December 23, 2025

Healgen Scientific LLC
℅ Jenny Shia
LSI International Inc
504 East Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K253567
Trade/Device Name: Healgen Accurate Urine Drug Screen Dip Card; Healgen Accurate Home Urine Drug Test Dip Card
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL NFT PTH NFY NFV PTG NGG NGM QBF QAW NFW
Dated: November 16, 2025
Received: November 17, 2025

Dear Jenny Shia:

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: 2025.12.23 09:15:09 -05'00'

Joseph Kotarek, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253567

Device Name
Healgen Accurate Urine Drug Screen Dip Card;
Healgen Accurate Home Urine Drug Test Dip Card

Indications for Use *(Describe)*
The Healgen Accurate Urine Drug Screen Dip Card is a rapid lateral flow immunoassays for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, THC-COOH, Norfentanyl and Tramadol 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)
6-MAM	6-Monoacetylmorphine	10
AMP	d-Amphetamine	500 or 1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylecgonine	150 or 300
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine	300
MDMA	Methylenedioxymethamphetamine	500
MET	d-Methamphetamine	500 or 1000
MTD	Methadone	300
OPI	Morphine	300 or 2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	d-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ9-THC-COOH	50
NFYL	Norfentanyl	5
TML	Tramadol	100

The single or multi-test panels can consist of up to eighteen (18) of the above listed analytes in any combination with or without on-board adulteration/specimen validity tests (SVT).
The tests provide only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed 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.

The Healgen Accurate Home Urine Drug Test Dip Card is a rapid qualitative immunoassay.
The device provides preliminary results for the detection of potential abuse of one or more drugs in human urine at the cutoff concentrations of table below.
This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10

BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	EDDP	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	Ecstasy	500
OPI	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50
6-MAM	6-Monoacetylmorphine	10
NFYL	Norfentanyl	5
TML	Tramadol	100

This drug test dip card may contain any combination of the drug tests listed in the table above but only one cutoff concentration under same drug condition will be included per device.
This test provides only preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. GC/MS or LC/MS is the preferred confirmatory method. Evaluate preliminary positive results carefully.

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
K253567

1. **Date:** November 16, 2025
2. **Submitter:** Healgen Scientific LLC.
   3818 Fuqua Street
   Houston, TX 77047
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 Name:** Healgen Accurate Urine Drug Screen Dip Card
   Healgen Accurate Home Urine Drug Test Dip Card
5. **Classification:** Class II

Product Code **Target Drug**	**Regulation Section**	**Panel**
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NGL Buprenorphine (BUP) Morphine (MOP/OPI) Oxycodone (OXY) 6-Monoacetylmorphine(6-MAM) Norfentanyl (NFYL) Tramadol (TML)	862.3650, Opiate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine and cocaine metabolite test system	Toxicology
PTG 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGM	Unclassified	Toxicology

Phencyclidine (PCP)		
QBF Propoxyphene(PPX)	862.3700 Propoxyphene test system.	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids (THC 50)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Devices:

Healgen Accurate Urine Drug Screen Dip Card (K240686)

7. Intended Use

The Healgen Accurate Urine Drug Screen Dip Card is a rapid lateral flow immunoassays for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, THC-COOH, Norfentanyl and Tramadol 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)
6-MAM	6-Monoacetylmorphine	10
AMP	d-Amphetamine	500 / 1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylecgonine	150 / 300
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine	300
MDMA	Methylenedioxymethamphetamine	500
MET	d-Methamphetamine	500 / 1000
MTD	d/l-Methadone	300
OPI	Morphine	300 / 2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	d-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ^9-THC-COOH	50
NFYL	Norfentanyl	5
TML	Tramadol	100

The single or multi-test panels can consist of up to eighteen (18) of the above listed analytes in any combination with or without on-board adulteration/specimen validity tests (SVT).

The tests provide only a preliminary result. A more specific alternative chemical method must be

used to obtain a confirmed 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.

The Healgen Accurate Home Urine Drug Test Dip Card is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs in human urine at the cutoff concentrations of table below.
This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	EDDP	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	Ecstasy	500
OPI	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50
6-MAM	6-Monoacetylmorphine	10
NFYL	Norfentanyl	5
TML	Tramadol	100

This drug test dip card may contain any combination of the drug tests listed in the table above but only one cutoff concentration under same drug condition will be included per device.
This test provides only preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. GC/MS or LC/MS is the preferred confirmatory method. Evaluate preliminary positive results carefully.

8. Device Description

Healgen Accurate Home Urine Drug Test Dip Card and Healgen Accurate Urine Drug Screen Dip Card are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine.

The device is a dip card format. Each test device is sealed with two sachets of desiccant in an aluminum pouch. The device is in a ready-to-use format and no longer requires assembly before use.

9. Substantial Equivalence Information

Similarities			
Item	**Device**		**Predicate (K240686)**
Intended use	Qualitative detection of drugs of abuse in urine. For over-the-counter use		Same.
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
Target Drug and Cut Off Values	**Target Drugs**	**Cutoff (ng/mL)**	Same except no NFYL and TML
	Amphetamine(AMP)	1000 or 500	
	Secobarbital (BAR)	300	
	Buprenorphine (BUP)	10	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methylenedioxymethamphetamine (MDMA)	500	
	Methamphetamine (MET)	1000 or 500	
	Morphine (MOP300/OPI2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene(PPX)	300	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC)	50	
	6-Monoacetylmorphine(6-MAM)	10	
	Norfentanyl (NFYL)	5	
	Tramadol (TML)	100	
Configurations	Test Dip Card		Same

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

Healgen Accurate Home Urine Drug Test Dip Card or Healgen Accurate Urine Drug Screen Dip Card is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

12. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Other samples were prepared by spiked target drug in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test dipcards. The results obtained are summarized only for Tramadol (TML) and Norfentanyl (NFYL) in the following tables. The rest data were reported in the k240686.

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
TML 100	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
NFYL 5	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+

b. Linearity/assay reportable range:
Not applicable. This device is intended for qualitative use only.

c. Stability:
The device is stable at 2-30℃ for 36 months based on real time stability study.

d. Analytical specificity/Interference:
To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of the device. The results obtained are summarized only for Tramadol (TML) and Norfentanyl (NFYL) in the following tables. The rest data were reported in the k240686.

Norfentanyl with Cutoff 5ng/mL

Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Norfentanyl	5	100%
Fentanyl	10	50%
Acetyl fentanyl	150	3.3%
Acetyl Norfentanyl	200	2.5%
(±)-β-Hydroxythiofentanyl HCl	2,500	0.2%
Acryl Fentanyl	2,500	0.2%
Butyryl Fentanyl	5,000	0.1%
Cis-d, I 3-Methylfentanyl	50,000	0.01%
Furanyl Fentanyl	10,000	0.05%
Para-fluoro butyrl Fentanyl (P-FBF)	80,000	0.01%
Para-fluoro Fentanyl	40,000	0.005%
9-HydroxyRisperidone	10,000	0.05%
Alfentanil	20,000	0.03%
Isobutyryl Fentanyl	5,000	0.1%
Norcarfentail Oxalate	50,000	0.01%
Remifentanil	15,000	0.03%
Valeryl Fentanyl	20,000	0.03%
Thienyl Fentnayl	50	10%
Trans-d, I 3-Methylfentanyl	50	10%
4-Fluoro-isobutyryl Fentanyl	>20,000	--
Despropionyl fentanyl (4-ANPP)	>20,000	--
MT-45	>100,000	--
Ocfentanil	>100,000	--
Risperidone	>100,000	--

Sufentanil	>100,000	--
Carfentanil Oxalate	>10,000	--
Labetalol Hydrochloride	>100,000	--
Trazodone	>100,000	--
U-47700	>100,000	--
ω-1-Hydroxyfentanyl	>20,000	--
6-Acetyl morphine	>100,000	--
Amphetamine	>100,000	--
Buprenorphine	>100,000	--
Buprenorphine -3-D-Glucuronide	>100,000	--
Codeine	>100,000	--
Dextromethorphan	>100,000	--
Dihydrocodeine	>100,000	--
EDDP	>100,000	--
EMDP	>100,000	--
Fluoxetine	>100,000	--
Heroin	>100,000	--
Hydrocodone	>100,000	--
Hydromorphone	>100,000	--
Ketamine	>100,000	--
Levorphanol tartrate	>100,000	--
Meperidine	>100,000	--
Methadone	>100,000	--
Morphine	>100,000	--
Morphine-3-β-D-glucuronide	>100,000	--
Naloxone hydrochloride	>100,000	--
Naltrexone hydrochloride	>100,000	--
Norbuprenorphine	>100,000	--
Norcodeine	>100,000	--
Norketamine	>100,000	--
Normeperidine	>100,000	--
Normorphine	>100,000	--
Noroxycodone	>100,000	--
Oxycodone	>100,000	--
Oxymorphone	>100,000	--
Pentazocine (Talwin)	>100,000	--
Pipamperone	>100,000	--
Tapentadol hydrochloride	>100,000	--
Thioridazine	>100,000	--
Tilidine	>100,000	--
Tramadol	>100,000	--
o-Desmethyl Tramadol	>100,000	--
n-Desmethyl Tramadol	>100,000	--

Tramadol with Cutoff 100ng/mL

Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Tramadol	100	100%
n-Desmethyl Tramadol	400	25%
o-Desmethyl Tramadol	1,000	10%
o-Desmethyl Venlafaxine	>10,000	--
Venlafaxine HCl	>100,000	--

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff.

Compounds that show no interference at a concentration of 100µg/mL are summarized in the following table.

(-) Cotinine	Diclofenac sodium	Nitroglycerin
3-Hydroxytyramine	Diflunisal	Norethindrone
7-Aminoclonazepam (except MDMA test)	Digoxin	Norpropoxyphene
7-Aminoflunitrazepam	Dimethyl-aminoantipyrine	Norpseudoephedrine
7-Aminonitrazepam	Diphenhydramine HCl	Nortriptyline(except TCA test)
Acetaminophen	Diphenylhydantoin	Noscapine
Acetone (1000 mg/dL)	Disopyramide	Octopamine
Acetophenetidin	Dopamine HCl	O-Hydroxyhippuric acid
Acetylsalicylic acid	Doxepine(except TCA test)	Olanzapine
Acyclovir	Doxylamine	Omeprazole
Albumin(100mg/dL)	D-Pseudoephedrine	Oxalic acid (100mg/dL)
Albuterol	Duloxetine(except TCA test)	Oxazepam (except BZO test)
Albuterol sulfate(Proair HFA)	Ecgonine methyl ester	Oxazepam Glucuronide (except BZO test)
Alpha Methadol	EMDP	Oxolinic acid
Aminophylline	Ephedrine hydrochloride (except MET test)	Oxymetazoline
Aminopyrine	Erythromycin	Paliperidone
Amitriptyline(except TCA test)	Esomeprazole Magnesium	Papaverine
Amlodipine besylate	Estradiol	Penicillin-G

Amobarbital(except BAR test)	Estrone	PenicillinV Potassium
Amoxicillin	Ethanol(1%)	Perphenazine
Ampicillin	Fenfluramine(except MET test)	Phenacetin
Apomorphine	Fenofibrate	Phencyclidine(except PCP test)
Aripiprazole	Fenoprofen	Phenelzine
Ascorbic acid	Fluoxetine Hydrochloride	Phenylethylamine
Aspartame	Fluphenazine	Phenobarbital(except BAR test)
Aspirin	Fotemustine	Phentermine(except AMP test)
Atomoxetine	Furosemide	Phenylpropanolamine
Atorvastatin Calcium	Gabapentin	Prednisone
Atropine	Galactose	Pregablin
Azithromycin	Gatifloxacin	Procaine
Baclofen	Gemfibrozil	Promazine(except TCA test)
Benzilic acid	Gentisic acid	Promethazine
Benzocaine	Glucose(3000 mg/dL)	Propoxyphene(except PPX test)
Benzoic acid	Guaiacolglyceryl ether	Propranolol
Benzoylecogonine (except COC test)	Hemoglobin	Pseudoephedrine
Benzphetamine	Hexobarbital	Pyridoxine
Benzylpiperiazine	Hydralazine	Pyrilamine
Bilirubin	Hydrochlorothiazide	Pyrogallol
Boric Acid (1%)	Hydrocortisone	Quetiapine
Bromo-2,5,Dimethoxyphenethylamine	Hydroxybutyric Acid	Quinidine
Bupropion	Ibuprofen	Quinine
Caffeine	Imipramine(except TCA test)	Quinolinic Acid
Cannabidiol	Isoproterenol	Ranitidine
Captopril	Isoxsuprine	Riboflavin
Carbamazepine	Ketamine	Rifampicin
Carfentanil	Ketoprofen	Salicylic acid
Carisoprodol	LAAM HCl	Secobarbital(except BAR test)
Cefradine	Labetalol	Serotonin
Cephalexin	Lamotrigine	Serotonin (5- Hydroxytyramine)
Cetirizine	L-Ephedrine	Sertraline
Chloral hydrate	L-Epinephrine	Sildenafil Citrate
Chloramphenicol	Levofloxacin Hydrochloride	Simvastatin

Chlordiazepoxide (except BZO test)	Levonorgestrel	Sodium Azide
Chloroquine	Levothyroxine Sodium	Sulfamethazine
Chlorothiazide	Lidocaine Hydrochloride	Sulindac
Chlorpheniramine(except TCA test)	Lisinopril	Telmisartan
Chlorpromazine	Loperamide	Tetracycline
Cholesterol	Loratidine	Tetrahydrocortisone 3-(β-Dglucuronide)
Ciprofloxacin Hydrochloride	Lorazepam Glucuronide(except BZO test)	Tetrahydrocortisone, 3-acetate
Citalopram	L-phenylephrine	Tetrahydrozoline
Clarithromycin	LSD	THC (except THC test)
Clofibrate	L-thyroxine	Theophylline
Clomipramine(except TCA test)	Magnesium	Thiamine
Clonidine	Maprotiline	Thioridazine
Clozapine	Meperidine	Trazodone Hydrochloride
Conjugated Estrogens	Meprobamate	Triamterene
Cortisone	Metformin	Trifluoperazine
Creatine Hydrate	Methapyrilene	Trifluoromethylphenyl-piperazine
Creatinine	Methaqualone	Trimethobenzamide
Cyclobenzaprine(except TCA test)	Methoxyphenamine (except MET test)	Trimethoprim
Cyproheptadine	Methylphenidate	Tryptamine
D,L-Epinephrine	Metoprolol Tartrate	Tyramine (except AMP test)
D,L-Isoproterenol	Metronidazole	Urea (2000 mg/dL)
D,L-Lorazepam (except BZO test)	Mifepristone	Uric acid
D,L-Octopamine	N-Acetylprocainamide	Valproic acid (250 µg/mL)
D,L-Propranolol	Nacl (4000 mg/dL)	Venlafaxine HCl
D,L-Tryptophan	Nalidixic acid	Verapamil
D,L-Tyrosine	Naloxone (except OXY test)	Vitamin B2
Delorazepam	Naltrexone (except OXY test)	Vitamin C
Demoxepam(except BZO test)	Naproxen	Zaleplon
Deoxycorticosterone	N-desmethyl Tapentadol	Zolpidem
Desloratadine	Niacinamide	Zomepirac
Desipramine(except TCA test)	Nicotine	β-Estradiol

Dextromethorphan	Nicotinic Acid	γ-Cyclodextrin
Diclofenac	Nifedipine	γ-Globulin (500mg/dL)

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

B. Method comparison study

The method comparison studies for the device were performed in-house with three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The results obtained are summarized only for Tramadol (TML) and Norfentanyl (NFYL) in the following tables. The rest data were reported in the k240686.

Drug test	Test Dipcard Result		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
TML (100)	Operator A	+	0	0	1	12	27
		-	10	15	14	1	0
	Operator B	+	0	0	1	11	27
		-	10	15	14	2	0
	Operator C	+	0	0	1	12	27
		-	10	15	14	1	0
NFYL (5)	Operator A	+	0	0	2	13	25
		-	10	15	13	2	0
	Operator B	+	0	0	2	13	25
		-	10	15	13	2	0
	Operator C	+	0	0	2	14	25
		-	10	15	13	1	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Accurate Result
TML 100	Operator A	TC-TML06058	87.96	+
	Operator B	TC-TML06002	96.78	+
	Operator C	TC-TML06067	83.87	+
	Operator B	TC-TML06005	100.73	-

	Operator C	TC-TML06023	109.70	-
	Operator B	TC-TML06061	116.75	-
	Operator A	TC-TML06035	120.71	-
NFYL 5	Operator A	TC-FYL06048	4.37	+
	Operator C	TC-FYL06040	4.41	+
	Operator B	TC-FYL06017	4.46	+
	Operator B	TC-FYL06019	4.57	+
	Operator C	TC-FYL06052	4.64	+
	Operator A	TC-FYL06045	4.95	+
	Operator B	TC-FYL06047	5.57	-
	Operator B, C	TC-FYL06054	5.63	-
	Operator A	TC-FYL06033	5.68	-
	Operator A	TC-FYL06043	5.73	-

C. Lay person study

141 male and 139 female tested Healgen Accurate Urine Drug Screen Dip Card. They had diverse educational and professional backgrounds and their age range from 21 to > 50. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC-MS/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

Result of Healgen Accurate Urine Drug Screen Dip Card Configuration 1:

Drug	**Cutoff (ng/mL)**	**Results**	**Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP	**1000**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BAR	**300**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
BUP	**10**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BZO	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20

		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
COC	**300**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
EDDP	**300**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
FYL	**5**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MDMA	**500**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MET	**1000**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MOP	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MTD	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
OXY	**100**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
PCP	**25**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
PPX	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
TCA	**1000**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
THC	**50**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
TML	**100**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
6-MAM	**10**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%

Result of Healgen Accurate Urine Drug Screen Dip Card Configuration 2:

Drug	**Cutoff (ng/mL)**	**Results**	**Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP	**500**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
BAR	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BUP	**10**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BZO	**300**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
COC	**150**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
EDDP	**300**	**Negative**	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20

		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
FYL	**5**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MDMA	**500**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MET	**500**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MOP	**2000**	**Negative**	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
MTD	**300**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
OXY	**100**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
PCP	**25**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
PPX	**300**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
TCA	**1000**	**Negative**	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
THC	**50**	**Negative**	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
TML	**100**	**Negative**	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
6-MAM	**10**	**Negative**	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

Clinical Studies:
Not applicable.

13. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that Healgen Accurate Home Urine Drug Test Dip Card and Healgen Accurate Urine Drug Screen Dip Card are substantially equivalent to the predicate devices.