

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

**A. 510(k) Number:**

k093175

**B. Purpose for Submission:**

New device

**C. Measurand:**

Buprenorphine, Propoxyphene, and Oxycodone in human urine

**D. Type of Test:**

Qualitative immunochromatographic test for drugs of abuse in human urine

**E. Applicant:**

Guangzhou Wondfo Biotech Co., Ltd.

**F. Proprietary and Established Names:**

Wondfo One Step Buprenorphine Urine Test

Wondfo One Step Oxycodone Urine Test

Wondfo One Step Propoxyphene Urine Test

**G. Regulatory Information:**

1. Regulation section:

Regulation	Classification	Product Code	Device Name
21 CFR §862.3650 Opiate test system	II	DJG	Buprenorphine
21 CFR §862.3650 Opiate test system	II	DJG	Oxycodone
21 CFR §862.3700 Propoxyphene test system	II	JXN	Propoxyphene

4. Panel:

Toxicology (91)

## H. Intended Use:

1. Intended use(s):

See below.

2. Indication(s) for use:

a. Wondfo One Step Buprenorphine Urine Test

The Wondfo One Step Buprenorphine Urine Test Strip is intended for the qualitative determination of buprenorphine in human urine at the cut-off concentration of 10 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and not for use in point-of-care settings. For in vitro diagnostic use.

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.

b. Wondfo One Step Oxycodone Urine Test

The Wondfo One Step Oxycodone Urine Test Strip is intended for the qualitative determination of oxycodone in human urine at the cut-off concentration of 100 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and is not for use in point-of-care settings. For in vitro diagnostic use.

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.

c. Wondfo One Step Propoxyphene Urine Test

The Wondfo One Step Propoxyphene Urine Test Strip is intended for the qualitative determination of d-propoxyphene in human urine at the cut-off concentration of 300 ng/ml.

The assay is in strip format. The device is intended for healthcare professionals in a central laboratory setting only and is not for use in point-

of-care settings. For in vitro diagnostic use.

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 conditions for use statement(s):

The devices are for prescription use.

The Wondfo One Step Buprenorphine, Oxycodone, and Propoxyphene Urine Tests provide only preliminary analytical test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Liquid chromatography/mass spectrometry (LC/MS) or gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. 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.

These devices are designated for central laboratory use only.

Tests for buprenorphine cannot distinguish between abused drugs and certain prescribed medications.

4. Special instrument requirements:

There are no instrument requirements. The devices are visually read single-use devices.

**I. Device Description:**

The devices are for use in human urine. The Wondfo Buprenorphine, Oxycodone, and Propoxyphene assays are single-test test strips.

For the test strips, users dip the strip into the urine and the reaction is initiated by movement of the sample through the test strip.

The test strips include a procedural control for each test to indicate that the assay is working correctly. Negative and positive results are determined by the presence or absence of a line in the test portion of the device. Users read the results at a specified time after the addition of the urine sample to the device.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Predicate Device Name	Predicate 510(k)
Acon BUP One Step Buprenorphine Test Strip and Acon BUP One Step Buprenorphine Test Device	k060466
Acon BUP One Step Oxycodone Test Strip and Acon BUP One Step Oxycodone Test Device	k033047
Acon BUP One Step Propoxyphene Test Strip and Acon BUP One Step Propoxyphene Test Device	k040445

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicates
Intended Use	Same	For the qualitative determination of buprenorphine, oxycodone, or propoxyphene in human urine.
Calibrator	Same	Buprenorphine (buprenorphine) Oxycodone (oxycodone) Propoxyphene (propoxyphene)
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.
Type Of Test	Same	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result
Specimen Type	Same	Human urine
Cut Off Values	Same	Buprenorphine (buprenorphine):10 ng/ml Oxycodone (oxycodone): 100 ng/ml Propoxyphene (propoxyphene): 300 ng/ml

<b>Differences</b>		
Item	Device	Predicate
Intended testing sites	For healthcare professionals in central laboratories	For healthcare professionals in point-of-care sites
Configurations	Strip	Strip, Cartridge

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

None referenced.

**L. Test Principle:**

Each assay (buprenorphine, oxycodone, propoxyphene) employs lateral flow immunochromatographic technology.

Buprenorphine, oxycodone, or propoxyphene are detected in human urine by competitive binding between mouse monoclonal antibodies to one of its respective drug and drug-labeled conjugate (containing a chromagen). Binding of the 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 (mouse monoclonal anti-IgG) which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was assessed with three lots of Wondfo test strips tested by three users over five consecutive days. Seven separate normal urine samples were spiked with the target drug at concentrations of 0, -50% cutoff, -25% cutoff, cutoff, + 25% cutoff, +50% cutoff and +200% cutoff. Target levels were confirmed by GC/MS. All samples were blinded to the users and tested randomly. Each operator performed a total of 75 samples for each concentration for each of the three drugs. Results were as follows:

Buprenorphine	Buprenorphine concentration (ng/ml)	% of Cutoff	Results #Neg./#Pos.	Agreement
Lot I:	0	Negative	75/0	100%
	5	-50%	75/0	100%
	7.5	-25%	62/13	82.7%
	10	Cutoff	9/66	88%
	12.5	+25%	4/71	94.7%
	15	+50%	0/75	100%
	20	+100%	0/75	100%
Lot II:	0	Negative	75/0	100%
	5	-50%	75/0	100%

	7.5	-25%	63/12	84%
	10	Cutoff	8/67	89.3%
	12.5	+25%	3/72	96%
	15	+50%	0/75	100%
	20	+100%	0/75	100%
Lot III:	0	Negative	75/0	100%
	5	-50%	75/0	100%
	7.5	-25%	61/14	81.3%
	10	Cutoff	9/66	88%
	12.5	+25%	2/73	97.3%
	15	+50%	0/75	100%
	20	+100%	0/75	100%

Oxycodone	Oxycodone concentration (ng/ml)	% of Cutoff	Results #Neg./#Pos.	Agreement
Lot I:	0	Negative	75/0	100%
	5	-50%	75/0	100%
	75	-25%	63/12	84%
	100	Cutoff	10/65	86.7%
	125	+25%	3/72	96%
	150	+50%	0/75	100%
	200	+100%	0/75	100%
Lot II:	0	Negative	75/0	100%
	5	-50%	75/0	100%
	75	-25%	64/11	85.3%
	100	Cutoff	11/64	85.3%
	125	+25%	4/71	94.7%
	150	+50%	0/75	100%
	200	+100%	0/75	100%
Lot III:	0	Negative	75/0	100%
	5	-50%	75/0	100%
	75	-25%	63/12	84%
	100	Cutoff	9/66	88%
	125	+25%	2/73	97.3%
	150	+50%	0/75	100%
	200	+100%	0/75	100%

Propoxyphene	Propoxyphene concentration (ng/ml)	% of Cutoff	Results #Neg./#Pos.	Agreement
Lot I:	0	Negative	75/0	100%
	150	-50%	75/0	100%
	225	-25%	65/10	86.7%
	300	Cutoff	9/66	88%
	375	+25%	6/69	92%
	450	+50%	0/75	100%
	600	+100%	0/75	100%
Lot II:	0	Negative	75/0	100%
	150	-50%	75/0	100%
	225	-25%	64/11	85.3%
	300	Cutoff	11/64	85.3%
	375	+25%	4/71	94.7%
	450	+50%	0/75	100%
	600	+100%	0/75	100%
Lot III:	0	Negative	75/0	100%
	150	-50%	75/0	100%
	225	-25%	54/21	72%
	300	Cutoff	64/11	85.3%
	375	+25%	9/66	88%
	450	+50%	0/75	100%
	600	+100%	0/75	100%

*b. Linearity/assay reportable range:*

Not applicable - these devices are qualitative only.

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

Real-time stability, accelerated stability and shipping studies were performed on three lots each of Wondfo One-Step Buprenorphine, Oxycodone and Propoxyphene test strips. Stability data supports the sponsor's recommended storage conditions of 4-30° C for 24 months.

These devices have internal process controls. A colored line appearing in the control region confirms that sufficient sample volume has been applied and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if a line fails to appear in the control region. External

controls are not supplied with this device.

*d. Detection limit:*

Analytical performance of the device around the cutoff is described in the precision section See 1.a. above.

*e. Analytical specificity:*

**Structurally-related compounds:**

Buprenorphine, Oxycodone and Propoxyphene were each tested in duplicate for structurally related compounds using 3 lots of test strips. Structurally related compounds at 100,000 ng/mL were added to drug-free urine. Any compounds demonstrating interference were serially diluted and tested to determine the lowest concentration that produced a positive result. Cross-reactivity was calculated by dividing the concentration at which the compound yielded a positive result by the designated cut-off concentration and multiplying by 100%. Other drugs or drug metabolites not listed may interfere with Buprenorphine, Oxycodone or Propoxyphene assays and cause false results. The results are summarized below:

**Buprenorphine**

Compounds	Response equivalent to cutoff in ng/mL	Cross Reactivity (%)
Buprenorphine-3-D-Glucuronide	15	66.67
Norbuprenorphine	20	50
Norbuprenorphine-3-D-Glucuronide	200	5

**Oxycodone**

Compounds	Response equivalent to cutoff in ng/mL	Cross Reactivity (%)
Dihydrocodeine	20,000	0.5
Codeine	100,000	0.1
Hydromorphone	100,000	0.1
Morphine	>100,000	Not detected
Acetylmorphine	>100,000	Not detected
Buprenorphine	>100,000	Not detected
Ethylmorphine	>100,000	Not detected

**Propoxyphene**

Compounds	Response equivalent to cutoff in ng/mL	Cross Reactivity (%)
d-Norpropoxyphene	300	100

### **Structurally unrelated compounds:**

To evaluate the interference with buprenorphine, oxycodone and propoxyphene from non-related compounds, the interference studies were conducted. The compounds were added to either drug-free urine or urine containing buprenorphine, oxycodone or d-propoxyphene with concentrations at 50% below, 25% below, 25% above and 50% above cutoff level at a high target concentration of 100,000 ng/mL. Three lots of each test strip were used in the study. In addition, buprenorphine was evaluated for interference from tramadol. No negative or positive interference was observed for the following compounds:

Acetophenetidin	Deoxycorticosterone	Meprobamate	Quinine
Nalidixic acid	Dextromethorphan	Methoxyphenamine	Ranitidine
Acetylsalicylic acid	Diclofenac	Nalidixic acid	Salicylic acid
Aminopyrine	Di flunisal	Naloxone	Serotonin
Amoxicillin	Digoxin	Naltrexone	Sulfamethazine
Ampicillin	Diphenhydramine	Naproxen	Sulindac
L-Phenylephrine	L-Ephedrine	Niacinamide	Tetracycline
Apomorphine	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate
Atropine	$\beta$ -Estradiol	D-Norpropoxyphene	Morphine-3- $\beta$ -Dglucuronide
Benzilic acid	Estrone-3-sulfate	Noscapine	Tetrahydrozoline
Benzoic acid	Erythromycin	D,L-Octopamine	Thiamine
Benzphetamine	Fenoprofen	Oxalic acid	Thioridazine
Bilirubin	Furosemide	Oxolinic acid	D,L-Tyrosine
Deoxycorticosterone	Gentisic acid	Oxymetazoline	Tolbutamide
Caffeine	Hemoglobin	Papaverine	Triamterene
Chloralhydrate	Hydralazine	Penicillin-G	Trifluoperazine
Chloramphenicol	Hydrochlorothiazide	Perphenazine	Trimethoprim
Chlorothiazide	Hydrocortisone	Phenelzine	Tyramine
D,L-Chlolorpheniramine	O-Hydroxyhippuric acid	L-Phenylephrine	D,L-Tryptophan
Chlorpromazine	3-Hydroxytyramine	$\beta$ -Phenylethylamine	Urine acid
Chlorquine	D, L-Isoproterenol	Phenylpropanolamine	Verapamil
Cholesterol	Isoxsuprine	Prednisone	Labetalol
Clonidine	D,L-Propanolol	Zomepirac	Quinidine
Cortisone	Ketoprofen	L-Cotinine	Tramadol (Buprenorphine only)
D-Pseudoephedrine	Creatinine	Loperamide	

### **Specific Gravity:**

The effect of specific gravity on the Wondfo One-Step Buprenorphine, Oxycodone and Propoxyphene devices was determined by evaluating 11 urine samples with specific gravities ranging from 1.000-1.040 and spiking them with the target drugs at 50% below the cutoffs and 50% above the cutoffs. Testing was performed in duplicate on 3 lots of test strips. No interference from specific gravity was observed at concentrations of 1.000 to 1.035.

### **pH:**

The effect of pH on the Wondfo One-Step Buprenorphine, Oxycodone and Propoxyphene devices was determined by spiking a negative urine pool with the target drugs at 50% below the cutoffs and 50% above the cutoffs. pH was adjusted in increments of 1 pH unit across the range from 3.0-10.0 and each urine was tested in duplicate with three lots of test strips. No interference from pH was observed at pH levels of 4.0 to 9.0.

f. Assay cut-off:

Cutoff concentrations are:

Device	Cut-off Concentration
Wondfo One-Step Buprenorphine	10 ng/mL
Wondfo One-Step Oxycodone	100 ng/mL
Wondfo One-Step Propoxyphene	300 ng/mL

Cutoff studies were performed for buprenorphine, oxycodone and propoxyphene using a combination of clinical and spiked samples for each drug (n=150 per drug). The testing protocol was identical for each drug.

25 clinical samples were collected for each of the three drugs. Concentrations of buprenorphine, oxycodone or propoxyphene in the samples were determined by GC/MS. An additional 125 drug free negative samples were obtained for each drug and spiked with either buprenorphine, oxycodone or propoxyphene at -50% cutoff, -25% cutoff, cutoff, +25% cutoff, and +50 % cutoff. Absence of any drugs in the negative urines and concentrations after spiking were confirmed by GC/MS.

5 clinical samples and 25 spiked samples were tested at each concentration for each drug in replicates of 30 using three strip lots (n=90) and 3 operators. Results are summarized below:

**Buprenorphine**

Lot	-50% cutoff (pos/neg)	-25% cutoff (pos/neg)	Cutoff (pos/neg)	+25% cutoff (pos/neg)	+50% cutoff (pos/neg)
1	0/90	11/79	83/7	88/2	90/0
2	0/90	9/81	82/8	88/2	90/0
3	0/90	11/79	87/3	88/2	90/0

**Oxycodone**

Lot	-50% cutoff (pos/neg)	-25% cutoff (pos/neg)	Cutoff (pos/neg)	+25% cutoff (pos/neg)	+50% cutoff (pos/neg)
1	0/90	7/83	80/10	88/2	90/0
2	0/90	9/81	83/7	86/4	90/0
3	0/90	13/77	80/10	88/2	90/0

### **Propoxyphene**

Lot	-50% cutoff (pos/neg)	-25% cutoff (pos/neg)	Cutoff (pos/neg)	+25% cutoff (pos/neg)	+50% cutoff (pos/neg)
1	0/90	10/80	80/10	86/4	90/0
2	0/90	6/84	83/7	86/4	90/0
3	0/90	11/79	86/4	89/1	90/0

#### 2. Comparison studies:

##### a. *Method comparison with predicate device:*

Method comparison studies for buprenorphine, oxycodone and propoxyphene were evaluated in the same manner using all natural urine samples using one lot of test strips and three operators. 10 samples were negative for all three drugs. 40 samples ranging from less than 50% cutoff to the cutoff and 40 samples ranging from cutoff to greater than 50% cutoff were evaluated. The test strip results were compared to GC/MS.

Discrepant samples were analyzed by GC/MS. Metabolites detected for buprenorphine were buprenorphine and nor-buprenorphine. Oxycodone detected only oxycodone, and propoxyphene detected both d-propoxyphene and d nor-propoxyphene. The results obtained by each user with the Wondfo One-Step devices, including discrepant results compared to GC/MS are below.

### **Buprenorphine**

#### **Viewer A:**

Wondfo Result	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	20
Negative	20	19	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer A result
-50% cutoff to cutoff	Total result 8.9	+
Cutoff to +50% cutoff	10.5	-
	11.5	-
	12	-
	12.9	-

#### **Viewer B:**

Wondfo Result	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	20
Negative	20	18	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL) Total result	Viewer B result
-50% cutoff to cutoff	7.0	+
	8.9	+
Cutoff to +50% cutoff	10.5	-
	11.5	-
	12.0	-
	12.9	-

#### Viewer C:

Wondfo Result	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	16	20
Negative	20	20	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL) Total result	Viewer C result
Cutoff to +50% cutoff	10.5	-
	11.5	-
	12.0	-
	12.9	-

### Oxycodone

#### Viewer A:

Wondfo Result	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	23
Negative	20	19	2	0

% agreement among positives is 95% (95% Confidence Interval 79.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer A result
-50% cutoff to cutoff	94.2	+
Cutoff to +50% cutoff	110.1	-
	112.3	-

**Viewer B:**

Wondfo Result	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	14	23
Negative	20	18	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77.0% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer B result
-50% cutoff to cutoff	94.2	+
	94.5	+
Cutoff to +50% cutoff	109.3	-
	110.1	-
	112.3	-

**Viewer C:**

Wondfo Result	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	13	23
Negative	20	20	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer C result
Cutoff to +50% cutoff	109.3	-
	110.1	-
	112.3	-
	118.7	-

**Propoxyphene:**

**Viewer A:**

Wondfo Result	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	19
Negative	26	12	4	0

% agreement among positives is 90% (95% Confidence Interval 74.5% - 100%)

% agreement among negatives is 95% (95% Confidence Interval 79.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer A result
-50% cutoff to cutoff	289.2	+
	290.3	+
Cutoff to +50% cutoff	308.2	-
	318.2	-
	320.8	-
	342.7	-

#### Viewer B:

Wondfo Result	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	18	19
Negative	26	13	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77.0% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82.0% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer B result
-50% cutoff to cutoff	289.2	+
Cutoff to +50% cutoff	308.2	-
	320.8	-
	342.7	-

#### Viewer C:

Wondfo Result	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	16	19
Negative	26	14	5	0

% agreement among positives is 87.5% (95% Confidence Interval 72.0% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

% of the cutoff	Concentration GC/MS (ng/mL)	Viewer C result
Cutoff to +50% cutoff	308.2	-
	310.2	-
	318.2	-
	320.8	-
	342.7	-

b. *Matrix comparison:*

These devices are intended for use with human urine only.

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):

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.