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

A. 510(k) Number:

k130213

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine, Secobarbital, Oxazepam, Benzoylecgonine, Methadone, Methamphetamine, Opiates, Phencyclidine, Cannabinoid (THC)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

LumiQuick Diagnostics Inc.

F. Proprietary and Established Names:

QuickProfile Single Drugs of Abuse Screen Device
QuickProfile Multi-Drugs of Abuse Screen Device

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR part 862.3100 Amphetamine test system	Toxicology (91)
DIS	Class II	21 CFR part 862.3150 Barbiturate test system	Toxicology (91)
JXM	Class II	21 CFR part 862.3170 Benzodiazepine test system	Toxicology (91)
DIO	Class II	21 CFR part 862.3250 Cocaine and cocaine metabolite test system	Toxicology (91)
DJR	Class II	21 CFR part 862.3620 Methadone test system	Toxicology (91)

DJC	Class II	21 CFR part 862.3610 Methamphetamine test system	Toxicology (91)
DJG	Class II	21 CFR part 862.3650 Opiate test system	Toxicology (91)
LCM	Unclassified	Phencyclidine	Toxicology (91)
LDJ	Class II	21 CFR part 862.3870 Cannabinoid test system.	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Please see indications for use below.

2. Indication(s) for use:

   LumiQuick's QuickProfile Single Drugs of Abuse and QuickProfile Multi-Drugs of Abuse Screen Devices are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to nine of the following drugs in a variety of combinations in human urine. Both devices are available in test strip, dip panel, cassette panel and cup formats. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

AMP	Amphetamine	1000 ng/ml
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	300 ng/ml
MTD	Methadone	300 ng/ml
MAMP	Methamphetamine	1000 ng/ml
OPI	Morphine	300 ng/ml
PCP	Phencyclidine	25 ng/ml
THC	THC 11-nor-Δ^9-THC-9-COOH	50 ng/ml

   These devices are intended for prescription use only. These assays provide 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) or Liquid Chromatography / Mass Spectrometry (LC/MS) are 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 indicated.

3. Special conditions for use statement(s):

   For Prescription Use.

4. Special instrument requirements:

Not applicable; these are visually read single use devices

I. Device Description:

The QuickProfile Single Drugs of Abuse Device and Quick Profile Multi-Drugs of Abuse Screen Device are one-step, colloidal gold based chromatographic immunoassays for the rapid, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and Marijuana in human urine. The single and multi-test devices contain one or more than one test strip. Both devices are available in test strip, dip panel, cassette panel and cup formats.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Innovacon Spectrum II Test Card

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

k061718

3. Comparison with predicate:

Item	QuickProfile Single Drugs of Abuse and QuickProfile Multi-Drugs of Abuse Screen Devices (Candidate Device)	Innovacon Spectrum II Test Card (Predicate-k061718)
Intended Use	Rapid chromatographic immunoassays for the qualitative and simultaneous detection of one or more drugs of abuse in a variety of combinations in human urine. The devices are intended for prescription use only.	Same
Method of Measurement	Test strip, Dip panel, Cassette panel, and Cup	Test card; Cup
Test Principle	Enzyme Immunoassay (EIA)	Same
Sample Matrix	Urine	Same
Time	5 Minutes	Same
Cutoff Levels	Amphetamine 1000 ng/ml	Same

	Secobarbital 300 ng/ml	
	Oxazepam 300 ng/ml	
	Benzoylecgonine 300 ng/ml	
	Methadone 300 ng/ml	
	Methamphetamine 1000 ng/ml	
	Opiates 300 ng/ml	
	Phencyclidine 25 ng/ml	
	THC 50 ng/ml	

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

None were referenced.

L. Test Principle:

The QuickProfile Single Drugs of Abuse and QuickProfile Multi-Drugs of Abuse Screen Device are one-step immunoassays in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs that may be present in urine. The single and multi-test devices contain one or more than one test strips (single drug or 2 drugs per test strip) in the dip panel, cassette panel and cup formats. The drug-protein conjugates are pre-coated on the test band of the membrane and the drug mouse antibody-colloidal gold conjugate pads are placed at one end of the membrane. In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates move along with the sample solution by capillary action to the immobilized drug-protein conjugate zones on the test band region. The colored antibody-gold conjugates then attach to the drug-protein conjugates to form visible lines as the antibodies complex with the drug conjugates. Therefore, the formation of the visible precipitant in the test band occurs when the test urine is negative for the drug. When drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

      1. Intra-assay precision around the cutoff

A commercially available panel (blinded) of GC/MS confirmed urine-based control samples containing multiple drugs were used for the study. These samples contained the following concentrations: Negative, 50%, 75%, 100%, 125%, 150%, and 200% of the cutoff level of drug analytes. Two additional concentrations were prepared using these controls to generate samples at 25% and 175% of the cut off level. Test Strip, Dip Panel, Cassette Panel and Cup formats, for 9 target drugs were tested. Each control level was tested in duplicates for ten consecutive days, 3 lots per format, one device lot per professional (3 professionals). Results were consistent between lots. Representative lot results are presented in the tables below:

Amphetamine (AMP):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100

1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Opiates 300 (OPI):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Benzodiazepines (BZO):

Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100

75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cocaine (COC):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100

450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Methamphetamine (MAMP):

Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100
500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
250	25%	20	20		100

500	50%	20	20		100
750	75%	20	20		100
1000	100%	20		20	100
1250	125%	20		20	100
1500	150%	20		20	100
1750	175%	20		20	100
2000	200%	20		20	100

Marijuana (THC):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
12.5	25%	20	20		100
25	50%	20	20		100
37.5	75%	20	20		100
50	100%	20		20	100
62.5	125%	20		20	100
75	150%	20		20	100
87.5	175%	20		20	100
100	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
12.5	25%	20	20		100
25	50%	20	20		100
37.5	75%	20	20		100
50	100%	20		20	100
62.5	125%	20		20	100
75	150%	20		20	100
87.5	175%	20		20	100
100	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
12.5	25%	20	20		100
25	50%	20	20		100
37.5	75%	20	20		100
50	100%	20		20	100
62.5	125%	20		20	100
75	150%	20		20	100

87.5	175%	20		20	100
100	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
12.5	25%	20	20		100
25	50%	20	20		100
37.5	75%	20	20		100
50	100%	20		20	100
62.5	125%	20		20	100
75	150%	20		20	100
87.5	175%	20		20	100
100	200%	20		20	100

Barbiturate (BAR):

Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Phencyclidine (PCP):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
6.25	25%	20	20		100
12.5	50%	20	20		100
18.75	75%	20	20		100
25	100%	20		20	100
31.25	125%	20		20	100
37.5	150%	20		20	100
43.75	175%	20		20	100
50	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
6.25	25%	20	20		100

12.5	50%	20	20		100
18.75	75%	20	20		100
25	100%	20		20	100
31.25	125%	20		20	100
37.5	150%	20		20	100
43.75	175%	20		20	100
50	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
6.25	25%	20	20		100
12.5	50%	20	20		100
18.75	75%	20	20		100
25	100%	20		20	100
31.25	125%	20		20	100
37.5	150%	20		20	100
43.75	175%	20		20	100
50	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
6.25	25%	20	20		100
12.5	50%	20	20		100
18.75	75%	20	20		100
25	100%	20		20	100
31.25	125%	20		20	100
37.5	150%	20		20	100
43.75	175%	20		20	100
50	200%	20		20	100

Methadone (MTD):
Test Strip

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100

525	175%	20		20	100
600	200%	20		20	100

Dip Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cassette Panel

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

Cup

Conc (ng/ml)	Cut-off %	No. of Tested	No. of Negative	No. of Preliminary	% Agreement
0	Negative	20	20		100
75	25%	20	20		100
150	50%	20	20		100
225	75%	20	20		100
300	100%	20		20	100
375	125%	20		20	100
450	150%	20		20	100
525	175%	20		20	100
600	200%	20		20	100

b. Linearity/assay reportable range:

Not Applicable.

c. *Traceability, Stability, Expected values (controls, , calibrators, or methods):*
External controls are not supplied with this device. The labeling states that users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

Stability
Accelerated and real time studies have been conducted for the QuickProfile Single Drug of Abuse and QuickProfile Multi-Drugs of Abuse Screen Devices. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims the following expiration date for the unopened (shelf-life) stability: 18 months for all formats (test strip, cassette panel, cup and dip panel).

For open pouch stability the user is instructed in the labeling as follows: "Do not open pouches until ready to perform the assay."

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*
Interference was evaluated by spiking various concentrations of each substance into GC/MS confirmed urine-based control material at the following levels: Negative, 50% and 150% of cutoff. Compounds chemically related to each drug were tested to determine possible interference. Each compound was tested in three replicates. The highest concentration at which each substance does not interfere is presented below for each substance:

Compound	Concentration (µg/mL)
Acetaminophen	100
Acetone	200
Albumin	50,000
Amitriptyline	100
Ampicillin	100
Aspartame	100
Aspirin	100
Atropine	100
Benzocaine	100
Bilirubin	150
Caffeine	100
Chloroquine	100
Chlorpheniramine	100
Creatinine	100
Dextromethorphan	100
Dextrorphan tartrate	100
4-Dimethyllaminoantiyrine	100

Dopamine	100
(+/-)-Ephedrine	100
(-)-Ephedrine	100
Erythromycin	100
Ethanol	1000
Furosemide	100
Glucose	1,200
Guaiacol Glyceryl Ether	100
Hemoglobin	200,000
Ibuprofen	100
Imipramine	100
Isoproterenol	100
Lidocaine	100
Methadone	100
N-Methyl-Ephedrine	100
(+)-Naproxen	100
Oxalic Acid	100
Penicillin-G	100
Pheniramine	100
Phenothiazine	100
L-Phenylephrine	100
b-Phenylethyl-amine	100
Procaine	100
Protonix	100
Pseudoephedrine	100
Ranitidine	100
Quinidine	100
Sulindac	100
Tyramine	100
Vitamin C (Ascorbic Acid)	100

Cross-reactivity was tested by adding various drugs, drug metabolites, and other structure-similar compounds that are likely to be present in the urine. All compounds were prepared in a drug-free pool of human urine. Each compound that indicated positive results was diluted until negative results were observed and the minimum level of cross reactivity was identified. Each compound was tested in replicates of three. Results are provided below:

Amphetamine related compounds	Concentration (ng/ml)	% Cross Reactivity
d-Amphetamine	1000	100
l-Amphetamine	30,000	3.33
d-Methamphetamine	>100,000	< 1
l-Methamphetamine	>100,000	< 1
3,4-Methylenediioxyamphetamine (MDA)	2,500	40
3,4-Methylenediioxy-methamphetamine (MDMA)	>100,000	< 1

3,4-Methylenediioxyethylamphetamine (MDEA)	>100,000	< 1

Opiates 300 related compounds	Concentration (ng/ml)	% Cross Reactivity
Morphine	300	100
Codeine	300	100
Diacetyl Morphin (Heroin)	1,250	24
Ethylmorphine	300	100
Hydromorphone	1,000	30
Hydrocodone	1,250	24
Oxymorphon	10,000	3
Oxycodone	>100,000	< 0.3
Merperidine	>100,000	<0.3
6-Acetylmorphine	100	300
Morphine-3-glucuronid	300	100
Nalbupine	>100,000	< 0.3
Nalorphine	750	40
Naloxone	25,000	1.2
Natrexone	100,000	0.3
Normorphone	2,000	15
Procaine	>100,000	< 0.3

Benzodiazepines related compounds	Concentration (ng/ml)	% Cross Reactivity
Oxazepam	300	100
Alprazolam	300	100
Bromazepam	1,000	30
Chlordiazepoxide	300	100
Clobazam	300	100
Clonazepam	2,000	15
Diazepam	300	100
Estazolam	500	60
Fentanyl	>100,000	< 0.3
Flunitrazepam	300	100
Flurazepam	>100,000	< 0.3
Lorazepam	1,000	30
Lormetazepam	1,000	30
Midazolam	>100,000	< 0.3
Nitrazepam	100	300
Nordiazepam	500	60
Prazepam	>100,000	< 0.3
Temazepam	300	100
Triazolam	1,000	30

Cocaine related compounds	Concentration (ng/ml)	% Cross Reactivity
Benzoylecgonine	300	100
Cocaine	300	100
Ecgonine	>100,000	< 0.3
Ecgonine Methyl Ester	>100,000	< 0.3

Methamphetamine related compounds	Concentration (ng/ml)	% Cross Reactivity
(+)-Methamphetamine	1,000	100
d-Amphetamine	100,000	1.00
Chloroquine	>100,000	< 1
(+/-) Ephedrine	>100,000	< 1
(-)-Methamphetamine	10,000	10
3,4-Methylenediioxy-methamphetamine (MDMA)	1,000	< 1
3,4-Methylenediioxyamphetamine (MDA)	>100,000	100
3,4-Methylenediioxyethylamphetamine (MDEA)	10,000	10
(+/-) N-Methyl-1-(3,4-methylenedioxyphenyl)-2-butanamine (MBDB)	50,000	2

THC related compounds	Concentration (ng/ml)	% Cross Reactivity
11-nor-Δ9-THC-9-COOH	50	100
Δ8-tetrahydrocannabinol	50,000	0.10
Δ9-tetrahydrocannabinol	500	10
11-hydroxy-Δ9-THC	50,000	0.10
Cannabinol	>100,000	< 0.05
Cannabidiol	>100,000	< 0.05

Barbiturates related compounds	Concentration (ng/ml)	% Cross Reactivity
Secobarbital	300	100
Amobarbital	150	200
Butalbital	2,000	15
Pentobarbital	300	100
Phenobarbital	300	100

PCP related compounds	Concentration (ng/ml)	% Cross Reactivity
Phencyclidine	25	100
Cis-Tramadol	10,000	0.25

Dextromethorphan	50,000	0.05
N-Desmethyl-cis-tramadol	10,000	0.25

Methadone related compounds	Concentration (ng/ml)	% Cross Reactivity
Methadone	300	100
Doxylamine	>100,000	< 0.3
EDDP	>100,000	< 0.3

pH and Specific Gravity

To test for possible positive and/or negative interference from pH, urine samples containing drug concentrations of 0%, 75%, 125% and 150% of cutoff and with a pH of 3.0, 5.0, 6.5, 7.5 and 8.5 were used. Three replicates per sample were tested. No positive or negative interference due to pH was observed.

To test for possible positive and/or negative interference from specific gravity, urine samples having specific gravity of 1.000-1.009, 1.010-1.020, 1.021-1.029 and ≥1.030 were used. The samples were spiked to negative, 75%, 125%, and 150% of cutoff of all drug analytes. No positive or negative interference due to specific gravity was observed.

f. Assay cut-off:

A separate cut-off study was conducted similarly to the precision study above, with similar results obtained. See precision studies above in section M.1.a.

2. Comparison studies:

a. Method comparison with predicate device:

The study was performed using commercially available blinded-level and unaltered clinical urine specimens confirmed by GC/MS or LC/MS methodology. Tests were performed by 3 lab technicians. A minimum of 41 negative urine and 43 positive urine samples for each analyte (drug) were tested in duplicate in the following formats: Cup, Dip Panel, Test Strip and Cassette Panel. The results are presented below:

Amphetamine comparison with GC/MS value:

AMP		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0

Test Strip	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0

Barbiturates (BAR) comparison with GC/MS value:

BAR		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	5	41	100.0
	-	34	16	6	0	0	100.0
Dip Panel	+	0	0	0	5	41	100.0
	-	34	16	6	0	0	100.0
Test Strip	+	0	0	0	5	41	100.0
	-	34	16	6	0	0	100.0
Cassette Panel	+	0	0	0	5	41	100.0
	-	34	16	6	0	0	100.0

Benzodiazepines (BZO) comparison with GC/MS value:

BZO		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	10	59	100.0
	-	34	8	12	0	0	100.0
Dip Panel	+	0	0	0	10	59	100.0
	-	34	8	12	0	0	100.0
Test Strip	+	0	0	0	10	59	100.0
	-	34	8	12	0	0	100.0
Cassette Panel	+	0	0	0	10	59	100.0
	-	34	8	12	0	0	100.0

Cocaine (COC) comparison with GC/MS value:

COC		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	9	39	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	9	39	100.0
	-	34	5	10	0	0	100.0
Test Strip	+	0	0	0	9	39	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	9	39	100.0
	-	34	5	10	0	0	100.0

Methadone (MTD) comparison with GC/MS value:

MTD		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	8	35	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	8	35	100.0
	-	34	5	10	0	0	100.0
Test Strip	+	0	0	0	8	35	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	8	35	100.0
	-	34	5	10	0	0	100.0

Methamphetamine (MAMP) comparison with GC/MS value:

MAMP		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0
Test Strip	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	10	40	100.0
	-	34	5	10	0	0	100.0

Opiates 300 (OPI) comparison with GC/MS value:

OPI 300		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	10	39	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	10	39	100.0
	-	34	5	10	0	0	100.0
Test Strip	+	0	0	0	10	39	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	10	39	100.0
	-	34	5	10	0	0	100.0

Phencyclidine (PCP) comparison with GC/MS value:

PCP		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	4	42	100.0
	-	34	2	5	0	0	100.0
Dip Panel	+	0	0	0	4	42	100.0

	-	34	2	5	0	0	100.0
Test Strip	+	0	0	0	4	42	100.0
	-	34	2	5	0	0	100.0
Cassette Panel	+	0	0	0	4	42	100.0
	-	34	2	5	0	0	100.0

Marijuana (THC) comparison with GC/MS value:

THC		Drug-Free Urine	< -50% of the cut-off	-50% of the cut-off to the cut-off	Cut-off to +50% of the cutoff	> +50% of the cut-off	% Agreement
Cup	+	0	0	0	10	37	100.0
	-	34	5	10	0	0	100.0
Dip Panel	+	0	0	0	10	37	100.0
	-	34	5	10	0	0	100.0
Test Strip	+	0	0	0	10	37	100.0
	-	34	5	10	0	0	100.0
Cassette Panel	+	0	0	0	10	37	100.0
	-	34	5	10	0	0	100.0

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.