DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2015

HEALGEN SCIENTIFIC LLC
C/O JOE XIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG MD 20877

Re: K150096
Trade/Device Name: Healgen MDMA (Ecstasy) Test (Strip, Cassette, Cup, Dip Card),
Healgen Phencyclidine Test (Strip, Cassette, Cup, Dip Card)
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: II
Product Code: LAF, LCM
Dated: January 12, 2015
Received: January 20, 2015

Dear Mr. 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 (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. 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.

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k150096

Device Name
Healgen MDMA (Ecstasy) Test (Strip, Cassette, Cup, Dip Card)
Healgen Phencyclidine Test (Strip, Cassette, Cup, Dip Card)

Indications for Use *(Describe)*
Healgen MDMA (Ecstasy) Test is an immunochromatographic assay for the qualitative determination of Methylenedioxymethamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. It is intended for prescription and for over-the-counter use.

Healgen Phencyclidine Test is an immunochromatographic assay for the qualitative determination of Phencyclidine in human urine at a Cut-Off concentration of 25 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. It is intended for prescription and for over-the-counter use.

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.

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510(k) SUMMARY

1. Date: February 26, 2015

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

3. Contact person: Jianqiu Fang
HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX 77401
Telephone: 713-733-8088
Fax: 713-733-8088
Email: bryan@healgen.com

4. Device Name: Healgen MDMA (Ecstasy) Test (Strip, Cassette, Cup, Dip Card)
Healgen Phencyclidine Test (Strip, Cassette, Cup, Dip Card)
Classification:

Product Code	CFR #	Panel
LCM	This device has not been classified.	
LAF	21 CFR, 862.3610 Methamphetamine Test System	Toxicology

5. Predicate Devices:
K052115
First Check Multi Drug Cup 12

6. Intended Use / Indications for Use
Healgen MDMA (Ecstasy) Test is an immunochromatographic assay for the qualitative determination of Methylenedioxymethamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for prescription and for over-the-counter use.

Healgen Phencyclidine Test is an immunochromatographic assay for the qualitative determination of Phencyclidine in human urine at a Cut-Off concentration of 25 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for prescription and for over-the-counter use.

7. Device Description

Healgen MDMA (Ecstasy) Test and Healgen Phencyclidine Test are immunochromatographic assays for Methylenedioxymethamphetamine and Phencyclidine. Each assay test is a lateral flow system for the qualitative detection of Methylenedioxymethamphetamine and Phencyclidine (target analyte) in human urine. The products are in vitro diagnostic devices, which come in the form of: Strips, Cassettes, DipCards, or Cups. Each product contains a Test Device (in one of the four formats), and a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen MDMA (Ecstasy) Test and Healgen Phencyclidine Test and the predicate device is provided in Table 1 & Table 2.

Table 1: Features Comparison of Healgen MDMA (Ecstasy) Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Methylenedioxymethamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

Table 2: Features Comparison of Healgen Phencyclidine Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Phencyclidine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	25 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

9. Test Principle

Healgen MDMA (Ecstasy) Test and Healgen Phencyclidine Test are rapid tests for the qualitative detection of Methylenedioxymethamphetamine and Phencyclidine in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cut-offconcentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the test has been performed properly.

10. Performance Characteristics

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, at the 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 GC/MS. All sample aliquots were blind labeled and randomized by the person who prepared samples and did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days by three different operators for

each format of devices. Different set of operators tested each format. The results obtained are summarized in the following tables:

MDMA (Ecstasy)

Strip Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MDMA1201001	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201002	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201003	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MDMA1201004	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201005	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201006	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MDMA1201007	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201008	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201009	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MDMA1201010	50-/0+	50-/0+	50-/0+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201011	50-/0+	50-/0+	50-/0+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MDMA1201012	50-/0+	50-/0+	50-/0+	50-/0+	30-/20+	50+/0-	50+/0-	50+/0-	50+/0-

Phencyclidine

Strip Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:PCP1111001	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:PCP1111002	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:PCP1111003	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:PCP1111004	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**18-/32+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111005	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**18-/32+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111006	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**18-/32+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

Dip Card Format

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:PCP1111007	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**22-/28+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111008	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**22-/28+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111009	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**22-/28+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

CUP Format

Drug \ Result	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:PCP1111010	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**16-/34+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111011	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**16-/34+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
Lot:PCP1111012	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**16-/34+**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30℃ for 24 months based on the accelerated stability study at 45℃ and real time stability determination at both 4 ℃ and 30℃.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% cut-off and all negative at and below -25% cut-off for both Methylenedioxymethamphetamine and Phencyclidine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)

MDMA (Ecstasy) Test	Methylenedioxymethamphetamine	500
Phencyclidine Test	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 concentration at 25% below and 25% above cut-off levels. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different formats.

MDMA (Ecstasy)

Acetophenetidin	Ethyl Morphine	Phenelzine
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Phenobarbital
Acetylsalicylic Acid (Aspirin)	Fenoprofen	Phentermine
Aminopyrine	Furosemide	Phenylephrine-L
Amitriptyline	Gentisic acid	Phenylethylamine
Amoxicillin	Hemoglobin	Phenylpropanolamine
Amobarbital	Hydralazine	Prednisolone Acetate
D-Amphetamine	(+/-)-4-Hydroxyamphetamine HCL	Prednisone
L-Amphetamine	Hydrochlorothiazide	Procaine(Novocaine)
Amphetamine Sulfate	Hydrocodone	Promazine
Ampicinine(Ampicillin)	Hydrocortisone	Promethazine
Apomorphine	a -Hydroxyhippuric acid	Propoxyphene,d-
L-Ascorbic Acid	p-Hydroxymethamphetamine	Propranolol
Aspartame	Ibuprofen	Pseudoephedrine HCL
Atropine	Imipramine	Quinidine
Benzilic acid	Isoxsuprine	Quinine
Benzphetamine	Isoproterenol-(+/-)	Ranitidine(Zantac)
Bezoic Acid	Ketamine	Salicylic Acid
Bilirubin	Levorphanol	Secobarbital
Caffeine	Loperamide	Serotonin
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide HCL	Meprobamate	Sulindac
Chloroquine	Methadone	Temazepam
Chlorothiazide	Methoxyphenamine	11-Nor-Δ^9-Tetrahydrocannabinol

Chlorpheniramine	Methylphenidate	Tetracycline
Chlorpromazine	Nalbuphine	Tetrahydrozoline
Cholesterol	Nalidixic acid	Thebaine
Clomipramine	Naloxone hydrochloride	Thiamine
Clonidine hydrochloride	Naltrexone hydrochloride	L-Thyroxine
Codeine	Naproxen	ThioridazineHydrochloride
Cortisone	Niacinamide	Triamterene
Cotinine(-)	Nifedipine	Triflupromazine Hydrochloride
Creatinine	Norethindrone	Trimethoprim
Deoxyepinephrine	Norpropoxyphene	Trimipramine
Dextromethorphan	Noscapine	Tryptamine
Diazepam	Oxazepam	DL-Tryptophan
Diflunisal	Oxycodone	Tyramine
Digoxin	Oxymetazoline	D/L-Tyrosine
Doxylamine	Papaverine	Uric Acid
Ecgonine methylester	Penicillin	Verapamil
R(-)-Epinephrine	Pentobarbital	Zomepirac
Erythromycin	Perphenazine	
Estrone-3-sulfate	Phencyclidine	

Phencyclidine

Acetophenetidin	Ethyl-p-aminobenzoate	Phenelzine
N-Acetylprocainamide	Fenoprofen	Phenobarbital
Acetylsalicylic Acid (Aspirin)	Furosemide	Phentermine
Aminopyrine	Gentisic acid	Phenylephrine-L
Amitriptyline	Hemoglobin	Phenylethylamine
Amoxicillin	Hydralazine	Phenylpropanolamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Prednisolone Acetate
D-Amphetamine	Hydrochlorothiazide	Prednisone
L-Amphetamine	Hydrocodone	Procaine(Novocaine)
Amphetamine Sulfate	Hydrocortisone	Promazine
Ampicinine(Ampicillin)	a -Hydroxyhippuric acid	Promethazine
Apomorphine	p-Hydroxymethamphetamine	Propoxyphene,d-
L-Ascorbic Acid	Ibuprofen	Propranolol
Aspartame	Imipramine	Pseudoephedrine HCL
Atropine	Isoxsuprine	Quinidine
Benzilic acid	Isoproterenol-(+/-)	Quinine

Benzphetamine	Ketamine	Ranitidine(Zantac)
Bezoic Acid	Labetalol	Salicylic Acid
Bilirubin	Levorphanol	Secobarbital
Caffeine	Loperamide	Serotonin
Chloramphenicol	Maprotiline	Sulfamethazine
Chlordiazepoxide HCL	Meprobamate	Sulindac
Chloroquine	Methadone	Temazepam
Chlorothiazide	Methoxyphenamine	11-Nor-Δ^9-Tetrahydrocannabinol
Chlorpheniramine	(+/-)-Methylenedioxyamphetamine(MDA)	Tetracycline
Chlorpromazine	Methylphenidate	Tetrahydrozoline
Cholesterol	Nalbuphine	Thebaine
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone hydrochloride	L-Thyroxine
Codeine	Naltrexone hydrochloride	ThioridazineHydrochloride
Cortisone	Naproxen	Triamterene
Cotinine(-)	Niacinamide	Triflupromazine Hydrochloride
Creatinine	Nifedipine	Trimethoprim
Deoxyepinephrine	Norethindrone	Trimipramine
Dextromethorphan	Norpropoxyphene	Tryptamine
Diazepam	Noscapine	DL-Tryptophan
Diflunisal	Oxazepam	Tyramine
Digoxin	Oxycodone	D/L-Tyrosine
Doxylamine	Oxymetazoline	Uric Acid
Ecgonine methylester	Papaverine	Verapamil
R(-)-Epinephrine	Penicillin	Zomepirac
Erythromycin	Pentobarbital	
Estrone-3-sulfate	Perphenazine	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

MDMA	**Result**	**%**

Methylenedioxymethamphetamine **(Cut-off=500 ng/mL)**		**Cross-Reactivity**
Methylenedioxymethamphetamine	Positive at 500 ng/mL	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	Positive at 3000 ng/mL	17%
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 300 ng/mL	167%
d-methamphetamine	Positive at 2500 ng/mL	20%
d-amphetamine	>100,000	Not detected
l-amphetamine	>100,000	Not detected
l-methamphetamine	>100,000	Not detected

Phencyclidine **(Cut-off=25 ng/mL)**	**Result**	**% Cross-Reactivity**
Phencyclidine	Positive at 25 ng/mL	100%
4-Hydroxy Phencyclidine	Positive at 90 ng/mL	28%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. 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 formats.

2. Comparison Studies

The method comparison studies for the MDMA (Ecstasy) Test, and the Phencyclidine Test were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

MDMA (Ecstasy)

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24

	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of MDMA (Ecstasy) Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	1008	509	Negative
Viewer A	1033	505	Negative
Viewer A	1076	507	Negative
Viewer B	1008	509	Negative
Viewer B	1033	505	Negative
Viewer B	1076	507	Negative
Viewer B	1037	511	Negative
Viewer C	1008	509	Negative
Viewer C	1033	505	Negative
Viewer C	1076	507	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of MDMA (Ecstasy) Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	1008	509	Negative
Viewer A	1033	505	Negative
Viewer A	1076	507	Negative
Viewer B	1033	505	Negative
Viewer B	1037	511	Negative

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer B	1076	507	Negative
Viewer C	1033	505	Negative
Viewer C	1076	507	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of MDMA (Ecstasy) Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	1008	509	Negative
Viewer A	1033	505	Negative
Viewer A	1076	507	Negative
Viewer B	1008	509	Negative
Viewer B	1033	505	Negative
Viewer B	1076	507	Negative
Viewer B	1037	511	Negative
Viewer C	1008	509	Negative
Viewer C	1033	505	Negative
Viewer C	1076	507	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	24

	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of MDMA (Ecstasy) Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	1033	505	Negative
Viewer A	1076	507	Negative
Viewer B	1033	505	Negative
Viewer C	1008	509	Negative
Viewer C	1033	505	Negative
Viewer C	1076	507	Negative

Phencyclidine

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Phencyclidine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	774	26	Negative
Viewer A	721	25	Negative
Viewer A	779	27	Negative
Viewer B	774	26	Negative
Viewer B	721	25	Negative
Viewer B	702	27	Negative
Viewer C	721	25	Negative
Viewer C	704	27	Negative

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer C	779	27	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	12	24
	Negative	10	15	15	4	0

Discordant Results of Phencyclidine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	774	26	Negative
Viewer A	721	25	Negative
Viewer B	774	26	Negative
Viewer B	721	25	Negative
Viewer B	702	27	Negative
Viewer C	774	26	Negative
Viewer C	721	25	Negative
Viewer C	704	27	Negative
Viewer C	779	27	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	12	24
	Negative	10	15	15	4	0

Discordant Results of Phencyclidine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	774	26	Negative
Viewer A	721	25	Negative
Viewer A	779	27	Negative
Viewer B	774	26	Negative
Viewer B	721	25	Negative
Viewer B	702	27	Negative
Viewer C	774	26	Negative
Viewer C	721	25	Negative
Viewer C	779	27	Negative
Viewer C	704	27	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Phencyclidine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	774	26	Negative
Viewer A	721	25	Negative
Viewer A	779	27	Negative
Viewer B	774	26	Negative
Viewer B	721	25	Negative

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer B	702	27	Negative
Viewer C	721	25	Negative
Viewer C	779	27	Negative
Viewer C	704	27	Negative

Lay-user study

A lay user study was performed at three intended user sites with 557 lay persons testing the MDMA(Ecstasy) devices and another set of 555 persons testing the Phencyclidine devices. Total of 1112 individuals performed the study. A total of 230 females and 327 males tested the MDMA(Ecstasy) samples, and 226 females and 329 males tested the Phencyclidine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/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.

Comparison between GC/MS and Lay Person Results (MDMA(Ecstasy) Strip)

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	125	0	20	100%
-50% Cutoff	19	250	0	19	100%
-25% Cutoff	20	375	1	19	95%
+25% Cutoff	20	625	19	1	95%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

Comparison between GC/MS and Lay Person Results (MDMA(Ecstasy) Cassette)

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	19	125	0	19	100%
-50% Cutoff	20	250	0	20	100%
-25% Cutoff	20	375	1	19	95%
+25% Cutoff	20	625	19	1	95%

+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

Comparison between GC/MS and Lay Person Results (MDMA(Ecstasy) DipCard)

% of Cutoff	**Number of samples**	**MDMA Concentration by GC/MS (ng/mL)**	**Lay person results**		**The percentage of correct results (%)**
			No. of Positive	**No. of Negative**	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	125	0	20	100%
-50% Cutoff	20	250	0	20	100%
-25% Cutoff	20	375	1	19	95%
+25% Cutoff	20	625	19	1	95%
+50% Cutoff	20	750	20	0	100%
+75% Cutoff	20	875	20	0	100%

Comparison between GC/MS and Lay Person Results (MDMA(Ecstasy) Cup)

% of Cutoff	**Number of samples**	**MDMA Concentration by GC/MS (ng/mL)**	**Lay person results**		**The percentage of correct results (%)**
			No. of Positive	**No. of Negative**	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	125	0	20	100%
-50% Cutoff	20	250	0	20	100%
-25% Cutoff	20	375	1	19	95%
+25% Cutoff	20	625	19	1	95%
+50% Cutoff	19	750	19	0	100%
+75% Cutoff	20	875	20	0	100%

Comparison between GC/MS and Lay Person Results (Phencyclidine Strip)

% of Cutoff	**Number of samples**	**Phencyclidine Concentration by GC/MS (ng/mL)**	**Lay person results**		**The percentage of correct results (%)**
			No. of Positive	**No. of Negative**	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	19	6	0	19	100%
-50% Cutoff	20	12.5	0	20	100%
-25% Cutoff	20	19	1	19	95%
+25% Cutoff	20	31	19	1	95%
+50% Cutoff	20	37.5	20	0	100%
+75% Cutoff	20	44	20	0	100%

Comparison between GC/MS and Lay Person Results (Phencyclidine Cassette)

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	6	0	20	100%
-50% Cutoff	19	12.5	0	19	100%
-25% Cutoff	20	19	1	19	95%
+25% Cutoff	20	31	19	1	95%
+50% Cutoff	20	37.5	20	0	100%
+75% Cutoff	20	44	20	0	100%

Comparison between GC/MS and Lay Person Results (Phencyclidine DipCard)

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	6	0	20	100%
-50% Cutoff	20	12.5	0	20	100%
-25% Cutoff	20	19	2	18	90%
+25% Cutoff	20	31	18	2	90%
+50% Cutoff	20	37.5	20	0	100%
+75% Cutoff	19	44	19	0	100%

Comparison between GC/MS and Lay Person Results (Phencyclidine Cup)

% of Cutoff	Number of samples	Phencyclidine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	6	0	20	100%
-50% Cutoff	19	12.5	0	19	100%
-25% Cutoff	20	19	2	18	90%
+25% Cutoff	20	31	19	1	95%
+50% Cutoff	20	37.5	20	0	100%
+75% Cutoff	19	44	19	0	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

   Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that the Healgen MDMA(Ecstasy) Test, and Healgen Phencyclidine Test are substantially equivalent to the predicate.