March 16, 2026

Healgen Scientific, LLC
℅ Jenny Xia
Director
LSI International, Inc.
504e Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K253705
Trade/Device Name: Healgen® Accurate Oral Fluid Drug Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC, DKZ, DIO, LDJ, LCM, DJG, DJR
Dated: November 16, 2025
Received: November 24, 2025

Dear Jenny Xia:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.03.16 10:45:20 -04'00'

Joseph Kotarek
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k253705

Device Name
Healgen® Accurate Oral Fluid Drug Test

Indications for Use *(Describe)*
The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiates, Oxycodone , and Phencyclidine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10

The test provides only preliminary test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. It is not intended to distinguish between prescription use or abuse of the drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
K253705

1. Date: February 27, 2026

2. Submitter: HEALGEN SCIENTIFIC LLC
5213 Maple Street
Bellaire, TX 77401

3. Contact person: Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email:jxia@lsi-consulting.org

4. Device Names: Healgen® Accurate Oral Fluid Drug Test

Classification: Class II

Product Code	CFR #	Panel
DKZ	21CFR 862.3100, Amphetamine Test System	Toxicology
DIO	21 CFR 862.3250, Cocaine and metabolites Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoids Test System	Toxicology
DJC	21 CFR 862.3610, Methamphetamine Test System	Toxicology
LCM	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology
DJG	21 CFR 862.3650, Opiate Test System	Toxicology
DJR	21 CFR, 862.3610 Methadone Test System	Toxicology

5. Predicate Devices:

Premier Biotech OralTox® Oral Fluid Drug Test, K181305

6. Intended Use

The Healgen® Accurate Oral Fluid Drug Test is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiates, Oxycodone , and Phencyclidine in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20

Phencyclidine (PCP)	Phencyclidine	10

The test provides only preliminary test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. It is not intended to distinguish between prescription use or abuse of the drug. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Device Description

The Healgen® Accurate Oral Fluid Drug Test is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Cocaine, marijuana, Methadone, Methamphetamine, Opiates, Oxycodone and Phencyclidine in oral fluids. 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.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen® Accurate Oral Fluid Drug Test and the predicate devices are provided in following tables.

Table 1: Features Comparison of Healgen® Accurate Oral Fluid Drug Test and the Predicate Device

Item	Device	Predicate – K181305
Indication(s) for Use	For the qualitative determination of drug analytes in human oral fluid.	Same
Calibrators	d-Amphetamine Benzoylecgonine Delta-9-Tetrahydrocannabinol Methadone d-Methamphetamine Morphine Oxycodone Phencyclidine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays	Same
Type of Test	Qualitative	Same
Specimen Type	Human Oral fluid	Same
Cut-Off Values	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL OPI 40 ng/mL PCP 10 ng/mL OXY 20 ng/mL MTD 30 ng/mL	Same
Intended Use	For prescription use	Same

Differences		
Device Format	Rectangular prism shaped cup	Half cylinder shaped cup

9. Test Principle

The Healgen® oral fluid drug test device is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

10. Performance Characteristics

1. Analytical Performance

a. Precision-Reproducibility-Cut-Off

Precision-Reproducibility-Cut-Off 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 target drug in negative oral fluid samples. Each drug concentration was confirmed by LC/MS/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device lot in a randomized order. The following are summaries.

AMP

Results Device 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
LC-MS	*0*	*12.2*	*26.0*	*37.1*	*51.0*	*64.6*	*77.1*	*87.8*	*101.2*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-

COC

Results Device 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
LC-MS (ng/mL)	*0*	*5.3*	*10.2*	*16.2*	*21.3*	*26.8*	*31.9*	*35.2*	*40.7*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

MET

Results Device 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

LC-MS (ng/mL)	*0*	*12.2*	*25.3*	*36.7*	*50.2*	*62.3*	*78.0*	*87.0*	*99.1*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	28-/22+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

MTD

Results Device 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
LC-MS (ng/mL)	*0*	*7.8*	*15.8*	*23.4*	*31.6*	*38.2*	*44.5*	*52.9*	*59.7*
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-

OPI

Results Device 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
LC-MS (ng/mL)	*0*	*10.4*	*20.7*	*30.4*	*40.1*	*51.4*	*61.2*	*70.8*	*81.7*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-

OXY

Results Device 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
LC-MS (ng/mL)	*0*	*5.4*	*10.6*	*15.7*	*20.4*	*25.2*	*32.8*	*37.8*	*43.6*
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

PCP

Results Device 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
LC-MS (ng/mL)	*0*	*2.7*	*5.3*	*8.0*	*10.7*	*13.2*	*16.0*	*18.8*	*21.5*
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	49+/1-	50+/0-	50+/0-	50+/0-

THC

Result Device 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
LC-MS (ng/mL)	0	10.3	20.7	30.8	41.3	51.1	60.7	72.8	80.2
Lot 1:	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2:	50-/0+	50-/0+	50-/0+	48-/2+	28-/22+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3:	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

The following cut-off values are verified.

Calibrator	Cutoff (ng/mL)
d-Amphetamine	50
Benzoylecgonine	20
Delta-9-Tetrahydrocannabinol	40
Methadone	30
d-Methamphetamine	50
Morphine	40
Oxycodone	20
Phencyclidine	10

b. Linearity

Not applicable.

c. Stability

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

d. Interference

Potential interfering substances were added to drug-free oral fluid and target drugs oral fluid with concentrations at 50% below and 50% above Cut-Off levels. These oral fluid samples were tested using three batches of the Healgen device. Compounds that showed no interference for drugs at a concentration of 100μg/mL are summarized in the following tables.

Acetaminophen	Deoxycorticosterone	Naproxen
Acetylcodeine	Dextromethorphan	Nicotinamide
Allobarbital	Digoxin	Nicotine
Alprazolam	Diltiazem HCl	Noscapine
Amobarbital	Diphenhydramine HCl	Omeprazole
Apomorphine	DL-Propranolol	Papaverine
Atenolol	Estradiol	Pentazocine
Atropine	Estrone	Phenytoin
Baclofen	Fluconazole	Pioglitazone HCl
Benzocaine	Furosemide	Prednisolone
Butabarbital	Hexobarbital	Prednisone
Caffeine	Hydrochlorothiazide	Procainamide HCl
Carbamazepine	Ibuprofen	Promethazine
Chlordiazepoxide	Imipramine	Quinine HCl
Chlorpromazine	Lamotrigine	R,R(-)-Pseudoephedrine
Cimetidine	Levetiracetam	Salicylic Acid
Citalopram HBr	Lidocaine	Sertraline HCL
Clobazam	Lormetazepam	Simvastin
Clomipramine	L-Thyroxine	Theophylline
Clonazepam	Metformin HCl	Thiamine
Clonidine	Methylphenidate HCl	Topiramate
Clopidogrel bisulfate	Metoprolol	Valproic Acid
Cortisol	Metronidazole	Verapamil
Cotinine	Montelukast sodium salt	Zonisamide
d,l-Salbutamol	Naltrexone HCl (except for OXY)	Dihydrocodeine (except for OPI & OXY)
Doxylamine	Ecgonine methylester (except for COC)	Phentermine (except for AMP)
Naloxone HCl (except for OXY)		

Food items such as methanol cough drops, cough syrup, cola, mouthwash, coffee, tea, milk, sugar, chewing gum, alcohol, baking soda, salt, cranberry juice, orange juice, food coloring (red, blue, green), toothpaste, tomatoes and MSG were added in either drug-free oral fluid or oral fluid containing the target drugs with concentrations of 50% below and 50% above cutoff levels to a concentration of 5%. None of the substances showed interference.

Hemoglobin showed no interference at 10mg/dL.

e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in oral fluid samples were tested using three batches of the Healgen device. The following are summaries.

Drug	Concentration (ng/mL)	% Cross-Reactivity
AMPHETAMINE (AMP)		
D-Amphetamine	50	100%
l-Amphetamine	2,500	2%
d/l-Amphetamine	100	50%
Methylenedioxyamphetamine (MDA)	62.5	80%
3-Hydroxy Tyramine	2,500	2%
d,l-Phenylpropanolamine	10,000	0.5%
Phenethylamine	1,000	5%
Phentermine	12,500	0.4%
d-Methamphetamine	50,000	0.1%
l-Methamphetamine	50,000	0.1%
Hydroxyamphetamine	12,500	0.4%
Dimethylamylamine (DMAA)	50,000	0.1%
Methoxyamphetamine	200	25%
Benzodioxolylbutanamine(BDB)	10,000	0.5%
d,l-p-Chloramphetamine	300	16.7%
Methylenedioxyethylamphetamine	>100,000	<0.05%
Methylenedioxymethamphetamine	>100,000	<0.05%
Methylbenzodioxolylbutanamine	>100,000	<0.05%
para-Methoxymethamphetamine	>100,000	<0.05%
Phendimetrazine	>100,000	<0.05%
Phenmetrazine	>100,000	<0.05%
Ephedrine (d-,or l-,or d-l form)	>100,000	<0.05%
d-Pseudoephedrine	>100,000	<0.05%
Isoxsuprine	>100,000	<0.05%
l-Pseudoephedrine	>100,000	<0.05%
Fenfluramine	>100,000	<0.05%
Mephentermine	>100,000	<0.05%
COCAINE (COC)		
Benzoylecgonine	20	100%
Cocaine	20	100%
Cocaethylene	25	80%
Ecgonine	15,00	1.3%
Ecgonine methylester	12,500	0.16%
Norcocaine	500	4%
Procaine	>100,000	<0.02%

Drug	Concentration (ng/mL)	% Cross-Reactivity
MARIJUANA (THC)		
Δ^9-Tetrahydrocannabinol	40	100%
11-nor-Δ^9-THC-9 COOH	4	1000%
Δ^8-Tetrahydrocannabinol	80	50%
11-hydroxy-Δ^9-THC	45	89%
Cannabinol	200	20%
Cannabidiol (CBD)	2,200	1.8%
11-Nor-Δ^9-THC-carboxy-glucuronide	60	66.7%
(+)-11-nor-9-carboxy-Δ^9-THC	50	80%
11-nor-Δ^8-THC-9-COOH	20	200%
8-beta-11-dihydroxy-Δ^9-THC	200	20%
8-beta-hydroxy-Δ^9-THC	200	20%
Exo-THC	75	53.3%
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	15	266.7%
Δ^8-THC Carboxylic Acid	20	200%
Δ^9-THC Carboxylic Acid	4	1000%
(-)-Δ^9-THC-D3	3,000	1.3%
11-Nor-9beta-hydroxyhexahydrocannabinol (11-Nor-9beta-HHC) solution	125	32%
METHADONE (MTD)		
Methadone	30	100%
Phencyclidine	5,000	0.6%
LAAM	10,000	0.3%
Alpha-Methadol	150	20%
Doxylamine	>100,000	<0.03%
2-Ethylidene-1,5-dimethyl-3,3-diphenyl(EDDP) pyrrolidine(EDDP)	>100,000	<0.03%
2-Ethyl-5-methyl-3,3-diphenyl pyrrolidine(EMDP)	>100,000	<0.03%
METHAMPHETAMINE (MET)		
d-Methamphetamine	50	100%
l-Methamphetamine	1,250	4%
Methoxymethamphetamine	25	200%
Ephedrine	800	6.25%
Phenylephrine	4,000	1.25%
Procaine	2,000	2.5%
Methylephedrine	5,000	1%
Methylenedioxyethylamphetamine	250	20%
3,4-methylenedioxy-methamphetamine(MDMA)	50	100%

Drug	Concentration (ng/mL)	% Cross-Reactivity
d-Amphetamine	25,000	0.2%
3,4-methylenedioxyamphetamine	25,000	0.2%
(±)-Amphetamine	10,000	0.5%
l-Amphetamine	>100,000	<0.05%
OPIATES (OPI)		
Morphine	40	100%
Acetylmorphine	50	80%
Codeine	10	400%
Ethylmorphine	24	166.7%
Heroin(diacetylmorphine)	50	80%
Hydromorphone	100	40%
Thebaine	1,500	2.67%
Norcodeine	1,500	2.67%
Oxycodone	25,000	0.16%
Oxymorphone	25,000	0.16%
Nalorphine	10,000	0.4%
Hydrocodone	100	40%
6-monoacetylmorphine(6-AM)	25	160%
Morphine 3- β-d-glucuronide	50	80%
Bilirubin	3,500	1.14%
Dihydrocodeine	50	80%
Normorphine	12,500	0.32%
Morphine-6-β-d-glucuronide	100	40%
OXYCODONE (OXY)		
Oxycodone	20	100%
Hydrocodone	1,562.5	1.28%
Hydromorphone	750	2.67%
Naloxone HCl	5,000	0.4%
Oxymorphone	48.8	40.98%
Dihydrocodeine	3,125	0.64%
Naltrexone HCl	2,000	1%
Heroin(diacetymorphine)	12,500	0.16%
Buprenorphine	>100,000	<0.02%
Codeine	>100,000	<0.02%
Morphine	>100,000	<0.02%
Morphine 3- β-d-glucuronide	>100,000	<0.02%
Ethylmorphine	>100,000	<0.02%
6-monoacetylmorphine(6-AM)	>100,000	<0.02%
PHENCYCLIDINE (PCP)		
Phencyclidine	10	100%
Cyclizine	5,000	0.2%

Drug	Concentration (ng/mL)	% Cross-Reactivity
Venlafaxine	50,000	0.02%
Tenocyclidine (TCP)	2,000	0.5%
l-(l-phenylcyclohexyl) morpholine	15	66.7%
4-hydroxyphencylidine	10	100%
Hydrocodone	>100,000	<0.01%
Hydromorphone	>100,000	<0.01%
Nalorphine	>100,000	<0.01%
EDDP	>100,000	<0.01%
Ketamine	>100,000	<0.01%
Prazepam	>100,000	<0.01%
Amitriptyline	>100,000	<0.01%
(+) Brompheniramine	>100,000	<0.01%
(+) Chlorphenamine	>100,000	<0.01%
Desmethylvenlafaxine	>100,000	<0.01%
Chlorpromazine	>100,000	<0.01%
Clomipramine	>100,000	<0.01%
Cyclobenzaprine	>100,000	<0.01%
Dextromethorphan	>100,000	<0.01%
Doxepin	>100,000	<0.01%
Doxylamine	>100,000	<0.01%
Imipramine	>100,000	<0.01%
Thioridazine	>100,000	<0.01%
Dexbrompheniramine	>100,000	<0.01%

f. Effect of Oral fluid pH

To investigate the effect of oral fluid pH, oral fluid samples with pH 4 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.

g. Drug Recovery Study

Negative oral fluid samples in glass bottles were spiked with target drugs to concentrations of -50% and +50% of the cutoffs. The samples were transferred to Healgen devices and store at room temperature, at 2-8℃, at -20ºC and at 40ºC. Over 90% recoveries were observed for the drugs in the Healgen devices. Oral fluid samples can be stored in the device at -20ºC for at least 100 days. Oral fluid samples can be shipped overnight in the device for LC-MS confirmation.

Room Temperature (20 to 25℃) (3-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	107.05%	98.13%	109.77%	102.80%	105.55%	109.55%	97.51%	106.12%
MIN	93.32%	91.16%	93.58%	98.67%	91.19%	97.06%	91.54%	93.81%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	109.38%	109.47%	109.66%	107.71%	105.76%	108.91%	98.00%	108.44%
MIN	102.87%	95.44%	104.06%	100.46%	92.56%	101.85%	92.67%	94.44%

2-8℃ (10-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	109.91%	103.56%	108.91%	105.96%	108.01%	107.54%	105.58%	109.38%
MIN	97.71%	91.16%	90.75%	91.39%	93.12%	90.20%	91.54%	96.91%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	109.79%	109.03%	109.81%	105.18%	106.81%	109.18%	106.45%	108.72%
MIN	91.17%	91.15%	97.92%	92.66%	90.50%	93.19%	92.00%	93.25%

-20℃ (100-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	109.27%	98.81%	108.91%	100.00%	108.28%	98.04%	105.58%	106.12%
MIN	98.31%	90.26%	91.13%	92.72%	96.18%	91.18%	91.54%	100.00%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	95.63%	103.07%	108.95%	101.96%	103.82%	100.68%	103.65%	108.90%
MIN	92.62%	95.00%	97.92%	96.30%	91.74%	93.19%	92.67%	92.57%

40℃ (1-day storage)

-50% cutoff	**AMP 25**	**COC 10**	**MET 25**	**MTD 15**	**OPI 20**	**OXY 10**	**PCP 5**	**THC 20**
MAX	108.30%	105.83%	109.58%	105.12%	105.01%	104.90%	106.67%	109.37%
MIN	95.44%	94.29%	92.83%	98.05%	93.61%	96.45%	98.46%	96.29%
+50% cutoff	**AMP 75**	**COC 30**	**MET 75**	**MTD 45**	**OPI 60**	**OXY 30**	**PCP 15**	**THC 60**
MAX	103.68%	107.00%	109.76%	104.55%	102.43%	102.42%	109.03%	107.12%
MIN	99.12%	99.75%	106.56%	99.67%	95.84%	93.73%	103.60%	92.06%

2. Comparison Studies

Method comparison studies for the Healgen Device were performed at six testing sites. Operators tested total 1430 samples for target drugs. The obtained test results are compared to LC/MS/MS results. The results are presented in the tables below

AMP

Drug Concentration	**Number of Negative**	**Number of Positive**	**Total**	**The percentage of correct result**
Drug free	833	0	833	100%
< -50% Cut off	261	0	261	100%
-50% Cut off ~ Cut off	30	1	31	97%
Cut off ~ +50% Cut off	2	12	14	86%
＞+50% Cut off	0	95	95	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA02-043	41.377	Pos
HA03-096	52.62	Neg
HA01-188	56.82	Neg

COC

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	833	0	833	100%
< -50% Cut off	176	0	176	100%
-50% Cut off ~ Cut off	17	4	21	81%
Cut off ~ +50% Cut off	2	21	23	91%
＞+50% Cut off	0	181	181	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA02B-020	16.55	Pos
HA02-075	16.788	Pos
HA03-026	17.037	Pos
HA02-038	19.574	Pos
HA01-121	22.596	Neg
HA02B-104	22.60	Neg

MTD

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	1040	0	1040	100%
< -50% Cut off	223	0	223	100%
-50% Cut off ~ Cut off	18	1	19	95%
Cut off ~ +50% Cut off	1	10	11	91%
＞+50% Cut off	0	32	32	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
WA011	28.8	Pos
HA01-297	33.04	Neg

MET

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	838	0	838	100%
< -50% Cut off	296	0	296	100%
-50% Cut off ~ Cut off	29	1	30	97%
Cut off ~ +50% Cut off	0	17	17	100%
＞+50% Cut off	0	55	55	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA01-149	41.36	Pos

OPI

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	799	0	799	100%
< -50% Cut off	233	0	233	100%
-50% Cut off ~ Cut off	27	1	28	96%
Cut off ~ +50% Cut off	1	11	12	92%
＞+50% Cut off	0	162	162	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results

HA02-119	33.62	Pos
HA01-201	42.81	Neg

OXY

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	854	0	854	100%
< -50% Cut off	269	0	269	100%
-50% Cut off ~ Cut off	16	0	16	100%
Cut off ~ +50% Cut off	1	38	39	97%
＞+50% Cut off	0	56	56	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA03-344	22.53	Neg

PCP

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	1023	0	1023	100%
< -50% Cut off	233	0	233	100%
-50% Cut off ~ Cut off	23	0	23	100%
Cut off ~ +50% Cut off	0	15	15	100%
＞+50% Cut off	0	47	47	100%

THC

Drug Concentration	Number of Negative	Number of Positive	Total	The percentage of correct result
Drug free	725	0	725	100%
< -50% Cut off	252	0	252	100%
-50% Cut off ~ Cut off	87	4	91	96%
Cut off ~ +50% Cut off	11	14	25	56%
＞+50% Cut off	0	141	141	100%

Discordant Results

Sample #	LC/MS Concentration (ng/mL)	Healgen Test Results
HA01-288	35.42	Pos
HA03-097	37.094	Pos
HA03-103	38.145	Pos
HA02-071	38.982	Pos
HA01-141	40.67	Neg
HA03-030	40.680	Neg
HA02-100	40.95	Neg
HA03-145	43.409	Neg
HA02-166	43.91	Neg
HA01-081	44.868	Neg
HA01-035	45.231	Neg
HA02B-244	45.27	Neg
HA03-163	47.22	Neg
HA01-221	49.26	Neg
HA01-144	49.75	Neg

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that the Healgen® Accurate Oral Fluid Drug Test is substantially equivalent to the predicate.