methamphetamine 1029 ng/mL amphetamine
Methamphetamine	500	Positive	184 ng/mL methamphetamine 957 ng/mL amphetamine
Methamphetamine	500	Positive	269 ng/mL methamphetamine 397 ng/mL amphetamine
Methamphetamine	500	Positive	306 ng/mL methamphetamine 244 ng/mL amphetamine
Methamphetamine	500	Positive	385 ng/mL methamphetamine 235 ng/mL amphetamine
Methamphetamine	500	Positive	388 ng/mL methamphetamine 178 ng/mL amphetamine
Methamphetamine	500	Positive	402 ng/mL methamphetamine 226 ng/mL amphetamine
Methamphetamine	500	Positive	409 ng/mL methamphetamine 147 ng/mL amphetamine
Methamphetamine	500	Positive	413 ng/mL methamphetamine 708 ng/mL amphetamine
Methamphetamine	500	Positive	413 ng/mL methamphetamine 130 ng/mL amphetamine
Methamphetamine	500	Positive	458 ng/mL methamphetamine 180 ng/mL amphetamine
Methamphetamine	500	Positive	471 ng/mL methamphetamine 108 ng/mL amphetamine

Qualitative Method Comparison Data for Methamphetamine 500 ng/mL Cutoff					
Candidate Device Results	Negative	**<50 % of the cutoff** concentration (1-250 ng/mL)	**Near Negative Cutoff** (250-500 ng/mL)	**Near Positive Cutoff** (500-750 ng/mL)	**High Positive** (>750 ng/mL)
Positive (43 samples)	0	4	9	9	34
Negative (43 samples)	4	20	6	0	0

Summary of Discordant Results (Qualitative)

Assay	Cutoff Value (ng/mL)	Candidate Device Result	GC/MS or LC/MS result
Methamphetamine	500	Positive	16 ng/mL methamphetamine 584 ng/mL amphetamine
Methamphetamine	500	Positive	114 ng/mL methamphetamine 621 ng/mL amphetamine
Methamphetamine	500	Positive	133 ng/mL methamphetamine 1029 ng/mL amphetamine
Methamphetamine	500	Positive	184 ng/mL methamphetamine 957 ng/mL amphetamine

Assay	Cutoff Value (ng/mL)	Candidate Device Result	GC/MS or LC/MS result
Methamphetamine	500	Positive	269 ng/mL methamphetamine 397 ng/mL amphetamine
Methamphetamine	500	Positive	306 ng/mL methamphetamine 244 ng/mL amphetamine
Methamphetamine	500	Positive	385 ng/mL methamphetamine 235 ng/mL amphetamine
Methamphetamine	500	Positive	388 ng/mL methamphetamine 178 ng/mL amphetamine
Methamphetamine	500	Positive	409 ng/mL methamphetamine 147 ng/mL amphetamine
Methamphetamine	500	Positive	413 ng/mL methamphetamine 708 ng/mL amphetamine
Methamphetamine	500	Positive	413 ng/mL methamphetamine 130 ng/mL amphetamine
Methamphetamine	500	Positive	458 ng/mL methamphetamine 180 ng/mL amphetamine
Methamphetamine	500	Positive	471 ng/mL methamphetamine 108 ng/mL amphetamine

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 Part 809.10.

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