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

A. 510(k) Number:

k093114

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamines and methamphetamines in human urine

D. Type of Test:

Qualitative and semi-quantitative immunoassay

E. Applicant:

Microgenics, Inc.

F. Proprietary and Established Names:

DRI Amphetamines Assay

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.3100, Enzyme Immunoassay, Amphetamine
21 CFR § 862.3610, Methamphetamine test system

2. Classification:

Class II

3. Product code:

DKZ - enzyme immunoassay, amphetamine
LAF - gas chromatography, methamphetamine

4. Panel:

91 (Toxicology)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The DRI® Amphetamines Assay is intended for the qualitative or semiquantitative determination of amphetamine and methamphetamine in human urine. The assay has cutoff levels of 500 and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting amphetamine and methamphetamine in urine on automated clinical analyzers. The assay is calibrated with methamphetamine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a con firmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

3. Special conditions for use statement(s):

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

4. Special instrument requirements:

The studies in the submission were performed on the Olympus AU680.

I. Device Description:

The DRI Amphetamines Assay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies, which can detect amphetamine and/or methamphetamine in urine with minimal cross-reactivity to various over-the-counter structurally unrelated compounds.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CEDIA DAU Amphetamine Assay

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

   k943993

3. Comparison with predicate:

Feature	CEDIA®Amphetamines Assay (K943993)	Thermo Scientific DRI® Amphetamines Assay (K093114)
Intended Use	Qualitative and semi-quantitative detection of amphetamines and methamphetamines	Same
Cutoff	500 and 1000 ng/mL	Same
Sample Type	Urine	Same
Reagents	Lyophilized Two reagent assay (R1 and R2)	Liquid ready to use Two reagent assay (R1 and R2)
Calibrators	Liquid ready-to-use (0, 500, 1000, 3000, 5000 ng/mL)	Liquid ready-to-use (0, 500, 1000, 3000, 5000 ng/mL)
Storage condition	2-8°C	2-8°C

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

CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement

CLSI EP9-A2, Method Comparison and Bias Estimation using patient samples

L. Test Principle:

The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. In the presence of free drug, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity is

determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Drug free human urine samples spiked with d-amphetamine and d-methamphetamine individually at concentrations between 0 and 2000 ng/mL were tested for Inter-Assay precision in qualitative and semi-quantitative assays. Samples were tested following a randomized CLSI precision protocol for 40 runs in 20 days, n=80. The results are summarized below.

Qualitative Summary

Analyte	Sample Concentration (ng/mL)	N	500 Cutoff #Neg/#Pos	1000 Cutoff #Neg/#Pos
Amphetamine	0	80	80/0	80/0
	150	80	80/0	80/0
	375	80	80/0	80/0
	625	80	0/80	80/0
	750	80	0/80	80/0
	1250	80	0/80	0/80
	1500	80	0/80	0/80
Methamphetamine	0	80	80/0	80/0
	150	80	80/0	80/0
	375	80	80/0	80/0
	625	80	0/80	80/0
	750	80	0/80	80/0
	1250	80	0/80	0/80
	1500	80	0/80	0/80

Semi-quantitative Summary

Analyte	Sample Concentration (ng/mL)	N	Mean (ng/mL)	Within-Run CV%	Total CV%
Amphetamine	150	80	145.9	6.2	6.9
	375	80	372.8	2.7	2.9
	625	80	683.9	1.6	2.0
	750	80	775.4	1.8	2.3
	1250	80	1317.9	1.8	2.2
	1500	80	1467.6	1.6	2.2

Methamphetamine	150	80	168.4	4.4	5.5
	375	80	392.8	2.0	2.8
	625	80	626.1	1.5	1.9
	750	80	770.4	1.3	1.5
	1250	80	1284.1	1.2	1.5
	1500	80	1515.1	1.4	1.8

Intra assay precision and performance around the cutoff was verified by evaluating methamphetamine and amphetamine samples spiked to -50%, and -25% below the cutoff, cutoff, and +25%, +50% above the cutoff for both the 500 ng/mL and 1000 ng/mL cutoffs in qualitative and semi quantitative modes. Each sample was run 20 times in one day. The results are summarized below.

Qualitative Summary

Analyte	**Sample Concentration (ng/mL)**	**N**	**500 Cutoff #Neg/#Pos**	**1000 Cutoff #Neg/#Pos**
Amphetamine	150	20	20/0	20/0
	375	20	20/0	20/0
	500	20	10/10	20/0
	625	20	0/20	20/0
	750	20	0/20	20/0
	1000	20	0/20	11/9
	1250	20	0/20	0/20
	1500	20	0/20	0/20
Methamphetamine	150	20	20/0	20/0
	375	20	20/0	20/0
	500	20	10/10	20/0
	625	20	0/20	20/0
	750	20	0/20	20/0
	1000	20	0/20	10/10
	1250	20	0/20	0/20
	1500	20	0/20	0/20

Amphetamine, semi-quantitative

Level	**150 ng/mL**	**375 ng/mL**	**500 ng/mL**	**625 ng/mL**	**750 ng/mL**	**1000 ng/mL**	**1250 ng/mL**	**1500 ng/mL**
Mean (ng/mL)	152.2	383.3	491.6	615.1	801.0	997.6	1373.2	1476.3
SD	6.7	6.4	9.7	13.1	13.8	13.7	22.6	16.2
%CV	4.4	1.7	2.0	2.1	1.7	1.4	1.6	1.1
Recovery	101%	102%	98%	98%	107%	100%	110%	98%

GC/MS (ng/mL)	130	369	493	605	756	923	1293	1546

Methamphetamine, semi-quantitative

Level	**150 ng/mL**	**375 ng/mL**	**500 ng/mL**	**625 ng/mL**	**750 ng/mL**	**1000 ng/mL**	**1250 ng/mL**	**1500 ng/mL**
Mean (ng/mL)	168.5	408.2	523.5	639.9	784.9	1057.4	1314.3	1541.3
SD	6.1	7.2	4.1	7.7	8.5	11.7	13.5	18.3
%CV	3.6	1.8	0.8	1.2	1.1	1.1	1	1.2
Recovery	112	109	105	102	105	106	105	103
GC/MS (ng/mL)	140	371	498	608	771	1008	1350	1414

b. Linearity/assay reportable range:

Drug free urine was spiked to 2000 ng/mL with methamphetamine, then diluted in 10% increments with drug free urine and analyzed using the semi-quantitative DRI Amphetamines assay. The measured results were within ±4% of the expected values for all concentrations tested. A linear regression calculation was performed and resulted in a slope of 0.984, a y-intercept of 13.87 ng/mL, and a correlation coefficient of 0.999. The results are summarized below.

Dilution (%)	**Mean (ng/ml)**	**Expected (ng/ml)**	**% Recovery**
0%	0.0	0.0	N/A
10 %	203.6	197.2	103.2
20%	400.8	394.5	101.6
30%	614.6	591.7	103.9
40%	811.8	789.0	102.9
50%	986.0	986.2	100.0
60%	1180.0	1183.4	99.7
70%	1353.4	1380.7	98.0
80%	1551.8	1577.9	98.3
90 %	1748.6	1775.2	98.5
100 %	1972.4	1972.4	100.0

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

The assay is calibrated to methamphetamine and five level calibrators were cleared under 510(k) number k983159. All calibrators can be used to generate a semi-quantitative result, or either the 500 ng/mL or 1000 ng/mL calibrator

can be used as qualitative cutoff reference for distinguishing positive from negative samples.

Controls were previously cleared under 510(k) number k040758.

The sponsor provided the stability study protocols for reagent stability studies conducted at 2-8◦C. On-board stability studies demonstrated that the reagents are stable for 60 days when stored on the analyzer as claimed in the package insert.

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

e. Analytical specificity:
Cross reactivity was evaluated by spiking compounds into drug free urine and tested in the qualitative and semi quantitative assays. The compounds, concentrations tested, and results are summarized below.
The following compounds produced a positive result at the concentrations shown in the table.

500 cutoff

Compound	**Concentration tested (ng/mL)**	**Semi-quantitative (ng/mL)**	**Qualitative Negative/Positive**
d-Amphetamine	500	521	Positive
d-Methamphetamine	500	504	Positive
Methylenedioxy-amphetamine (MDA)	1400	502	Positive
Methylenedioxy-methamphetamine(MDMA)	800	537	Positive

1000 cutoff

Compound	**Concentration tested (ng/mL)**	**Semi-quantitative (ng/mL)**	**Qualitative Negative/Positive**
d-Amphetamine	1000	1048	Positive
d-Methamphetamine	1000	1098	Positive
Methylenedioxy-amphetamine (MDA)	2500	1051	Positive
Methylenedioxy-methamphetamine (MDMA)	1300	1046	Positive

Compound	500 Cutoff Concentration (ng/mL)	1000 Cutoff Concentration (ng/mL)
Acetaminophen	1000000	1000000
Acetylsalicylic Acid	1000000	1000000
l-Amphetamine	12500	12500
Benzoylecgonine	1000000	1000000
Benzphetamine	20000	20000
Benzylpiperazine	40000	63000
Bupropion	13000	50000
Caffeine	1000000	1000000
Cetirizin Dihydrochloride	1000000	1000000
Chlorpromazine	500000	500000
Codeine	1000000	1000000
Dextromethorphan	1000000	1000000
d-Ephedrine	1000000	2000000
l-Ephedrine	100000	350000
d,l-Ephedrine	200000	700000
Fenfluramine	1200	4000
Isometheptene	6000	20000
Isoxsuprine	100000	100000
Meperidine	1000000	1000000
Mephentermine	15000	25000
Methadone	1000000	1000000
lI-Methamphetamine	3500	10000
Methapyrilene	100000	500000
Methylphenidate	150000	500000
Metronidazole	1000000	1000000
Morphine	1000000	1000000
Norpseudoephedrine	600000	1000000
Oxazepam	500000	500000
Phencyclidine	1000000	1000000
Phendimetrazine	40000	200000
Phenethylamine	30000	100000
Phenmetrazine	1500	4000
Phenobarbital	1000000	1000000
Phenothiazine	10000	10000
Phentermine	17500	25000
Phenylephrine	300000	500000
Phenylpropanolamine	200000	250000

Procainamide	13000	20000
Promethazine	500000	500000
Propranolol	200000	200000
d-Pseudoephedrine	75000	250000
l-Pseudoephedrine	150000	500000
Ranitidine	250000	600000
Scopolamine	35000	100000
Secobarbital	1000000	1000000
Thioridazine	1000000	1000000
Trifluoperazine	1000000	1000000
Triflupromazine	1000000	1000000
Tyramine	300000	500000
3-0H-Tyramine	500000	500000

To evaluate interference the sponsor spiked potentially interfering compounds into low and high amphetamine and methamphetamine controls for the 500 ng/mL and 1000 ng/mL cutoffs. The compounds and concentrations listed in the table below were found not to interfere for the qualitative assays and the semi-quantitative assay.

500 cutoff – 375 ng/mL Amphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
Low Control	375 ng/mL	Negative	358.5	96%
Acetaminophen	100 ug/mL	Negative	358.5	96%
Acetone	1 g/dL	Negative	361.5	96%
Ascorbic acid	1 g/dL	Negative	339	90%
Aspirin	100 ug/mL	Negative	352.5	94%
Caffeine	100 ug/mL	Negative	362.5	97%
Creatinine	500 mg/dL	Negative	416	111%
Ethanol	1 g/dL	Negative	356	95%
Galactose	10 mg/dL	Negative	360	93%
Y -Globulin	500 mg/dL	Negative	349	95%
Glucose	3 g/dL	Negative	356.5	96%
Hemoglobin	150 mg/dL	Negative	377.5	101%
Human serum albumin	500 mg/dL	Negative	367.5	98%
Ibuprofen	100 I..lg/mL	Negative	352	94%
Oxalic acid	100 mg/dL	Negative	347.5	93%
Riboflavin	7.5 mg/dL	Negative	345	92%
Sodium	1 g/dL	Negative	346	92%

chloride				
Urea	1.25 g/dL	Negative	352	94%
pH	3	Negative	350	93%
pH	4	Negative	359.5	96%
pH	5	Negative	356.5	95%
pH	6	Negative	360	96%
pH	7	Negative	353.5	94%
pH	8	Negative	349	93%
pH	9	Negative	365.5	97%
pH	10	Negative	350.5	93%
pH	11	Negative	357	95%
Specific Gravity	1.004 g/mL	Negative	340	91%
Specific Gravity	1.007 g/mL	Negative	357.5	95%
Specific Gravity	1.011 g/mL	Negative	346.5	92%
Specific Gravity	1.014 g/mL	Negative	350.5	93%
Specific Gravity	1.017 g/mL	Negative	357	95%
Specific Gravity	1.022 g/mL	Negative	364	97%
Specific Gravity	1.026 g/mL	Negative	366.5	98%
Specific Gravity	1.030 g/mL	Negative	367.5	98%
Specific Gravity	1.034 g/mL	Negative	373	99%
Specific Gravity	1.038 g/mL	Negative	378	101%

500 cutoff – 625 ng/mL Amphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
High Control	625 ng/mL	Positive	646.5	103%
Acetaminophen	100 ug/mL	Positive	669.0	107%
Acetone	1 g/dL	Positive	660.0	106%
Ascorbic acid	1 g/dL	Positive	624.0	100%
Aspirin	100 ug/mL	Positive	656.5	105%
Caffeine	100 ug/mL	Positive	659.5	106%
Creatinine	500 mg/dL	Positive	683.0	109%
Ethanol	1 g/dL	Positive	653.5	105%
Galactose	10 mg/dL	Positive	648.5	104%
Y -Globulin	500 mg/dL	Positive	654.0	105%
Glucose	3 g/dL	Positive	645.0	103%
Hemoglobin	150 mg/dL	Positive	661.0	106%
Human serum albumin	500 mg/dL	Positive	652.5	104%
Ibuprofen	100 I..lg/mL	Positive	650.0	104%

Oxalic acid	100 mg/dL	Positive	638.0	102%
Riboflavin	7.5 mg/dL	Positive	639.0	102%
Sodium chloride	1 g/dL	Positive	645.5	103%
Urea	1.25 g/dL	Positive	643.0	103%
pH	3	Positive	634.0	101%
pH	4	Positive	635.0	102%
pH	5	Positive	618.0	99%
pH	6	Positive	648.5	104%
pH	7	Positive	637.0	102%
pH	8	Positive	635.5	102%
pH	9	Positive	639.0	102%
pH	10	Positive	648.0	104%
pH	11	Positive	641.0	103%
Specific Gravity	1.004 g/mL	Positive	625.0	100%
Specific Gravity	1.007 g/mL	Positive	641.0	103%
Specific Gravity	1.011 g/mL	Positive	639.5	102%
Specific Gravity	1.014 g/mL	Positive	641.5	103%
Specific Gravity	1.017 g/mL	Positive	642.0	103%
Specific Gravity	1.022 g/mL	Positive	649.5	104%
Specific Gravity	1.026 g/mL	Positive	665.5	106%
Specific Gravity	1.030 g/mL	Positive	659.0	105%
Specific Gravity	1.034 g/mL	Positive	655.5	105%
Specific Gravity	1.038 g/mL	Positive	656.5	105%

1000 cutoff – 750 ng/mL Amphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
Low Control	750 ng/mL	Neqative	755.5	101%
Acetaminophen	100 ug/mL	Negative	761.5	102%
Acetone	1 g/dL	Negative	748.5	100%
Ascorbic acid	1 g/dL	Negative	724.0	97%
Aspirin	100 ug/mL	Negative	757.5	101%
Caffeine	100 ug/mL	Negative	758.0	101%
Creatinine	500 mg/dL	Negative	797.0	106%
Ethanol	1 g/dL	Negative	759.0	101%
Galactose	10 mg/dL	Negative	759.5	101%
Y -Globulin	500 mg/dL	Negative	761.0	101%
Glucose	3 g/dL	Negative	757.5	101%
Hemoglobin	150 mg/dL	Negative	790.0	105%

Human serum albumin	500 mg/dL	Negative	775.5	103%
Ibuprofen	100 I..lg/mL	Negative	753.0	100%
Oxalic acid	100 mg/dL	Negative	756.5	101%
Riboflavin	7.5 mg/dL	Negative	746.0	99%
Sodium chloride	1 g/dL	Negative	741.0	99%
Urea	1.25 g/dL	Negative	754.0	101%
pH	3	Negative	737.5	98%
pH	4	Negative	737.0	98%
pH	5	Negative	752.5	100%
pH	6	Negative	761.5	102%
pH	7	Negative	756.5	101%
pH	8	Negative	781.5	104%
pH	9	Negative	777.5	104%
pH	10	Negative	780.0	104%
pH	11	Negative	786.0	105%
Specific Gravity	1.004 g/mL	Negative	756.0	101%
Specific Gravity	1.007 g/mL	Negative	754.0	101%
Specific Gravity	1.011 g/mL	Negative	757.5	101%
Specific Gravity	1.014 g/mL	Negative	789.5	105%
Specific Gravity	1.017 g/mL	Negative	772.0	103%
Specific Gravity	1.022 g/mL	Negative	765.0	102%
Specific Gravity	1.026 g/mL	Negative	771.5	103%
Specific Gravity	1.030 g/mL	Negative	803.0	107%
Specific Gravity	1.034 g/mL	Negative	789.0	105%
Specific Gravity	1.038 g/mL	Negative	788.5	105%

1000 cutoff – 1250 ng/mL Amphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
High Control	1250 ng/mL	Positive	1291.0	103%
Acetaminophen	100 ug/mL	Positive	1298.0	104%
Acetone	1 g/dL	Positive	1312.0	105%
Ascorbic acid	1 g/dL	Positive	1212.0	97%
Aspirin	100 ug/mL	Positive	1275.5	102%
Caffeine	100 ug/mL	Positive	1320.5	106%
Creatinine	500 mg/dL	Positive	1376.0	110%
Ethanol	1 g/dL	Positive	1288.0	103%

Galactose	10 mg/dL	Positive	1283.5	103%
Y -Globulin	500 mg/dL	Positive	1305.0	104%
Glucose	3 g/dL	Positive	1296.0	104%
Hemoglobin	150 mg/dL	Positive	1268.5	101%
Human serum albumin	500 mg/dL	Positive	1285.0	103%
Ibuprofen	100 I..lg/mL	Positive	1294.0	104%
Oxalic acid	100 mg/dL	Positive	1289.5	103%
Riboflavin	7.5 mg/dL	Positive	1288.5	103%
Sodium chloride	1 g/dL	Positive	1275.5	102%
Urea	1.25 g/dL	Positive	1295.5	104%
pH	3	Positive	1238.0	99%
pH	4	Positive	1261.0	101%
pH	5	Positive	1258.5	101%
pH	6	Positive	1291.0	103%
pH	7	Positive	1273.5	102%
pH	8	Positive	1283.0	103%
pH	9	Positive	1283.0	103%
pH	10	Positive	1281.0	102%
pH	11	Positive	1276.0	102%
Specific Gravity	1.004 g/mL	Positive	1262.0	101%
Specific Gravity	1.007 g/mL	Positive	1267.5	101%
Specific Gravity	1.011 g/mL	Positive	1292.5	103%
Specific Gravity	1.014 g/mL	Positive	1287.0	103%
Specific Gravity	1.017 g/mL	Positive	1281.5	103%
Specific Gravity	1.022 g/mL	Positive	1309.0	105%
Specific Gravity	1.026 g/mL	Positive	1301.5	104%
Specific Gravity	1.030 g/mL	Positive	1304.0	104%
Specific Gravity	1.034 g/mL	Positive	1300.5	104%
Specific Gravity	1.038 g/mL	Positive	1239.0	111%

500 cutoff – 375 ng/mL Methamphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
Low Control	375 ng/mL	353.0	Negative	94%
Acetaminophen	100 ug/mL	359.5	Negative	96%
Acetone	1 g/dL	355.0	Negative	95%
Ascorbic acid	1 g/dL	359.0	Negative	96%
Aspirin	100 ug/mL	344.5	Negative	92%

Caffeine	100 ug/mL	366.5	Negative	98%
Creatinine	500 mg/dL	405.0	Negative	108%
Ethanol	1 g/dL	353.5	Negative	94%
Galactose	10 mg/dL	357.5	Negative	95%
Y -Globulin	500 mg/dL	367.0	Negative	98%
Glucose	3 g/dL	359.5	Negative	96%
Hemoglobin	150 mg/dL	375.0	Negative	100%
Human serum albumin	500 mg/dL	361.5	Negative	96%
Ibuprofen	100 I..lg/mL	353.5	Negative	94%
Oxalic acid	100 mg/dL	361.5	Negative	96%
Riboflavin	7.5 mg/dL	357.0	Negative	95%
Sodium chloride	1 g/dL	361.5	Negative	96%
Urea	1.25 g/dL	356.0	Negative	95%
pH	3	373.5	Negative	100%
pH	4	370.0	Negative	99%
pH	5	384.0	Negative	102%
pH	6	366.0	Negative	98%
pH	7	384.0	Negative	102%
pH	8	378.5	Negative	101%
pH	9	374.0	Negative	100%
pH	10	380.5	Negative	101%
pH	11	374.0	Negative	100%
Specific Gravity	1.004 g/mL	366.5	Negative	98%
Specific Gravity	1.007 g/mL	375.5	Negative	100%
Specific Gravity	1.011 g/mL	371.0	Negative	99%
Specific Gravity	1.014 g/mL	367.5	Negative	98%
Specific Gravity	1.017 g/mL	373.0	Negative	99%
Specific Gravity	1.022 g/mL	399.5	Negative	107%
Specific Gravity	1.026 g/mL	375.0	Negative	100%
Specific Gravity	1.030 g/mL	375.5	Negative	100%
Specific Gravity	1.034 g/mL	382.0	Negative	102%
Specific Gravity	1.038 g/mL	379.0	Negative	101%

500 cutoff – 625 ng/mL Methamphetamine control

Interference Compound	**Concentration**	**Qualitative**	**Semi-quantitative (ng/mL)**	**Semi-quantitative %Recovery**
High Control	625 ng/mL	Positive	619.0	99%
Acetaminophen	100 ug/mL	Positive	635.0	102%

Acetone	1 g/dL	Positive	632.5	101%
Ascorbic acid	1 g/dL	Positive	625.0	100%
Aspirin	100 ug/mL	Positive	613.0	98%
Caffeine	100 ug/mL	Positive	632.5	101%
Creatinine	500 mg/dL	Positive	651.0	104%
Ethanol	1 g/dL	Positive	630.5	101%
Galactose	10 mg/dL	Positive	628.5	101%
Y -Globulin	500 mg/dL	Positive	617.0	99%
Glucose	3 g/dL	Positive	620.0	99%
Hemoglobin	150 mg/dL	Positive	640.0	102%
Human serum albumin	500 mg/dL	Positive	625.0	100%
Ibuprofen	100 I..lg/mL	Positive	607.0	97%
Oxalic acid	100 mg/dL	Positive	619.5	99%
Riboflavin	7.5 mg/dL	Positive	638.0	102%
Sodium chloride	1 g/dL	Positive	615.0	98%
Urea	1.25 g/dL	Positive	638.0	102%
pH	3	Positive	656.0	105%
pH	4	Positive	646.0	103%
pH	5	Positive	646.5	103%
pH	6	Positive	631.0	101%
pH	7	Positive	646.5	103%
pH	8	Positive	644.0	103%
pH	9	Positive	639.5	102%
pH	10	Positive	639.5	102%
pH	11	Positive	625.5	100%
Specific Gravity	1.004 g/mL	Positive	630.5	101%
Specific Gravity	1.007 g/mL	Positive	629.5	101%
Specific Gravity	1.011 g/mL	Positive	637.0	102%
Specific Gravity	1.014 g/mL	Positive	623.5	100%
Specific Gravity	1.017 g/mL	Positive	634.0	101%
Specific Gravity	1.022 g/mL	Positive	634.5	102%
Specific Gravity	1.026 g/mL	Positive	657.0	105%
Specific Gravity	1.030 g/mL	Positive	646.0	103%
Specific Gravity	1.034 g/mL	Positive	652.0	104%
Specific Gravity	1.038 g/mL	Positive	661.5	106%

1000 cutoff – 750 ng/mL Methamphetamine control

Interference Compound	Concentration	Qualitative	Semi-quantitative (ng/mL)	Semi-quantitative %Recovery
Low Control	750 ng/mL	Negative	769.0	102%
Acetaminophen	100 ug/mL	Negative	764.0	102%
Acetone	1 g/dL	Negative	752.0	100%
Ascorbic acid	1 g/dL	Negative	764.5	102%
Aspirin	100 ug/mL	Negative	765.0	102%
Caffeine	100 ug/mL	Negative	776.0	103%
Creatinine	500 mg/dL	Negative	777.5	104%
Ethanol	1 g/dL	Negative	751.5	100%
Galactose	10 mg/dL	Negative	770.5	103%
Y -Globulin	500 mg/dL	Negative	766.5	102%
Glucose	3 g/dL	Negative	762.0	102%
Hemoglobin	150 mg/dL	Negative	769.0	103%
Human serum albumin	500 mg/dL	Negative	787.5	105%
Ibuprofen	100 I..lg/mL	Negative	773.0	103%
Oxalic acid	100 mg/dL	Negative	771.5	103%
Riboflavin	7.5 mg/dL	Negative	757.5	101%
Sodium chloride	1 g/dL	Negative	773.5	103%
Urea	1.25 g/dL	Negative	767.0	102%
pH	3	Negative	780.5	104%
pH	4	Negative	782.5	104%
pH	5	Negative	784.5	105%
pH	6	Negative	777.0	104%
pH	7	Negative	778.5	104%
pH	8	Negative	782.0	104%
pH	9	Negative	785.0	105%
pH	10	Negative	778.0	104%
pH	11	Negative	784.0	105%
Specific Gravity	1.004 g/mL	Negative	752.0	100%
Specific Gravity	1.007 g/mL	Negative	768.5	102%
Specific Gravity	1.011 g/mL	Negative	764.0	102%
Specific Gravity	1.014 g/mL	Negative	769.5	103%
Specific Gravity	1.017 g/mL	Negative	738.5	98%
Specific Gravity	1.022 g/mL	Negative	759.0	101%
Specific Gravity	1.026 g/mL	Negative	745.5	99%
Specific Gravity	1.030 g/mL	Negative	782.0	104%
Specific Gravity	1.034 g/mL	Negative	752.5	100%

Specific Gravity	1.038 g/mL	Negative	748.5	100%

1000 cutoff – 1250 ng/mL Methamphetamine control

Interference Compound	Concentration	Qualitative	Semi-quantitative (ng/mL)	Semi-quantitative %Recovery
High Control	1250 ng/mL	Positive	1219.0	98%
Acetaminophen	100 ug/mL	Positive	1267.5	101%
Acetone	1 g/dL	Positive	1223.0	98%
Ascorbic acid	1 g/dL	Positive	1197.0	96%
Aspirin	100 ug/mL	Positive	1245.0	100%
Caffeine	100 ug/mL	Positive	1262.5	101%
Creatinine	500 mg/dL	Positive	1276.5	102%
Ethanol	1 g/dL	Positive	1226.5	98%
Galactose	10 mg/dL	Positive	1245.0	100%
Y -Globulin	500 mg/dL	Positive	1233.5	99%
Glucose	3 g/dL	Positive	1249.0	100%
Hemoglobin	150 mg/dL	Positive	1281.0	102%
Human serum albumin	500 mg/dL	Positive	1232.5	99%
Ibuprofen	100 I..lg/mL	Positive	1201.0	96%
Oxalic acid	100 mg/dL	Positive	1238.0	99%
Riboflavin	7.5 mg/dL	Positive	1269.5	102%
Sodium chloride	1 g/dL	Positive	1247.0	100%
Urea	1.25 g/dL	Positive	1228.0	98%
pH	3	Positive	1274.5	102%
pH	4	Positive	1250.5	100%
pH	5	Positive	1247.5	100%
pH	6	Positive	1237.5	99%
pH	7	Positive	1252.0	100%
pH	8	Positive	1255.0	100%
pH	9	Positive	1244.5	100%
pH	10	Positive	1256.0	100%
pH	11	Positive	1261.0	101%
Specific Gravity	1.004 g/mL	Positive	1269.5	102%
Specific Gravity	1.007 g/mL	Positive	1260.5	101%
Specific Gravity	1.011 g/mL	Positive	1281.5	103%
Specific Gravity	1.014 g/mL	Positive	1242.5	99%
Specific Gravity	1.017 g/mL	Positive	1263.0	101%
Specific Gravity	1.022 g/mL	Positive	1271.0	102%

Specific Gravity	1.026 g/mL	Positive	1283.5	103%
Specific Gravity	1.030 g/mL	Positive	1306.5	105%
Specific Gravity	1.034 g/mL	Positive	1259.5	101%
Specific Gravity	1.038 g/mL	Positive	1305.5	104%

f. Assay cut-off:

There are two cutoff concentrations claimed for both amphetamine and methamphetamine: 500 ng/mL and 1000 ng/mL.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a method comparison study to evaluate the performance of the device for d-amphetamine and d-methamphetamine. The DRI amphetamines assay recognizes both amphetamine and methamphetamine equivalently and does not discriminate between the two drugs. This study evaluated 160 unaltered clinical samples by the DRI amphetamines assay and compared the results separately to GC/MS results for amphetamine and methamphetamine. The agreement between amphetamine GC/MS results and methamphetamine GC/MS results and the new device results for both qualitative and semi-quantitative modes of the device are listed in the tables below.

Qualitative (Total Samples) - 500 Cutoff (DRI vs. AMP GC/MS)

New Device (DRI)	**Low negative by GC/MS (less than -50%)**	**Near cutoff negative by GC/MS (between -50% and cutoff)**	**Near cutoff positive by GC/MS (between cutoff and +50%)**	**High positive by GC/MS (greater than +50%)**	**Percent Agreement with GC/MS**
Positive	34	24	14	49	100.0%
Negative	16	1	0	0	22.4%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	17	0	17

Positive New device (DRI)	58	63	121
Total	75	63	138

Discordant Samples

The method comparison samples were categorized based upon the d-amphetamine GC/MS concentration only. The table below identifies those samples with a d-amphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS -Amph (ng/mL)	GC/MS -Meth (ng/mL)	GC/MS -Total (ng/mL)	DRI (Neg/Pos)
500	2	47	1653	1700	Pos
500	9	68	1621	1689	Pos
500	10	68	334	402	Pos
500	11	69	1666	1735	Pos
500	12	69	1707	1776	Pos
500	13	70	444	514	Pos
500	14	70	1513	1583	Pos
500	15	76	1679	1755	Pos
500	16	82	533	615	Pos
500	17	83	481	564	Pos
500	21	100	538	638	Pos
500	22	100	675	775	Pos
500	23	109	1446	1555	Pos
500	26	123	661	784	Pos
500	27	128	503	631	Pos
500	28	128	1221	1349	Pos
500	29	141	1259	1400	Pos
500	30	148	942	1090	Pos
500	32	160	1254	1414	Pos
500	33	161	1415	1576	Pos
500	34	168	1319	1487	Pos
500	35	168	1595	1763	Pos
500	37	184	548	732	Pos
500	39	189	1067	1256	Pos
500	40	200	1024	1224	Pos
500	41	202	393	595	Pos

500	43	203	1230	1433	Pos
500	44	211	1421	1632	Pos
500	45	212	1241	1453	Pos
500	46	214	97	311	Pos
500	47	231	1782	2013	Pos
500	48	232	207	439	Pos
500	49	240	449	689	Pos
500	50	246	460	706	Pos
500	51	258	1029	1287	Pos
500	52	264	1642	1906	Pos
500	53	270	479	749	Pos
500	54	271	1338	1609	Pos
500	55	272	1080	1352	Pos
500	56	273	516	789	Pos
500	57	298	2772	3070	Pos
500	58	300	101	401	Pos
500	59	307	2411	2718	Pos
500	60	317	2668	2985	Pos
500	61	325	2828	3153	Pos
500	62	330	2543	2873	Pos
500	63	374	693	1067	Pos
500	64	380	709	1089	Pos
500	65	402	132	534	Pos
500	66	407	747	1154	Pos
500	67	417	1088	1505	Pos
500	68	426	1599	2025	Pos
500	69	450	828	1278	Pos
500	71	486	860	1346	Pos
500	72	490	1287	1777	Pos
500	73	493	1005	1498	Pos
500	74	494	924	1418	Pos
500	75	498	919	1417	Pos

Semi-Quantitative (Total Samples) - 500 Cutoff (DRI vs. AMP GC/MS)

New Device (DRI)	Low negative by GC/MS (less than -50%)	Near cutoff negative by GC/MS (between -50% and cutoff)	Near cutoff positive by GC/MS (between cutoff and +50%)	High positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
Positive	34	24	14	49	100.0%
Negative	16	1	0	0	22.7%

	Negative *GC/MS*	Positive *GC/MS*	Total
Negative New device (DRI)	17	0	17
Positive New device (DRI)	58	63	121
Total	75	63	138

Discordant Samples

The method comparison samples were categorized based upon the d-amphetamine GC/MS concentration only. The table below identifies those samples with a d-amphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS -Amph (ng/mL)	GC/MS -Meth (ng/mL)	GC/MS -Total (ng/mL)	DRI (Neg/Pos)
500	2	47	1653	1700	1661
500	9	68	1621	1689	1709
500	10	68	334	402	1462
500	11	69	1666	1735	1731
500	12	69	1707	1776	1711
500	13	70	444	514	567
500	14	70	1513	1583	1834
500	15	76	1679	1755	2010
500	16	82	533	615	649
500	17	83	481	564	630
500	21	100	538	638	1045

500	22	100	675	775	864
500	23	109	1446	1555	1719
500	26	123	661	784	816
500	27	128	503	631	654
500	28	128	1221	1349	1341
500	29	141	1259	1400	1667
500	30	148	942	1090	1192
500	32	160	1254	1414	1940
500	33	161	1415	1576	1958
500	34	168	1319	1487	2079
500	35	168	1595	1763	1839
500	37	184	548	732	868
500	39	189	1067	1256	1670
500	40	200	1024	1224	1439
500	41	202	393	595	596
500	43	203	1230	1433	1710
500	44	211	1421	1632	1767
500	45	212	1241	1453	1837
500	46	214	97	311	560
500	47	231	1782	2013	2952
500	48	232	207	439	518
500	49	240	449	689	634
500	50	246	460	706	636
500	51	258	1029	1287	1596
500	52	264	1642	1906	3035
500	53	270	479	749	744
500	54	271	1338	1609	1583
500	55	272	1080	1352	1823
500	56	273	516	789	685
500	57	298	2772	3070	1809
500	58	300	101	401	502
500	59	307	2411	2718	2183
500	60	317	2668	2985	1600
500	61	325	2828	3153	1764
500	62	330	2543	2873	2309
500	63	374	693	1067	1004
500	64	380	709	1089	965
500	65	402	132	534	765
500	66	407	747	1154	1243
500	67	417	1088	1505	1934
500	68	426	1599	2025	4546

500	69	450	828	1278	1391
500	71	486	860	1346	1398
500	72	490	1287	1777	8824
500	73	493	1005	1498	1831
500	74	494	924	1418	1649
500	75	498	919	1417	1356

Qualitative (Total Samples) - 1000 Cutoff (DRI vs. AMP GC/MS)

New Device (DRI)	Low negative by GC/MS (less than -50%)	Near cutoff negative by GC/MS (between -50% and cutoff)	Near cutoff positive by GC/MS (between cutoff and +50%)	High positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
Positive	40	15	19	20	97.5%
Negative	35	8	1	0	43.9%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	43	1	44
Positive New device (DRI)	55	39	94
Total	98	40	138

Discordant Samples

The method comparison samples were categorized based upon the d-amphetamine GC/MS concentration only. The table below identifies those samples with a d-amphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS - Amph (ng/mL)	GC/MS - Meth (ng/mL)	GC/MS - Total (ng/mL)	DRI (Neg/Pos)
1000	2	47	1653	1700	Pos
1000	9	68	1621	1689	Pos
1000	10	68	334	402	Pos

1000	11	69	1666	1735	Pos
1000	12	69	1707	1776	Pos
1000	14	70	1513	1583	Pos
1000	15	76	1679	1755	Pos
1000	21	100	538	638	Pos
1000	23	109	1446	1555	Pos
1000	28	128	1221	1349	Pos
1000	29	141	1259	1400	Pos
1000	30	148	942	1090	Pos
1000	32	160	1254	1414	Pos
1000	33	161	1415	1576	Pos
1000	34	168	1319	1487	Pos
1000	35	168	1595	1763	Pos
1000	39	189	1067	1256	Pos
1000	40	200	1024	1224	Pos
1000	43	203	1230	1433	Pos
1000	44	211	1421	1632	Pos
1000	45	212	1241	1453	Pos
1000	47	231	1782	2013	Pos
1000	51	258	1029	1287	Pos
1000	52	264	1642	1906	Pos
1000	54	271	1338	1609	Pos
1000	55	272	1080	1352	Pos
1000	57	298	2772	3070	Pos
1000	59	307	2411	2718	Pos
1000	60	317	2668	2985	Pos
1000	61	325	2828	3153	Pos
1000	62	330	2543	2873	Pos
1000	66	407	747	1154	Pos
1000	67	417	1088	1505	Pos
1000	68	426	1599	2025	Pos
1000	69	450	828	1278	Pos
1000	71	486	860	1346	Pos
1000	72	490	1287	1777	Pos
1000	73	493	1005	1498	Pos
1000	74	494	924	1418	Pos
1000	75	498	919	1417	Pos
1000	76	500	1989	2489	Pos
1000	77	513	938	1451	Pos

1000	78	522	957	1479	Pos
1000	79	541	1013	1554	Pos
1000	82	572	1050	1622	Pos
1000	83	576	1052	1628	Pos
1000	85	595	2396	2991	Pos
1000	88	656	2533	3189	Pos
1000	89	715	2415	3130	Pos
1000	93	771	1190	1961	Pos
1000	94	780	287	1067	Pos
1000	95	814	2984	3798	Pos
1000	96	816	0	816	Pos
1000	97	929	0	929	Pos
1000	98	998	367	1365	Pos
1000	99	1101	0	1101	Neg

Semi-quantitative (Total Samples) - 1000 Cutoff (DRI vs. AMP GC/MS)

New Device (DRI)	**Low negative by GC/MS (less than -50%)**	**Near cutoff negative by GC/MS (between -50% and cutoff)**	**Near cutoff positive by GC/MS (between cutoff and +50%)**	**High positive by GC/MS (greater than +50%)**	**Percent Agreement with GC/MS**
Positive	41	15	19	20	97.5%
Negative	34	8	1	0	42.9%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	42	1	43
Positive New device (DRI)	56	39	95
Total	98	40	138

Discordant Samples

The method comparison samples were categorized based upon the d-amphetamine GC/MS concentration only. The table below identifies those samples with a d-amphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS - Amph (ng/mL)	GC/MS - Meth (ng/mL)	GC/MS - Total (ng/mL)	DRI (Neg/Pos)
1000	2	47	1653	1700	1661
1000	9	68	1621	1689	1709
1000	10	68	334	402	1462
1000	11	69	1666	1735	1731
1000	12	69	1707	1776	1711
1000	14	70	1513	1583	1834
1000	15	76	1679	1755	2010
1000	21	100	538	638	1045
1000	23	109	1446	1555	1719
1000	28	128	1221	1349	1341
1000	29	141	1259	1400	1667
1000	30	148	942	1090	1192
1000	32	160	1254	1414	1940
1000	33	161	1415	1576	1958
1000	34	168	1319	1487	2079
1000	35	168	1595	1763	1839
1000	39	189	1067	1256	1670
1000	40	200	1024	1224	1439
1000	43	203	1230	1433	1710
1000	44	211	1421	1632	1767
1000	45	212	1241	1453	1837
1000	47	231	1782	2013	2952
1000	51	258	1029	1287	1596
1000	52	264	1642	1906	3035
1000	54	271	1338	1609	1583
1000	55	272	1080	1352	1823
1000	57	298	2772	3070	1809
1000	59	307	2411	2718	2183
1000	60	317	2668	2985	1600
1000	61	325	2828	3153	1764
1000	62	330	2543	2873	2309
1000	63	374	693	1067	1004
1000	66	407	747	1154	1243
1000	67	417	1088	1505	1934
1000	68	426	1599	2025	4546
1000	69	450	828	1278	1391

1000	71	486	860	1346	1398
1000	72	490	1287	1777	8824
1000	73	493	1005	1498	1831
1000	74	494	924	1418	1649
1000	75	498	919	1417	1356
1000	76	500	1989	2489	45791
1000	77	513	938	1451	1589
1000	78	522	957	1479	1818
1000	79	541	1013	1554	1662
1000	82	572	1050	1622	1823
1000	83	576	1052	1628	1721
1000	85	595	2396	2991	3655
1000	88	656	2533	3189	1880
1000	89	715	2415	3130	1785
1000	93	771	1190	1961	4848
1000	94	780	287	1067	1441
1000	95	814	2984	3798	3117
1000	96	816	0	816	1218
1000	97	929	0	929	1047
1000	98	998	367	1365	1651

Qualitative (Total Samples) - 500 Cutoff (DRI vs. MAMP GC/MS)

New Device (DRI)	**Low negative by GC/MS (less than -50%)**	**Near cutoff negative by GC/MS (between -50% and cutoff)**	**Near cutoff positive by GC/MS (between cutoff and +50%)**	**High positive by GC/MS (greater than +50%)**	**Percent Agreement with GC/MS**
Positive	3	11	11	60	100.0%
Negative	19	7	0	0	65.0%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	26	0	26
Positive New device (DRI)	14	71	85
Total	40	71	111

Discordant Samples

The method comparison samples were categorized based upon the d-methamphetamine GC/MS concentration only. The table below identifies those samples with a d-methamphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS -Amph (ng/mL)	GC/MS -Meth (ng/mL)	GC/MS -Total (ng/mL)	DRI (Neg/Pos)
500	16	101	300	401	Pos
500	17	132	402	534	Pos
500	21	207	232	439	Pos
500	23	287	780	1067	Pos
500	27	334	68	402	Pos
500	29	339	1142	1481	Pos
500	30	356	1203	1559	Pos
500	31	367	998	1365	Pos
500	34	393	202	595	Pos
500	36	444	70	514	Pos
500	37	449	240	689	Pos
500	38	460	246	706	Pos
500	39	479	270	749	Pos
500	40	481	83	564	Pos

Semi-quantitative (Total Samples) - 500 Cutoff (DRI vs. MAMP GC/MS)

New Device (DRI)	Low negative by GC/MS (less than -50%)	Near cutoff negative by GC/MS (between -50% and cutoff)	Near cutoff positive by GC/MS (between cutoff and +50%)	High positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
Positive	3	11	11	60	100.0%
Negative	19	7	0	0	65.0%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	26	0	26
Positive New device (DRI)	14	71	85
Total	40	71	111

Discordant Samples

The method comparison samples were categorized based upon the d-methamphetamine GC/MS concentration only. The table below identifies those samples with a d-methamphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	**Sample #**	**GC/MS -Amph (ng/mL)**	**GC/MS -Meth (ng/mL)**	**GC/MS -Total (ng/mL)**	**DRI (Neg/Pos)**
500	16	101	300	401	502
500	17	132	402	534	765
500	21	207	232	439	518
500	23	287	780	1067	1441
500	27	334	68	402	1462
500	29	339	1142	1481	1810
500	30	356	1203	1559	1797
500	31	367	998	1365	1651
500	34	393	202	595	596
500	36	444	70	514	567
500	37	449	240	689	634
500	38	460	246	706	636
500	39	479	270	749	744
500	40	481	83	564	630

Qualitative (Total Samples) - 1000 Cutoff (DRI vs. MAMP GC/MS)

New Device (DRI)	**Low negative by GC/MS (less than**	**Near cutoff negative by GC/MS (between -50% and**	**Near cutoff positive by GC/MS (between cutoff and**	**High positive by GC/MS (greater than +50%)**	**Percent Agreement with GC/MS**

	-50%)	cutoff)	+50%)		
Positive	5	9	22	31	100.0%
Negative	35	9	0	0	75.9%

	Negative *GC/MS*	**Positive *GC/MS***	**Total**
Negative New device (DRI)	44	0	44
Positive New device (DRI)	14	53	67
Total	58	53	111

Discordant Samples

The method comparison samples were categorized based upon the d-methamphetamine GC/MS concentration only. The table below identifies those samples with a d-methamphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	**Sample #**	**GC/MS -Amph (ng/mL)**	**GC/MS -Meth (ng/mL)**	**GC/MS -Total (ng/mL)**	**DRI (Neg/Pos)**
1000	23	287	780	1067	Pos
1000	27	334	68	402	Pos
1000	29	339	1142	1481	Pos
1000	30	356	1203	1559	Pos
1000	31	367	998	1365	Pos
1000	45	538	100	638	Pos
1000	49	693	374	1067	Pos
1000	51	747	407	1154	Pos
1000	52	828	450	1278	Pos
1000	53	860	486	1346	Pos
1000	54	919	498	1417	Pos
1000	55	924	494	1418	Pos
1000	56	938	513	1451	Pos
1000	57	942	148	1090	Pos
1000	58	957	522	1479	Pos

Semi-Quantitative (Total Samples) - 1000 Cutoff (DRI vs.

MAMP GC/MS)

New Device (DRI)	Low negative by GC/MS (less than -50%)	Near cutoff negative by GC/MS (between -50% and cutoff)	Near cutoff positive by GC/MS (between cutoff and +50%)	High positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
Positive	5	10	22	31	100.0%
Negative	35	8	0	0	74.1%

	Negative *GC/MS*	Positive *GC/MS*	Total
Negative New device (DRI)	43	0	43
Positive New device (DRI)	15	53	68
Total	58	53	111

Discordant Samples

The method comparison samples were categorized based upon the d-methamphetamine GC/MS concentration only. The table below identifies those samples with a d-methamphetamine GC/MS concentration below the cutoff, in which the observed result on the DRI amphetamines assay was positive.

Cutoff Value (ng/mL)	Sample #	GC/MS - Amph (ng/mL)	GC/MS - Meth (ng/mL)	GC/MS - Total (ng/mL)	DRI (Neg/Pos)
1000	23	287	780	1067	1441
1000	27	334	68	402	1462
1000	29	339	1142	1481	1810
1000	30	356	1203	1559	1797
1000	31	367	998	1365	1651
1000	45	538	100	638	1045
1000	49	693	374	1067	1004
1000	51	747	407	1154	1243
1000	52	828	450	1278	1391
1000	53	860	486	1346	1398

1000	54	919	498	1417	1356
1000	55	924	494	1418	1649
1000	56	938	513	1451	1589
1000	57	942	148	1090	1192
1000	58	957	522	1479	1818

b. Matrix comparison:

Not applicable, human urine is the only sample matrix used.

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.