

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

A. 510(k) Number:

k152025

B. Purpose for Submission:

New Device

C. Measurand:

Methadone and Buprenorphine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Assure Tech. Co., Ltd.

F. Proprietary and Established Names:

AssureTech Buprenorphine Strip
AssureTech Methadone Strip
AssureTech Buprenorphine/Methadone Panel Dip
AssureTech Buprenorphine/Methadone Quick Cup
AssureTech Buprenorphine/Methadone Turn Key-Split Cup

G. Regulatory Information:

1. Regulation section:

21 CFR, 862.3620 Methadone Test System
21 CFR 862.3650 Opiate test system

2. Classification:

Class II

3. Product code:

DJR, DJG

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

AssureTech Buprenorphine Strip:

The AssureTech Buprenorphine Strip test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a Cut-Off concentration of 10ng/mL. This test is calibrated to Buprenorphine (calibrator).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only. The test is intended for over-the-counter and for prescription use.

AssureTech Methadone Strip:

The AssureTech Methadone Strip test is an immunochromatographic assay for the qualitative determination of Methadone in human urine at a Cut-Off concentration of 300ng/mL. This test is calibrated to Methadone (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only. The test is intended for over-the-counter and for prescription use.

AssureTech Buprenorphine/Methadone Panel Dip:

The AssureTech Buprenorphine/Methadone Panel Dip test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only. The tests are intended for over-the-counter and for prescription use.

AssureTech Buprenorphine/Methadone Quick Cup:

The AssureTech Buprenorphine/Methadone Quick Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300 ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only. The tests are intended for over-the-counter and for prescription use.

AssureTech Buprenorphine/Methadone Turn Key-Split Cup:

The AssureTech Buprenorphine/Methadone Turn Key-Split Cup test is an immunochromatographic assay for the qualitative determination of Buprenorphine and Methadone in human urine at a Cut-Off concentration of 10ng/mL and 300

ng/mL, respectively. These tests are calibrated to Buprenorphine and Methadone (calibrators).

The test may yield preliminary positive results when prescription drug Buprenorphine is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Buprenorphine in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For *in vitro* diagnostic use only. The tests are intended for over-the-counter and for prescription use.

3. Special conditions for use statement(s):

For Prescription and Over-the-counter Use

4. Special instrument requirements:

Not applicable; this is a visually read single use device.

I. Device Description:

The AssureTech Buprenorphine Strip, AssureTech Methadone Strip, AssureTech Buprenorphine/Methadone Panel Dip, AssureTech Buprenorphine/Methadone Quick Cup and AssureTech Buprenorphine/Methadone Turn Key-Split Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Buprenorphine and/or Methadone (target analytes) in human urine. The Quick Cup format does not contain a turn-key for device activation. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Chemtrue[®] BUP/TCA Single/Multi-Panel Drug Screen Dip Card/Cup/Cassette Tests
Chemtrue[®] Multi-Panel Drug Screen Dip Card Tests
Chemtrue[®] Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

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

k142396

3. Comparison with predicate:

Item	Device	Predicate
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	Buprenorphine, Methadone	Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen	Human Urine	Same
Cut-Off Values	10 ng/mL (Buprenorphine) and 300 ng/mL (Methadone)	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Strip, Panel Dip, Cup with or without turn-key	Dip Card, Cup, Cassette Tests

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

None referenced

L. Test Principle:

AssureTech Buprenorphine Strip, AssureTech Methadone Strip, AssureTech Buprenorphine/Methadone Panel Dip, AssureTech Buprenorphine/Methadone Quick Cup and AssureTech Buprenorphine/Methadone Turn Key-Split Cup are rapid tests for the

qualitative detection of Buprenorphine and/or Methadone in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were carried out for samples with concentrations of -100%, -75%, -50%, -25%, cutoff, +25%, +50%, +75% and +100% cut off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by GC/MS. These studies were conducted by 3 operators with 3 lots of each device in two runs per day for 25 days (n=50). The results obtained are summarized in the following tables.

Buprenorphine

AssureTech Buprenorphine Strip

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine /Methadone Panel Dip

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Turn-Key Split Cup

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Methadone

AssureTech Methadone Strip

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Panel Dip

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Turn-Key Split Cup

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	1-/49+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

AssureTech Buprenorphine/Methadone Quick Cup

Lot #	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

b. *Linearity/assay reportable range:*

Not applicable.

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

External control materials are not supplied with the devices; however, the package inserts list information on how to obtain control materials.

Sample Storage and Stability:

Protocols and acceptance criteria for real time, accelerated and transportation simulation stability studies were described and found to be acceptable. The real time stability data supports the sponsor's claim that the devices are stable at 4-30 °C for 24 months.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

The potential effect of endogenous and exogenous interferents was tested by spiking the interferents into drug-free urine and target drug(s) urine with concentrations at 25% below and 25% above the cut-off levels. Compounds that showed no positive or negative interference at a concentration of 100µg/mL are summarized in the following tables. The substances tested and concentrations are shown below:

Buprenorphine and Methadone:

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phentermine
Amitriptyline	Hemoglobin	Phenylephrine-L
Amoxicillin	Hydralazine	Phenylethylamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Phenylpropanolamine
D-Amphetamine	Hydrochlorothiazide	Prednisolone Acetate
L-Amphetamine	Hydrocodone	Prednisone
Amphetamine Sulfate	Hydrocortisone	Procaine(Novocaine)
Ampicillin(Ampicillin)	Hydroxyhippuric acid	Promazine
Apomorphine	p-Hydroxymethamphetamine	Promethazine

L-Ascorbic Acid	Ibuprofen	Propoxyphene,d-
Aspartame	Imipramine	Propranolol
Atropine	Isoxsuprine	Pseudoephedrine HCL
Benzilic acid	Isoproterenol-(+/-)	Quinidine
Benzphetamine	Ketamine	Quinine
Bezoic Acid	Labetalol	Ranitidine(Zantac)
Bilirubin	Levorphanol	Salicylic Acid
Caffeine	Loperamide	Secobarbital
Chloramphenicol	Maprotiline	Serotonin
Chlordiazepoxide HCL	Meprobamate	Sulfamethazine
Chloroquine	Methadone*	Sulindac
Chlorothiazide	Methoxyphenamine	Temazepam
Chlorpheniramine	(+/-)- Methylenedioxyamphetamine (MDA)	11-Nor- Δ 9- Tetrahydrocannabinol
Chlorpromazine	Methylphenidate	Tetracycline
Cholesterol	Nalbuphine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone hydrochloride	L-Thyroxine
Cortisone	Naltrexone hydrochloride	ThioridazineHydroch loride
Cotinine(-)	Naproxen	Triamterene
Creatinine	Niacinamide	Triflupromazine Hydrochloride
Deoxyepinephrine	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	Norpropoxyphene	Tryptamine
Diflunisal	Noscapine	DL-Tryptophan
Digoxin	Oxazepam	Tyramine
Doxylamine	Oxymetazoline	D/L-Tyrosine
Ecgonine methylester	Papaverine	Uric Acid
R(-)-Epinephrine	Penicillin	Verapamil
Erythromycin	Pentobarbital	Zomepirac
Estrone-3-sulfate	Perphenazine	

* Tested with Buprenorphine assay only

To test specificity, drug metabolites and other compounds structurally similar to methadone and buprenorphine were tested using three batches of each device. The lowest concentration that caused a positive result for each compound is listed below. There were no differences observed between the different formats. Results are summarized below:

Buprenorphine (Cut-off=10 ng/mL)	Result	% Cross-Reactivity
Buprenorphine	Positive at 10 ng/mL	100%
Buprenorphine -3-D- Glucuronide	Positive at 10 ng/mL	100%
Norbuprenorphine	Positive at 50 ng/mL	20%
Norbuprenorphine-3-D- Glucuronide	Positive at 100 ng/mL	10%
Morphine	Negative at 100,000	<0.01%
Oxymorphone	Negative at 100,000	<0.01%
Hydromorphone	Negative at 100,000	<0.01%

Methadone (Cut-off=300 ng/mL)	Result	% Cross-Reactivity
Methadone	Positive at 300 ng/mL	100%
Doxylamine	Positive at 5000 ng/mL	6%
LAAM HCl	Positive at 10000 ng/mL	3%
Alpha Methadol	Positive at 2000 ng/mL	15%
EDDP	Negative at 100,000	<0.3%
EMDP	Negative at 100,000	<0.3%

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above the cutoff levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% cutoff and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cut-off concentration appears in the precision/reproducibility section above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies for the AssureTech Buprenorphine Tests and the AssureTech Methadone Tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive)

unaltered clinical samples. The samples were compared to GC/MS results. The results are presented in the tables below:

Buprenorphine

Strip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of Buprenorphine Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	11178	9.8	Positive
Viewer A	20805	9.6	Positive
Viewer B	20805	9.6	Positive
Viewer C	20805	9.6	Positive
Viewer A	31718	10.9	Negative
Viewer B	18342	10.6	Negative

Panel Dip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer C	Positive	0	0	2	14	25
	Negative	10	20	8	1	0

Discordant Results of Buprenorphine Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	11178	9.8	Positive
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive
Viewer B	20805	9.6	Positive
Viewer C	11178	9.8	Positive
Viewer C	20805	9.6	Positive
Viewer A	18342	10.6	Negative
Viewer B	31718	10.9	Negative
Viewer C	31718	10.9	Negative

Turn-Key Split Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer C	Positive	0	0	1	13	25
	Negative	1	20	9	2	0

Discordant Results of Buprenorphine Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Turn-Key Split Cup
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive
Viewer C	11178	9.8	Positive
Viewer A	31718	10.9	Negative
Viewer B	18342	10.6	Negative
Viewer C	18342	10.6	Negative
Viewer C	31718	10.9	Negative

Quick Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Viewer C	Positive	0	0	2	14	25
	Negative	10	20	8	1	0

Discordant Results of Buprenorphine Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	20805	9.6	Positive
Viewer B	11178	9.8	Positive
Viewer C	11178	9.8	Positive
Viewer C	20805	9.6	Positive
Viewer A	31718	10.9	Negative
Viewer C	18342	10.6	Negative

Methadone (MTD)

Strip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	14	25
	Negative	10	20	9	1	0

Discordant Results of MTD Strip

Viewer	Sample Number	GC/MS Result	Strip Viewer Results
Viewer A	36406	293	Positive
Viewer A	15168	291	Positive
Viewer B	15168	291	Positive
Viewer C	15168	291	Positive
Viewer A	82949	305	Negative
Viewer B	82949	305	Negative
Viewer C	82949	305	Negative

Panel Dip		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	15	25
	Negative	10	20	8	0	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of MTD Panel Dip

Viewer	Sample Number	GC/MS Result	Panel Dip Viewer Results
Viewer A	36406	293	Positive
Viewer A	15168	291	Positive
Viewer B	15168	291	Positive
Viewer C	15168	291	Positive
Viewer B	82949	305	Negative

Turn-Key Split Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	1	20	9	1	0
Viewer B	Positive	0	0	1	15	25
	Negative	1	20	9	0	0
Viewer C	Positive	0	0	1	14	25
	Negative	1	20	9	1	0

Discordant Results of MTD Turn-Key Split Cup

Viewer	Sample Number	GC/MS Result	Split Cup Viewer Results
Viewer A	15168	291	Positive
Viewer B	15168	291	Positive
Viewer C	36406	293	Positive
Viewer A	82949	305	Negative
Viewer C	82949	305	Negative

Quick Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Viewer B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Viewer C	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Discordant Results of MTD Quick Cup

Viewer	Sample Number	GC/MS Result	Quick Cup Viewer Results
Viewer A	36406	293	Positive
Viewer B	36406	293	Positive
Viewer B	15168	291	Positive
Viewer C	36406	293	Positive
Viewer A	82949	305	Negative
Viewer B	82949	305	Negative

Lay-user study:

A lay user study was performed at three intended user sites with 273 study subjects for 3 formats and 147 study subjects for 2 formats. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to >50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquotted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device format was tested.

Comparison between GC/MS and Lay Person Results for Buprenorphine Strip:

% of Cutoff	Number of samples	Buprenorphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	21	0	0	21	100
-75%Cutoff	21	2.2	0	21	100
-50% Cutoff	21	5.5	0	21	100
-25% Cutoff	21	7.6	1	20	95
+25% Cutoff	21	12.6	21	0	100
+50% Cutoff	21	16.2	21	0	100
+75% Cutoff	21	17.8	21	0	100

Comparison between GC/MS and Lay Person Results for MTD Strip

% of Cutoff	Number of sample	Methadone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	2	0	0	21	100
-75% Cutoff	2	69	0	21	100
-50% Cutoff	2	162	0	21	100
-25% Cutoff	2	251	1	20	95
+25% Cutoff	2	389	20	1	95
+50% Cutoff	2	463	21	0	100
+75% Cutoff	2	510	21	0	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Panel DipCard

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100
-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	1+/20-	2+/19-	95	90
+25%	21	12.6	389	20+/1-	20+/1-	95	95
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Turn-Key Split Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100
-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	2+/19-	0+/21-	90	100
+25%	21	12.6	389	20+/1-	20+/1-	95	95
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	100

Comparison between GC/MS and Lay Person Results for BUP/MTD Quick Cup

% Cutoff	No of samples	Concentration by GC/MS(ng/mL)		Lay person results		Correct Results (%)	
		Buprenorphine	Methadone	BUP	MTD	BUP	MTD
-100%	21	0	0	0+/21-	0+/21-	100	100
-75%	21	2.2	69	0+/21-	0+/21-	100	100
-50%	21	5.5	162	0+/21-	0+/21-	100	100
-25%	21	7.6	251	0+/21-	1+/20-	100	95
+25%	21	12.6	389	20+/1-	21+/0-	95	100
+50%	21	16.2	463	21+/0-	21+/0-	100	100
+75%	21	17.8	510	21+/0-	21+/0-	100	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

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.