



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

**I Background Information:**

**A 510(k) Number**

K240287

**B Applicant**

Hangzhou Laihe Biotech Co., Ltd.

**C Proprietary and Established Names**

LYHER® Oral fluid Multi-Drug Test Kit (Cube)

**D Regulatory Information**

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

**II Submission/Device Overview:**

**A Purpose for Submission:**

New device

**B Measurand:**

d-Amphetamine, d-Methamphetamine, Benzoylcegonine, Morphine, Phencyclidine and Delta-9-Tetrahydrocannabinol

**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® Oral fluid Multi-Drug Test Kit (Cube) is a rapid lateral flow immunoassay for the qualitative detection of d-Amphetamine, d-Methamphetamine, Benzoylcegonine, Morphine, Phencyclidine and Delta-9-Tetrahydrocannabinol in human oral fluid. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrator	Cut-off (ng/ml)
Opiates(OPI)	Morphine	40
Cocaine (COC)	Benzoylcegonine	20
Amphetamine (AMP)	d-Amphetamine	50
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methamphetamine (MET)	d-Methamphetamine	50
Phencyclidine (PCP)	Phencyclidine	10

The tests provide only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test 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:**

None

#### **IV Device/System Characteristics:**

##### **A Device Description:**

The LYHER® Oral fluid Multi-Drug Test Kit (Cube) is an immunochromatographic assay that uses a lateral flow system for the qualitative detection of d-Amphetamine, d-Methamphetamine, Benzoylcegonine, Morphine, Phencyclidine and Delta-9-Tetrahydrocannabinol in human oral fluid. The LYHER® Oral fluid Multi-Drug Test Kit (Cube) device consists of a cube device, an oral fluid collection swab and a package insert.

##### **B Principle of Operation:**

Each device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The goat-anti-rabbit IgG antibody-coated particles will then be captured by immobilized drug-specific conjugate. If the level of drug in the oral fluid specimen is below the cutoff concentration, the T line appears as a visible burgundy line. If the level of drug in the oral fluid 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):**

OralTox Oral Fluid Drug Test

##### **B Predicate 510(k) Number(s):**

K171403

##### **C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K240287</u>	<u>K171403</u>
Device Trade Name	LYHER® Oral fluid Multi-Drug Test Kit (Cube)	OralTox Oral Fluid Drug Test
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	For the qualitative determination of	Same

	Amphetamine, cocaine, cannabinoids, methamphetamine, opiate, phencyclidine in human oral fluid	
Methodology	Lateral flow immunochromatographic assay based on competitive binding	Same
Specimen Type	Human oral fluid	Same
Cutoffs	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL OPI 40 ng/mL PCP 10 ng/mL	Same
<b>General Device Characteristic Differences</b>		
Configuration	Cube	Cups

## VI Standards/Guidance Documents Referenced:

None referenced.

## 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, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative oral fluid samples. All drug concentration were confirmed by LC-MS/MS and all sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. Precision of the product was characterized at three different sites using 3 operators with 3 lots of cubes. For each concentration, two runs per day for 30 days per device lot were performed in a randomized order. Results are summarized below.

**Amphetamine**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	+25% cut off	+50% Cut off	+75% cut off	+100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	54+/6-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	5+/55-	47+/13-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	5+/55-	47+/13-	55+/5-	60+/0-	60+/0-	60+/0-

**Cocaine**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	+25% cut off	+50% Cut off	+75% cut off	+100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	6+/54-	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	6+/54-	49+/11-	55+/5-	60+/0-	60+/0-	60+/0-

**Methamphetamine**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	+25% cut off	+50% Cut off	+75% cut off	+100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	6+/54-	47+/13-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	6+/54-	48+/12-	54+/6-	60+/0-	60+/0-	60+/0-

**Morphine**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	+25% cut off	+50% Cut off	+75% cut off	+100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	6+/54-	49+/11-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	6+/54-	49+/11-	55+/5-	60+/0-	60+/0-	60+/0-

**Phencyclidine**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	+25% cut off	+50% Cut off	+75% cut off	+100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	6+/54-	48+/12-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	6+/54-	48+/12-	54+/6-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-

**Cannabinoids**

	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
Lot 1	0+/60-	0+/60-	0+/60-	6+/54-	49+/11-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	0+/60-	0+/60-	0+/60-	6+/54-	48+/12-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	0+/60-	0+/60-	0+/60-	5+/55-	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-

### *Sample Volume:*

A sample volume study was conducted to confirm the reproducibility of adequate sample volume collection by the device. Operators collected samples at two sites from a total 150 subjects (including drug users) following the device's instructions for use. Operators swept the inside of volunteer's mouth (cheek, gums, and tongue), and then held the swab in the subject's mouth for 3 minutes.

Mean volume collected by the swabs for cube format was 2.05 mL with a minimum volume of 1.6 mL, and a maximum volume of 2.5 mL.

### 2. Linearity:

Not applicable.

### 3. Analytical Specificity/Interference:

**Exogenous Interference:** Potential interference from structurally unrelated compounds were tested by spiking the potentially interfering compound at a concentration of 10 ug/mL into drug free oral fluid or fluid containing the target drug with concentrations of 50% below and 50% above cutoff level. The following compounds were found not to interfere with test results at a concentration of 10 ug/mL for all samples tested.

Acetaminophen	Digoxin	Nicotinamide
Acetylcodeine	Dihydrocodeine	Nicotine
Allobarbitol	diltiazem HCl	Noscapine
Alprazolam	Diphenhydramine HCl	Omeprazole
Amobarbital	DL-Propranolol	Papaverine
Apomorphine	Doxylamine	Pentazocine
Atenolol	Ecgonine methyl ester	Phentermine
Atropine	Estradiol	Phenylpropanolamine
Baclofen	Estrone	Phenytoin
Benzocaine	Fluconazole	Pioglitazone HCl
Butabarbital	Furosemide	Prednisolone
Caffeine	Hexobarbital	Prednisone
Cannabidiol	Hydrochlorothiazide	Procainamide HCl
Carbamazepine	Ibuprofen	Procaine HCL
Chlordiazepoxide	Imipramine	Promethazine
Chlorpromazine	Lamotrigine	Quinine HCl
Cimetidine	Levetiracetam	R,R(-)-Pseudoephedrine
Citalopram HBr	Lidocaine	Salicylic Acid
Clobazam	Lormetazepam	Sertraline HCL
Clomipramine	L-Thyroxine	Simvastatin
Clonazepam	Metformin HCl	Theophylline

Clonidine	Methylphenidate HCl	Thiamine
Clopidogrel bisulfate	Metoprolol	Topiramate
Cortisol	Metronidazole	Valproic Acid
Cotinine	Montelukast sodium salt	Verapamil
d,l-Salbutamol	Naloxone	Zonisamide
Deoxycorticosterone	Naltrexone	
Dextromethorphan	Naproxen	

The following potential interference from substances commonly present in oral fluid were evaluated by spiking into drug free oral fluid or oral fluid containing the target drug with concentrations of 50% below and 50% above cutoff level to a concentration of 5%: alcohol, baking soda, chewing gum, coffee, cola, cough syrup, cranberry juice, food coloring (blue, green, and red), methanol cough drops, milk, mouthwash, monosodium glutamate (MSG), orange juice, salt, sugar, tea, toothpaste, and tomatoes. None of these substances showed any interference with any of the analytes in the candidate device.

Potential interference from cigarette smoking was evaluated by asking a participant to smoke a cigarette, and after 15 minutes an oral fluid sample was collected and spiked with each drug at concentrations of cutoff +/- 50%. No interference was seen with any of the analytes in the candidate device.

Potential interference from Hemoglobin (blood) was evaluated by adding it to drug free oral fluid and oral fluid containing the target drug with concentrations of 50% above and 50% below cutoff level to a concentration of 100 ug/mL. No interference was seen with any of the analytes in the candidate device.

Effect of oral fluid pH: To investigate the effect of oral fluid pH, oral fluid samples with pH 3 to 9 were spiked with target drugs at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of the device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

**Cross-reactivity.** To evaluate cross reactivity, drug metabolites and other components that may be present in oral fluid samples were tested using three lots of the device. The following are summaries of the cross-reactivities.

<b>d-Amphetamine (Cut-off=50 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
D-Amphetamine	50	100
L-Amphetamine	4000	1.25
D,L-Amphetamine	125	40
Methoxyamphetamine	500	10
Methylenedioxyamphetamine(MDA)	150	33
Benzodioxolylbutanamine (BDB)	10000	0.5
3-Hydroxy Tyramine	5000	1
d,l-p-Chloramphetamine	500	10

<b>d-Amphetamine (Cut-off=50 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
Phenethylamine	4000	1.25
Hydroxyamphetamine	800	6.25
d,l-Phenylpropanolamine	Negative at 10000	<0.5%
Phentermine		
Methylenedioxyethylamphetamine (MDEA)		
Methylenedioxy-methamphetamine (MDMA)		
d-Methamphetamine		
l-Methamphetamine		
Dimethylamylamine (DMAA)		
Methylbenzodioxolylbutanamine		
para-Methoxymethamphetamine		
Phendimetrazine		
Phenmetrazine		
D-Ephedrine		
L-Ephedrine		
D,L-Ephedrine		
diphenhydramine		
d-Pseudoephedrine		
Fenfluramine		
Isoxsuprine		
l-Pseudoephedrine		
Mephentermine		

<b>Cocaine (Cut-off=20ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
Cocaine	20	100%
Benzoylcegonine	20	100%
Cocaethylene	25	80%
Procaine	Negative at 20000	<0.1%
Ecgonine	1500	1.30%
Ecgonine methyl ester	12500	0.16%
Norcocaine	Negative at 20000	<0.1%



<b>d-Methamphetamine (Cutoff=50 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross- Reactivity</b>
D-Methamphetamine	50	100%
L-Methamphetamine	3000	2%
Methoxymethamphetamine	50	100%
Ephedrine	400	13%
Phenylephrine	4000	1%
Procaine	2000	3%
Methylephedrine	400	13%
Methylenedioxy- ethylamphetamine (MDEA)	400	13%
3,4-methylenedioxy- methamphetamine (MDMA)	50	100%
Amphetamine	Negative at 10000	<0.5%
L-Amphetamine	Negative at 10000	<0.5%
D- Amphetamine	Negative at 10000	<0.5%
3,4-methylenedioxy- amphetamine (MDA)	Negative at 10000	<0.5%

<b>Morphine (Cut-off=40 ng/mL)</b>	<b>Result Positive at(ng/mL)</b>	<b>% Cross- Reactivity</b>
Morphine	40	100%
Acetylmorphine	30	133%
Codeine	10	400%
Ethylmorphine	30	133%
Heroin	50	80%
Hydromorphone	100	40%
Thebaine	1500	3%
Norcodeine	1500	3%
Morphine 6-β-glucuronide	50	80%
Oxycodone	25000	0.2%
Oxymorphone	25000	0.2%
Nalorphine	10000	0.4%
Hydrocodone	100	40%
6-Monoacetylmorphine	30	133%
Morphine 3-β-glucuronide	50	80%

<b>PCP (Cutoff=10ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross- Reactivity</b>
Phencyclidine	10	100%
Tenocyclidine (TCP)	2000	0.5%
1-(1-phenylcyclohexyl)morpholine(PCM)	20	50.00%
4-hydroxyphencyclidine	20	50.00%
Hydrocodone	Negative at 30000	<0.03%
Hydromorphone	Negative at 30000	<0.03%
Nalorphine	Negative at 30000	<0.03%
EDDP	Negative at 100000	<0.01%
Ketamine	Negative at 100000	<0.01%
Prazepam	Negative at 100000	<0.01%
Amitriptyline	Negative at 100000	<0.01%
(+) Brompheniramine	Negative at 100000	<0.01%
(+) Chlorphenamine	Negative at 100000	<0.01%
desmethylvenlafaxine	Negative at 100000	<0.01%
Chlorpromazine	Negative at 100000	<0.01%
Clomipramine	Negative at 100000	<0.01%
Cyclizine	Negative at 100000	<0.01%
Cyclobenzaprine	Negative at 100000	<0.01%
Dexbrompheniramine	Negative at 100000	<0.01%
Dextromethorphan	Negative at 100000	<0.01%
Diphenhydramine	Negative at 100000	<0.01%
Doxepin	Negative at 100000	<0.01%
Doxylamine	Negative at 100000	<0.01%
Imipramine	Negative at 100000	<0.01%
Thioridazine	Negative at 100000	<0.01%
Venlafaxine	Negative at 100000	<0.01%

<b>Delta-9-Tetrahydrocannabinol (Cut-off=40 ng/mL)</b>	<b>Result Positive at(ng/mL)</b>	<b>% Cross-Reactivity</b>
Delta-9-Tetrahydrocannabinol	40	100%
11-nor-Δ9-THC-9 COOH	12	333%
Δ8-Tetrahydrocannabinol	12500	0.32%
11-hydroxy-Δ9-THC	400	10%
Cannabinol	12500	0.32%
Cannabidol	Negative at 12500	0.32%
11-Nor-Δ9-THC-carboxy-glucuronide	80	50%
(-)-11-nor-9-carboxy-Δ9-THC	60	67%
11-nor-Δ8-THC-9-COOH	5	800%
8-beta-11-dihydroxy-Δ9-THC	400	10%
8-beta-hydroxy-Δ9-THC	300	13%
Exo-THC	80	50%
l-11-Nor-Δ9-THC-9-Carboxylic Acyl-Glucuronide	15	267%
Δ8-THC	6000	1%
Δ8-THC Carboxylic Acid	5	800%
Δ9-THC Carboxylic Acid	12	333%

4. Assay Reportable Range:

Not applicable.

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

**Sample Recovery**

Volume:

A sample volume study was conducted to confirm that adequate sample volume could be extracted from the device for confirmatory testing after collection and shipping. Operators collected samples at two sites from a total 150 subjects (including drug users) following the device's instructions for use. Devices containing oral fluid samples were then sent to the confirmation laboratory using overnight shipping. The sponsor reported that the confirmation lab was able to extract sufficient sample volume for the confirmation testing of all six analytes for all samples collected.

#### Analyte recovery:

In order to confirm that preliminary positive results can be adequately measured via confirmation testing after being subject to the temperature conditions required for shipping and storage, negative oral fluid samples in glass bottles were spiked with a single analyte/bottle to concentrations approximately -50% and +50% of the cutoff. Samples were spiked using known standards. Each drug concentration was confirmed by LC-MS/MS. The samples were transferred to Lyher devices using the collection sponges. For each of 3 storage conditions (-20°C, 20-25°C, and 40°C), 12 devices were used (4 devices from each of 3 lots. For each device, drug was measured by LC-MS/MS at day 0 and the devices containing the specimens were stored under the specified condition. Drug in the devices stored at 20-25°C and 40°C was measured by LC-MS/MS at two (2) days, and drug in the devices stored at -20°C was measured by LC-MS/MS at 90 days. The minimum and maximum recovery across all lots per storage condition is shown below.

#### Room Temperature 20-25°C (two day storage) % Recovery

	MET +50	MET -50	COC +50	COC -50	OPI +50	OPI -50
Max	105.7	109.6	108.3	109.7	107.0	100.5
Min	91.7	94.0	98.3	96.5	91.0	91.5
	AMP +50	AMP -50	PCP +50	PCP -50	THC +50	THC -50
Max	105.7	109.6	107.4	105.1	103.9	109.8
Min	91.7	94.0	92.7	93.1	92.0	91.1

#### 40 °C (two day storage) % Recovery

	MET +50	MET -50	COC +50	COC -50	OPI +50	OPI -50
Max	103.7	110.2	109.3	109.3	107.7	109.4
Min	91.4	93.5	94.6	96.8	91.7	91.6
	AMP +50	AMP -50	PCP +50	PCP -50	THC +50	THC -50
Max	103.8	110.2	109.1	106.6	107.0	109.2
Min	91.4	93.5	95.4	92.3	91.2	91.4

#### -20 °C (90 day storage) % Recovery

	MET +50	MET -50	COC +50	COC -50	OPI +50	OPI -50
Max	108.1	109.2	107.2	106.4	108.4	104.9
Min	91.7	93.6	93.4	92.8	93.1	91.3
	AMP +50	AMP -50	PCP +50	PCP -50	THC +50	THC -50
Max	108.1	109.2	105.7	109.6	107.2	109.2
Min	91.6	93.6	92.1	90.5	91.7	93.0

Results indicate that samples may be stored at room temperature for up to two days, elevated temperature for up to two days (40 °C), and for up to 90 days at – 20 °C, prior to confirmatory testing.

#### 6. Detection Limit:

Not applicable.

## 7. Assay Cut-Off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section VII A1 above.

## B Comparison Studies:

### 1. Method Comparison with Predicate Device:

Method comparison studies were performed at three testing sites A, B, and C with three operators and two lots of the candidate device. One lot was used at site A and a second lot was used at sites B and C. Subjects provided three independent samples, each to one of three different operators. Operators tested all samples and compared to LC-MS/MS results. The results are presented in the tables below:

#### **d-Amphetamine**

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	93	74	9	0
	Positive	0	0	1	180	183

#### Discordant Results (d-Amphetamine)

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202301228	49.2	Pos
Operator 3	202301233	51.2	Neg
Operator 2	202301282	50.3	Neg
Operator 3	202301282	50.3	Neg
Operator 1	202301776	53.5	Neg
Operator 3	202401819	50.6	Neg
Operator 1	202401878	53.0	Neg
Operator 1	202401892	50.1	Neg
Operator 1	202401974	50.7	Neg
Operator 3	202401995	51.0	Neg

#### **Cocaine**

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	69	83	8	0
	Positive	0	0	4	172	186

#### Discordant Results (Cocaine)

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202301824	21.3	Neg
Operator 1	202301842	19.6	Pos
Operator 3	202301842	19.6	Pos
Operator 1	202301863	20.2	Neg
Operator 3	202301863	20.2	Neg
Operator 2	202301868	20.8	Neg
Operator 1	202301891	19.1	Pos
Operator 2	202401343	20.8	Neg
Operator 3	202401440	19.5	Pos
Operator 1	202401495	20.4	Neg
Operator 3	202401495	20.4	Neg
Operator 3	202401517	20.1	Neg

#### d-Methamphetamine

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	63	70	7	0
	Positive	0	0	2	164	189

#### Discordant Results (d-Methamphetamine)

Operator 2	202301396	56.6	Neg
Operator 1	202301412	50.4	Neg
Operator 3	202301414	44.4	Pos
Operator 2	202301444	37.1	Pos
Operator 2	202301460	50.9	Neg
Operator 3	202401183	51.2	Neg
Operator 1	202401185	51.7	Neg
Operator 1	202401301	50.9	Neg
Operator 3	202401301	50.9	Neg

#### Morphine

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	57	84	6	0

	Positive	0	0	3	183	180
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#### Discordant Results (Morphine)

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202301524	39.5	Pos
Operator 2	202301524	39.5	Pos
Operator 1	202301531	40.2	Neg
Operator 2	202301531	40.2	Neg
Operator 2	202301578	41.6	Neg
Operator 1	202301580	38.3	Pos
Operator 2	202301799	44.5	Neg
Operator 1	202301803	46.6	Neg
Operator 2	202401044	40.9	Neg

#### Phencyclidine

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	51	109	13	0
	Positive	0	0	5	170	192

#### Discordant Results (Phencyclidine)

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	202301979	9.59	Pos
Operator 1	202301987	10.2	Neg
Operator 3	202301987	10.2	Neg
Operator 1	202302035	9.68	Pos
Operator 2	202302036	10.2	Neg
Operator 3	202302036	10.2	Neg
Operator 2	202302045	11.6	Neg
Operator 2	202302060	9.96	Pos
Operator 2	202401633	10.1	Neg
Operator 3	202401633	10.1	Neg
Operator 1	202401669	9.89	Pos
Operator 2	202401680	10.2	Neg
Operator 1	202401683	11.1	Neg
Operator 3	202401729	10.1	Neg
Operator 1	202401739	9.83	Pos
Operator 2	202401776	11	Neg
Operator 1	202401777	10	Neg
Operator 1	202401791	10.1	Neg

**Cannabinoids**

	Lyher Test result	Negative oral fluid	<-50% cut off	-50% cut off - cut off	Cut off - +50%cut off	>+50%cut off
All operators	Negative	360	93	96	8	0
	Positive	0	0	3	172	195

**Discordant Results (Cannabinoids)**

Operator	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	202302124	41.1	Neg
Operator 3	202302127	40.7	Neg
Operator 1	202302138	37.6	Pos
Operator 2	202302200	28.4	Pos
Operator 3	202402037	38.8	Pos
Operator 1	202402048	41.4	Neg
Operator 2	202402091	41.5	Neg
Operator 3	202402164	41	Neg
Operator 3	202402175	40.8	Neg
Operator 1	202402180	40.2	Neg
Operator 3	202402180	40.2	Neg

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 Cut-Off:**

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.