



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

I Background Information:

A 510(k) Number

K232597

B Applicant

Hangzhou Laihe Biotech Co., Ltd.

C Proprietary and Established Names

LYHER® Urine Multi-Drug Test Kit(Cup), LYHER® Urine Multi-Drug Test Kit(Cassette), LYHER® Urine Multi-Drug Test Kit(Dipcard)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
LCM	Unclassified		

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Amphetamine, Methamphetamine, Cocaine, Morphine, Marijuana, and Phencyclidine

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The LYHER® Urine Multi-Drug Test Kit (Cup), LYHER® Urine Multi- Drug Test Kit (Cassette), and LYHER® Urine Multi-Drug Test Kit (Dipcard) are rapid lateral flow immunoassays for the qualitative detection of d-Amphetamine, d-Methamphetamine, Benzoyllecgonine, Morphine, Phencyclidine and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1000
Cocaine (COC)	Benzoyllecgonine	300
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50
Methamphetamine (MET)	d-Methamphetamine	1000
Opiates(OPI)	Morphine	2000
Phencyclidine (PCP)	Phencyclidine	25

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 6 analytes. The drug screen tests are intended for prescription use only. The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result. Gas Chromatography/Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not Applicable.

IV Device/System Characteristics:

A Device Description:

The LYHER® Urine Multi-Drug Test Kit(Cup), LYHER® Urine Multi-Drug Test Kit(Cassette), LYHER® Urine Multi-Drug Test Kit(Dipcard) are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Amphetamine, d-Methamphetamine, Benzoyllecgonine, Morphine, Phencyclidine and THC-COOH in human urine. The LYHER® Urine Multi-Drug Test Kit (Cup) device consists of 25 or 40 cup devices and a package insert. The LYHER® Urine Multi-Drug Test Kit (Dipcard) device consists of 10/15/20/25 Dip Card devices, a package insert. The LYHER® Urine Multi-Drug Test Kit (Cassette) device consists of 10/15/20/25 cassette devices, 10/15/20/25 droppers, a package insert.

B Principle of Operation:

Each device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. The product contains membrane strips coated with drug-protein conjugates on the T zone, goat anti-rabbit polyclonal antibody at the C zone, and a conjugate pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against to the corresponding drugs and colloidal gold particles coated with rabbit IgG.

If the level of drug in the urine specimen is below the cutoff concentration, the T line appears as a visible burgundy line. If the level of drug in the urine specimen is above the cutoff, no T line develops. The control line (C line) serves as an internal quality control. The control line should always appear as a burgundy-colored band regardless of the presence of the drug, if enough sample volume has been added to the test and if the sample has correctly migrated up the test strip.

V Substantial Equivalence Information:

A Predicate Device Name(s):

B Predicate 510(k) Number(s):

K182123

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232597		K182123	
Device Trade Name	LYHER® Urine Multi-Drug Test Kit(Cup) LYHER® Urine Multi-Drug Test Kit(Cassette) LYHER® Urine Multi-Drug Test Kit(Dipcard)		Advin Biotech, Inc ATTEST Drug Screen Cup ATTEST Drug Screen Dip Card	
General Device Characteristic Similarities				
Intended Use/Indications For Use	Qualitative detection of drugs of abuse and/or their metabolites in urine		Same	
Methodology	Lateral flow immunochromatographic assay based on competitive binding		Same	
Type of Test	Qualitative		Same	
Specimen Type	Human Urine		Same	
General Device Characteristic Differences				
Configurations	Cup, Dip Card, Cassette		Cup, Dip Card	
Cut-off Values	Calibrator	Cutoff ng/mL	Calibrator	Cutoff ng/mL
	d-Amphetamine	1000	6-monoacetylmorphine	10
	Benzoyllecgonine	300	d-amphetamine	500
	11-nor- Δ^9 -THC-9-COOH	50	d-amphetamine	1000
	d-Methamphetamine	1000	Secobarbital	300
	Morphine	2000	Oxazepam	300
			Buprenorphine	10
			Benzoyllecgonine	150
		Benzoyllecgonine	300	

	Phencyclidine	25	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
			d/l-methylenedioxy-methamphetamine	500
			d-methamphetamine	500
			d-methamphetamine	1000
			d/l-methadone	300
			Morphine	300
			Morphine	2,000
			Oxycodone	100
			Phencyclidine	25
			d-propoxyphene	300
			Nortriptyline	1,000
			THC-COOH	5

VI Standards/Guidance Documents Referenced:

None.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Three operators performed the study using three lots of each test format (dip card, test cup, and cassette). Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. Each concentration was tested using 3 lots, by 6 operators. Each specimen was analyzed in 50 replicates by each of the testing personnel at three representative POC sites by using three lots of the product separately.

The test results of the specimens at the concentrations at and below -25% of the cut off obtained by all the three personnel were all negative while the test results of the specimens at

the concentration at and above +25% of the cut off value were all positive. One representative lot for each configuration is provided below.

Precision Study Result of Cassette:

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
THC 50	Neg	50	50	50	50	5	0	0	0	0
	Pos	0	0	0	0	45	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
AMP 1000	Neg	50	50	50	50	5	0	0	0	0
	Pos	0	0	0	0	45	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
COC 300	Neg	50	50	50	50	10	0	0	0	0
	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
MET 1000	Neg	50	50	50	50	5	0	0	0	0
	Pos	0	0	0	0	45	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
OPI 2000	Neg	50	50	50	50	8	0	0	0	0
	Pos	0	0	0	0	42	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
PCP 25	Neg	50	50	50	50	12	0	0	0	0
	Pos	0	0	0	0	38	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50

Precision Study Result of Dip Card:

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
THC 50	Neg	50	50	50	50	9	0	0	0	0
	Pos	0	0	0	0	41	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
AMP 1000	Neg	50	50	50	50	9	0	0	0	0
	Pos	0	0	0	0	41	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
COC 300	Neg	50	50	50	50	10	0	0	0	0
	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
MET 1000	Neg	50	50	50	50	10	0	0	0	0
	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
OPI 2000	Neg	50	50	50	50	10	0	0	0	0
	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
	Neg	50	50	50	50	10	0	0	0	0

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
PCP 25	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50

Precision Study Result of Cup:

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
THC 50	Neg	50	50	50	50	11	0	0	0	0
	Pos	0	0	0	0	39	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
AMP 1000	Neg	50	50	50	50	11	0	0	0	0
	Pos	0	0	0	0	39	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
COC 300	Neg	50	50	50	50	10	0	0	0	0
	Pos	0	0	0	0	40	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
MET 1000	Neg	50	50	50	50	9	0	0	0	0
	Pos	0	0	0	0	41	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
OPI 2000	Neg	50	50	50	50	9	0	0	0	0
	Pos	0	0	0	0	41	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50
PCP 25	Neg	50	50	50	50	11	0	0	0	0
	Pos	0	0	0	0	39	50	50	50	50
	Total	50	50	50	50	50	50	50	50	50

2. Linearity:

Not Applicable.

3. Analytical Specificity/Interference:

Interfering Substances:

Analytical specificity for each test format was determined by adding potential interfering substances found in human urine of physiological or pathological conditions to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device configuration. Compounds that showed no interference to the assays in this submission at a concentration of 100µg/mL are summarized in the following table. There were no differences observed for each of the different devices (i.e. cassette, dipcard, and cup).

Substances		
Acetaminophen	Erythromycin	Penicillin-G
Acetone	Ethanol	Pheniramine

Acetylsalicylic acid	Furosemide	Phenothiazine
Albumin	Gabapentin	Pregablin
Ampicillin	Glucose	Procaine
Ascorbic acid	Guaiacol glyceryl ether	Propoxyphene
Aspartame	Hemoglobin	Quinidine
Atropine	Ibuprofen	Ranitidine
Benzocaine	Isoproterenol	Riboflavin
Bilirubin	Isoproterenol	Sertraline
Caffeine	Ketamine	Sodium chloride
Chloroquine	Lidocaine	Sulindac
Chlorpheniramine	l-Phenylephrine	Theophylline
Creatine	Methadone	Tyramine
Dexbrompheniramine	Methylephedrine	β -Phenylethylamine
Dextromethorphan	Naproxen	Phencyclidine(PCP)
Dimenhydrinate	Niacinamide	Cocaine
Dimethylaminoantipyrine	Nicotine	Morphine
Diphenhydramine	Norephedrine	Δ 9-tetrahydrocannabinol
Dopamine	Oxalic acid	Methylamphetamine
EDDP	Oxycodone	MDMA
Ephedrine	Pantoprazole	Amphetamine

Cross Reactivity:

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three lot of each device configuration (cassette, dipcard, and cup). The lowest concentration that caused a positive result for each compound are listed below. There were no differences observed for different devices (i.e. cassette, dipcard, and cup).

Compound	Concentration (ng/mL)	%Cross Reactivity
Amphetamine (AMP)		
D-Amphetamine	1000	100%
D,L-Amphetamine sulfate	2500	40%
β -Phenylethylamine	60000	1.67%
(\pm)3,4-Methylenedioxyamphetamine (MDA)	1500	66.7%
Phentermine	2500	40%
Tryptamine	60000	1.67%
Tyramine	5000	20%
L-amphetamine	100000	1%
COCAINE (COC)	ng/ml	
Benzoyllecgonine	300	100%
Cocaine	750	40%
Cocaethylene	10000	3%
Ecgonine	20000	1.5%
Ecgonine methylester	50000	0.6%

MARIJUANA (THC)		
Cannabinol	20000	0.25%
11-nor- Δ 8-THC-9 COOH	30	167%
11-nor- Δ 9 -THC-9 COOH	50	100%
Δ 8 -THC	15000	0.33%
Δ 9 -THC	15000	0.33%
(\pm)-11-Hydroxy- Δ 9-THC	5000	1%
METHAMPHETAMINE (MET)		
p-Hydroxymethamphetamine	30000	3.33%
D-Methamphetamine	1000	100%
L-Methamphetamine	8000	12.5%
(\pm)-3,4-Methylenedioxy-methamphetamine	2000	50%
Mephentermine	50000	2%
D-Amphetamine	100000	1%
L-Amphetamine	100000	1%
(1R, 2S)-(-)-Ephedrine	100000	1%
(+/-) 3,4-Methylenedioxy-nethylamphetamine (MDEA)	30000	3.33%
OPIATES (OPI)		
Morphine	2000	100%
Codeine	1500	133%
Ethylmorphine	30000	6.67%
Hydrocodone	80000	2.5%
Hydromorphone	10000	20%
Levophanol	5000	40%
6-Monoacetylmorphine	2000	100%
Morphine 3- β -D-glucuronide	5000	40%
Norcodeine	30000	6.67%
Normorphone	100000	2%
Oxycodone	100000	2%
Oxymorphone	100000	2%
Procaine	60000	3.33%
Thebaine	30000	6.67%
6-Acetylmorphine (6-AM)	2000	100%
Diacetylmorphine (heroin)	5000	40%
Phencyclidine (PCP)		
Phencyclidine	25	100%
4-hydroxy-PCP	12500	0.2%

Effect of Urine Specific Gravity and Urine pH:

To investigate the effect of urine specific gravity and urine pH, urine samples, with

1.003 to 1.032 specific gravity or urine samples with pH 3 to 9 were spiked with target drugs at 25% below and 25% above Cut-off levels. These samples were tested using three lots of each configuration (cassette, dipcard, and cup). Results were all positive for samples at and above +25% Cut-off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different devices.

4. Assay Reportable Range:

Not Applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The assay is traceable to a commercially-available, certified, standard material with the concentration verified by GC-MS or LC-MS/MS.

6. Detection Limit:

Not Applicable.

7. Assay Cutoff:

For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to the Precision section VII.A.1., above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies for the LYHER[®] Urine Multi-Drug Test were performed with three operators for each test configuration of the device (cassettes, dipcards, and cups). Operators ran at least 80 (40 negative and 40 positive) unaltered clinical samples for each analyte. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below:

AMP

AMP Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	12	1	0
	Positive	0	0	0	22	17
Operator 2	Negative	43	0	11	0	0
	Positive	0	0	1	23	17
Operator 3	Negative	43	0	12	0	0
	Positive	0	0	0	23	17

Discordant Results of AMP Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202300501	994	Positive
Operator 1	202300517	1008	Negative

AMP Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	12	1	0
	Positive	0	0	0	22	17
Operator 2	Negative	43	0	12	0	0
	Positive	0	0	0	23	17
Operator 3	Negative	43	0	11	0	0
	Positive	0	0	1	23	17

Discordant Results of AMP Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	202300501	994	Positive
Operator 1	202300517	1008	Negative

AMP Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	12	0	0
	Positive	0	0	0	23	17
Operator 2	Negative	43	0	12	0	0
	Positive	0	0	0	23	17
Operator 3	Negative	43	0	11	0	0
	Positive	0	0	1	23	17

Discordant Results of AMP Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	202300501	994	Positive

COC

COC Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	42	0	13	1	0
	Positive	0	0	1	37	5
Operator 2	Negative	42	0	14	0	0
	Positive	0	0	0	38	5
Operator 3	Negative	42	0	13	0	0
	Positive	0	0	1	38	5

Discordant Results of COC Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300680	298	Positive
Operator 3	202300680	298	Positive
Operator 1	202300684	303	Negative

COC Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	42	0	14	1	0
	Positive	0	0	0	37	5
Operator 2	Negative	42	0	13	0	0
	Positive	0	0	1	38	5
Operator 3	Negative	42	0	13	0	0
	Positive	0	0	1	38	5

Discordant Results of COC Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202300680	298	Positive
Operator 3	202300680	298	Positive
Operator 1	202300684	303	Negative

COC Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	42	0	14	0	0
	Positive	0	0	0	38	5
Operator 2	Negative	42	0	13	1	0
	Positive	0	0	1	37	5
	Negative	42	0	13	0	0

Operator 3	Positive	0	0	1	38	5
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Discordant Results of COC Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202300680	298	Positive
Operator 3	202300680	298	Positive
Operator 2	202300684	303	Negative

MET

MET Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	10	0	0
	Positive	0	0	2	24	16
Operator 2	Negative	43	0	11	0	0
	Positive	0	0	1	24	16
Operator 3	Negative	43	0	11	1	0
	Positive	0	0	1	23	16

Discordant Results of MET Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300331	932	Positive
Operator 1	202300374	561	Positive
Operator 2	202300374	561	Positive
Operator 3	202300374	561	Positive
Operator 3	202300393	1007	Negative

MET Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	11	0	0
	Positive	0	0	1	24	16
Operator 2	Negative	43	0	11	0	0
	Positive	0	0	1	24	16
Operator 3	Negative	43	0	11	1	0
	Positive	0	0	1	23	16

Discordant Results of MET Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300374	561	Positive
Operator 2	202300374	561	Positive
Operator 3	202300374	561	Positive
Operator 3	202300393	1007	Negative

MET Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	43	0	11	0	0
	Positive	0	0	1	24	16
Operator 2	Negative	43	0	11	0	0
	Positive	0	0	1	24	16
Operator 3	Negative	43	0	11	1	0
	Positive	0	0	1	23	16

Discordant Results of MET Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300374	561	Positive
Operator 2	202300374	561	Positive
Operator 3	202300374	561	Positive
Operator 3	202300393	1007	Negative

OPI

OPI Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	0	10	0	0
	Positive	0	0	0	33	8
Operator 2	Negative	45	0	9	1	0
	Positive	0	0	1	32	8
Operator 3	Negative	45	0	10	0	0
	Positive	0	0	0	33	8

Discordant Results of OPI Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202300180	2006	Negative
Operator 2	202300201	1978	Positive

OPI Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	0	10	0	0
	Positive	0	0	0	33	8
Operator 2	Negative	45	0	9	0	0
	Positive	0	0	1	33	8
Operator 3	Negative	45	0	10	1	0
	Positive	0	0	0	32	8

Discordant Results of OPI Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	202300180	2006	Negative
Operator 2	202300201	1978	Positive

OPI Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	0	10	1	0
	Positive	0	0	0	32	8
Operator 2	Negative	45	0	9	0	0
	Positive	0	0	1	33	8
Operator 3	Negative	45	0	9	0	0
	Positive	0	0	1	33	8

Discordant Results of OPI Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300180	2006	Negative
Operator 2	202300201	1978	Positive
Operator 3	202300201	1978	Positive

PCP

PCP Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	2	11	1	0
	Positive	0	0	1	34	8
Operator 2	Negative	45	2	12	1	0
	Positive	0	0	0	34	8
Operator 3	Negative	45	2	12	2	0
	Positive	0	0	0	33	8

Discordant Results of PCP Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202300810	23.0	Positive
Operator 2	202300822	25.2	Negative
Operator 3	202300822	25.2	Negative
Operator 1	202301750	25.2	Negative
Operator 3	202301750	25.2	Negative

PCP Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	2	12	0	0
	Positive	0	0	0	35	8
Operator 2	Negative	45	2	11	2	0
	Positive	0	0	1	33	8
Operator 3	Negative	45	2	12	0	0
	Positive	0	0	0	35	8

Discordant Results of PCP Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202300810	23.0	Positive
Operator 2	202300822	25.2	Negative
Operator 2	202301750	25.2	Negative

PCP Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	45	2	12	1	0
	Positive	0	0	0	34	8
Operator 2	Negative	45	2	12	0	0
	Positive	0	0	0	35	8
Operator 3	Negative	45	2	12	0	0
	Positive	0	0	0	35	8

Discordant Results of PCP Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202301750	25.2	Negative

THC

THC Cassettes	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	44	4	17	1	0
	Positive	0	0	0	24	15
Operator 2	Negative	44	4	16	2	0
	Positive	0	0	1	23	15
Operator 3	Negative	44	4	17	0	0
	Positive	0	0	0	25	15

Discordant Results of THC Cassettes

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202301036	50.5	Negative
Operator 2	202301060	52.3	Negative
Operator 2	202301069	49.6	Positive
Operator 2	202301651	51.1	Negative

THC Dipcards	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	44	4	16	0	0
	Positive	0	0	1	25	15
Operator 2	Negative	44	4	17	3	0
	Positive	0	0	0	22	15
Operator 3	Negative	44	4	17	1	0
	Positive	0	0	0	24	15

Discordant Results of THC Dipcards

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202301036	50.5	Negative
Operator 2	202301060	52.3	Negative
Operator 1	202301069	49.6	Positive
Operator 3	202301099	52.3	Negative
Operator 2	202301651	51.1	Negative

THC Cups	Test result	Negative urine	<-50% cut off	-50% cut off~cut off	Cut off~+50%cut off	>+50%cut off
Operator 1	Negative	44	4	16	0	0
	Positive	0	0	1	25	15
Operator 2	Negative	44	4	17	1	0
	Positive	0	0	0	24	15
Operator 3	Negative	44	4	17	2	0
	Positive	0	0	0	23	15

Discordant Results of THC Cups

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202301036	50.5	Negative
Operator 3	202301060	52.3	Negative
Operator 1	202301069	49.6	Positive
Operator 3	202301651	51.1	Negative

2. Matrix Comparison:

Not Applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not Applicable.

D Clinical Cutoff:

Not Applicable.

E Expected Values/Reference Range:

Not Applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.