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

A. 510(k) Number:
k050024

B. Purpose for Submission:
New Device

C. Measurands:
Amphetamine, Barbiturates, Benzodiazepines, Marijuana, Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Phencyclidine, and Tricyclic Antidepressants

D. Type of Test:
Qualitative immunoassay

E. Applicant:
Guangzhou Wondfo Biotech Co, Ltd.

F. Proprietary and Established Names:
One Step Urine Test for Amphetamine, Barbiturates, Benzodiazepines, Cannabinoids, Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Opiates, Phencyclidine, and Tricyclic Antidepressants.

One Step Multi-Drug Urine Test Panel

G. Regulatory Information:
1. <u>Regulation section:</u>
   21 CFR 862.3100, 862.3150, 862.3170, 862.3870, 862.3250, 862.3620, 862.3610, 862.3640, 862.3650, 862.3910
2. <u>Classification:</u>
   All class II
3. <u>Product Codes:</u>
   DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DPK, DJG, LCM, LFG
4. <u>Panel:</u>
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   One Step Multiple Drugs of Abuse Assays is used for the qualitative determination of the following drugs of abuse in urine:

Product Name	Cutoff
Amphetamine (amphetamine)	1000 ng/ml
Barbiturates (secobarbital)	300 ng/ml
Benzodiazipines (oxazepam)	300 ng/ml
Cocaine (benzoylecgonine)	300 ng/ml
Methamphetamine (methamphetamine)	1000 ng/ml
Morphine (morphine)	300 ng/ml
Opiates (morphine)	2000 ng/ml
Methadone (methadone)	300 ng/ml
Methylenedioxymethamphetamine (methylenedioxymethamphetamine)	500 ng/ml
Phencyclidine (phencyclidine)	25 ng/ml
Tricyclic antidepressant drugs (nortriptyline)	1000 ng/ml
Cannabinoids (tetrahydrocannabinol-COOH)	50 ng/ml

   The configurations of the One Step Multiple Drugs of Abuse Assays are available in any combination of the above tests. These devices are intended to be used by healthcare professionals only. For in vitro diagnostic use. Measurements obtained by this device are used in the diagnosis and treatment of use or overdose of the drugs listed above.

   This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

3. Special condition for use statement(s):

The Guangzhou Wondfo assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The assay is not designated for use in point-of-care settings.

Tests for barbiturates, benzodiazepines, opiates, and tricyclic antidepressants cannot distinguish between abused drugs and certain prescribed medications.

Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:
Not applicable. The devices are visually read single-use devices.

I. Device Description:
The sponsor has included data from three different configurations, all of which use the same strip(s). One configuration is a single-use dipstick device. Operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip. The second configuration combines from 2 to 12 strips in a multi-drug urine test panel. Operators dip the test strips into the urine and the reaction is initiated by movement of the sample through the test strips. The third configuration uses the same strips in a cassette format. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

J. Substantial Equivalence Information:
1. Predicate device name(s):
ACON, Inc One Step Drug Screening Test Card
2. Predicate K number(s):
K020771

3. Comparison with predicate:

    Both devices are for the qualitative determination of the same analyte(s) in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices. The reagent formulations vary between the two devices.

Similarities		
Item	**Device**	**Predicate**
Calibrator	Same	Amphetamine (d-amphetamine) Methamphetamine (d-methamphetamine) Cocaine (Benzoylecgonine) Cannabinoids (11-nor-delta-9-THC-9-COOH) Phencyclidine (Phencyclidine) Morphine (Morphine) Opiates (Morphine) Methadone (Methadone) Barbiturates (Secobarbital) Benzodiazepines (Oxazepam)
Antibodies	Same	Mouse, Monoclonal
Methodology	Same	Qualitative Lateral Flow Immunochromatographic
Internal Control	Same	Procedural control indicates adequate sample volume and integrity of the strip
Differences		
Item	**Device**	**Predicate**
Calibrator	TCA (Nortryptyline) MDMA (Methylenedioxy methamphetamine)	TCA, MDMA not included
Point of Care Use	No	Yes
Configurations	Strip, Cassette, Multi-Drug Test Panel	Test Card, Test Card with Integrated Cup

K. Standard/Guidance Document Referenced (if applicable):
The sponsor did not reference any standards in their submission.

L. Test Principle:
The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

Description of the test antibodies: monoclonal mouse antibody against d-amphetamine, d-methamphetamine, Benzoylecgonine, 11-nor-delta-9-THC-9-COOH, Phencyclidine, Morphine (for both the morphine and opiates assay), Methadone, Secobarbital, Oxazepam, Nortryptyline, and Methylenedioxymethamphetamine.

Description of the control line antibody: Polyclonal Goat anti-Mouse

M. Performance Characteristics (if/when applicable):
   1. Analytical performance:
       a. *Precision/Reproducibility:*

           To assess the precision of the device, the sponsor used both spiked and clinical samples. The spiked samples were prepared at the following concentrations: cutoff – 50%, cutoff – 25%, cutoff, cutoff +25%, and the cutoff + 50%. All samples were analyzed with GC-MS to confirm the concentration. Each concentration was then tested using three lots of the candidate device. For each drug, thirty samples (five clinical and 25 spiked) were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot. See summary data below.

           Specimen description: drug free urine spiked with d-amphetamine, d-methamphetamine, benzoylecgonine, 11-nor-delta-9-THC-9-COOH, phencyclidine, morphine (for both the morphine and opiates assay), methadone, secobarbital, oxazepam, nortryptyline, and methylenedioxymethamphetamine. The sponsor also used clinical samples containing the same compounds. The study protocol was the same for all 12 analytes:

           Number of days: one
           Replicates per day: at each concentration, 90 replicates per lot
           Lots of product used: three
           Number of operators: three
           Operator: laboratorian
           Testing Facility: manufacturer

           Results of the studies are presented below:

Cocaine Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	82/8
300	90	53/37
375	90	13/77
450	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	80/10
300	90	36/54
375	90	13/77
450	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	80/10
300	90	36/54
375	90	13/77
450	90	0/90

Barbiturates Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	79/11
300	90	42/48
375	90	18/72
450	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	79/11
300	90	42/48
375	90	18/72
450	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	79/11
300	90	42/48
375	90	18/72
450	90	0/90

Cannabinoid (THC) Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Opiates Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
1000	90	90/0
1500	90	80/10
2000	90	44/46
2500	90	12/78
3000	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
1000	90	90/0
1500	90	80/10
2000	90	44/46
2500	90	12/78
3000	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
1000	90	90/0
1500	90	80/10
2000	90	44/46
2500	90	12/78
3000	90	0/90

PCP Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
13	90	90/0
17	90	93/7
25	90	47/43
32	90	14/76
38	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
13	90	90/0
17	90	93/7
25	90	47/43
32	90	14/76
38	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
13	90	90/0
17	90	93/7
25	90	47/43
32	90	14/76
38	90	0/90

Amphetamine Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	32/58
1250	90	14/76
1500	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	32/58
1250	90	14/76
1500	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	32/58
1250	90	14/76
1500	90	0/90

TCA Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	41/49
1250	90	13/77
1500	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	41/49
1250	90	13/77
1500	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	78/12
1000	90	41/49
1250	90	13/77
1500	90	0/90

Benzodiazepines Precision Study Results

Lot 1

concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	79/11
300	90	41/49
375	90	9/81
450	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	79/11
300	90	41/49
375	90	11/79
450	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	80/10
300	90	41/49
375	90	11/79
450	90	0/90

Morphine Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	77/13
300	90	28/62
375	90	8/82
450	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	77/13
300	90	28/62
375	90	8/82
450	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	77/13
300	90	28/62
375	90	6/84
450	90	0/90

Methadone Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	75/15
300	90	41/49
375	90	7/83
450	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	75/15
300	90	41/49
375	90	7/83
450	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
150	90	90/0
225	90	75/15
300	90	41/49
375	90	7/83
450	90	0/90

MDMA Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
250	90	90/0
325	90	86/14
500	90	30/50
625	90	9/81
750	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
250	90	90/0
325	90	86/14
500	90	30/50
625	90	9/81
750	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
250	90	90/0
325	90	86/14
500	90	30/50
625	90	9/81
750	90	0/90

Methamphetamine Precision Study Results

Lot 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

Lot 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

Lot 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
500	90	90/0
750	90	81/9
1000	90	34/56
1250	90	13/77
1500	90	0/90

The sponsor also conducted a bridging study to demonstrate comparable performance between the strip format and the cassette format. Note: the multi-strip format is not housed in plastic but consists of multiple strips with a holder. Since these are dipped and read in the same manner as the single dipsticks, they were not included in the bridging study.

Amphetamines Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	1/59	0/60	98
Cutoff + 25%	1/59	0/60	98

Barbiturates Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	0/60	1/59	98
Cutoff + 25%	1/59	0/60	98

Benzodiazepines Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	0/60	1/59	98
Cutoff + 25%	1/59	0/60	98

Cocaine Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	60/0	98
Cutoff	2/58	0/60	97
Cutoff + 25%	1/59	0/60	98

MDMA Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	60/0	58/2	97
Cutoff	0/60	1/59	98
Cutoff + 25%	1/59	0/60	98

Marijuana Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	58/2	60/0	97
Cutoff	1/59	1/59	100
Cutoff + 25%	0/60	1/59	98

Methamphetamine Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	60/0	98
Cutoff	1/59	0/60	98
Cutoff + 25%	1/59	0/60	98

Morphine Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	1/59	1/59	100
Cutoff + 25%	1/59	0/60	98

Methadone Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	2/58	0/60	97
Cutoff + 25%	1/59	0/60	98

Opiates Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	60/0	98
Cutoff	1/59	0/60	98
Cutoff + 25%	1/59	0/60	98

Phencyclidine Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	59/1	59/1	100
Cutoff	1/59	0/60	98
Cutoff + 25%	1/59	0/60	98

Tricyclic Antidepressants Bridging Study

Concentration	Strip Results (neg/pos)	Cassette Results (neg/pos)	% Agreement
Cutoff -25%	60/0	58/2	97
Cutoff	1/59	0/60	98
Cutoff + 25%	1/59	0/60	98

b. *Linearity/assay reportable range:*
    Not applicable. The assay is intended for qualitative use.

c. *Traceability (controls, calibrators, or method):*

    This device has an internal process control. A colored line appearing in the control region confirms that sufficient sample volume has traveled along the strip and that the membrane is intact. Users are informed that the test is invalid if a colored line fails to appear in the control region. External controls are not supplied with this device; however, users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. *Detection limit:*

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. This information appears in the precision section, above.

e. *Analytical specificity:*
Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Amphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	300
d-amphetamine	1,000
d-methamphetamine	1,000
3,4-Methylenedioxyethylamphetamine(MDEA)	2,000
dl-amphetamine	3,000
Phentermine	3,000
l-methamphetamine	3,000
3,4-Methylenedioxyamphetamine (MDA)	5,000
l-amphetamine	50,000

Methamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
3,4-Methylenedioxyethylamphetamine(MDEA)	600
d-methamphetamine	1,000
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	2,000
3,4-Methylenedioxyamphetamine (MDA)	3,000
l-methamphetamine	8,000
trimethobenzamide	10,000
d-amphetamine	50,000
l-amphetamine	50,000
β-phenylethylamine	50,000
chloroquine	50,000
ephedrine	50,000

MDMA

Drug Compound	Response equivalent to cutoff in ng/mL
3,4-Methylenedioxyethylamphetamine(MDEA)	300
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	3,000
d-methamphetamine	8,000
l-methamphetamine	10,000
d-amphetamine	50,000
l-amphetamine	60,000

Morphine (cutoff 300 ng/mL)

Drug compound	Response equivalent to cutoff in ng/mL
Codeine	300
Heroin	300
Morphine	300
Ethylmorphine	300
6-monoacetylmorphine	400
Morphine-3-β-glucuronide	1,000
Hydrocodone	5,000
Hydromorphone	5,000
Oxycodone	30,000
Thebaine	30,000

Opiates (cutoff 1000 ng/mL)

Drug compound	Response equivalent to cutoff in ng/mL
Codeine	2,000
Heroin	2,000
Morphine	2,000
Morphine-3-β-glucuronide	2,000
6-monoacetylmorphine	5,000
Hydromorphone	5,000
Ethylmorphine	5,000
Hydrocodone	12,500
Norcodeine	12,500
Oxycodone	25,000
Normorphine	50,000
Levorphanol	75,000
Thebaine	100,000
Procaine	150,000

Cocaine

Compound	Response equivalent to cutoff in ng/mL
Benzoylecogonine	300
Cocaine HCl	750
Cocaethylene	12,500
Ecgonine	32,000

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
11-Nor-Δ^8-Tetrahydrocannabinol carboxylic acid	30
11-Nor-Δ^9-Tetrahydrocannabinol carboxylic acid	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
Δ^8-Tetrahydrocannabinol	7,500
Δ^9–Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
Phencyclidine	25
Phencyclidine Morpholine	50
4-hydroxyphencyclidine	12,500

Barbiturates

Compound	Response equivalent to cutoff in ng/mL
Butabarbital	75
Phenobarbital	100
Butethal	100
Alphenol	150
Aprobarbital	200
Secobarbital	300
Pentobarbital	300
Amobarbital	300
Cyclopentobarbital	600
Butalbital	2,500

Benzodiazepines

Compound	Response equivalent to cutoff in ng/mL
Nitrazepam	100
Clobazam	100
Temazepam	100
Alprazolam	200
Diazepam	200
Clorazepate dipotassium	200
Norchlordiazepoxide	200
Oxazepam	300
Flunitrazepam	400
Nordiazepam	400
Clonazepam	800
Chlordiaepoxide	1,500
Lorazepam	1,500
α – hydroxyalprazolam	1,500
Bromazepam	1,500
Delorazepam	1,500
Estazolam	2,500
Trazolam	2,500
Midazolam	12,500

Methadone

Compound	Response equivalent to cutoff in ng/mL
Methadone	300
Doxylamine	50,000

Tricyclic Antidepressants (TCA)

Compound	Response equivalent to cutoff in ng/mL
Desipramine	200
Imipramine	400
Nortriptyline	1,000
Nordoxepine	1,000
Amitriptyline	1,500
Promazine	1,500
Doxepine	2,000
Maprotiline	2,000
Trimipramine	3,000
Clomipramine	12,500
Promethazine	25,000

To evaluate for interference the sponsor prepared three control samples for all 12 analytes: drug-free urine, drug-free urine spiked to an analyte concentration 50% below the cutoff, and drug-free urine spiked to an analyte concentration 50% above the cutoff of the targeted drug. 100 µg/mL of potentially interfering compounds were then added to separate aliquots of the control samples and analyzed. There were no deviations from the expected results; i.e., the drug-free and cutoff – 50% samples all read negative, and the cutoff + 50% sample all read positive. All of the compounds tested are listed in the package inserts.

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

To test for potential positive and negative interference from endogenous conditions the sponsor prepared two control samples, one with drug-free urine spiked to an analyte concentration 50% below the cutoff, and one with drug-free urine spiked to 50% above the cutoff of the targeted drug. Aliquots of the control samples were then altered to span the following ranges of conditions, and analyzed:
    4-9 pH
    1.000 to 1.035 specific gravity

There was no change in test results as compared to the results of the control sample. The sponsor did not evaluate the effects albumin on the assay.

    f. *Assay cut-off:*
        Of the 12 analytes in this submission, six use cutoffs recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA): cannabinoids, cocaine, opiates, phencyclidine, amphetamines, and MDMA (methylenedioxymethamphetamine). SAMHSA has not recommended cutoff concentrations for the other six analytes.

        Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:
    a. *Method comparison with predicate device:*
        Because the candidate device was compared to a reference method, GC/MS, it was not compared to a predicate device.

Sample description: Unaltered clinical urine samples were evaluated. A portion of samples having drug concentrations that were below the cutoff concentration of the assay were also evaluated by GC/MS.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 40% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one
Type of study site: Manufacturer's facility
Operator description: Manufacturer's staff

Candidate Device Results vs. stratified GC/MS Values - Amphetamine

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	4	11	29
Negative	28	8	0	0

% Agreement among positives is 100%
% Agreement among negatives is 90%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	11	29
Negative	28	11	0	0

% Agreement among positives is 100%
% Agreement among negatives is 98%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	5	11	29
Negative	28	7	0	0

% Agreement among positives is 100%
% Agreement among negatives is 88%

GC/MS values used to categorize samples in these tables are based on the concentration of d-amphetamine found in the sample.

Candidate Device Results vs. stratified GC/MS Values – Barbiturate

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	4	15	20
Negative	20	16	5	0

% Agreement among positives is 88%
% Agreement among negatives is 90%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	18	20
Negative	20	18	2	0

% Agreement among positives is 95%
% Agreement among negatives is 95%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	18	20
Negative	20	17	2	0

% Agreement among positives is 95%
% Agreement among negatives is 93%

GC/MS values used to categorize samples in these tables are based on the concentration of secobarbital found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Benzodiazepines

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	17	20
Negative	20	18	3	0

% Agreement among positives is 93%
% Agreement among negatives is 95%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	20	20
Negative	20	19	0	0

% Agreement among positives is 100%
% Agreement among negatives is 98%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	18	20
Negative	20	17	2	0

% Agreement among positives is 95%
% Agreement among negatives is 93%

GC/MS values used to categorize samples in these tables are based on the concentration of oxazepam found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Cocaine

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	11	29
Negative	20	19	0	0

% Agreement among positives is 100%
% Agreement among negatives is 98%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	9	29
Negative	20	19	2	0

% Agreement among positives is 95%
% Agreement among negatives is 98%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	9	29
Negative	20	18	2	0

% Agreement among positives is 95%
% Agreement among negatives is 95%

GC/MS values used to categorize samples in these tables are based on the concentration of benzoylecgonine found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Cannabinoids

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	4	18	22
Negative	22	14	0	0

% Agreement among positives is 100%
% Agreement among negatives is 90%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	17	22
Negative	22	18	1	0

% Agreement among positives is 98%
% Agreement among negatives is 100%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	15	22
Negative	22	18	3	0

% Agreement among positives is 93%
% Agreement among negatives is 100%

GC/MS values used to categorize samples in these tables are based on the concentration of 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Methadone

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	17	21
Negative	22	18	2	0

% Agreement among positives is 95%
% Agreement among negatives is 100%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	18	21
Negative	22	18	1	0

% Agreement among positives is 98%
% Agreement among negatives is 100%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	18	21
Negative	22	18	1	0

% Agreement among positives is 98%
% Agreement among negatives is 100%

GC/MS values used to categorize samples in these tables are based on the concentration of methadone found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Methamphetamine

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	5	19	20
Negative	26	9	1	0

% Agreement among positives is 98%
% Agreement among negatives is 88%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	2	3	19	20
Negative	24	11	1	0

% Agreement among positives is 98%
% Agreement among negatives is 88%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	1	5	18	20
Negative	25	9	2	0

% Agreement among positives is 95%
% Agreement among negatives is 85%

GC/MS values used to categorize samples in these tables are based on the concentration of d-methamphetamine found in the sample.

Candidate Device Results vs. stratified GC/MS Values - MDMA

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	19	20
Negative	20	20	1	0

% Agreement among positives is 98%
% Agreement among negatives is 100%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	19	20
Negative	20	17	1	0

% Agreement among positives is 98%
% Agreement among negatives is 93%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	19	20
Negative	20	18	1	0

% Agreement among positives is 98%
% Agreement among negatives is 95%

GC/MS values used to categorize samples in these tables are based on the concentration of d,l -3,4-Methylenedioxymethamphetamine (MDMA) found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Morphine

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	19	20
Negative	29	8	1	0

% Agreement among positives is 98%
% Agreement among negatives is 93%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	3	19	20
Negative	29	8	1	0

% Agreement among positives is 98%
% Agreement among negatives is 93%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	4	19	20
Negative	29	7	1	0

% Agreement among positives is 98%
% Agreement among negatives is 90%

GC/MS values used to categorize samples in these tables are based on the concentration of morphine found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Opiate

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	16	22
Negative	30	8	2	0

% Agreement among positives is 95%
% Agreement among negatives is 95%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	17	22
Negative	30	9	1	0

% Agreement among positives is 98%
% Agreement among negatives is 98%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	16	22
Negative	30	9	2	0

% Agreement among positives is 95%
% Agreement among negatives is 98%

GC/MS values used to categorize samples in these tables are based on the concentration of morphine found in the sample.

Candidate Device Results vs. stratified GC/MS Values - Phencyclidine

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	15	22
Negative	23	17	3	0

% Agreement among positives is 93%
% Agreement among negatives is 100%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	17	22
Negative	23	17	1	0

% Agreement among positives is 98%
% Agreement among negatives is 100%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	1	15	22
Negative	23	16	3	0

% Agreement among positives is 93%
% Agreement among negatives is 98%

GC/MS values used to categorize samples in these tables are based on the concentration of phencyclidine found in the sample.

Candidate Device Results vs. stratified GC/MS Values - TCA

A total of 80 samples (40 negative and 40 positive) were evaluated by the candidate device and by GC/MS. Each test device was read by three readers.

Reader A

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	10	30
Negative	29	11	0	0

% Agreement among positives is 100%
% Agreement among negatives is 100%

Reader B

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	10	30
Negative	29	9	0	0

% Agreement among positives is 100%
% Agreement among negatives is 95%

Reader C

Candidate Device Results	**Less** than half the cutoff concentration by GC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	0	10	30
Negative	29	11	0	0

% Agreement among positives is 100%
% Agreement among negatives is 100%

GC/MS values used to categorize samples in these tables are based on the concentration of nortriptyline found in the sample.

        b. *Matrix comparison:*
        Not applicable. The assay is intended for only one sample matrix.

   3. Clinical studies:
        a. *Clinical sensitivity:*
        Not applicable. Clinical studies are not typically submitted for this device type.
        b. *Clinical specificity:*
        Not applicable. Clinical studies are not typically submitted for this device type.
        c. *Other clinical supportive data (when a and b are 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.