Hangzhou Laihe Biotech Co., Ltd.
% Ethan Liu
RA specialist
Shanghai Thinkwell Consulting Co., Ltd
Xinling Rd., 211/6F
Shanghai, Shanghai 201100
China

Re: K232597

Trade/Device Name: LYHER® Urine Multi-Drug Test Kit(Cup), LYHER® Urine Multi-Drug Test Kit(Cassette), LYHER® Urine Multi-Drug Test Kit(Dipcard)
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DIO, DKZ, LDJ, DJC, LCM
Dated: November 27, 2023
Received: December 1, 2023

Dear Ethan Liu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2024.01.09 14:04:36 -05'00'

Joseph Kotarek, PhD
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232597

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

Indications for Use *(Describe)*
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, Benzoylecgonine, 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)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ9-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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
510(k) Number: K232597

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	Hangzhou Laihe Biotech Co., Ltd. Address: Room 401-406, F1-3, Building 1, No.425 Miaohouwang Road, Xixing Street, Binjiang District, Hangzhou, 310051 Zhejiang P.R. China Tel.: +86 571 8765 3090 Fax: +86 571 8665 8000 www.lyher.com
Contact Person:	Ethan Liu Shanghai Thinkwell Consulting Co., Ltd Address:Xinling Rd., 211/6F Shanghai, 201100,P.R. China Phone:0086-15216699240 Email:xtdeepwater@126.com
Date Prepared:	Dec 29, 2023

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

Classification:

Test	Product Code	CFR #	Panel
Opiates(OPI)	DJG	862.3650/Opiate test system.	Toxicology
Cocaine (COC)	DIO	862.3250/Cocaine and cocaine metabolite test system.	Toxicology
Amphetamine (AMP)	DKZ	862.3100/Amphetamine Test System	Toxicology
Marijuana (THC)	LDJ	862.3870/Cannabinoid test system.	Toxicology
Methamphetamine (MET)	DJC	862.3610/Methamphetamine test system.	Toxicology
Phencyclidine (PCP)	LCM	Unclassified	Toxicology

5.3 Predicate Device:
ATTEST Drug Screen Cup, ATTEST Drug Screen Dip Card, K182123

5.4 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, Benzoylecgonine, 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.

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

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Amphetamine (AMP)	d-Amphetamine	1000
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ9-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.

5.8 Substantial Equivalence
A summary comparison of features of the LYHER® Urine Multi-Drug Test Kit(Cup/Cassette/Dipcard) and the predicate devices is provided in following tables.

Item	Proposed Device	Predicate Device-K182123
Indications for Use	For the qualitative determination of drugs of abuse and/or their metabolites in human urine.	Same
Methodology	Lateral flow immunochromatographic assay based on competitive binding	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same

<table>
<tr>
<td>Cut-off Values</td>
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<table>
<tr><th>Test</th><th>Calibrator</th><th>Cut-off ng/mL</th></tr>
<tr><td>Opiates(OPI)</td><td>Morphine</td><td>2000</td></tr>
<tr><td>Cocaine (COC)</td><td>Benzoylecgonine</td><td>300</td></tr>
<tr><td>Amphetamine (AMP)</td><td>d-Amphetamine</td><td>1000</td></tr>
<tr><td>Marijuana (THC)</td><td>11-nor-Δ^9-THC-9-COOH</td><td>50</td></tr>
<tr><td>Methamphetamine (MET)</td><td>d-Methamphet-amine</td><td>1000</td></tr>
<tr><td>Phencyclidine (PCP)</td><td>Phencyclidine</td><td>25</td></tr>
</table>
</td>
<td>
<table>
<tr><th>Test</th><th>Calibrator</th><th>Cutoff ng/ml</th></tr>
<tr><td>6-Acetylmorphine</td><td>6-monoacetyl-morphine</td><td>10</td></tr>
<tr><td>Amphetamine 500</td><td>d-amphetamine</td><td>500</td></tr>
<tr><td>Amphetamine 1000</td><td>d-amphetamine</td><td>1000</td></tr>
<tr><td>Barbiturates</td><td>Secobarbital</td><td>300</td></tr>
<tr><td>Benzodiazepine</td><td>Oxazepam</td><td>300</td></tr>
<tr><td>Buprenorphine</td><td>Buprenorphine</td><td>10</td></tr>
<tr><td>Cocaine 150</td><td>Benzoylecgonine</td><td>150</td></tr>
<tr><td>Cocaine 300</td><td>Benzoylecgonine</td><td>300</td></tr>
<tr><td>EDDP</td><td>2-ethylidene-1,5-dimethyl-3-3-diphenyl-pyrrolidine</td><td>300</td></tr>
<tr><td>Ecstasy</td><td>d/l-methylenedioxy-meth-amphetamine</td><td>500</td></tr>
<tr><td>Methamphet-amine 500</td><td>d-methamphetamine</td><td>500</td></tr>
<tr><td>Methamphet-amine 1000</td><td>d-methamphetamine</td><td>1000</td></tr>
<tr><td>Methadone</td><td>d/l-methadone</td><td>300</td></tr>
<tr><td>Morphine</td><td>Morphine</td><td>300</td></tr>
<tr><td>Opiates</td><td>Morphine</td><td>2,000</td></tr>
<tr><td>Oxycodone</td><td>Oxycodone</td><td>100</td></tr>
<tr><td>Phencyclidine</td><td>Phencyclidine</td><td>25</td></tr>
<tr><td>Propoxyphene</td><td>d-propoxyphene</td><td>300</td></tr>
<tr><td>Tricyclics</td><td>Nortriptyline</td><td>1,000</td></tr>
<tr><td>Marijuana</td><td>THC-COOH</td><td>5</td></tr>
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</tr>
<tr><td>Intended Use</td><td>For prescription uses.</td><td>Same</td></tr>
<tr><td>Configura-tions</td><td>Cup,Dip Card, Cassette</td><td>Cup, Dip Card</td></tr>
</table>

5.9 Test Principle

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 polycolonal 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.

Testing is based on the principle of a competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample competing for the limited antibody binding sites.

5.10 Performance Characteristics

5.10.1 Analytical Performance

a. Precision

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. 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 has three lots, and 6 operators have joined the performance. Each specimen was analyzed in 50 replicates by each of the testing personnel at each Lab site 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.

b. Linearity

Not applicable

c. Stability

The devices are stable at 2-30 °C for 24 months based on the accelerated stability study.

d. Cut-off

Dilute the solution by negative urine to the concentration of +50% cut off, +25%cut off, cut off, -25%cut off, -50%cut off respectively. To test all these above specimens by three different batches of the candidate product and each concentration will be tested for 25 replicates.

The following cut-off values for the candidate devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Opiates(OPI)	Morphine	2000
Cocaine (COC)	Benzoylecgonine	300
Amphetamine (AMP)	d-Amphetamine	1000

Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50
Methamphetamine (MET)	d-Methamphetamine	1000
Phencyclidine (PCP)	Phencyclidine	25

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added 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 batches of each device. Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different devices

Amphetamine:

Substance	Substance	Substance
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	Δ9-tetrahydrocannabinol
Dopamine	Oxalic acid	
EDDP	Oxycodone	

Ephedrine	Pantoprazole	

Cocaine(COC)

Substance	Substance	Substance
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	Morphine
Dimethylaminoantipyrine	Nicotine	Methylamphetamine
Diphenhydramine	Norephedrine	MDMA
Dopamine	Oxalic acid	Δ9-tetrahydrocannabinol
EDDP	Oxycodone	Amphetamine
Ephedrine	Pantoprazole	

MET

Substance	Substance	Substance
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
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Diphenhydramine	Norephedrine	Δ9-tetrahydrocannabinol
Dopamine	Oxalic acid	
EDDP	Oxycodone	
Ephedrine	Pantoprazole	

OPI

Substance	Substance	Substance
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	Methylamphetamine
Diphenhydramine	Norephedrine	MDMA
Dopamine	Oxalic acid	Amphetamine
EDDP	Oxycodone	Δ9-tetrahydrocannabinol
Ephedrine	Pantoprazole	

PCP

Substance	Substance	Substance
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
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Diphenhydramine	Norephedrine	MDMA
Dopamine	Oxalic acid	Amphetamine
EDDP	Oxycodone	Δ9-tetrahydrocannabinol
Ephedrine	Pantoprazole	

THC

Substance	Substance	Substance
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
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Benzocaine	Isoproterenol	Riboflavin
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Chloroquine	Lidocaine	Sulindac
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Creatine	Methadone	Tyramine
Dexbrompheniramine	Methylephedrine	β-Phenylethylamine
Dextromethorphan	Naproxen	Phencyclidine(PCP)
Dimenhydrinate	Niacinamide	Cocaine
Dimethylaminoantipyrine	Nicotine	Morphine
Diphenhydramine	Norephedrine	Methylamphetamine
Dopamine	Oxalic acid	MDMA
EDDP	Oxycodone	Amphetamine
Ephedrine	Pantoprazole	

f. Specificity

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

Compound	Concentration (ng/mL)	%Cross Reactivity
Amphetamine (AMP)		
D-Amphetamine	1000	100%
D,L-Amphetamine sulfate	2500	40%
β-Phenylethylamine	60000	1.67%
(±)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	
Benzoylecgonine	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-△8-THC-9 COOH	30	167%
11-nor-△9 -THC-9 COOH	50	100%
△8 -THC	15000	0.33%
△9 -THC	15000	0.33%
(±)-11-Hydroxy-Δ9-THC	5000	1%
Cannabidiol	20000	0.25%
METHAMPHETAMINE (MET)		
p-Hydroxymethamphetamine	30000	3.33%
D-Methamphetamine	1000	100%
L-Methamphetamine	8000	12.5%
(±)-3,4-Methylenedioxymethamphetamine	2000	50%
Mephentermine	50000	2%
D-Amphetamine	100000	1%

Compound	Concentration (ng/mL)	%Cross Reactivity
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%

g. 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 device. 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.

5.10.2 Method comparison

Method comparison studies for the LYHER® Urine Multi-Drug Test were performed in-house with three laboratory assistants for each device. Operators ran samples unaltered clinical samples. The samples were blind labeled and compared to GC/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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	59	202300501	994	Positive
Operator 1	75	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	59	202300501	994	Positive
Operator 1	75	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	59	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	17	202300680	298	Positive
Operator 3	17	202300680	298	Positive
Operator 1	21	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	17	202300680	298	Positive
Operator 3	17	202300680	298	Positive
Operator 1	21	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
Operator 3	Negative	42	0	13	0	0
	Positive	0	0	1	38	5

Discordant Results of COC Cups

Operator	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	17	202300680	298	Positive
Operator 3	17	202300680	298	Positive
Operator 2	21	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	15	202300331	932	Positive
Operator 1	58	202300374	561	Positive
Operator 2	58	202300374	561	Positive
Operator 3	58	202300374	561	Positive
Operator 3	77	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	58	202300374	561	Positive
Operator 2	58	202300374	561	Positive
Operator 3	58	202300374	561	Positive
Operator 3	77	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	58	202300374	561	Positive
Operator 2	58	202300374	561	Positive
Operator 3	58	202300374	561	Positive
Operator 3	77	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	59	202300180	2006	Negative
Operator 2	80	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 3	59	202300180	2006	Negative
Operator 2	80	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	59	202300180	2006	Negative
Operator 2	80	202300201	1978	Positive
Operator 3	80	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	25	202300810	23.0	Positive
Operator 2	37	202300822	25.2	Negative
Operator 3	37	202300822	25.2	Negative
Operator 1	100	202301750	25.2	Negative
Operator 3	100	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	25	202300810	23.0	Positive
Operator 2	37	202300822	25.2	Negative
Operator 2	100	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	100	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 1	12	202301036	50.5	Negative
Operator 2	36	202301060	52.3	Negative
Operator 2	45	202301069	49.6	Positive
Operator 2	92	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	12	202301036	50.5	Negative
Operator 2	36	202301060	52.3	Negative
Operator 1	45	202301069	49.6	Positive
Operator 3	75	202301099	52.3	Negative
Operator 2	92	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	SN.	Specimen No.	LC/MS results	Results of Lyher kit
Operator 2	12	202301036	50.5	Negative
Operator 3	36	202301060	52.3	Negative
Operator 1	45	202301069	49.6	Positive
Operator 3	92	202301651	51.1	Negative

5.11 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Hangzhou Laihe Biotech Co., Ltd has demonstrated that proposed device LYHER® Urine Multi-Drug Test Kit(Cup), LYHER® Urine Multi-Drug Test Kit(Cassette), LYHER® Urine Multi-Drug Test Kit(Dipcard) are substantially equivalent to ATTEST Drug Screen Cup, ATTEST Drug Screen Dip Card, K182123.